As a corrective action, following the monthly inventory, an independent check will be conducted to confirm compliance. The independent check will be done by a WHNP for four months to determine compliance, auditing 25% of the monthly inventory.

Regarding T 170-2, a thermometer has been added to the Recovery Room refrigerator with a record sheet to document daily the temperature of this refrigerator by the CNA. A staff refrigerator has been purchased and resides in the Doctor’s office. It also has a thermometer and record sheet to document daily the temperature of the refrigerator.

AHCW has modified the instrument cleaning P&P Manual and added a permanent mark to the sink to show the 1 gallon sink line. (AHCW P&P Manual 2.4.3.7.b section A.1.c) The Alconox dilution instructions were posted above the sink. Present at the time of inspection was a 1 gallon measuring device which Staff #3 failed to bring to the inspectors’ attention. The procedure implemented has been verified and spot audits (conducted at least twice per week) by the Administrator are being done.
<table>
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<th>T 170</th>
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|       | protective covering, without a data written on the IV to state when the Ringer's Lactate had been opened, on December 11, 2012, at 10:00 a.m. The Administrator surmised that the Ringer's Lactate had been opened on December 8, 2012, the date of the last procedure, during interview in the agency's hall on December 11, 2012, at 10:15 a.m. During interview at 10:03, the Administrator acknowledged that it could not be determined when the IV bag had the plastics covering was removed due to it being undated. 

The Administrator verified during interview that infection control issues had not been resolved from the initial survey. This interview occurred in the agency's office, on December 10, 2012, at 16:15. |

<table>
<thead>
<tr>
<th>T 210</th>
<th>12 VAC 5-412-240 D Medical testing, patient counseling and labor</th>
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<tr>
<td></td>
<td>D. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.</td>
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</table>

This RULE is not met as evidenced by: Based on record review and interview, it was determined that's three (#13,#12 and #15) Patients of eleven Patients (#1-#5, #7-#9 #12 and #14-#15) physicians failed to document adequately, the complete examination of the products of conception for all patients. |

Patient #8 (Clinical record #8) had the procedure
T 275  Continued From Page 7

C. 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. 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 that three (#1-#3) of three (#1-#3) vials of Diphenhydramine HCL (Benadryl for allergy and itching) 50 mg (milligrams) with an expiration date of 08/31/12 was available for use.

Findings:

During the initial tour of the laboratory room, on 12/10/12, at 3:00 p.m., in the refrigerator, three one (1) ml (milliliter) vials of Diphenhydramine HCL (Benadryl) 50 mg (milligrams) was found on the second shelf. The three (#1-#3) vials of Diphenhydramine HCL 50 mg (milligrams) which had an expiration date of 09/31/12, were available for use.

These expired vials were verified by Employee #2.

The Administrator stated that she was aware that they were expired and intended to discard them. This interview occurred on 12/10/12, at 15:15, in the Patient's waiting room.

T 285  12 VAC 5-412-260 E Administration, storage and dispensing of dru

E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in

The investigation revealed that the expired vials were placed into the refrigerator by the Administrator. This was not in compliance with the AHCW P&P Manual. A Letter of Reprimand was issued to the Administrator.

The P&P Manual is modified (3.5.4 Section A) to specifically expand the number of AHCW employees involved when an expired drug or medical device is identified within the facility. This policy requires specific actions by employees to be taken regarding the separation and control of the expired item.

As a corrective action, following the monthly inventory and weekly audit conducted by the LPN and CNA, an independent check will be conducted monthly by the clinic consultant, a Board Certified WHNP. This random audit will cover approximately 25% of the clinic locations and focus on locations where discrepancies have occurred previously. Also included in the WHNP audit will be any items identified by the LPN and CNA audits. These audits will continue until the Quality Assurance Committee is satisfied that the issue has been resolved and reflected within the Committee minutes.

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The investigation revealed that the expired vials were placed into the refrigerator by the Administrator. This was not in compliance with the AHCW P&P Manual. A Letter of Reprimand was issued to the Administrator. The P&P Manual is modified (3.5.4 Section A) to specifically expand the number of AHCW employees involved when an expired drug or medical device is identified within the facility. This policy requires specific actions by employees to be taken regarding the separation and control of the expired item.
Letters of Reprimand were issued to the Administrator and the CRNA for this item, specifically, to the CRNA for non-compliance with charting in the Administered Medicine Log Book and to the Administrator for failure to review the charting done by the CRNA.

The Administered Medicine Log Sheets have been revised, have been evaluated and are now in service. This single sheet / drug format incorporates a section for wastage with appropriate verifications and signatures. The changed Policy (AHCW 3.5.4.E) has been previously submitted and the current Log Sheet is attached. This log sheet will be monitored monthly by the nursing staff and Administrator for six months.
### State of Virginia

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(X3) Provider/Supplier/Lic. Identification Number</th>
<th>(X3) Multiple Construction</th>
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<tr>
<td>FTAF 012</td>
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<th>(X5) Date Survey Completed</th>
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<td>12/11/2012</td>
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**Name of Provider or Supplier**

AMETHYST HEALTH CENTER FOR WOMEN, INC

**Street Address, City, State, Zip Code**

9380-B FORESTWOOD LANE
MANASSAS, VA 20110

<table>
<thead>
<tr>
<th>(X4) ID Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each deficiency must be preceded by full regulatory or LSC identifying information)</th>
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<tbody>
<tr>
<td>T 340</td>
<td>Continued From Page 10 hold and physical examination;</td>
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<td></td>
<td>3. Signed consent;</td>
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<td>4. Confirmation of pregnancy; and</td>
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<td>5. Procedure report to include:</td>
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<td>a. Physician orders;</td>
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<td>b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;</td>
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<td>c. Anesthesia record;</td>
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<td>e. Surgical medication and medical treatments;</td>
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<td>g. Physician and nurses' progress notes;</td>
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<td>h. Condition at time of discharge;</td>
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<td>i. Patient instructions, preoperative and postoperative;</td>
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<td>j. Names of referral physicians or agencies.</td>
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This RULE: is not met as evidenced by: Based on document review and interview the facility staff failed to ensure the medical record was accurate and complete for 8 patients, Patient #1, 3, 4, 7, 9, and 12.

The findings include:

1. Patient #4 had a complete procedure on 9/21/12. The medical record did not include a signature from the admitting physician indicating he performed and or reviewed the history and physical of Patient #4. In the area of the medical record where the recovery of the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #1 it was checked as given. In an interview with the Administrator she stated, "(Name of Physician) does not order doxycycline. That is an error (the check mark)."

Patient #9 had a complete procedure on 9/24/12.

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<th>ID Prefix Tag</th>
<th>Provider's Plan of Correction (Each corrective action should be cross-referenced to the appropriate deficiency)</th>
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<td>T 340</td>
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Regarding T 340-1, The Medical Director and Administrator have verbally cautioned the Consultant Physicians and clinical staff to maintain vigilance regarding their patient charting. This is audited by the LPN and CNA on all procedure days who audit 50% of the charts.

**Complete Date**

2/16/13
The medical record did not include a signature from the admitting physician indicating he performed and reviewed the history and physical of Patient #4. In the area of the medical record where the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #9 it was checked as given. In an interview with the Administrator she stated, "(Name of Physician) does not order doxycycline. That is an error (the check mark)."

Patient #4, 7 and 9 all were administered medications prior to having their procedures. Patient #4 had ibuprofen 800 mg, 400 mg of misoprostol and 0.5 mg of Xanax. Patient #9 had a completed procedure on 11/29/12 and received ibuprofen 800 mg, Valium 10 mg and Demerol 50 mg. Patient #9 was given 400 mg of misoprostol and 0.5 mg of Xanax. All three patients' orders were not signed by the physician and were administered by an unlicensed person.

2. Patient #3 (Clinical record #3) completed the procedure on 11/17/12. Clinical record #3 failed to have preoperative medications documented within the clinical record #3 by the nurse administering the medications.

Patient #1 (Clinical record #1) completed the procedure performed on 12/08/12. Clinical record #1 failed to have physicians and nurse’s progress notes documented post procedure.

Patient #12 (Clinical record #12) had the procedure performed on 12/08/12. Clinical record #12 failed to have physicians and nurse’s progress notes documented post procedure.

The Administrator verified that Patient #8’s physician had not ordered doxycycline for any of his patients for discharge. This interview occurred on 2/16/13.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

A. BUILDING

B. WING

DATE SURVEY COMPLETED

NAME OF PROVIDER OR SUPPLIER
AMETHYST HEALTH CENTER FOR WOMEN, INC

STREET ADDRESS, CITY, STATE, ZIP CODE
9380-B FORESTWOOD LANE
MANASSAS, VA  20110

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)

DATE COMPLETE

An unannounced Revisit to the initial licensure survey conducted through June 01, 2012, was conducted at the above referenced facility December 10, 2012 through December 11, 2012 by two (2) Medical Facility Inspectors from the Virginia Department of Health's Office of Licensure and Certification. Complaint #2012-AC018 was investigated at the time of the Revisit survey.

The following citation was not corrected by the facility, and therefore was re-cited:
12 VAC 5-412-260 C  Administration, storage and dispensing of drugs

The following citations are new findings:
12VAC5-412-170 C - Personnel
12VAC5-412-220-B - Infection Prevention
12VAC5-412-240 D - Medical Testing, patient counseling, & lab services
12VAC5-412-260E Administration, storage and dispensing of drugs
12VAC5-412-310 - Medical Records

The facility was found out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies of new findings and one non corrected finding were identified and will follow in this report.

The Complaint #2012-AC018 was unsubstantiated due to a lack of sufficient evidence.

C.  Each abortion facility shall obtain a criminal history record check pursuant to 32.1-128.02 of the Code of Virginia on any compensated

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

STATE FORM

If continuation sheet 1 of 13
employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.

This RULE: is not met as evidenced by:

Based on document review and interview the facility staff failed to have criminal record checks performed for staff who have access to controlled substances within the facility.

The findings include:

On 12/11/12 the personnel files of the CRNA (Certified Registered Nurse Anesthetist), LPN (Licensed Practical Nurse) and 2 physicians were reviewed. The files did not contain a criminal history check pursuant to 32.1-126.02 of the Code of Virginia. The Administrator stated, "They do not have access to where we keep the drugs. They only have access once they are removed from the safe."

B. 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;
4. Use of standard precautions;
5. Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety & Health Administration.
Continued From Page 2

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 observations and interviews the facility staff failed to ensure supplies were not expired, that proper cleaning of instruments was done, once removed from it’s protective covering IV solution was dated as to when it would expire, proper cleaning of equipment used on patients was done and that proper hand hygiene was performed following patient care.

The findings include:

1. On 12/11/12 at approximately 9:45 A.M. following the observation of a abdominal and vaginal sonogram performed by the Administrator the probes were cleaned with a disinfectant wipe then dried with a paper towel. The disinfectant wipe states it must be allowed to stay on the equipment to dry for at least 3-5 minutes. The Administrator then pulled off the paper covering from the pillow case and the table.

The Administrator then pulled out a new pillow covering and laid it on the pillow. The pillow had not been wiped with a disinfectant wipe. The table was then wiped with a disinfectant wipe but not the table extension which had been pulled out for the patient to place her legs on.

At approximately 11:15 A.M. on 12/11/12 the
Continued From Page 3

Administrator was observed leaving the sonogram room behind a patient with gloves on her hands. The Administrator entered the video/consulting room and placed a video in the player and pushed buttons to turn the television on. While speaking to the patient she removed her gloves.

After leaving the room she went to the hallway sink rinsed her fingers in the water for 2-3 seconds and then dried her hands. She did not use any soap products.

The Administrator was informed about the observations and stated, "I did not realize I needed to let the disinfectant dry. You are correct about the gloves."

2. Observations conducted December 10, 2012 during the initial tour revealed within the anesthesia chart, in the procedure room, two ten (10) cc syringes that expired on September 30, 2012. Six (6) of ten (10) 25 gauge needles expired on on October 31, 2012, with four (4) of ten (10) 25 gauge needles expired on September 30, 2012. Failure to determine the ten (10) large red top blood tubes vials and one (1), purple top blood tube were without labels and the Surveyor could not determine the expiration dates.

Three (3) plastic vacutainers (used to obtain blood) expired on March 31, 2012, in the Ultrasound room, were observed during the initial tour. Observation with the Ultrasound room, within the second drawer of the exam table revealed a small medication cup that contained four pills. Two white pills with a hexagon shapes and with Z088 stamped on the pills, one oval large white pill with the number 5003 imprinted on it, and one white pill with 123 marked on it.

Forty seven (47) twenty gauge needles expired on September 30, 20112, twenty four (24) twenty
gauge needles expired on June 30, 2010, twelve (12) five cc syringes expired on June 30, 2010 within the drawers on the exam table within the Ultrasound room. Three ammonia inhalants could not be matched back to a bottle that contained the expiration dates resulting in the Surveyor being unable to determine if the inhalants had expired or not.

No documentation of the daily temperatures on the refrigerator that keeps the Ginger Ale cold for the patients post procedures was observed by the Surveyors during the initial tour in the Recovery Room. This observation was revealed by staff member #2 during the initial tour on December 10, 2012, at approximately 2:45 p.m., one egg was found along with one-half of a green pepper. Staff Member #2 acknowledged that the eggs and pepper were for her lunch, during interview, on December 10, 2012, at approximately 2:55 p.m. All of the above documents were verified by Employee #2, during the initial tour.

Employee #3 stated that she use one (#1) Tablespoon (TSP) of Alconox (A powdered precision cleaner for surgical instruments) per a gallon of water in the dirty utility room, on December 10, 2012, at 3:00 p.m. The Surveyor read the instructions on the bottle label of Alconox, which instructed on the bottle's label that two and one half (2 and 1/2) TBS were diluted with one (1) gallon water. Staff #2 failed to have a means of measuring the gallon of water precisely. During interview, Staff #2 stated that she/he knew from experience how much water to put in the sink. No permanent line was outlined in the sink to reflect the amount to equal one gallon.

A bag of 1000 cc of Ringer's Lactate (IV) was noted hanging from an IV pole, on a stretcher in the agency's hall, that had no plastic outside

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### Statement of Deficiencies and Plan of Correction

**State of Virginia**

**FTAF 012**  
**MULTIPLE CONSTRUCTION**

**NAME OF PROVIDER OR SUPPLIER**  
AMETHYST HEALTH CENTER FOR WOMEN, INC

**STREET ADDRESS, CITY, STATE, ZIP CODE**  
9380-B FORESTWOOD LANE, MANASSAS, VA 20110

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<td>T 210</td>
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<td>12 VAC 5-412-240 D Medical testing, patient counseling and labor</td>
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**STATE FORM**  
021199  
6W3111

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**Summary Statement of Deficiencies**

- Protective covering, without a date written on the IV to state when the Ringer's Lactate had been opened, on December 11, 2012, at 10:00 a.m. The Administrator surmised that the Ringer's Lactate had been opened on December 8, 2012, the date of the last procedure, during interview in the agency's hall on December 11, 2012, at 10:15 a.m. During interview at 10:03, the Administrator acknowledged that it could not be determined when the IV bag had the plastics covering was removed due to it being undated.

- The Administrator verified during interview that infection control issues had not been resolved from the initial survey. This interview occurred in the agency's office, on December 10, 2012, at 16:15.

- Patients of eleven physicians failed to document adequately, the complete examination of the products of conception for all patients.

- This RULE: is not met as evidenced by:
  
  Based on record review and interview, it was determined that's three (#18, #12 and #15) patients failed to document adequately, the complete examination of the products of conception for all patients.

- Patient #8 (Clinical record #8) had the procedure
performed on on 09/07/12. Clinical record #8 failed to a physician's documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. “Tissue volume was moderate and pregnancy tissue was complete with gestational age of nine weeks was documented by the physician for Patient #8.

Patient #12 (Clinical record #12) had the procedure performed on on 11/30/12. Clinical record #128 failed to a physician's documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. “Tissue volume was moderate and pregnancy tissue was complete with gestational age of nine weeks” was documented by the physician for Patient #12.

Patient #15 (Clinical record #15) had the procedure performed on on 11/17/12. Clinical record #15 failed to a physician's documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. “Tissue volume was moderate and estimated blood loss of 20 cc, and with gestational age of seven weeks” was documented by the physician for Patient #12.

The Administrator verified that all physicians had not documented well the products of conception. This interview occurred in the agency's office, on 12/11/12, at 11:05 a.m.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

**NAME OF PROVIDER OR SUPPLIER**
AMETHYST HEALTH CENTER FOR WOMEN, INC

**STREET ADDRESS, CITY, STATE, ZIP CODE**
9380-B FORESTWOOD LANE, MANASSAS, VA 20110

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<td>During the initial tour of the laboratory room, on 12/10/12, at 3:00 p.m., in the refrigerator, three one (1) ml (milliliter)vials of Diphenhydramine HCL (Benadryl) 50 mg (milligrams) was found on the second shelf. The three (#1-#3) vials of Diphenhydramine HCL 50 mg (milligrams) which had an expiration date of 08/31/12, were available for use.</td>
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<td>These expired vials were verified by Employee #2.</td>
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<td>The Administrator stated that she was aware that they were expired and intended to discard them. This interview occurred on 12/10/12, at 16:15, in the Patient's waiting room.</td>
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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.

This RULE: is not met as evidenced by; Based on interviews and document reviews the facility staff failed to ensure all Schedule II-V drugs received, administered and disposed of was done so in accordance with the Drug Control Act found in the Code of Virginia 54.1-3404. Narcotic log book contained documentation of information that had scribbling over dates, patient names and amounts of medications administered and arrows rather than documentation of what and how much of a medication was administered. The narcotics log also did not contain witnessed wastage of narcotics. The facility administered Propofol (unscheduled), Fentanyl (Schedule II), Versed (Schedule III) for conscious sedation and failed to document the medications’ wasting.

The findings include:

On 12/11/12 the narcotic log book was observed. The administrator stated only the CRNA (Certified Registered Nurse Anesthetist) documents in the narcotic log book. The log book had no separate documentation noting the beginning amounts of drugs. All drugs were documented on one page.

The dates of 10/27/12 and 11/17/12 were reviewed and the following is noted: Patient #1 on the narcotic list for 10/27/12 received 3 mg of Versed from a 5 mg per cc vial there is no documentation of what happened to the other 2 mg. A total of 7 patients for this date had similar entries. On 11/17/12 there were 7 patients with similar entries and on another listing with no date there were 8 patients with similar listings. All of the above patients had similar
<table>
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<tr>
<th>ID</th>
<th>PREFIX</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID</th>
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<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<tr>
<td>T285</td>
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<td>Continued From Page 9 listings for Propofol (20 cc vial with 10 mg per 1 cc) Propofol 80 mg was given to Patient #1 on 10/27/12 with no documentation of the wastage. Pharmacy Purchasing and Products, Tools to Effectively Manage Controlled Substances January 2011 Vol. 8 No. 1 page 8 by Ira Kurland, RPh and Tim L'Hommedieu, PharmD, MS stated the following: *The process for wasting controlled medications, such as narcotics, requires a witness and includes the following: Two authorized users are required. One user will be designated as witness to the wasting process. ...., whose job description or licensing allows the handling of controlled substances, may serve as a witness in the absence of a second nurse. The witness must view the vial, syringe, tablet, etc, that is used to prepare the medication dose. The witness is required to visualize the solution vial, syringe, tablet, etc, to verify the medication being wasted. The witness must watch the solution ejected from the syringe (preferably in a solid waste/trash receptacle) or watch the destruction of the unused portion (e.g., the tablet). Unplanned wasting (e.g., patient refusal of medication) must be witnessed when the medication is actually wasted using the procedure described above.</td>
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<tr>
<td>T340</td>
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<td>12 VAC 5-412-310 Medical records An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following: 1. Patient identification; 2. Admitting information, including a patient</td>
<td>T340</td>
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<td>2/19/13</td>
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</table>
### Statement of Deficiencies and Plan of Correction

#### Provider/Supplier/CLIA Identification Number:

- **FTAF 012**

#### Multiple Construction

- **A. Building**

#### Name of Provider or Supplier

**Amethyst Health Center for Women, Inc**

#### Address

- **9380-B Forestwood Lane**
- **Manassas, VA 20110**

#### Date Survey Completed

- **12/11/2012**

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### Summary Statement of Deficiencies

<table>
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<tr>
<th>ID Prefix</th>
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<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-referenced to the Appropriate Deficiency)</th>
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<tr>
<td>T 340</td>
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</table>

- **History and physical examination;**
- **3. Signed consent;**
- **4. Confirmation of pregnancy; and**
- **5. Procedure report to include:**
  - a. Physician orders;
  - b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
  - c. Anesthesia record;
  - d. Operative record;
  - e. Surgical medication and medical treatments;
  - f. Recovery room notes;
  - g. Physician and nurses' progress notes,
  - h. Condition at time of discharge,
  - i. Patient instructions, preoperative and postoperative; and
  - j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by;

Based on document review and interview the facility staff failed to ensure the medical record was accurate and complete for 6 patients, Patient #1, 3, 4, 7, 9, and 12.

The findings include:

1. **Patient #4** had a complete procedure on 9/21/12. The medical record did not include a signature from the admitting physician indicating he performed and or reviewed the history and physical of Patient #4. In the area of the medical record where the recovery of the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #1 it was checked as given. In an interview with the Administrator she stated, " (Name of Physician) does not order doxycycline. That is an error (the check mark). "

Patient #9 had a completed procedure on 8/24/12.
The medical record did not include a signature from the admitting physician indicating he performed and or reviewed the history and physical of Patient #4. In the area of the medical record where the recovery of the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #9 it was checked as given. In an interview with the Administrator she stated, "(Name of Physician) does not order doxycycline. That is an error (the check mark)."

Patient #4, 7 and 9 all were administered medications prior to having their procedures. Patient #4 had ibuprofen 800 mg, 400 mg of misoprostol and 0.5 mg of Xanax. Patient #9 had a completed procedure on 11/29/12 and received ibuprofen 800 mg, Valium 10 mg and Demerol 50 mg. Patient #9 was given 400 mg of misoprostol and 0.5 mg of Xanax. All three patients' orders were not signed by the physician and were administered by an unlicensed person.

2. Patient #3 (Clinical record #3) completed the procedure on 11/17/12. Clinical record #3 failed to have preoperative medications documented within clinical record #3 by the nurse administering the medications.

Patient #1 (Clinical record #1) completed the procedure performed on 12/08/12. Clinical record #1 failed to have physicians and nurse 's progress notes documented post procedure.

Patient #12 (Clinical record #12) had the procedure performed on 12/08/12. Clinical record #12 failed to have physicians and nurse's progress notes documented post procedure.

The Administrator verified that Patient #8's physician had not ordered doxycycline for any of his patients for discharge. This interview occurred...
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<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID PREFIX</th>
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<th>PROVIDER'S PLAN OF CORRECTION</th>
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<td>T 340</td>
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<td>Continued From Page 12</td>
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in the agency's office, on 12/11/12, at 11:05 a.m.
An unannounced Licensure Biennial survey was conducted 10/20/2014 through 10/21/2014. Three Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.

This RULE: is not met as evidenced by:
Based on document review and interview the facility's governing body:

1. Failed to ensure the appointment of a qualified person to perform the duties of the administrator, whenever the administrator was not available.

2. Failed to ensure qualified licensed personnel prepared injectable medications during procedures.

3. Failed to ensure the policies and procedures were reviewed annually and documented in the policy/procedure manual and failed to ensure the facility's policies reflected the updated State licensing regulation requirements for personnel.

4. Failed to ensure the facility had an on-going comprehensive, integrated, self-assessment program.

5. Failed to ensure the quality committee

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**T-000 Initial Comments**

- AHCW was caught unawares that revised Facility Regulations were in effect until the Administrator was notified by the inspectors. Their advice "to check the VDH/OLC website for updates" was an attempt to be helpful.
- However, it would appear, given the limited number of facilities covered by this regulation and given that e-mail or fax information is provided within the application for licensure, direct notification of regulation change would not be onerous to the State.
- It is of note that the Regulatory Identification provided, for some deficiencies, within the deficiency report utilized the numbering associated with the Regulations that were superseded on 20 June 2013. AHCW responses utilize the 6/20/2013 numbering.

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**RECEIVED**

**DEC 19 2014**

**VDH/OLC**
gathered and analyzed data to identify unforeseen and unexpected trends for the seven requires areas for licensure implemented documented corrective action for problems, and prepared at least an annual report for the governing body.

The findings included:

1. An interview was conducted on October 20, 2014 at 12:01 p.m., Staff #1 and Staff #3. Staff #1 explained to the survey team upon entrance the administrator was not available. The surveyor requested to perform the entrance conference with the alternate administrator. Staff #1 reported he/she was not aware of anyone being an alternate for the administrator. Staff #1 stated, "I will call [name of the administrator] and let you talk to [him/her]." A telephone interview was conducted on October 20, 2014 at approximately 12:11 p.m. with Staff #2. During the telephone interview Staff #2 reported that he/she would not be able to return to the facility until 3:00 p.m. The surveyor requested to perform the entrance conference with the appointed alternate administrator. Staff #2 stated, "I don't have an alternate administrator."

2. An interview was conducted on October 21, 2014 at 9:50 a.m. with Staff #4. The surveyor requested to observe the preparation of injectable medications utilized during the procedure. Staff #4 stated, "I don't prepare the Lidocaine injections. [Name of Staff #1] prepares the Lidocaine injections in the room just prior to the procedure."

A second surveyor conducted observations during a procedure on October 21, 2014 at approximately 10:36 a.m. The observation confirmed Staff #1, a non-licensed healthcare personnel, prepared the injectable Lidocaine utilized by the physician during the abortion procedure.

T-020 12 VAC 5-412-140 C
Management and Administration
- The Governing body will undertake a review of the revised Regulations (12 VAC 5-412 effective 6/20/2013) immediately and take all required actions necessary to mitigate all deficiencies noted within this report. The Governing Body will meet with the Administrator and fully review the updated Policy and Procedure Manual (including 12 VAC 5-412) prior to the completion date for correcting Deficiencies noted in this report (18 December 2014).
- Appointment of an acting administrator is responded to in T-055
- Injectable Medication preparation id responded to in T-285
- Annual Review of the AHCW Policy & Procedure Manual is responded to in T-035
- Facility Ongoing assessment program is responded to in T-315
- Quality Committee procedures and annual report for Governing Body and Licensee is responded to in T-335
3. Review of the facility's policies and procedures on October 20, 2014 at 5:35 p.m. did not contain evidence the policy and procedure manual had been reviewed and updated since 2012.

An interview was conducted on October 20, 2014 at 6:30 p.m., with Staff #2. The surveyor requested documentation that the governing body or the administrator had reviewed the facility's policy and procedure manual annually. Staff #2 stated, "I didn't realize they needed to be reviewed annually." Staff #2 was not aware of the additional requirements for personnel policies in the State licensing regulations, which had been updated in June 2013.

4. An interview and review of the facility's quality program was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 initially stated he/she did not understand the State licensure requirement of implementing "an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement."

5. An interview and review of the facility's quality program documents was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 and the surveyor reviewed the facility's quality program documentation. The facility's documentation did not include the required seven elements of: staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; and staff concerns regarding patient care. Staff #2 reported the quality committee had not collected or evaluated data for the seven required areas.
The review revealed documents titled "Quality Meeting," which listed items discussed as part of the facility's quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were implemented. Staff #2 reported the quality committee did not compile a report for the governing body to review at least annually.

12 VAC 5-412-160 C Administrator

C. A qualified individual shall be appointed in writing to act in the absence of the administrator.

This RULE: is not met as evidenced by:
Based on document review and interview the administrator failed to ensure the governing body appointed a qualified individual to cover the duties when the administrator was not available.

The findings included:

An interview was conducted on October 20, 2014 at 12:01 p.m., Staff #1 and Staff #3. Staff #1 explained to the survey team upon entrance the administrator was not available. The surveyor requested to perform the entrance conference with the alternate administrator. Staff #1 reported he/she was not aware of anyone being an alternate for the administrator. Staff #1 stated, "I will call [name of the administrator] and let you talk to [him/her]." A telephone interview was conducted on October 20, 2014 at approximately 12:11 p.m. with Staff #2. During the telephone interview Staff #2 reported that he/she would not
be able to return to the facility until 3:00 p.m. The surveyor requested to perform the entrance conference with the appointed alternate administrator. Staff #2 stated, "I don't have an alternate administrator." Staff #2 verbally authorized Staff #1 to assist the surveyors and conduct the entrance conference.

An interview was conducted on October 20, 2014 at 1:15 p.m., with Staff #1. The surveyor inquired about the delay in receiving information requested during the entrance conference. Staff #1 informed the surveyor he/she did not have keys to the locked drawers to obtain a list of patients seen at the facility as requested. Staff #1 reported he/she did not have access to the file cabinets to retrieve other information the surveyors had requested during the entrance conference. Staff #1 stated, "I have called [Name of the administrator] and asked [him/her] to get here as soon as possible. I really don't have access to much of anything."

Review of the facility's by-laws documented an alternative to the administrator would be appointed to cover the responsibilities of the administrator in the administrator's absence. Page 5 of 6 in the facility's "By-Laws Section 3.2" read in part "The Administrator shall designate an Assistant Administrator to act on [his/her] behalf during [his/her] absence." Review of governing body minutes did not reveal the facility had a current alternative/assistant to the administrator.

An interview was conducted on October 20, 2014 at 6:22 p.m., with Staff #2. Staff #2 reported during the initial survey an alternative had been appointed. Staff #2 reported the individual left the position and no one had been designated to be responsible for the administrator's duties when the administrator was not available.
T-065 12 VAC 5-412-180 B Personnel  

B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member.

This RULE is not met as evidenced by:

Based on document review and staff interviews it was determined the facility failed to implement a mechanism to verify professional credentials for five (5) of seven (7) staff members. (Employee files #2, #4, #5, #6 and #7)

The findings included:

At the entrance conference on 10/20/2014 at 12:15 p.m., Staff #1 and Staff #3 were asked to provide a list of current staff including contract staff and to include date of hire and title for the surveyor to review. Staff #2 arrived at 2:15 p.m. and was asked again about providing the list of current staff. The review of personnel records found five (5) of seven (7) employees (Employee files #2, #4, #5, #6 and #7) failed to contain evidence that verify professional credentials of licensed staff members.

The findings related to verifying professional credentials were discussed with Staff #1 on 10/21/2014 at 3:15 p.m. Staff #2 reported he/she was not aware of a requirement related to staff license needing to be validated until it was brought to his/her attention by the surveyor.

During the exit interview on 10/21/2014, Staff #2 acknowledged that the facility failed to maintain the system in the manner required by this Virginia...
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER
AMETHYST HEALTH CENTER FOR WOMEN, INC

STREET ADDRESS, CITY, STATE, ZIP CODE
9380-B FORESTWOOD LANE
MANASSAS, VA 20110

CORRECTED COPY

T 065
Continued From Page 6

regulation.

T 070
12 VAC 5-412-170 C Personnel

C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.

This RULE: is not met as evidenced by:
Based on document review and staff interview it was determined the facility failed to obtain a criminal history record check as specified in section §32.1-126.02 of the Code of Virginia for two (2) of seven (7) employees in the survey sample (Employee files #4 and #5) not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.

The findings included:

At the entrance conference on 10/20/2014 at 12:15 p.m., Staff #1 and Staff #3 were asked to provide a list of current staff including contract staff and to include date of hire and title for the surveyor to review Staff #2 arrived at 2:15 p.m. and was asked again about providing the list of current staff and include whose job duties provide access to controlled substances. The review of personnel records found two (2) of seven (7) employees (Staff #4 and #5) have access to controlled substances and did not have a criminal history record check.

The findings related to the criminal history record checks were discussed with Staff #2 on 10/21/2014 at 3:15 p.m. Staff #2 acknowledged

T-070 12 VAC 5-412-180 C Personnel
Complete Date: 11/14/14

- Regarding Staff 4, a criminal background check from the City of Manassas was within the employee file. Subsequent to the inspection a State Criminal Background check was received.

- Regarding Employee 5, a credentialed contracted consultant, licensed by the Virginia Board of Medicine and the DEA. VDH/OLC was contacted on 11 February 2013 for clarification and was advised that NO CRIMINAL BACKGROUND CHECK was required. This was documented in responses to VDH/OLC Survey conducted 12/11/2012 Reference T 170.

AHCW has started background checks on its credentialed physicians and Va state Criminal check forms which had already been mailed are in our submittal.

AHCW has only just been notified in the last week that our provisions would not cover the physicians.
the agency has a process to obtain a criminal record report on applicants from the Virginia Department of State Police; however it was not until it was brought to his/her attention by the surveyor that the criminal history record checks were not being obtained as stated in the agency’s policy and procedures and Virginia regulations.

During the exit interview on 10/21/2014, Staff #2 acknowledged that the facility failed to maintain the system in the manner required by this regulation and their own approved and established procedure.

12 VAC 5-412-170 H Personnel

H. Personnel policies and procedures shall include, but not be limited to:
1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;
2. Process for verifying current professional licensing or certification and training of employees or independent contractors;
3. Process for annually evaluating employee performance and competency;
4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility, and
5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.

This RULE is not met as evidenced by:
Based on document reviews and staff interviews it was determined the facility failed to implement the policy for verifying current professional licensing or certification and annually evaluating employee performance.

And that they and employees would have to obtain criminal background checks even though they have no access to narcotic keys or the medicine safe as it used to.

12 VAC 5-412-180 H Personnel

Regarding annual verification of current professional licensing, the AHCW response is T-065 of this document,

Regarding annual performance review, the AHCW Administrator was counseled and immediately reviews were done and completed and placed within the personnel record.

The Policy and Procedure Manual will be updated to reflect Annual Performance Reviews to be conducted in January.
performance for seven (7) of seven (7) employees in the survey sample (Employee files #1, #2, #3, #4, #5, #6 and #7).

The findings included:

The review of personnel records on 10/21/2014 failed to contain evidence that verify professional credentials of licensed staff members for five (5) of seven (7) staff members (Employee files #2, 4, 5, 6 and 7); and six (6) of seven (7) staff (Staff #1, 2, 3, 4, 6 and 7) had no evidence of an annual performance evaluation or evidence policies were being implemented. The six (6) staff members had been employed over one (1) year.

The findings related to implementing the policy for verifying current professional licensing or certification and evaluating employees were discussed with Staff #2 on 10/21/2014 at 3:15 p.m. Staff #2 acknowledged that although the agency has a process to complete employee annual performance evaluations, he/she knew the personnel files should have contained these documents but failed to do so. Staff #2 reported he/she was not aware staff license needed to be validated until it was brought to his/her attention by the surveyor.

During the exit interview on 10/21/2014, Staff #2 acknowledged that the facility failed to maintain the facility's system in the manner required by this regulation and their own approved and established procedure.

T 100 12 VAC 5-412-170 I Personnel

1. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and

T-100 12 VAC 5-412-180 I Personnel Complete Date: 12/18/14

- Prior inspections required AHCW to maintain employee health information separately from Personnel records in a controlled container. In accordance with the regulations, employee health records have been placed in an envelope within the employee record.
- The AHCW P&P Manual will be updated to reflect this changed direction by regulation.
Unauthorized use. Employee health-related information shall be maintained separately within the employee's personnel file.

This RULE: is not met as evidenced by:

- Based on document review and staff interview, the facility failed to maintain employee health-related information be maintained separately within the employees' personnel files for seven (7) of seven (7) employees (Employee Files #1, #2, #3, #4, #5, #6 and #7).

The findings included:

- The agency policy and procedure manuals were reviewed on 10/20/2014. Seven (7) employee files (Staff #1-7) were reviewed on 10/21/2014 at approximately 2:30 p.m. Seven (7) of seven (7) employee files reviewed had health information within the employee file.

The findings related to maintaining employee files were discussed with Staff #2 on 10/21/2014 at 3:15 p.m. Staff #2 acknowledged that although the agency has a process to store all employee files in one (1) separate folder, he/she confirmed the findings in the employee files.

During the exit interview on 10/21/2014, Staff #2 acknowledged that the facility failed to maintain the facility's system in the manner required by this regulation.

A. Physicians and non-physician health care practitioners shall constitute the clinical staff. Clinical privileges of physicians and non-physician health care practitioners shall be clearly defined.
This RULE: is not met as evidenced by:
Based on document review and interview the
delineation of privileges for two of three
physicians. (Credentialing Files #1 and #2)

The findings included:

Review of the physician files for credentialing was
conducted on October 21, 2014. Review of
Credentialing File #1 did not document the
physician’s clinical privileges. Review of
Credentialing File #2 revealed a contract defining
privileges, but the contract had not been signed
and dated by the physician. Credentialing File #2
did not contain documentation, which defined the
physician’s privileges.

An interview was conducted on October 21, 2014
at approximately 2:00 p.m., with Staff #2. Staff #2
was informed of the findings. Staff #2 stated in
regards to Credentialing File #2, “I can’t believe
[he/she] didn’t sign the contract, but it’s not
signed.” Staff #2 verified Credentialing Files #1
and #2 did not have documented delineation of
privileges.

B. Abortions shall be performed by physicians
who are licensed to practice medicine in Virginia
and who are qualified by training and experience
to perform abortions. The facility shall develop,
implement and maintain policies and procedures
to ensure and document that abortions that
occur in the facility are only performed by
physicians who are qualified by training and
experience.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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<th>Provider/Supplier/Clinic Identification Number:</th>
<th>Multiple Construction Identification Number:</th>
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<tbody>
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<td>AF-0007</td>
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**NAME OF PROVIDER OR SUPPLIER**
AMETHYST HEALTH CENTER FOR WOMEN, INC

**STREET ADDRESS, CITY, STATE, ZIP CODE**
2360-B FORESTWOOD LANE
MANASSAS, VA 20110

**CORRECTED COPY**

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<tr>
<th>(X1) ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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This RULE is not met as evidenced by:
Based on document review and interview the facility failed to obtain documentation of physicians' education and training for qualification to perform abortions for two of three physicians (Credentialing Files #1 and #2).

The findings included:

Review of the physician files for credentialing was conducted on October 21, 2014. Review of Credentialing File #1 did not have documentation of the physician's education or training which qualified him/her to perform abortions. Credentialing File #2 did not have documentation of the physician's education or training which qualified him/her to perform abortions.

An interview was conducted on October 21, 2014 at approximately 2:00 p.m., with Staff #2. Staff #2 stated, "[Name of Credentialing File #1] has been performing abortions for more than 40 years. [He/she] is definitely qualified and so is [Name of Credentialing File #2]." Staff #2 verified Credentialing Files #1 and #2 did not have documentation related to their training or education. Staff # 2 stated, "I guess I needed to get their CVs (curriculum vitae) and put it in their files."

[According to On-infreeedictionary.com: "A Curriculum Vitae [Sic] is a form of resume, which documents a person's background, skills, experience and education ..."

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<th>T 115</th>
<th>12 VAC 5-412-180 C Clinical staff</th>
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C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order and be readily available and accessible until the last patient is discharged.

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<th>T-115</th>
<th>12 VAC 5-412-190 C Clinical staff</th>
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Complete Date: 12/18/14
- Physicians did not adhere to the facility policy regarding discharge. The Policy and Procedure Manual will be updated to specifically state that physicians MUST sign the discharge order in order for the physician to depart the facility.
- Physicians did not adhere to the facility policy that an adequately trained health care practitioner must remain with the patient until discharged from the facility. The Policy and Procedure Manual will be updated to place responsibility on the physician to ensure that adequately trained health care personnel remain with the patient until discharge.
- The Medical Director will provide counseling to all physicians regarding discharge procedures and Staff 5 will receive a Letter of Admonishment to be placed into the personnel file regarding this violation of facility policy.
Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The facility shall develop, implement and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the facility.

This RULE: is not met as evidenced by:
Based on interview and document review the facility failed to implement their policy for the discharge process for seven (7) out of ten (10) patients included in the survey sample. (Patients #2, #4, #5, #7-#10).
The findings included:
Review of ten (10) medical records revealed that seven (7) out of ten (10) patients (#2, #4, #5, #7-#10) did not have a discharge order signed by the physician. The agency policy states, "The recovery room practitioner will inform the physician when the patient is ready for discharge processing and the physician will sign the discharge order."
During observation of the post-procedure process, the facility failed to implement the policy that adequately trained staff, remain on the premises until the patient is discharged from the facility. During the observation of patient in recovery room, post-procedure, it was noted that after the patient was assessed as stable, Staff #5 left the facility. No adequately trained health care practitioner remained in the facility to ensure patient safety until discharged from the facility.
Staff #4, the nurse remaining in the recovery room...
T 115 Continued From Page 13

is an licensed practical nurse (LPN), who must work under the supervision of a physician or registered nurse.
An interview was conducted with Staff #2 on 10/20/14 at approximately 4:00 p.m. Staff #2 acknowledged that seven patient records did not have a discharge order signed by the physician.

T 130 12 VAC 5-412-200 Minors

No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian or other authorized person. If the emancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to 16 1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to obtain an informed consent for one (1) of three (3) minors that received an abortion (Patient #10) and

2. Failed to ensure that the signature of the responsible parent or guardian had been notarized in accord with the Code of Virginia (16.1-241) for three (3) of three (3) minors included in the survey sample. (Patients #1, #4 and #10)

The findings included:

1. Review of Patient #10's medical record revealed the patient was admitted to the facility on July 22, 2014 and underwent an abortion procedure on August 5, 2014. Review of the informed consent revealed the form was

T-130 12 VAC 5-412-230 B Patient Services; Patient Counseling Complete Date: 12/18/14
- The AHCW consent form for informed minors consent will be created and include specific warnings that special circumstances exists. Specifically a block for notarization will be added and warning text box will articulate the specific statute.
Additionally, Patient Records of Minors will be color coded to reflect the need for specific informed consent.
- The AHCW Policy and Procedure will be updated to reflect the updated form.
- All employees handling informed consent will be counseled by the Administrator regarding this regulation.

12/18/14
incomplete. The form lacked the date for the procedure and the date the parent or legal
 guardian signed the form.

An interview was conducted on October 20, 2014 at approximately 6:10 p.m., with Staff #2. Staff #2
was informed of the findings. Staff #2 reviewed Patient #10’s medical record. Staff #2 stated,
"The nurse signed this [he/she] should have seen it wasn't filled out right." Staff #2 verified the
facility performed an abortion on an unemancipated minor.

2. Review of Patient #1’s medical record revealed the patient was admitted to the facility on
September 9, 2014 and underwent an abortion procedure on October 17, 2014. The responsible
parent/legal guardian signature had not been notarized.

Review of Patient #4’s medical record revealed the patient had been admitted to the facility on
October 8, 2014 and underwent an abortion procedure on October 10, 2014. The responsible
parent/legal guardian signature had not been notarized.

Review of Patient #10’s medical record revealed the patient was admitted to the facility on July 22,
2014 and underwent an abortion procedure on August 5, 2014. The responsible parent/legal
 guardian signature had not been notarized.

An interview was conducted on October 20, 2014 at approximately 6:10 p.m., with Staff #2. Staff #2
stated, "We used to do that. We used to send them to [name of local entity] and all they charged
was a dollar. Our consultant told us we didn’t have to do that anymore so we stopped."

[The Code of Virginia at subsection 16.1-241 read]
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER
AMETHYST HEALTH CENTER FOR WOMEN, INC

ADDRESS
9380-B FORESTWOOD LANE
MANASSAS, VA 20110

STATEOF VIRGINIA

X1 PROVIDER/SUPPLIER/LICA
AF-0007

X2 MULTIPLE CONSTRUCTION
A BUILDING
B. WANG

X3 DATE SURVEY COMPLETED
10/21/2014

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID
T 130 Continued From Page 15

T 130

PREVIOUS

NEW

ID
T 150 12 VAC 5-412-210 D Patients' rights

D. The patient shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to

STATE FORM 07/19/80

XV2L11

RECEIVED DECEMBER 19, 2014

VDH/OLC

T-150 12 VAC 5-412-200 D Patient's Rights Complete Date: 12/18/14

- The P&P Manual will be updated to reflect that the patient will receive a copy and sign/date a second copy of the complaint procedures before the procedure which will be inserted into the Patient Record.

This is entered in the submittal.

- The inspectors interviewed Staff 1 and 3, who by their position have nothing to do with preadmission procedures. Consequently, it is highly likely they were unfamiliar with this form.

- AHCW is unable to reconcile inspector statement in their findings:
  1. Para 3 states” The form had OLC complaint information” with 2. Para 2 “complaint procedure..., did not have information for contacting OLC”. The form provided the inspectors was “AHCW Patient Rights and Responsibilities dated 11 February 2012”. Findings 1 and 2 are referring to the same form.
service.

This RULE is not met as evidenced by:

Based on interview and record review, the agency failed to provide documentation that patients received the complaint procedure and information during admission for ten (10) of ten (10) patients included in the survey sample. (Patient #1 - #10)

The findings included:

1. Review of ten (10) patient records on 10/20/14, at approximately 3:45 PM, revealed that in ten (10) out of ten (10) patient records (#1-#10), there were no signatures acknowledging receipt of the OLC complaint information and telephone number, dated on patient admission, which is at least 24 hours prior to the procedure.

Facility policy states, "The patient shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service."

On 10/21/14 at approximately 3:30 PM, Staff #1, #3, and #4, were shown a complaint form taken from the interview room, and were questioned about the process of providing the patients with a copy of this form on admission. The form had OLC complaint information, but no area designated for the patient to sign and acknowledge receipt. Staff #1-#3 denied ever seeing this complaint information being given to a patient on admission, and claimed that they had never been advised to provide to patients.

2. Review of ten (10) patient records on 10/20/14, at approximately 3:45 PM, revealed that in nine (9) out of ten (10) patients records (#1-#4, #6 - #10) signed and dated on the procedure date, did not have complaint process and OLC information...
T 150 Continued From Page 17

documented as given.

During an interview on 10/20/14 at approximately 4:30 PM, Staff #2 acknowledged that the patient files did not have signatures on a complaint process dated on the admission dates. Staff #2 provided a copy of a form with OLC complaint information that is given to the patients on admission. This procedure could not be substantiated as the form did not designate an area for the patients signature to acknowledge receipt. Staff #2 acknowledged that the complaint procedure provided to nine patients, on the day of the procedure, did not have the information for contacting OLC.

T 155 12 VAC 5-412-210 E Patients’ rights

E. The facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:
1. Facility contact person; and
2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The facility shall display a copy of this information in a conspicuous place.

This RULE: is not met as evidenced by:
Based on observation, it was determined that the facility failed to display, in a conspicuous place, information on how to make a complaint.

The findings included:

On 10/20/14, at approximately 3:00 PM, a tour of the facility revealed there were no postings in the
recovery room with information for making a complaint to the OLC Complaint Unit, including the toll-free complaint hotline number.

T 155 Continued From Page 18

T 155

12 VAC 5-412-220 A Infection prevention

A. The abortion facility shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care," published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.

1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.

2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.

3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

This RULE: is not met as evidenced by:

Based on document review and staff interviews the facility failed to designate an individual with training and expertise in infection prevention, participating in the development of infection prevention policies and procedures and involved

T 165 12 VAC 5-412-220 A.3

Infection Prevention

Complete Date: 12/18/14

- Staff 2 has arranged and attended specific infection prevention training annually by CENTAS. Staff 2 has acted as the facility infection preventionist and will be formally designated by the medical director and the governing body. This designation will be placed in the Employment Record.
T-165 Continued From Page 19

in the annual review.

The findings included:

A review of seven (7) personnel records
(Employee files #1-7) failed to contain evidence
that verified any person with training and expertise
in infection prevention had assumed the
responsibilities/role of the infection preventionist.

The facility failed to implement its policy and
procedures and the administrator failed to
appoint a designated qualified individual as
required in the Virginia licensure regulations.

The findings related to having a designated
qualified individual in infection prevention was
discussed with Staff #2 on 10/21/2014 at 4:00
p.m. Staff #2 acknowledged the facility does not
have a qualified individual for the role in infection
prevention and he/she allowed this requirement to
be overlooked until it was brought to his/her
attention by the surveyor.

During the exit interview on 10/21/2014, Staff #2
acknowledged that the facility failed to maintain
the system in the manner required by this Virginia
licensure regulations.

T-170 12 VAC 5-412-220 B Infection
Prevention

Complete Date: 12/18/14

- Staff 5 violated facility infection
control procedures and will be
counseled by the Medical Director and
Administrator regarding these
violations. Staff 1 made statements to
the inspectors that were false regarding
not being trained in infection
prevention regarding PPE.

- AHCW will update the P&P
and provide a means of verifying
Infection Prevention Training for
credentialed employees.

- Infection Training will be
reviewed by the Quality Committee/
Governing Body annually

12/18/14
indications for use of soap and water and use of alcohol based hand rubs;
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 observation, interview and review of CDC recommendation for Infection Protection for Outpatient Settings, it was determined that the facility failed to ensure infection prevention policies were followed, and that adequate training for staff was provided.
The findings included:
Observation of a procedure performed on 10/21/14 at approximately 10:30 AM revealed that Staff #5 did not perform hand hygiene after entering the procedure room and before donning sterile gloves. Staff #5 did not remove the personal protective equipment (PPE) gown after the procedure.
According to Infection Prevention for Outpatient Settings:
Minimum Expectations for Safe Care, Key situations where hand hygiene should be performed include: 1) Before touching a patient, even if gloves are worn; 2) Prior to performing an aseptic task (e.g., placing an IV, preparing an injection)
Key recommendations for use of PPE in
T 170  Continued From Page 21

ambulatory care settings : 1) Educate on proper selection and use of PPE; 2) Do not wear the same gown for the care of more than one patient. It was observed on 10/21/14 at approximately 12:00 PM that Staff #1 wore the same PPE gown worn in a room with biohazard material and the room where sterilization of equipment is processed.

On 10/22/14 at approximately 12:00 PM, Staff #1 was questioned about the facility gowns procedures when moving from unclean rooms to clean rooms. Staff #1 said she was not trained to remove the gown when exiting the room with biological waste or to put on a clean gown when entering the sterilization room.

It was observed on 10/21/14 that Staff #4 wore the same PPE gown during two (2) procedures performed between 10:30 AM and 11:15 AM. On 10/21/14 at approximately 5:00 PM, Staff #4 acknowledged that she had worn the same gown throughout the day and stated that she did not know to put on a clean PPE gown prior to a procedure or to remove the PPE gown after a procedure.

3. Review of three (3) credentialing personnel files showed no evidence of training in proper infection prevention techniques or annual retraining in recommended infection prevention practices. The facility failed to implement their policies/procedures and failed to comply with the requirements of the Virginia licensure regulations.

The findings related to having the required training were discussed with Staff #2 on 10/21/2014 at 4:30 p.m. A request was made for any information related to employees' training in proper infection prevention techniques. Staff #2 reported he/she was not aware the required training failed to be
documented in the three (3) credentialing personnel files. Staff #2 reported the facility trains staff to comply with infection prevention practices as documented in seven (7) of seven (7) employee personnel files (Employee files #1-7); however he/she reported the facility failed to show evidence the three (3) credentialing employees were trained in infection prevention practices.

T 175 12 VAC 5-412-220 C Infection prevention

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);
4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment, 
   (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and

T-175 12 VAC 5-412-220 C.10 Infection Prevention
Complete Date: 11/10/14
- Immediately following the inspection the 2 damaged recliners were taken out of service and not replaced. The remaining 4 were cleaned and disinfected. The recovery room personnel were counseled regarding the procedure for cleaning the recovery room.
- Immediately following the inspection the administrator and procedure room employees inspected the procedure table and were not able to find the remnant of tape described in the inspectors' findings. The staff did find on the drawers of the procedure table labels (autoclave tape) on the drawers. These labels were removed and the procedure table was cleaned and disinfected.
(iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: is not met as evidenced by:
This is a re-cite related to staff's failure to change PPE and non-intact surfaces of direct care equipment.

Based on observation and interview, it was determined that the facility failed to implement procedures to properly disinfect environmental surfaces that are frequently touched or come in close contact to patients as required to remove pathogenic microorganisms for six (6) of six (6) recliners in the recovery area and one (1) of one (1) procedure table.
The findings included:
Observation of the recovery room 10/20/14, at approximately 12:30 PM, revealed that six (6) out of six (6) recliners in the recovery room were not cleaned properly and that two (2) out of six (6) recliners had rips in the vinyl. Tears in vinyl restrict the ability to disinfect the material on the chairs.

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and can harbor bacteria. During a tour of the facility on 10/20/14, at approximately 2:30 PM, it was revealed that the procedure table had a remnant of tape on the metal plate under the padding. The rough surface of the tape restricts the ability to disinfect and could harbor pathogens.

According to the CDC Guide to Infection Prevention for Outpatient Settings:

1) Responsibility for routine cleaning and disinfection of environmental surfaces should be assigned to appropriately trained (staff); 2) Cleaning procedures can be periodically monitored or assessed to ensure that they are consistently and correctly performed.

Staff #1 was present during recovery room inspection and facility tour. Staff #1 stated that some of the soil on the chair was from the floors being waxed that morning, but acknowledged the chairs had not been properly cleaned and disinfected. Staff #1 was made aware of the tape on the procedure table.

T 180 12 VAC 5-412-220 D Infection Prevention

D. The facility shall have an employee health program that includes:

1. Access to recommended vaccines;
2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;
3. An exposure control plan for blood-borne pathogens;
4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine;

T-180 12 VAC 5-412-220 D Infection Prevention

Complete Date: 12/18/14

- Documentation of employee refusal regarding screening and immunizations had previously been noted by the administrator in the employee health file. AHCW will update the P&P manual to incorporate a form which will be signed by the employee indicating their decline/refusal of screening and immunizations.
5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.

This RULE is not met as evidenced by:
Based on document review and staff interviews the facility failed to have an employee health program that documented screenings and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities for seven (7) of seven (7) employees and three (3) of three (3) physicians.

The findings included:

A review of seven (7) personnel records (Employee files #1-#7) and three (3) credentialing personnel records (Credentialing files #1-#3) failed to contain evidence verifying employees were offered/received screening for tuberculosis.

The findings related to having screening and immunizations offered/received by employees were discussed with Staff #2 on 10/21/2014 at 4:15 p.m. Staff #2 acknowledged the facility does have a process for offering employees screening and immunizations, including Hepatitis B and the influenza vaccine. Staff #2 reported many employees refuse the offered service. The surveyor inquired if Staff #2 had documented the employee's refusal. Staff #2 reported the facility had not developed a decline or refusal of immunizations form, and did not have documentation of the employees/physicians declined the screenings and immunizations.
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T 185 12 VAC 5-412-220 E
Infection Prevention

E. The facility shall develop, implement and maintain policies and procedures for the following patient education, follow-up, and reporting activities:
1. Discharge instructions for patients, to include instructions to call or return if signs of infection develop;
2. A procedure for surveillance, documentation and tracking of reported infections; and
3. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12 VAC 5-90), including outbreaks of disease.

This RULE: is not met as evidenced by:
Based on record review and interview the facility failed to document the patient's condition, or that instructions for infections were provided prior to discharge for seven (7) out of ten (10) patients included in the survey sample. (Patients #2, #3, #5, #7-#10)
2. The facility failed to develop a procedure for tracking infections and reporting the findings to the local health department.
The findings included:
Review of ten (10) patient records on 10/20/14 at approximately 2:30 PM, revealed seven (7) out of ten (10) patients #2, #3, #5, #7-#10 did not document condition of patients at discharge or have documentation verifying that infection prevention instructions had been provided to the patient.
On 10/21/14 at approximately 9:45 AM, Staff #5 took responsibility of not completing the patient record with the patient condition at discharge. Staff #5 stated, "That was me. I didn't complete it." Staff #2 was present during the record review and acknowledged the findings above. During an
summary statement of deficiencies
(each deficiency must be preceded by full regulatory or lsc identifying information)

T 185  Continued From Page 27

T 185

T 285  T 285

12 VAC 5-412-260 E
Administration, Dispensing and Storage of Drugs

- Staff 4 was counseled regarding her violation of AHCW Policy and Procedure. While all drugs were accounted for and dispensing recorded within patient records, the fact that the narcotic log required reconciliation due to the deliberate lack of documentation was clearly in violation. Staff 4's assertion that insufficient time was given after the procedure was patently false.

- Staff 1, is a CNA and as such preparing injectable Medication is prohibited by regulations. The inspector's finding in T-285 2. Paragraph 3 stated that the inspector looked for "training for the preparation of medication" which is confusing given that Staff 1, being and identified in the finding as a CNA, cannot prepare injectable medication regardless of any training found within the Personnel record. The Administrator failed to ensure that only LPN's or RN's prepared injectable medications and will be counseled by the Medical Director.

On 10/20/14 at approximately 2:10 PM, an observation was conducted to review the facilities controlled medication inventory and narcotics log Staff #2 counted remaining tablets for 2mg Dilaudid, 0.5 mg Xanax, and 10 mg Vicodin. The
T 285  Continued From Page 28

bottle of dilauded had no remaining tablets. The
narcotic log indicated that on 10/10/14, there was
one tablet remaining. The narcotic log indicated
there were 264 xanax tablets on 10/14/14. The
patient identification for the last tablet
administered was not documented. A count by
Staff #2 revealed 263 tablets remaining. The
narcotic log indicated there were 364 vicodin
tables on 10/17/14. Staff #2 counted 363 vicodin
tables.

During an interview conducted on 10/20/14 at
approximately 3:00 PM, Staff #2 acknowledged
the medication count did not equal the narcotic
log. Staff #2 stated that "the girls didn't document
in the record" after administering the medications.
Patient files with procedures performed on
10/14/10 were reviewed and one patient had
received one 0.5 xanax tablet that was not
documented on the narcotics log. Patient files with
procedures performed on 10/18/14 were
reviewed. One 2 mg dilauded and one 10 mg
vicodin tablets were administered but not noted on
the log. Patient record documentation resolved the
differences in the log count and the actual
remaining medications.

Staff #4, interviewed on 10/21/14 at approximately
3:30 PM, acknowledged that the medication
administered on 10/14/10 and 10/18/14 had not
been documented on the log. Staff #4 said not
enough time was given after the procedures to
document the medications administered.

...
A second surveyor conducted observations during a procedure on October 21, 2014 at approximately 10:36 a.m. The observation confirmed Staff #1, a non-licensed healthcare personnel, prepared the injectable Lidocaine utilized by the physician during the abortion procedure.

Review of Staff #1's employee file did not contain additional training for the preparation of medication or a skills checklist to ensure proper technique.

An interview was conducted on October 21, 2014 at approximately 2:00 p.m., with Staff #2. Staff #2 was informed of the findings. Staff #2 stated, "[Name for Staff #1] is a certified nursing assistant, I thought [he/she] could prepare medications."

Review of the Code of Virginia subsection §54.1-3408 "Professional use of (controlled substances) by Practitioners" does not provide allowance for non-licensed persons to prepare local anesthesia injections; even under the supervision of a physician.

T 315 12 VAC 5-412-300 A Quality assurance

A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.

This RULE is not met as evidenced by:
Based on document review and interview the
quality committee failed to ensure the facility maintained an ongoing, comprehensive, integrated, self-assessment program.

The findings included:

An interview and review of the facility's quality program was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 initially stated he/she did not understand the State licensure requirement of implementing "an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement."

The review revealed documents titled "Quality Meeting," which listed items discussed as part of the facility's quality program meeting. The surveyor asked Staff #2 how the quality committee determined, which items to discuss and if the committee had formulated the items from data collected. Staff #2 denied that data had been collected as the basis for what was discussed during the quality committee's meetings.

An interview was conducted on October 21, 2014 at 5:01 p.m., the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 reported they had not received notification that the regulations had been revised. The surveyor informed Staff #2 that the State licensure office did not send out notices to each facility related to changes in the licensure regulations. The surveyor informed Staff #2 that it was the facility's responsibility to occasionally check the State's website for updated licensure regulations. Staff #2 stated, "We have not collected data or performed a program assessment."
This is a re-cite from 2012.

T 320 12 VA C 5-412-300 B Quality assurance

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:
1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

This RULE is not met as evidenced by:
Based on document review and interview the quality committee failed to ensure an evaluation of the the adequacy and appropriateness of services as required by the state licensure regulations.

The findings included:
An interview and review of the facility's quality program documents was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 and the surveyor reviewed the facility's quality program documentation. The facility's documentation did not include the required seven elements of:
staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; and staff concerns regarding patient care. Staff #2 reported the quality committee had not collected or evaluated dated for the seven
During an interview conducted on October 21, 2014 at 5:01 p.m. the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 denied awareness of the updated State licensure regulations. Staff #2 reported the quality committee had not collected, analyzed, or trended data for the required areas to identify unacceptable or unexpected outcomes.

This is a re-cite from 2012.

D. Measures shall be implemented to resolve problems or concerns that have been identified.

The RULE: is not met as evidenced by:

Based on document review and interview the quality committee failed to ensure measures were implemented to resolve identified problems and concerns.

The findings included:

An interview and review of the facility's quality program was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 initially stated he/she did not understand the State licensure requirement of implementing "an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement."

The review revealed documents titled "Quality Meeting," which listed items discussed as part of

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<th>T 320</th>
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<td>T 320</td>
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<table>
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<tr>
<th>T 330</th>
<th>12 VAC 5-412-300 D Quality assurance</th>
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T-330 12 VAC 5-412-210 D Quality Management Complete Date: 12/18/14
1. The Correction of identified deficiencies will be reported to the Quality Committee and reflected within the Meeting minutes. This change to the P&P will be updated and the P&P reviewed at the next Quality Meeting.
the facility's quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were implemented.

This is a re-cite from 2012.

T 335 2 VAC 5-412-300 E Quality assurance

E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

This RULE is not met as evidenced by:
Based on document review and interview the quality committee failed to compile results of deficient practices or corrective action implemented to the governing body.

The findings included:

An interview and review of the facility's quality program was conducted on October 21, 2014 at 5:00 p.m., with Staff #2. Staff #2 initially stated he/she did not understand the State licensure
**T 335** Continued From Page 34

requirements related to "an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement."

The review revealed documents titled "Quality Meeting," which listed items discussed as part of the facility's quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were implemented. Staff #2 reported the quality committee did not compile a report for the governing body to review at least annually.

This is a re-cite from 2012.

**T 340** 12 VAC 5-412-310 Medical records

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:

1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;

**T-340 12VAC 5-412-300 Health Information Records Complete Date: 12/18/14**

- Following review of the deficiencies an immediate review of the Patient Procedure Chart will be conducted and changes discussed with the Medical Director and Physicians. Revision will take place and instruction on utilization will take place. Additionally, persons responsible for entering information into the chart will be counseled regarding proper completion of required information.
d. Operative record;
e. Surgical medication and medical treatments;
f. Recovery room notes;
g. Physician and nurses' progress notes;
h. Condition at time of discharge;
i. Patient instructions, preoperative and postoperative; and
j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by:
Based on interview and document review, the facility patient records were incomplete and did not contain sufficient information:
1. Seven (7) out of ten (10) patient records (#2, #3#, #5, #7-10) did not have the systems assessment completed;
2. Ten (10) out of ten (10) patient records (patients #1-#10) did not have physician or nurse progress notes from the procedure through discharge.
3. Seven (7) out of ten (10) patient records (#2, #3#, #5, #7-10) did not have the condition at discharge documented.
4. Nine (9) out of ten (10) patient records (#2-#10), patient instructions, preoperative and postoperative were not documented.

The findings included:
1. Ten (10) patient records reviewed on 10/20/14, at approximately 1:00 PM, revealed that seven (7) out of ten (10) patient records (#2, #3#, #5, #7-10) did not have the systems assessment completed, making the history and physical examination documentation incomplete.
2. Ten (10) out of ten (10) patient records (patients #1-#10) did not have physician or nurse progress notes from the procedure through discharge. The medical records had a section titled "Doctor Notes," which was blank on all ten
medical records reviewed. The medical records did not provide a space for the nurses to document the patient's status and progress.

3. Seven (7) out of ten (10) patient records (#2, #3, #5, #7-10) did not have the condition at discharge documented. The facility's form had a section for documentation, which had been left blank.

4. For nine (9) out of ten (10) patient records (#2-#10), patient instructions, preoperative and postoperative were not documented. The form used had a section for documentation, but were left blank.

During an interview on 10/20/14, from approximately 4:00 PM to 5:30 PM, Staff #2 acknowledged the findings listed above.

B. Abortion facilities shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence.

This RULE: is not met as evidenced by:
Based on document review and staff interview, the facility failed to develop policies and procedure for reporting to the Office of Licensure and Certification (OLC) within 24 hours any occurrences, which involved:

1. Patient, visitor, and/or staff death or injury
2. What the notification to OLC should include
3. The facility's responsibility to report occurrences to law enforcement and the failure to develop policies and procedures to ensure compliance with:
4. Confidentiality of records shared with OLC
5. The training and requirement that facility staff were deemed Mandated reporters of suspected child abuse or neglect as defined under the Code
of Virginia §63.2-1509 for seven (7) of seven (7) employees. (Employee files #1-#7)

The findings included:

1. Review of the facility’s policy and procedure manual on 10/20/2014 through 10/21/2014 did not reveal the following policy and procedures:

   (B) The abortion facility shall report the following events to OLC:

   1. Abortion facilities shall report all patient, staff or visitor deaths.
   2. Any serious injury to a patient.
   3. Medication errors that necessitate a clinical intervention other than monitoring;
   4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and
   5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990.

2. Review of the facility’s policy and procedure manual on 10/20/2014 through 10/21/2014 did not reveal the following policy and procedures:

   (C) Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the following:

   1. Abortion facility name;
   2. Type and circumstance of the events being reported;
   3. Date of the event; and
   4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.

An interview was conducted on 10/21/2014 at
approximately 5:00 p.m. with Staff #2. A request was made for any information related to reporting events to the OLC. Staff #2 reported he/she was not aware of a requirement related to reporting all patient, staff or visitor deaths within 24 hours of occurrence. The surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 reported they had received notification that the regulations had been revised. Staff #2 reported the facility had not developed the additional policies, procedures, or processes to encompass the new reporting requirements to comply with the required reporting events to the OLC.

3. During an interview at approximately 5:30 PM with Staff #2, it was revealed that the facility had not updated their policies to the June 20, 2013 regulations which stated that compliance with 12VAC5-412-320 does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law enforcement or professional regulatory agencies. Staff #2 acknowledged that the facility was unaware of the new regulation and had not entered this into the policy manual.

4. During an interview at approximately 5:30 PM with Staff #2, it was revealed that the facility had not updated their policies to the June 20, 2013 regulations. Staff #2 acknowledged that the facility was unaware of the regulation that records shall be maintained as confidential by OLC and had not included this in the policy manual.

5. Review of seven employee files did not reveal documentation of education, training and acknowledgement related to being Mandated reporters of suspected child abuse or neglect as
An interview was conducted on 10/21/2014 at 5:01 p.m. with Staff #2. Staff #2 acknowledged the facility had failed to develop policies and procedure related to staff being mandated reporters of suspected child abuse or neglect.

On October 21, 2014 at 5:01 p.m., the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 reported they had not received notification that the regulations had been revised. The surveyor informed Staff #2 that the State licensure office did not send out notices to each facility related to changes in the licensure regulations. The surveyor informed Staff #2 that it was the facility's responsibility to occasionally check the State's website for updated licensure regulations.
Ms. Kathaleen Creegan-Tedeschi, Supervisor
Acute Care, Home Health and Hospice Services
Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Suite 401
Henrico, VA 23233

Dear Ms. Creegan-Tedeschi,


We have completed the Plan of Correction, as directed, on the Licensure Inspection Report form. Also included are attachments, where applicable, to provide proof of AHCW actions resolving the noted deficiencies.

Please contact me should you or your inspectors have any questions / concerns regarding this Plan of Correction.

Submitted:

[Signature]
Maria Elisabeth Beurskens
Owner and Administrator
Amethyst Health Center for Women, Inc.
### Statement of Deficiencies and Plan of Correction

**Name of Provider or Supplier:** Amethyst Health Center for Women, Inc.  
**Street Address, City, State, Zip Code:** 9386-B Forestwood Lane, Manassas, VA 20110  
**Identifying Number:** FTAF 012  
**Date Survey Completed:** 12/11/2012

<table>
<thead>
<tr>
<th>ID Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID Tag</th>
<th>Provider’s Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
<th>Complete Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>T 000</td>
<td>12 VAC 5-412 Initial comments</td>
<td>T 000</td>
<td>2/19/13</td>
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</table>

**Regarding T 000, AHCW has thoroughly investigated all items identified during the unannounced VDH/OLC inspection conducted on 12/10-11/2012.**

The fact that your inspectors found an uncorrected citation and re-cited AHCW was troubling and has been given serious review to establish the root cause of this item.

As a result of our investigation, we have corrected the items, where applicable, have modified our policies and procedures and if appropriate issued letters of discipline to the appropriate employees/consultants.

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<tr>
<th>ID Tag</th>
<th>Description</th>
<th>Date</th>
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<tbody>
<tr>
<td>T 070</td>
<td>12 VAC 5-412-170 C Personnel</td>
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<tr>
<td>C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated</td>
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**Laboratory Director’s or Provider/Supplier Representative’s Signature:** Maria Elizabeth Berzins

**Title:** President

**Date:** 2/13/2013

**State Form:** 021196  
**Number:** 6W33111
<table>
<thead>
<tr>
<th>ID PREFIX</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>COMPLETE DATE</th>
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<tbody>
<tr>
<td>T 070</td>
<td></td>
<td>Continued From Page 1</td>
<td>T 070</td>
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<td>Regarding T 070, AHCW stores all controlled substances within a safe. The keys to this safe are controlled by the Administrator. Access to this safe is limited to AHCW Clinical Staff or those whose job duties require access to remove drugs and put them into service. These individuals are required to have Criminal Background Checks. The LPN was a new employee at the time of inspection and now has a Criminal Background Check in her personnel file. The CRNA is contracted for service as a consultant and not an employee of AHCW. AHCW mistakenly believed that she was licensed by the board of Pharmacy but became aware that she was licensed by the Board of Nursing. The CRNA is no longer contracted by AHCW. In the future, any CRNA practicing at AHCW shall have a criminal Background Check. Physicians at AHCW are contracted consultants, licensed by the Virginia Board of Medicine and Registered by the DEA. These Physicians do not have access to the Controlled Substance Keys or Safe at AHCW. During the preparation of this response, AHCW contacted VDH/OLC on February 11,2013 for clarification regarding Physician's Criminal Background Check.</td>
<td>2/16/13</td>
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<tr>
<td>T 170</td>
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<td>12 VAC 5-412-220 B Infection prevention</td>
<td>T 170</td>
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employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.

This RULE: is not met as evidenced by:
Based on document review and interview the facility staff failed to have criminal record checks performed for staff who have access to controlled substances within the facility.

The findings include:
On 12/11/12 the personnel files of the CRNA (Certified Registered Nurse Anesthetist), LPN (Licensed Practical Nurse) and 2 physicians were reviewed. The files did not contain a criminal history check pursuant to 32.1-126.02 of the Code of Virginia. The Administrator stated, "They do not have access to where we keep the drugs. They only have access once they are removed from the safe."
### State of Virginia

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(X1) PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER:</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
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<tbody>
<tr>
<td>FTAF 012</td>
<td>A. BUILDING</td>
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<td>B. WING</td>
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**NAME OF PROVIDER OR SUPPLIER**

AMETHYST HEALTH CENTER FOR WOMEN, INC

**STREET ADDRESS, CITY, STATE, ZIP CODE**

9380-B FORESTWOOD LANE, MANASSAS, VA 20110

**DATE SURVEY COMPLETED**

12/11/2012

<table>
<thead>
<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>(X5) COMPLETE DATE</th>
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| T 170             | Continued From Page 2  
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 observations and interviews the facility staff failed to ensure supplies were not expired, that proper cleaning of instruments was done, once removed from its protective covering IV solution was dated as to when it would expire, proper cleaning of equipment used on patients was done and that proper hand hygiene was performed following patient care.  
The findings include:  
1. On 12/11/12 at approximately 9:45 A.M. following the observation of an abdominal and vaginal sonogram preformed by the Administrator the probes were cleaned with a disinfectant wipe then dried with a paper towel. The disinfectant wipe states it must be allowed to stay on the equipment to dry for at least 3-5 minutes. The Administrator then pulled off the paper covering from the pillow case and the table.  
The Administrator then pulled out a new pillow covering and laid it on the pillow. The pillow had not been wiped with a disinfectant wipe. The table was then wiped with a disinfectant wipe but not the table extension which had been pulled out for the patient to place her legs on.  
At approximately 11:15 A.M. on 12/11/12 the AHCW was advised that if the physicians were contracted consultants and they did not have access to the controlled Substance Keys or Safe then No Criminal Background Check was required. Further, this advice has been incorporated within AHCW P&P Manual (Section 3.5.4)  
Regarding T 170-1, a Sonography Procedure has been added to the AHCW P&P Manual (Section 3.4.2.b). This procedure specifically addresses the disinfection of the probes. This procedure also addresses the disinfection of the exam table and table leg extensions, gloving and hand sanitization. Further, the pillow has been removed from the Sonogram Room with a note in the procedure stating "No Pillows are to be Used in the Sonogram Room."  
As a result of observed non-compliance with Infection Control P&P, the Administrator has received a Letter of Reprimand, directed to take remedial infection control training on 2/19/2013, and the video player has been disinfected. | 2/16/13 |

**STATE FORM**

6W3111

**Americans United for Life**
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
<th>(X3) DATE SURVEY COMPLETED</th>
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<tr>
<td>FTAF 012</td>
<td>A. BUILDING __________________</td>
<td>12/11/2012</td>
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<td>B. WING __________________</td>
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</table>

**NAME OF PROVIDER OR SUPPLIER**
AMETHYST HEALTH CENTER FOR WOMEN, INC

**STREET ADDRESS, CITY, STATE, ZIP CODE**
9380-B FORESTWOOD LANE, MANASSAS, VA 20110

**SUMMARY STATEMENT OF DEFICIENCIES**
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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<tr>
<th>ID PREFIX TAG</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER’S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCE TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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| T 170         | T 170         | Continued From Page 3
Administrator was observed leaving the sonogram room behind a patient with gloves on her hands. The Administrator entered the video/consulting room and placed a video in the player and pushed buttons to turn the television on. While speaking to the patient she removed her gloves.

After leaving the room she went to the hallway sink rinsed her fingers in the water for 2-3 seconds and then dried her hands. She did not use any soap products.

The Administrator was informed about the observations and stated, “I did not realize I needed to let the disinfectant dry. You are correct about the gloves.”

2. Observations conducted December 10, 2012 during the initial tour revealed within the anesthesia cart, in the procedure room, two ten (#10) cc syringes that expired on September 30, 2012. Six (#6) of ten (#10) 25 gauge needles expired on October 31, 2012, with four (#4) of ten (#10) 25 gauge needles expired on September 30, 2012. Failure to determine the ten (#10) large red top blood tube vials and one (#1), purple top blood tube were without labels and the Surveyor could not determine the expiration dates.

Three (#3) plastic vacutainers (used to obtain blood) expired on March 31, 2012, in the Ultrasound room, were observed during the initial tour. Observation with the Ultrasound room, within the second drawer of the exam table revealed a small medication cup that contained four pills. Two white pills with a hexagon shapes and with 2088 stamped on the pills, one oval large white pill with the number 5003 imprinted on it, and one white pill with 123 marked on it.

Forty seven (#47) twenty gauge needles expired on September 30, 2112, twenty four (#24) twenty

The investigation revealed that there was confusion regarding responsibility for conducting inventory of the Procedure Room anesthesia cart between the CRNA and CNA. This responsibility now belongs to the CNA.

The investigation revealed and the expiration dates support that the Ultrasound Exam Table had previously been located within the Laboratory. Assertions were made that the expired items were misplaced. Regardless, the monthly inventory and inspection process have been expanded to include checking into all drawers and cabinets.

The pills were identified as Misoprostol and Ibuprofen. Clinical staff has been admonished that there shall be no “loose medicine” within the facility. Medicines shall only be given once they are poured from their labeled containers. All medicine is to be consumed as soon as it is poured. (AHCW P&P Manual Section 3.5.4 pg 3)

All ammonia inhalants shall be kept in their boxes.
T 170 Continued From Page 4

As a corrective action, following the monthly inventory, an independent check will be conducted to confirm compliance.

Regarding T 170-2, a thermometer has been added to the Recovery Room refrigerator with a record sheet to document daily the temperature of this refrigerator. A staff refrigerator has been purchased and resides in the Doctor’s office. It also has a thermometer and record sheet to document daily the temperature of the refrigerator.

AHCW has modified the instrument cleaning P&P Manual and added a permanent mark to the sink to show the 1 gallon sink line. (AHCW P&P Manual 2.4.3.7.b section A.1.c) The Alconox dilution instructions were posted above the sink. Present at the time of inspection was a 1 gallon measuring device which Staff #3 failed to bring to the inspectors’ attention.
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<td>protective covering, without a date written on the IV to state when the Ringer's Lactate had been opened, on December 11, 2012, at 10:00 a.m. The Administrator surmised that the Ringer's Lactate had been opened on December 8, 2012, the date of the last procedure, during interview in the agency's hall on December 11, 2012, at 10:15 a.m. During interview at 10:03, the Administrator acknowledged that it could not be determined when the IV bag had the plastics covering was removed due to it being undated. The Administrator verified during interview that infection control issues had not been resolved from the initial survey. This interview occurred in the agency's office, on December 10, 2012, at 16:15.</td>
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<th>T 210</th>
<th>12 VAC 5-412-240 D Medical testing, patient counseling and labor</th>
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<td>D. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.</td>
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This RULE: is not met as evidenced by: Based on record review and interview, it was determined that's three (#18,#12 and #15) Patients of eleven Patients (#1-#5, #7-#9 #12 and #14-#15) physicians failed to document adequately, the complete examination of the products of conception for all patients.

Patient #8 (Clinical record #8) had the procedure

<table>
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<tr>
<th>T 170</th>
<th>It is noted that all IV bags shall be dated upon opening. The staff was made aware of this in a facility in-service meeting, and an entry is noted in the AHCW P&amp;P Manual (3.8.2.B Section B.2). Following this review and reporting, a Facility in-service will be conducted by an independent evaluator. The Administrator received a Letter of Reprimand for this item.</th>
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<tr>
<th>T 210</th>
<th>The Medical Director has verbally cautioned the Consultant Physicians to maintain vigilance regarding their examinations of products of conception, fetal parts or villi, as well as ensuring that their findings are adequately documented in the future.</th>
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performed on on 09/07/12. Clinical record #8 failed to a physician's documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. "Tissue volume was moderate and pregnancy tissue was complete with gestational age of nine weeks was documented by the physician for Patient #8.

Patient #12 (Clinical record #12) had the procedure performed on on 11/30/12. Clinical record #128 failed to a physician's documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. "Tissue volume was moderate and pregnancy tissue was complete with gestational age of nine weeks" was documented by the physician for Patient #12.

Patient #15 (Clinical record #15) had the procedure performed on on 11/17/12. Clinical record #15 failed to a physician's documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. "Tissue volume was moderate and estimated blood loss of 20 cc, and with gestational age of seven weeks" was documented by the physician for Patient #12.

The Administrator verified that all physicians had not documented well the products of conceptions. This interview occurred in the agency's office, on 12/11/12, at 11:05 a.m.

| T 275 | | | 12 VAC 5-412-260 C Administration, storage and dispensing of dru | T 275 | | |                                                                                                              |                   |
C. 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. 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 that three (#1-#3) of three (#1-#3) vials of Diphenhydramine HCL (Benadryl for allergy and itching) 50 mg (milligrams) with an expiration date of 08/31/12 was available for use.

Findings:

During the initial tour of the laboratory room, on 12/10/12, at 3:00 p.m., in the refrigerator, three one (1) ml (milliliter) vials of Diphenhydramine HCL (Benadryl) 50 mg (milligrams) was found on the second shelf. The three (#1-#3) vials of Diphenhydramine HCL 50 mg (milligrams) which had an expiration date of 08/31/12, were available for use.

These expired vials were verified by Employee #2.

The Administrator stated that she was aware that they were expired and intended to discard them. This interview occurred on 12/10/12, at 16:15, in the Patient's waiting room.

E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in

<table>
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The investigation revealed that the expired vials were placed into the refrigerator by the Administrator. This was not in compliance with the AHCW P&P Manual. A Letter of Reprimand was issued to the Administrator. The P&P Manual is modified (3.5.4 Section A) to specifically expand the number of AHCW employees involved when an expired drug or medical device is identified within the facility. Actions required to be taken regarding the disposition of the expired item should prove to alleviate this recurring problem. As a corrective action, following the monthly inventory, an independent check will be conducted to confirm compliance.
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.

This RULE: is not met as evidenced by: Based on interviews and document reviews the facility staff failed to ensure all Schedule II-V drugs received, administered and disposed of was done in accordance with the Drug Control Act found in the Code of Virginia 54.1-3404. Narcotic log book contained documentation of information that had scribbling over dates, patient names and amounts of medications administered and arrows rather than documentation of what and how much of a medication was administered. The narcotics log also did not contain witnessed wastage of narcotics. The facility administered Propofol (unscheduled), Fentanyl (Schedule II), Versed (Schedule III) for conscious sedation and failed to document the medications' wasting.

The findings include:

On 12/11/12 the narcotic log book was observed. The administrator stated only the CRNA (Certified Registered Nurse Anesthetist) documents in the narcotic log book. The log book had no separate documentation noting the beginning amounts of drugs. All drugs were documented on one page.

The dates of 10/27/12 and 11/17/12 were reviewed and the following is noted: Patient #1 on the narcotic list for 10/27/12 received 3 mg of Versed from a 5 mg per cc vial there is no documentation of what happened to the other 2 mg. A total of 7 patients for this date had similar entries. On 11/17/12 there were 7 patients with similar entries and on another listing with no date there were 8 patients with similar listings. All of the above patients had similar
<table>
<thead>
<tr>
<th>T 285</th>
<th>Continued From Page 9</th>
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</thead>
<tbody>
<tr>
<td>listings for Propofol (20 cc vial with 10 mg per 1 cc) Propofol 80 mg was given to Patient #1 on 10/27/12 with no documentation of the wastage. Pharmacy Purchasing and Products, Tools to Effectively Manage Controlled Substances January 2011 Vol. 8 No. 1 page 8 by Ira Kurland, RPh and Tim L'Hommedieu, PharmD, MS stated the following:</td>
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<tr>
<td>&quot;The process for wasting controlled medications, such as narcotics, requires a witness and includes the following:</td>
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<td>Two authorized users are required. One user will be designated as witness to the wasting process.</td>
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<td>...., whose job description or licensing allows the handling of controlled substances, may serve as a witness in the absence of a second nurse.</td>
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<tr>
<td>The witness must view the vial, syringe, tablet, etc, that is used to prepare the medication dose.</td>
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<tr>
<td>The witness is required to visualize the solution vial, syringe, tablet, etc, to verify the medication being wasted.</td>
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<tr>
<td>The witness must watch the solution ejected from the syringe (preferably in a solid waste/trash receptacle) or watch the destruction of the unused portion (e.g., the tablet).</td>
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<tr>
<td>Unplanned wasting (e.g., patient refusal of medication) must be witnessed when the medication is actually wasted using the procedure described above.</td>
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<table>
<thead>
<tr>
<th>T 340</th>
<th>12 VAC 5-412-310 Medical records</th>
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<tbody>
<tr>
<td>An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:</td>
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<tr>
<td>1. Patient identification;</td>
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<td>2. Admitting information, including a patient</td>
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</table>
T 340 Continued From Page 10

history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
a. Physician orders;
b. Laboratory tests, pathologist's report of
tissue, and radiologist's report of x-rays;
c. Anesthesia record;
d. Operative record;
e. Surgical medication and medical treatments;
f. Recovery room notes;
g. Physician and nurses' progress notes,
h. Condition at time of discharge,
i. Patient instructions, preoperative and
postoperative, and
j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by:
Based on document review and interview the facility staff failed to ensure the medical record was accurate and complete for 6 patients, Patient #1, 3, 4, 7, 9, and 12.

The findings include:

1. Patient #4 had a complete procedure on 9/21/12. The medical record did not include a signature from the admitting physician indicating he performed and or reviewed the history and physical of Patient #4. In the area of the medical record where the recovery of the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #1 it was checked as given. In an interview with the Administrator she stated, "(Name of Physician) does not order doxycycline. That is an error (the check mark)."

Patient #9 had a completed procedure on 8/24/12.

T 340

Regarding T 340-1, The Medical Director and Administrator have verbally cautioned the Consultant Physicians and clinical staff to maintain vigilance regarding their patient charting.

2/16/13
<table>
<thead>
<tr>
<th>T 340</th>
<th>Continued From Page 11</th>
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<tbody>
<tr>
<td></td>
<td>The medical record did not include a signature from the admitting physician indicating he performed and or reviewed the history and physical of Patient #4. In the area of the medical record where the recovery of the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #9 it was checked as given. In an interview with the Administrator she stated, &quot;(Name of Physician) does not order doxycycline. That is an error (the check mark).&quot;</td>
</tr>
</tbody>
</table>

Patient #4, 7 and 9 all were administered medications prior to having their procedures. Patient #4 had ibuprofen 800 mg, 400 mg of misoprostol and 0.5 mg of Xanax. Patient #9 had a completed procedure on 11/29/12 and received ibuprofen 800 mg, Valium 10 mg and Demerol 50 mg. Patient #9 was given 400 mg of misoprostol and 0.5 mg of Xanax. All three patients' orders were not signed by the physician and were administered by an unlicensed person.

2. Patient #3 (Clinical record #3) completed the procedure on 11/17/12. Clinical record #3 failed to have preoperative medications documented within clinical record #3 by the nurse administering the medications.

Patient #1 (Clinical record #1) completed the procedure performed on 12/08/12. Clinical record #1 failed to have physicians and nurse 's progress notes documented post procedure.

Patient #12 (Clinical record #12) had the procedure performed on 12/08/12. Clinical record #12 failed to have physicians and nurse 's progress notes documented post procedure.

The Administrator verified that Patient #8's physician had not ordered doxycycline for any of his patients for discharge. This interview occurred regarding T 340-2, at AHCW all medications shall be administered by an R.N. or LPN. Unlicensed person(s) may NOT administer medications. AHCW P&P Manual (3.5.4 Section A pg 3.)
<table>
<thead>
<tr>
<th>ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>DATE</th>
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<tbody>
<tr>
<td>T 340</td>
<td>Continued From Page 12</td>
<td>T 340</td>
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<td></td>
<td>in the agency's office, on 12/11/12, at 11:05 a.m.</td>
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</table>

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**
AMETHYST HEALTH CENTER FOR WOMEN, INC

**STREET ADDRESS, CITY, STATE, ZIP CODE**
9380-B FORESTWOOD LANE
MANASSAS, VA 20110

**DATE SURVEY COMPLETED**
12/11/2012
You are required to submit a plan for correcting the deficiencies cited. Your statements should reflect the specific detailed actions you will take to correct each deficiency and prevent its recurrence, and measures that will be implemented to maintain compliance.

You must also give the specific calendar date on which correction of each deficiency will be completed. (Completion dates should be within thirty (30) days from the date of the inspection.)

After signing and dating the Plan of Correction, retain a copy for your files and return the original to this office within 15 (fifteen) working days of receiving this certified letter. The Administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with the Virginia Code § 32.1-27 or in denial, revocation or suspension of a license in accordance with 12VAC5-412-130.

A copy of the completed form will be kept on file in this office and will be available for public view. This Division is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

I would like to thank you and your staff for the cooperation and assistance that was extended to the surveyors. Should you have any questions, please do not hesitate to call me at (804) 367-2156.

Sincerely,

[Signature]

Kathleen Creegan-Tedeschi, Supervisor
Acute Care, Home Health and Hospice Services
Office of Licensure and Certification

Enclosure
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<tr>
<th>(X4) ID</th>
<th>ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tbody>
<tr>
<td>T 000</td>
<td>T 000</td>
<td>12 VAC 5-412 Initial comments</td>
<td>2/19/13</td>
</tr>
</tbody>
</table>

An unwarned Revisit to the initial licensure survey conducted conducted May 31, 2012, through June 01, 2012, was conducted at the above referenced facility. December 10, 2012 through December 11, 2012 by two (2) Medical Facility Inspectors from the Virginia Department of Health's Office of Licensure and Certification.

Complaint #2012-AC018 was investigated at the time of the Revisit survey.

The following citation was not corrected by the facility, and therefore was re-cited:
12 VAC 5-412-260 C Administration, storage and dispensing of drugs

The following citations are new findings:
12VAC5-412-170 C - Personnel
12VAC5-412-220-B - Infection Prevention
12VAC5-412-240 D - Medical Testing, patient counseling, & lab services
12VAC5-412-260E Administration, storage and dispensing of drugs
12VAC5-412-310 - Medical Records

The facility was found out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies of new findings and one non corrected finding were identified and will follow in this report.

The Complaint #2012-AC018 was unsubstantiated due to a lack of sufficient evidence.

12 VAC 5-412-170 C Personnel

C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated
<table>
<thead>
<tr>
<th>T 070</th>
<th>Continued From Page 1</th>
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<tbody>
<tr>
<td></td>
<td>employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.</td>
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<tr>
<td></td>
<td>This RULE: is not met as evidenced by:</td>
</tr>
<tr>
<td></td>
<td>Based on document review and interview the facility staff failed to have criminal record checks performed for staff who have access to controlled substances within the facility.</td>
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<td>The findings include:</td>
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<td></td>
<td>On 12/11/12 the personnel files of the CRNA (Certified Registered Nurse Anesthetist), LPN (Licensed Practical Nurse) and 2 physicians were reviewed. The files did not contain a criminal history check pursuant to 32.1-126.02 of the Code of Virginia. The Administrator stated, &quot;They do not have access to where we keep the drugs. They only have access once they are removed from the safe.&quot;</td>
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<table>
<thead>
<tr>
<th>T 170</th>
<th>12 VAC 5-412-220 B Infection prevention</th>
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<tbody>
<tr>
<td></td>
<td>B. Written infection prevention policies and procedures shall include, but not be limited to:</td>
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<tr>
<td></td>
<td>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;</td>
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<td>2. Training of all personnel in proper infection prevention techniques;</td>
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<td></td>
<td>3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;</td>
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<td></td>
<td>4. Use of standard precautions;</td>
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<td></td>
<td>5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety &amp; Health Administration.</td>
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</table>

Regarding T 070, AHCW stores all controlled substances within a safe. The keys to this safe are controlled by the Administrator. Access to this safe is limited to AHCW Clinical Staff or those whose job duties require access to remove drugs and put them into service. These individuals are required to have Criminal Background Checks.

The LPN was a new employee at the time of inspection and now has a Criminal Background Check in her personnel file.

The CRNA is contracted for service as a consultant and not an employee of AHCW. AHCW mistakenly believed that she was licensed by the board of Pharmacy but became aware that she was licensed by the Board of Nursing. The CRNA is no longer contracted by AHCW. In the future, any CRNA practicing at AHCW shall have a criminal Background Check.

Physicians at AHCW are contracted consultants, licensed by the Virginia Board of Medicine and Registered by the DEA. These Physicians do not have access to the Controlled Substance Keys or Safe at AHCW. During the preparation of this response, AHCW contacted VDH/OLC on February 11, 2013 for clarification regarding Physician's Criminal Background Check.
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<tr>
<th>ID TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<tr>
<td>T 170</td>
<td>Continued From Page 2</td>
<td>T 170</td>
<td>AHCW was advised that if the physicians were contracted consultants and they did not have access to the controlled Substance Keys or Safe then No Criminal Background Check was required. Further, this advice has been incorporated within AHCW P&amp;P Manual (Section 3.5.4)</td>
<td>2/16/13</td>
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<td>6. Use of personal protective equipment;</td>
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<td>7. Use of safe injection practices;</td>
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<td>8. Plans for annual retraining of all personnel in infection prevention methods;</td>
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<td>9. Procedures for monitoring staff adherence to recommended infection prevention practices;</td>
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<td></td>
<td>10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.</td>
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<td></td>
<td>This RULE: is not met as evidenced by:</td>
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<td></td>
<td>Based on observations and interviews the facility staff failed to ensure supplies were not expired,</td>
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<td></td>
<td>that proper cleaning of instruments was done, once removed from it's protective covering IV solution</td>
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<td></td>
<td>was dated as to when it would expire, proper cleaning of equipment used on patients was done and that</td>
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<td>proper hand hygiene was preformed following patient care.</td>
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<td></td>
<td>The findings include:</td>
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<tr>
<td></td>
<td>1. On 12/11/12 at approximately 9:45 A.M. following the observation of a abdominal and vaginal sonogram</td>
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<td>the probes were cleaned with a disinfectant wipe then dried with a paper towel. The disinfectant</td>
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<td>wipe states it must be allowed to stay on the equipment to dry for at least 3-5 minutes. The</td>
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<td>Administrator then pulled off the paper covering from the pillow case and the table.</td>
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<td></td>
<td>The Administrator then pulled out a new pillow covering and laid it on the pillow. The pillow had</td>
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<tr>
<td></td>
<td>not been wiped with a disinfectant wipe. The table was then wiped with a disinfectant wipe but not the</td>
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<td></td>
<td>table extension which had been pulled out for the patient to place her legs on.</td>
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<td>At approximately 11:15 A.M. on 12/11/12 the</td>
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Regarding T 170-1, a Sonography Procedure has been added to the AHCW P&P Manual (Section 3.4.2.b). This procedure specifically addresses the disinfection of the probes. This procedure also addresses the disinfection of the examine table and table leg extensions, gloving and hand sanitization. Further, the pillow has been removed from the Sonogram Room with a note in the procedure stating "No Pillows are to be Used in the Sonogram Room."

As a result of observed non-compliance with Infection Control P&P, the Administrator has received a Letter of Reprimand, directed to take remedial infection control training on 2/19/2013, and the video player has been disinfected.
Continued From Page 3

T 170

Administrator was observed leaving the sonogram room behind a patient with gloves on her hands. The Administrator entered the video/consulting room and placed a video in the player and pushed buttons to turn the television on. While speaking to the patient she removed her gloves.

After leaving the room she went to the hallway sink rinsed her hands in the water for 2-3 seconds and then dried her hands. She did not use any soap products.

The Administrator was informed about the observations and stated, "I did not realize I needed to let the disinfectant dry. You are correct about the gloves."

2. Observations conducted December 10, 2012 during the initial tour revealed within the anesthesia chart, in the procedure room, two ten (#10) cc syringes that expired on September 30, 2012. Six (#6) of ten (#10) 25 gauge needles expired on on October 31, 2012, with four (#4) of ten (#10) 25 gauge needles expired on September 30, 2012. Failure to determine the ten (#10) large red top blood tube vials and one (#1), purple top blood tube were without labels and the Surveyor could not determine the expiration dates.

Three (#3) plastic vacutainers (used to obtain blood) expired on March 31, 2012, in the Ultrasound room, were observed during the initial tour. Observation with the Ultrasound room, within the second drawer of the exam table revealed a small medication cup that contained four pills. Two white pills with a hexagon shapes and with Z088 stamped on the pills, one oval large white pill with the number 5003 imprinted on it, and one white pill with 123 marked on it.

Forty seven (#47) twenty gauge needles expired on September 30, 2112, twenty four (#24) twenty

Regarding T 170-2, the investigation revealed that there was confusion regarding responsibility for conducting inventory of the Procedure Room anesthesia cart between the CRNA and CNA. This responsibility now belongs to the CNA.

The investigation revealed and the expiration dates support that the Ultrasound Exam Table had previously been located within the Laboratory. Assertions were made that the expired items were misplaced. Regardless, the monthly inventory and inspection process have been expanded to include checking into all drawers and cabinets. Additionally, a weekly audit will be conducted by the LPN with the CNA for expired medications and the CNA for expired devices to insure that there are no more expired medications or devices.

The pills were identified as Misoprostol and Ibuprofen. Clinical staff has been admonished that there shall be no "loose medicine" within the facility. Medicines shall only be given once they are poured from their labeled containers. All medicine is to be consumed as soon as it is poured.

(AHCW P&P Manual Section 3.5.4 pg 3)

All ammonia inhalants shall be kept in their boxes.
As a corrective action, following the monthly inventory, an independent check will be conducted to confirm compliance.

Regarding T 170-2, a thermometer has been added to the Recovery Room refrigerator with a record sheet to document daily the temperature of this refrigerator. A staff refrigerator has been purchased and resides in the Doctor’s office. It also has a thermometer and record sheet to document daily the temperature of the refrigerator.

AHCW has modified the instrument cleaning P&P Manual and added a permanent mark to the sink to show the 1 gallon sink line. (AHCW P&P Manual 2.4.3.7.b section A.1.c) The Alconox dilution instructions were posted above the sink. Present at the time of inspection was a 1 gallon measuring device which Staff #3 failed to bring to the inspectors’ attention. The procedure implemented has been verified and spot audits (conducted at least twice per week) by the Administrator are being done.
<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCES TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<tr>
<td>T 170</td>
<td>Continued From Page 5 protective covering, without a date written on the IV to state when the Ringer's Lactate had been opened, on December 11, 2012, at 10:00 a.m. The Administrator surmised that the Ringer's Lactate had been opened on December 8, 2012, the date of the last procedure, during interview in the agency's hall on December 11, 2012, at 10:15 a.m. During interview at 10:03, the Administrator acknowledged that it could not be determined when the IV bag had the plastics covering was removed due to it being undated. The Administrator verified during interview that infection control issues had not been resolved from the initial survey. This interview occurred in the agency's office, on December 10, 2012, at 16:15.</td>
<td>T 170</td>
<td>It is noted that all IV bags shall be dated upon opening. The staff was made aware of this in a facility in-service meeting, and an entry is noted in the AHCW P&amp;P Manual (3.8.2.B Section B.2). Following this review and reporting, a Facility in-service will be conducted by an independent evaluator. The Administrator received a Letter of Reprimand for this item.</td>
<td>2/16/13</td>
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<tr>
<td>T 210</td>
<td>12 VAC 5-412-240 D Medical testing, patient counseling and labor D. All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately. This RULE: is not met as evidenced by: Based on record review and interview, it was determined that's three (#18, #12 and #15) Patients of eleven Patients (#1-#5, #7-#9 #12 and #14-#15) physicians failed to document adequately, the complete examination of the products of conception for all patients. Patient #8 (Clinical record #8) had the procedure</td>
<td>T 210</td>
<td>The Medical Director has verbally cautioned the Consultant Physicians to maintain vigilance regarding their examinations of products of conception, fetal parts or villi, as well as ensuring that their findings are adequately documented in the future. Each procedure day the LPN and CNA audit 50% of the patient records to insure physicians have documented their findings completely.</td>
<td>2/12/13</td>
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<td>ID PREFIX TAG</td>
<td>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
<td>ID PREFIX TAG</td>
<td>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
<td>COMPLETE DATE</td>
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<tr>
<td>T 210</td>
<td>Continued From Page 6 performed on on 09/07/12. Clinical record #8 failed to a physician's documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. “Tissue volume was moderate and pregnancy tissue was complete with gestational age of nine weeks was documented by the physician for Patient #8. Patient #12 (Clinical record #12) had the procedure performed on on 11/30/12. Clinical record #128 failed to a physician’s documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. “Tissue volume was moderate and pregnancy tissue was complete with gestational age of nine weeks” was documented by the physician for Patient #12. Patient #15 (Clinical record #15) had the procedure performed on on 11/17/12. Clinical record #15 failed to a physician’s documentation of the Decidua (First term trimester bleeding). The Villi (A protuberance that contributes to the formation of the placenta), and the fetal parts. “Tissue volume was moderate and estimated blood loss of 20 cc, and with gestational age of seven weeks” was documented by the physician for Patient #12. The Administrator verified that all physicians had not documented well the products of conceptions. This interview occurred in the agency’s office, on 12/11/12, at 11:05 a.m.</td>
<td>T 275</td>
<td>12 VAC 5-412-260 C Administration, storage and dispensing of dru</td>
<td>T 275</td>
</tr>
</tbody>
</table>
The investigation revealed that the expired vials were placed into the refrigerator by the Administrator. This was not in compliance with the AHCW P&P Manual. A Letter of Reprimand was issued to the Administrator.

The P&P Manual is modified (3.5.4 Section A) to specifically expand the number of AHCW employees involved when an expired drug or medical device is identified within the facility. This policy requires specific actions by employees to be taken regarding the separation and control of the expired item.

As a corrective action, following the monthly inventory and weekly audit conducted by the LPN and CNA, an independent check will be conducted monthly by the clinic consultant, a Board Certified WHNP. This random audit will cover approximately 25% of the clinic locations and focus on locations where discrepancies have occurred previously. Also included in the WHNP audit will be any items identified by the LPN and CNA audits. These audits will continue until the Quality Assurance Committee is satisfied that the issue has been resolved and reflected within the Committee minutes.
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.

This RULE: is not met as evidenced by; Based on interviews and document reviews the facility staff failed to ensure all Schedule II-V drugs received, administered and disposed of was done so in accordance with the Drug Control Act found in the Code of Virginia 54.1-3404. Narcotic log book contained documentation of information that had scribbling over dates, patient names and amounts of medications administered and arrows rather than documentation of what and how much of a medication was administered. The narcotics log also did not contain witnessed wastage of narcotics. The facility administered Propofol (unscheduled), Fentanyl (Schedule II), Versed (Schedule III) for conscious sedation and failed to document the medications' wasting.

The findings include:

On 12/11/12 the narcotic log book was observed. The administrator stated only the CRNA (Certified Registered Nurse Anesthetist) documents in the narcotic log book. The log book had no separate documentation noting the beginning amounts of drugs. All drugs were documented on one page.

The dates of 10/27/12 and 11/17/12 were reviewed and the following is noted: Patient #1 on the narcotic list for 10/27/12 received 3 mg of Versed from a 5 mg per cc vial there is no documentation of what happened to the other 2 mg. A total of 7 patients for this date had similar entries. On 11/17/12 there were 7 patients with similar entries and on another listing with no date there were 8 patients with similar listings. All of the above patients had similar letters of Reprimand were issued to the Administrator and the CRNA for this item, specifically, to the CRNA for non-compliance with charting in the Administered Medicine Log Book and to the Administrator for failure to review the charting done by the CRNA.

The Administered Medicine Log Sheets have been revised, have been evaluated and are now in service. This single sheet / drug format incorporates a section for wastage with appropriate verifications and signatures. The changed Policy (AHCW 3.5.4.E) has been previously submitted and the current Log Sheet is attached.
<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tr>
<td>T 285</td>
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<td>T 340</td>
<td>12 VAC 5-412-310 Medical records</td>
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listings for Propofol (20 cc vial with 10 mg per 1 cc) Propofol 80 mg was given to Patient #1 on 10/27/12 with no documentation of the wastage. Pharmacy Purchasing and Products, Tools to Effectively Manage Controlled Substances January 2011 Vol. 8 No. 1 page 8 by Ira Kurland, RPh and Tim L'Hommelieu, PharmD, MS stated the following:
"The process for wasting controlled medications, such as narcotics, requires a witness and includes the following:
Two authorized users are required. One user will be designated as witness to the wasting process. ...., whose job description or licensing allows the handling of controlled substances, may serve as a witness in the absence of a second nurse.
The witness must view the vial, syringe, tablet, etc, that is used to prepare the medication dose. The witness is required to visualize the solution vial, syringe, tablet, etc, to verify the medication being wasted.
The witness must watch the solution ejected from the syringe (preferably in a solid waste/trash receptacle) or watch the destruction of the unused portion (e.g., the tablet).
Unplanned wasting (e.g., patient refusal of medication) must be witnessed when the medication is actually wasted using the procedure described above.
T 340 Continued From Page 10

- History and physical examination;
- Signed consent;
- Confirmation of pregnancy; and
- Procedure report to include:
  - Physician orders;
  - Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
  - Anesthesia record;
  - Operative record;
  - Surgical medication and medical treatments;
  - Recovery room notes;
  - Physician and nurses' progress notes,
  - Condition at time of discharge,
  - Patient instructions, preoperative and postoperative; and
  - Names of referral physicians or agencies.

This RULE: is not met as evidenced by:
Based on document review and interview the facility staff failed to ensure the medical record was accurate and complete for 6 patients, Patient #1, 3, 4, 7, 9, and 12.

The findings include:

1. Patient #4 had a complete procedure on 9/21/12. The medical record did not include a signature from the admitting physician indicating he performed and or reviewed the history and physical of Patient #4. In the area of the medical record where the recovery of the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #1 it was checked as given. In an interview with the Administrator she stated, "(Name of Physician) does not order doxycycline. That is an error (the check mark)."

Patient #9 had a completed procedure on 8/24/12.

Regarding T 340-1, The Medical Director and Administrator have verbally cautioned the Consultant Physicians and clinical staff to maintain vigilance regarding their patient charting.
The medical record did not include a signature from the admitting physician indicating he performed and or reviewed the history and physical of Patient #4. In the area of the medical record where the recovery of the patient is documented there is a box beside of doxycycline to be checked which would indicate it was given to the patient. On Patient #9 it was checked as given. In an interview with the Administrator she stated, "(Name of Physician) does not order doxycycline. That is an error (the check mark)."

Patient #4, 7 and 9 all were administered medications prior to having their procedures. Patient #4 had ibuprofen 800 mg, 400 mg of misoprostol and 0.5 mg of Xanax. Patient #9 had a completed procedure on 11/29/12 and received ibuprofen 800 mg, Valium 10 mg and Demerol 50 mg. Patient #9 was given 400 mg of misoprostol and 0.5 mg of Xanax. All three patients’ orders were not signed by the physician and were administered by an unlicensed person.

2. Patient #3 (Clinical record #3) completed the procedure on 11/17/12. Clinical record #3 failed to have preoperative medications documented within clinical record #3 by the nurse administering the medications.

Patient #1 (Clinical record #1) completed the procedure performed on 12/08/12. Clinical record #1 failed to have physicians and nurse’s progress notes documented post procedure.

Patient #12 (Clinical record #12) had the procedure performed on 12/08/12. Clinical record #12 failed to have physicians and nurse’s progress notes documented post procedure.

The Administrator verified that Patient #8’s physician had not ordered doxycycline for any of his patients for discharge. This interview occurred

Regarding T 340-2, at AHCW all medications shall be administered by an R.N. or LPN. Unlicensed person(s) may NOT administer medications. AHCW P&P Manual (3.5.4 Section A pg 3.)

The CNA is in close proximity to the patient medication station and generally aware of medicine being dispensed to patients. She knows who is licensed to give medication and who is not. The CNA will serve as the auditor for unlicensed persons giving medications. Should the CNA become aware of any unlicensed employee administering a medication to a patient, she will intervene, notify the LPN or RN and the Administrator as well as the Medical Director.
<table>
<thead>
<tr>
<th>ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<tbody>
<tr>
<td>T 340</td>
<td>Continued From Page 12 in the agency's office, on 12/11/12, at 11:05 a.m.</td>
<td>T 340</td>
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</tbody>
</table>
Ms. Ruthanne Risser  
Department of Health  
Office of Licensure and Certification  
9960 Mayland Drive suite 401  
Henrico, VA 23233-4502

January 13, 2015

RE: Abortion Facility AF0019

Dear Ms Risser,

We have enclosed our plan of correction for deficiencies found at the time of inspection. Item T 265 as described on pages 8-9 is somewhat confusing. It appears that the description of finding prescription pads in an unsecure drawer was missing from the narrative. The last paragraph on page 8 does not follow with the first sentence on page 9. However, it was pointed out to us that the prescription pads were not secure; and so we addressed this deficiency.

We are hopeful that our response is complete and that our license will remain intact. Please let us know if you need any further clarification or information regarding our plan.

Thank you for your help in this manner.

Sincerely,

Gail Frances, MSN, NP  
Practice Administrator
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(AF-0019)

NAME OF PROVIDER OR SUPPLIER: ANNANDALE WOMEN & FAMILY CENTER
STREET ADDRESS, CITY, STATE, ZIP CODE: 2839 DUKE STREET, ALEXANDRIA, VA 22314

(X4) ID PREFIX TAG: T 000
SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION):

12 VAC 5-412 Initial comments

An announced Biennial Licensure Abortion Facility inspection was conducted at the above referenced facility on December 16, 2014 and December 17, 2014 by two (2) Medical Facility Inspectors from the Virginia Department of Health Office of Licensure and Certification.

The facility was not in compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficient practices are cited within this report.

T 005
12 VAC 5-412-70 Posting of license

The abortion facility license issued by the commissioner shall at all times be posted in a place readily visible and accessible to the public.

This RULE: is not met as evidenced by:
Based on observation and staff interview, the facility staff failed to post a copy of the license in a conspicuous place accessible to the public.

The findings included:

During the tour of the facility on 12/16/14 at 1:30 p.m., the survey team did not observe the license posted in the waiting area of the facility or in an area conspicuous to the public view. The license was observed to be posted in the "Recovery Room 2", in the back of the facility. When interviewed as to the posting of the license, Staff #1 stated, "We were told we could keep it back there. Only the abortion patients go back there..." When asked if anyone from the public/other patients who visit the clinic would see the posting, Staff #1 stated, "Only the abortion patients go back to that area and see it..."
T 055: The Board of Directors has added an amendment to the By-Laws authorizing the Practice Administrator to appoint an Alternate Administrator. The staff appointee was designated in writing.

By-Laws were signed 1/2/2015 and a copy is kept in the facility manual.

This is maintained by

Practice Administrator

1/2/15
The findings included:

1. Review of the personnel record for Staff Person #1, date of hire 1/22/2014, revealed the employment application did not include references, and the I-9 form dated 1/22/2014 had not been signed by Staff Person #1.
2. Review of the personnel record for Staff Person #2, date of hire 11/9/2012, revealed the employment application had not been signed and dated, and did not include references. The I-9 form was not complete.
3. Review of the personnel record for Staff Person #3, date of hire 6/30/2004, revealed the employment application did not include references, and the I-9 form was not complete.
4. Review of the personnel record for Staff Person #4, date of hire 9/10/2003, revealed the record lacked an employment application, and the I-9 form was not complete.
5. Review of the personnel record for Staff Person #5, date of hire 5/15/2014 revealed the employment application had not been signed, and did not include education information.

The policy and procedure which addressed personnel files, included the following statement, "Employee application and all required documentation would be completed".

Staff #1 was made aware of the findings on 12/17/14 at 6:30 p.m.

**T 070**: Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to

**T 065**: All employee records will be updated to include full application records, including signed I-9, references, and educational information. This will be completed by 1/23/2015

1/23/15
CONTINUED FROM PAGE 3

controlled substances within the abortion facility.

This RULE: is not met as evidenced by:
Based on a review of eight (8) employee records between 12/16/2014 and 12/17/2014 by two (2) Medical Facility Inspectors (MFI's), the facility staff failed to ensure that Criminal History Record Checks (CRC's) were obtained on three (3) employees as required by section 32.1-126.02 of the Code of Virginia (COV).

This findings included:

The COV section 32.1-126.02 requires a CRC be obtained on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the facility. CRC checks had not been obtained for Staff Person #1, a Registered Nurse (RN), Staff Person #7, a physician, and Staff Person #8, a physician.

Staff #1 was made aware of the findings on 12/17/14 at 6:30 p.m.

T070: The Criminal History Record Checks were in the files of two of the cited personnel. The third physician had just been retained and the CRC was applied for but not yet obtained. This physician works at other abortion facilities and has had a cleared CRC. We were not made aware of this deficiency or it would have been resolved at the the inspection. All records are within regulations effective 1/15/2015

This will be monitored by the QA Coordinator 1/15/15

RECEIVED
JAN 20 2015
VDH/OLC
**State of Virginia**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
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<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
<th>(X3) DATE SURVEY COMPLETED</th>
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<tbody>
<tr>
<td>AF-0019</td>
<td>A. BUILDING</td>
<td>___________________________</td>
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<td>B. WING</td>
<td>12/17/2014</td>
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**NAME OF PROVIDER OR SUPPLIER**

ANNANDALE WOMEN & FAMILY CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**

2839 DUKE STREET
ALEXANDRIA, VA 22314

<table>
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<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>(X5) COMPLETE DATE</th>
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<tbody>
<tr>
<td>T 085</td>
<td>Continued From Page 4 This RULE: is not met as evidenced by: Based on employee record review and staff interview, the facility staff failed to ensure each personnel file contained a current job description that reflected the individuals responsibilities and work assignments for 3 (three) of 8 (eight) employee records reviewed. Record #s 1, 5 and Staff #2. Three employee records did not contain a current job description. The findings included: Review of employee personal files revealed no current job description for Employee Record #1, a Registered Nurse, Employee Record #5, a Receptionist, and Staff #2, the Alternate Administrator. Staff # 1 stated on 12/17/14 at 4:30 p.m., the job descriptions would be placed in the records.</td>
<td>T 085: All employee records have appropriate job descriptions in their files. Effective 12/30/2014</td>
</tr>
<tr>
<td>T 100</td>
<td>12 VAC 5-412-170 I Personnel I. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health-related information shall be maintained separately within the employee’s personnel file. This RULE: is not met as evidenced by: Based on the review of eight (8) employee records between 12/16/2014 and 12/17/2014 by two (2) Medical Facility Inspectors (MFI's), the facility failed to ensure that the employee health-related information was maintained separately within the employee’s personnel file in 8 (eight) of 8 records reviewed. (Employee Records 1 through 8)</td>
<td>T 100</td>
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**RECEIVED**

JAN 20 2015
VDH/OLC

United for Life
The findings included:

Employee records reviewed for Staff Persons #1, 2, 3, 4, 5, 6, 7, and 8 revealed that the health information regarding Tuberculosis (TB) and Hepatitis B (HepB) were co-mingled with all other personnel information such as the employment application, I-9 form, annual evaluations, and job descriptions.

Staff #1 was made aware of the findings at 6:30 p.m. on 12/17/14.

12 VAC 5-412-240 A Medical testing, patient counseling and labor

A. Prior to the initiation of any abortion, a medical history and physical examination, to include confirmation of pregnancy, shall be completed for each patient.
1. Use of any additional medical testing, including but not limited to ultrasonography shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.
2. Medical testing shall include a recognized pregnancy test and determination on Rh factor.
3. The facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test.
4. A written report of each laboratory test and examination shall be a part of the patient's record.
T195: The manual contains written Policy and Procedure for STD Testing according to the CDC Guidelines. This was in the Manual at the inspection. We do not perform STD testing on women seeking abortions services. This is not the standard of care in the Northern Virginia region. None of the other abortion facilities in the Northern Virginia area perform STD testing on abortion patients. We have amended our chart to include STD testing documentation. This was completed 1/12/2015.

This will be maintained by QA coordinator.
Continued From Page 7

Based on observation and staff interview, the facility staff failed to ensure the narcotic keys were not accessible to unauthorized personnel/staff/patients in accordance with Federal Laws.

The narcotic keys were placed in an unlocked drawer in the back hallway of the facility in an area accessible to all staff and any patients. There were also blank prescription pads found in the same area.

The findings included:

On 12/16/14 at approximately 1:30 p.m., the survey team toured the facility. When asked to examine the narcotic storage area, Staff #1 went to a drawer in the back hallway of the facility and removed a set of keys from the drawer. The keys were identified as the narcotic and crash cart keys. Staff #1 used the keys to open the crash cart and then open a locked box containing the narcotics for the facility. After relocking the box and cart, Staff #1 put the keys back in the unlocked drawer in the hallway cabinet. "I will put these back so (they-refering to staff) can find them."

On 12/17/14 at 1:35 p.m., the survey team noted the keys to the narcotic medications remained in the same, unsecured drawer in the back hallway. At that time, patients and staff were in the area and could have potentially accessed the keys. The staff present on 12/17/14, included staff whose job responsibilities would not have included access to medications.

Staff #1 stated on 12/17/14 at 1:50 p.m., "The keys are kept in my office..." When shown the keys were in the unsecured drawer, Staff #1 removed the keys. Staff #1 stated, "The keys..."

T265: The keys for the crash cart and controlled substance box are always kept in the Practice Admin office. The keys referred to in this paragraph were keys to a supply closet. The personnel who handle controlled substances were reminded that keys must be in secure location. 12/18/2014

This will be monitored by Practice Administration.

Prescription pads have been removed from all public places. Staff has been advised to be on alert that prescription pads had been stored in a public place and to ensure that they were secured. Effective 12/18/2014

QA coordinator has been advised to inspect for prescription pads and storage of controlled substance key.

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<th>T 265</th>
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State of Virginia

Statement of Deficiencies and Plan of Correction

(X1) Provider/Supplier/CLA Identification Number: AF-0019

(X2) Multiple Construction
A. Building
B. Wing

(X3) Date Survey Completed: 12/17/2014

Name of Provider or Supplier: Annandale Women & Family Center

Street Address, City, State, ZIP Code: 2839 Duke Street, Alexandria, VA 22314

(X4) ID Prefix Tag

<table>
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<th>ID Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
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<tr>
<th>ID Prefix Tag</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-referenced to the Appropriate Deficiency)</th>
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<tr>
<th>ID TAG</th>
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<th>ID TAG</th>
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<tr>
<td>T 265</td>
<td>Continued From Page 8 prescription pads are blank, I guess they can be removed...&quot;</td>
<td>T 265</td>
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<tr>
<td>T 285</td>
<td>12 VAC 5-412-260 E Administration, storage and dispensing of dru 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. This RULE: is not met as evidenced by: Based on a review of the narcotic log book by two (2) Medical Facility Inspectors (MFI's) on 12/16/2014-12/17/2014, the facility failed to ensure that all Schedule II through V drugs received and administered were documented in the log book in accordance with the Drug Control Act found in the Code of Virginia (COV) 54.1-3404. The findings included: 1. Review of the facility’s narcotic log book revealed multiple instances where documentation in the book, including patient names, drug names and amounts, and dates had been scribbled over or marked through making the entry illegible. 2. Columns for quantity of drugs received and quantity on hand were not filled in correctly; the Physician had documented the number on hand in the column for amount received on several pages of the narcotic book, making the drug counts appear incorrect. The Administrator (Staff #1) was shown the narcotic log book on 12/17/14 at 3:00 p.m. and was asked to explain documentation to the MFI's. She stated, &quot;He (Physician's name) T285: The Controlled Substance Book and proper way of recording was reviewed with the Anesthesiologist. The correct annotations are being made and the QA coordinator has been advised to review. Effective 12/26/2014</td>
<td>T285</td>
<td>12/26/14</td>
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just didn't fill the log out right, but the count is correct. The survey team discussed with Staff #1 the requirements for the maintenance of an accurate and legible narcotic log. Staff #1 stated, "I will speak to (name) about it."

T 285 12 VAC 5-412-310 Medical records

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:
1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses' progress notes,
   h. Condition at time of discharge,
   i. Patient instructions, preoperative and postoperative; and
   j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by:
Based on staff interview and review of patient records, the facility staff failed to maintain a complete and accurate clinical record by ensuring a screening was done for sexually transmitted
T 340: Continued From Page 10

diseases (STD) consistent with the current guidelines issued by the Centers for Disease Control and Prevention.

There was no evidence contained in 9 (nine) of 9 (nine) patient records reviewed. Patient #s 1 (one) through 9 (nine) of an STD screening.

The findings included:

Review of the records for 9 (nine) patient revealed no evidence of STD screening.

On 12/17/14, at 5:15 p.m., Staff #1 stated, "We do not do the screenings because it is not the standard of care for abortion patients...we told them the last time we do not do them..."

T340: STD testing is not standard of care for abortion patients in this region. Our chart has been amended to include STD testing documentation. Completed 1/12/2015
METRO MEDICAL CENTERS, INC
BOARD OF DIRECTORS
AMENDMENT TO BY-LAWS

THE FACILITY TRADING AS ANNANDALE WOMEN & FAMILY CENTER, IN ORDER TO BE IN COMPLIANCE WITH THE STATE OF VIRGINIA REGULATIONS OVERSEEING ABORTION FACILITIES SPECIFICALLY 12 VAC-5-412-160C ADMINISTRATOR, HEREBY AUTHORIZED THE PRACTICE ADMINISTRATOR TO NAME AN ALTERNATE ADMINISTRATOR IN HER ABSENCE.

FURTHER, THIS BOD AUTHORIZED SAID PRACTICE ADMINISTRATOR TO WRITE A JOB DESCRIPTION FOR THIS ALTERNATE.

EFFECTIVE THIS DATE 1/5/15

GAIL FRANCES PRESIDENT

GENEVIEVE BORELLO DIRECTOR
ALTERNATE PRACTICE ADMINISTRATOR

QUALIFICATIONS: EMPLOYMENT WITH PRACTICE FOR A MINIMUM OF TWO YEARS
SUPERVISOR: PRACTICE ADMINISTRATOR

RESPONSIBILITIES: To act on the behalf of the Practice Administrator during periods of her absence due to vacation, illness or other reasons.

All policies and procedures established by the Operating Director and Practice Administrator are to be strictly followed. No new policies or procedures may be established during the absence of the Practice Administrator.

Any violations of policies and procedures noted during the PA absence must be reported in writing and presented at her return.

Any complications or post surgical problems of abortion patients must be documented in the chart and presented to the Gyn attending physician and to the PA upon her return.
SEXUALLY TRANSMITTED DISEASE

The Practice follows the protocol and procedures issued by CDC regarding testing and treatment of all STDs.

Procedures for testing and treatment of patients are reviewed and updated on an annual basis by the Practice Administrator and reviewed by the Quality Assurance Supervisor.

Abortion patients are not routinely tested for STD as it is not the Standard of Care. The abortion chart documentation allows the attending physician to opt for or against STD testing.

Protocol and procedures staff prophylaxis treatment of HIV follow guidelines set by OSHA and CDC.

Procedures for maintaining staff immunizations records are developed and implemented by the Practice Administrator.
T 000 12 VAC 5-412 Initial comments

An unannounced Licensure Biennial survey was conducted August 25, 2014. Three Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey.
The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

T 035 12 VAC 5-412-150 Policy and procedure manual

Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics:
1. Personnel;
2. Types of elective and emergency procedures that may be performed in the facility;
3. Types of anesthesia that may be used;
4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
5. Obtaining written informed consent of the patient prior to the initiation of any procedures;
6. When to use ultrasound to determine gestational age and when indicated to assess patient risk;
7. Infection prevention;
8. Risk and quality management;
9. Management and effective response to medical and/or surgical emergency;
10. Management and effective response to fire;
11. Ensuring compliance with all applicable federal, state and local laws;
12. Facility security;
13. Disaster preparedness;

Prior to inspection by the Virginia Department of Health ATWWC had a discharge policy in place, which was in the policy & procedure manual. Under "Admissions & Discharge Policy" tab. This may have been overlooked due to the fact they are on the same sheet.
A copy of this document has been submitted.
<table>
<thead>
<tr>
<th>T 035</th>
<th>Continued From Page 1</th>
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<tbody>
<tr>
<td>14. Patient rights;</td>
<td></td>
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<tr>
<td>15. Functional safety and facility maintenance; and</td>
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<tr>
<td>16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable. These policies and procedures shall be based on recognized standards and guidelines.</td>
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<tr>
<th>T 035</th>
<th>T095</th>
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<tbody>
<tr>
<td><em>A policy has been created to ensure compliance by reporting licensed and certified health care practitioners for violations of their licensing or certification standards.</em></td>
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<tr>
<td><em>The administrative and clinical directors will review the Virginia Department of Health website every six months to make sure regulations have been updated.</em></td>
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<tr>
<td><em>A policy has been implemented to ensure compliance with reporting licensed and certified health care practitioners. The directors will review the VDH website every six months to ensure compliance with all regulations.</em></td>
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</tbody>
</table>

This RULE is not met as evidenced by:

Based on document review and interview the facility failed to have a written policy which included criteria for discharge.

The findings included:

The facility's policy and procedure manuals were...
T 035: Continued From Page 2

reviewed on August 25, 2014. No policy was found pertaining to discharge criteria.

Staff #1 was interviewed on August 25, 2014 at approximately 6:30 pm. Staff #1 confirmed the facility has no written policy pertaining to discharge criteria.

T 095 12 VAC 5-412-170 H Personnel

H. Personnel policies and procedures shall include, but not be limited to:
   1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;
   2. Process for verifying current professional licensing or certification and training of employees or independent contractors;
   3. Process for annually evaluating employee performance and competency;
   4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and
   5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.

This RULE is not met as evidenced by:
Based on document review and interview the facility failed to have a written policy pertaining to reporting licensed and certified health care practitioners for violations of their licensing or certification to the appropriate board of the Department of Health Professions.

The findings included:

The facility's policy and procedure manuals were...
<table>
<thead>
<tr>
<th>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</th>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
<th>(X3) DATE SURVEY COMPLETED</th>
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<tr>
<td></td>
<td>AF-0004</td>
<td>A. BUILDING</td>
<td>08/25/2014</td>
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<td>NAME OF PROVIDER OR SUPPLIER</td>
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<td>B. WING</td>
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<td>A TIDEWATER WOMEN'S HEALTH CLINIC</td>
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<td>STREET ADDRESS, CITY, STATE, ZIP CODE</td>
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<td>NORFOLK, VA 23502</td>
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<td>(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
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<td>T 095</td>
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<td></td>
<td>Reviewed on August 25, 2014 at approximately 3:30 pm. No policy was found related to reporting licensed or certified practitioners for violations of their license or certification.</td>
<td>T 095</td>
<td></td>
<td></td>
<td>Consent 5. Judicial bypass. If any chart is found incomplete, employees will be retrained and monitored by directors to ensure compliance</td>
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<tr>
<td>T 175</td>
<td></td>
<td></td>
<td>12 VAC 5-412-200 Minors</td>
<td>T 175</td>
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<td>Employee have been retrained how to properly disinfect and clean per job descriptions.</td>
<td>9/8/14</td>
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<tr>
<td>T 130</td>
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<td>No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian or other authorized person. If the emancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.</td>
<td>T 130</td>
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<td></td>
<td>The directors will do a periodic check behind employees to ensure proper cleaning and disinfecting has been completed. If this periodic check finds improper cleaning and disinfecting techniques are being utilized or not done at all, retraining will be daily monitoring will be done in order to remain compliant</td>
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</table>

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to provide proof of proper consent for an abortion for one of three minors (Patient #3).

The findings included:

Thirteen patient records were reviewed on August 25, 2014 from approximately 12:45 pm through 6:00 pm. Three patient records reviewed were minors (Patient #1, #2, and #3). All three patients were under the age of eighteen at the time of the procedure. Patient #3’s medical record did not have a notarized consent. Patient #3’s date of birth is 11/04/1996.

According to the State of Virginia Code 16.1-241, Jurisdiction; consent for abortion, authorization...
The two fabric pillows have been discarded from the facility. We will no longer be using pillows on our procedure tables. We no longer use pillows. Pillows were disposed of on 8/25/14.

The patient examination table in room #2 has since been sanded & resurfaced to provide proper cleaning & disinfecting. The bucket attached to the table has been cleaned & sanitized & taken off table entirely. This bucket does not get used so we have chosen to remove it from the exam table to prevent this from happening again. Employees have been retrained to check examination table for rust & how to thoroughly clean.
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment;
   (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
   (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer’s recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE is not met as evidenced by:
Based on observation and interview the facility failed to follow the process and procedure for:

1. Cleaning and disinfecting reusable medical equipment for two of two patients observed in the recovery room (Patient #12 and #13).

2. Cleaning environmental surfaces with appropriate cleaning products.

The findings included:

We have added this to the corresponding job description as well as biweekly checklist to ensure this does not happen again. How to properly check the tables has been added to our cleaning schedule so they will be monitored and not overlooked.

All employees have been retrained on the importance of barrier protection and sanitizing equipment between patients.

The administrative & clinical directors will periodically monitor employees to ensure barrier protection & sanitization is being complete. Periodic monitoring will be ongoing to ensure proper barrier protection & sanitizing is being utilized. If any employee is noted to be using improper sanitizing techniques and/or no barrier protection, employee will be retrained to ensure compliance.
During the initial tour of the facility on August 25, 2014 at approximately 11:10 am the surveyors observed the floor in the ultrasound room was not properly cleaned. The floor was visibly soiled. This was confirmed when one surveyor used a moistened wipe the discoloration was no longer present. The ultrasound machine had dirty compartments where the gel is kept.

Two fabric pillows in unsealed plastic bags were found in operating/procedure rooms one and two on the patient examination tables. Staff #1 confirmed the pillows were used by patients. The patient examination table in operating/procedure room two was observed to have rust on it. When the examination table was broken down the tray bucket attached to the table was noted to be visibly soiled.

During patient observations in the recovery room at approximately 5:45 pm on August 25, 2014 two of two patients (Patients #12 and #13) had their blood pressure taken by Staff #2. Staff #2 did not clean the reusable blood pressure cuffs between patients.

Staff #1 and Staff #2 were present during the initial tour of the facility and confirmed the findings. Staff #2 was interviewed at approximately 7:00 pm. Staff #2 confirmed he/she did not clean the blood pressure cuffs between the patients in the recovery room. Staff #2 reported he/she normally cleans the blood pressure cuffs or puts a barrier between the cuff and the patient.

<table>
<thead>
<tr>
<th>T 230</th>
<th>12 VAC 5-412-250 C Anesthesia service</th>
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<tr>
<td></td>
<td>C. The facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care.</td>
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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
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<tr>
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<td>B. WING</td>
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**NAME OF PROVIDER OR SUPPLIER**

A TIDEWATER WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**

891 NORFOLK SQUARE
NORFOLK, VA 23502

<table>
<thead>
<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<tr>
<td>T 230</td>
<td>Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting. This RULE: is not met as evidenced by: Based on document review and interview the facility failed to have written discharge orders from anesthesia or physician defined discharge criteria for thirteen of thirteen patients (Patient Records #1-13). The findings included: Thirteen of thirteen patient records reviewed on August 25, 2014 from 12:45 pm through 6:00 pm had no discharge orders or physician defined discharge criteria (Patient Records #1-13). No record reviewed of patients who received sedation had any documentation of a discharge order from anesthesia or specific physician defined discharge criteria. Staff #1 and Staff #2 were interviewed on August 25, 2014 at approximately 7:10 pm. Staff #1 and Staff #2 verified the facility has no discharge form or specific physician defined discharge criteria.</td>
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<tr>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCE TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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<tr>
<td>Accessible, and physician handles disposal of medications in room at the close of clinic. If substances are found with no label, they will be discarded immediately. The staff realigned and monitored by directors to ensure compliance. T340</td>
<td>9/23/14</td>
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</tbody>
</table>

- Upon further review of the policy and procedure manual, we were able to locate our original discharge policy. Upon review, policy was not being implemented as documented. We have redone our recovery sheet to include condition of patient at the time of discharge, discharge orders to our surgical abortion recovery & discharge record form & have adjusted the use of the A.M.A. release. Physician progress notes on the Physician Encounter Form. |
This RULE: is not met as evidenced by: Based on observation and interview the facility failed to store drugs in accordance with federal and state laws.

The findings included:

During the initial tour of the facility two syringes of a clear unknown substance were found in a drawer in operating room/procedure room two. The two syringes were undated, unlabelled, and had no documentation of who had prepared the medications.

Staff #1 and Staff #2 were present during the finding. Neither Staff #1 or Staff #2 could provide any information pertaining to the medications. The medications were disposed of by the facility's staff.

T 340 12 VAC 5-412-310 Medical records

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:

1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;

• The directors will:
  • Sign each patient's Surgical Abortion Recovery & Discharge Record, which is witnessed by recovery room attendant. Each Surgical Abortion Recovery & Discharge Record includes patient condition at time of discharge. Physician progress notes on the Physician Encounter Form.
  • The directors will periodically review charts to ensure physician is complying with proper discharge criteria. A.M.A. sheet is only used when a patient wishes to leave against medical advice.

We are in the process of researching products that are best suited for our office that will raise the medicare records from floor level.

Directors will monitor that all medical records are stored appropriately to ensure compliance.
STATE OF VIRGINIA

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLEANING IDENTIFICATION NUMBER: AF-0004

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
08/25/2014

NAME OF PROVIDER OR SUPPLIER
A TIDEWATER WOMEN'S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE
891 NORTFOLK SQUARE
NORFOLK, VA 23502

(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) COMPLETION DATE

T 340 Continued From Page 9

- All medical records will be kept in designated area stored above floor1 level.
  #2 (T345) 8/28/14

- The doors to the records storage area is kept locked to ensure compliance. Staff restrained on importance of keeping area locked.

- The directors will randomly check the records storage area to ensure it is securely locked.

- If through random checks the door to storage area is found unlocked, staff will be retrained in order to ensure compliance.

- Signs have been placed on recovery room doors so patients know they can be used as emergency exits. We have since added signs.

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to have a complete clinical record for thirteen of thirteen patient records (Patient Records #1-#13).

The findings included:

Thirteen patient records were reviewed on August 25, 2014 from approximately 12:45 pm through 6:00 pm (Patient Records #1-#13). The review revealed the following information:

1. Thirteen of thirteen patient records reviewed had no discharge order written by the physician (Patient Records #1-#13).

2. Thirteen of thirteen patient records reviewed had no physician progress notes (Patient #1-#13).

3. Thirteen of thirteen patient records reviewed had no condition of the patient at the time of discharge documented (Patient Records #1-#13).

Staff #1 and Staff #2 were interviewed at approximately 7:10 pm. Staff #1 and Staff #2 confirmed the facility has no discharge form. Staff #1 and Staff #2 reported the AMA (against medical advice) form is used as a discharge form. Staff #1 reported the facility has progress notes but the notes are used only if additional...
T 340 Continued From Page 10

information about the patient is documented.

T 345 12 VAC 5-412-320 Record storage

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored.

This RULE: is not met as evidenced by:
Based on observations and interview the facility failed to have provisions for the safe storage of medical records.

The findings included:

During the initial tour of the facility at approximately 11:15 am on August 25, 2014 the medical record storage area was visited. Numerous medical records (approximately eight years) were stored in cardboard boxes on the floor in an unlocked room. Some medical records were stored on metal shelves.

Staff #1 and Staff #2 were present during the observations made in the medical records storage area. Staff #2 reported the medical records room is usually locked. Staff #1 and Staff #2 confirmed the door was not locked at the time of the initial tour.

T 365 12 VAC 5-412-350 A Disaster preparedness

A. Each abortion facility shall develop, implement and maintain policies and procedures...
to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.

This RULE is not met as evidenced by:

Based on observation and interview the facility failed to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters.

The findings included:

During the initial tour of the facility on August 25, 2014 at approximately 11:20 am the surveyors observed the exits from the recovery room to the doors which lead to the outside of the building are not clearly designated as exits. The recovery room had two doors which were not designated as exits. Once into the hallway from the recovery room there were multiple unmarked doors which would make it difficult to know how to exit from the building in the event of a fire or emergency.

According to the Occupational Safety and Health Administration (OSHA) "each exit must be clearly visible and marked by a sign reading exit. Each doorway or passage along an exit access that could be mistaken for an exit must be marked not an exit." According to NFPA (National Fire Protection Association) 101 section 7.10.1.2 states that "all exits other than main exterior exit doors that are obviously and clearly identifiable as Exits must be marked by an approved sign that is readily visible from any direction of Exit access."

Staff #1 and Staff #2 were present during the initial tour and confirmed the findings pertaining to the unmarked exits.
**NAME OF PROVIDER OR SUPPLIER**  
A TIDEWATER WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**  
891 NORFOLK SQUARE  
NORFOLK, VA 23502

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| T 375 | 12. VAC 5-412-360 A Maintenance |

**SUMMARY STATEMENT OF DEFICIENCIES**

- **A.** The facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be all be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

This RULE is not met as evidenced by:

- Based on observation and interview the facility failed to provide patients with a means of calling for assistance from the bathroom used by the patients after a procedure.

- The findings included:
  - The facility was toured on August 25, 2014 at approximately 11:00 am. No call light or means of calling for assistance from the facility's staff was found in the patient bathroom used by patients who have had procedures. This bathroom is located directly across from the recovery room area and is used by patients in the recovery room.
  - Staff #1 and Staff #2 were present and informed of the findings. Staff #2 reported he/she will instruct the patients to verbally call out if they need help. Staff #2 verified other than the patient calling for staff verbally there was no way a patient could request assistance while in the bathroom.
An unannounced Biennial Licensure for a First Trimester Abortion Facility was conducted on October 14, 2014 and October 17, 2014 by two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the revisit survey. The agency was not in compliance with the provisions of the Code of Virginia, and the State Board of Health 12 VAC 5-381 Regulations for the Licensure of Abortion Facilities. (Rev. 06/20//2013).

Deficiencies were identified and follow in the State Form.

<table>
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<tr>
<th>T 000</th>
<th>12 VAC 5-412 Initial comments</th>
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<th>T 010</th>
<th>12 VAC 5-412-140 A Organization and management</th>
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<td>12 VAC 5-412-140 A</td>
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<tr>
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<td>On October 27, 2014, a meeting of the</td>
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<td>Governing Authority was called by the</td>
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<td>Administrator and Medical Director of the</td>
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<td>facility. Prior to the inspection and</td>
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<td>discussions with the Virginia</td>
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<td>Department of Health inspectors, The</td>
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<td>Governing Authority was unaware that in</td>
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<td>addition to having the State required</td>
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<td>criminal background check, which both</td>
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<td>the Administrator and Acting Administrator</td>
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<td>had on file, it was also required they have</td>
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<td>specific verbiage regarding access to the</td>
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<td>keys for the locked narcotic cabinet and</td>
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<td>the receiving and securing narcotic</td>
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<td>medications in their job descriptions.</td>
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<td>To comply with this requirement, the</td>
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<td>Governing Authority then created an</td>
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<td>appropriate new verbiage for the</td>
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Observations were conducted on 10/14/14, at approximately 11:00 a.m., with Staff #1 and #2. During the initial tour of the facility, the observation revealed Staff #1 and #2 were in control of the keys to the locked narcotic cabinet. Staff #2 prepared to count the narcotics with the surveyors.

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T 010 Continued From Page 1

Staff #1 informed Staff #2 and the surveyors that he/she had accepted delivery of narcotic medications, which "have not been added to the count." Staff #1 stated, "The narcotics I received today are in a plastic bag inside the [narcotic] cabinet."

Review of personnel files revealed Staff #1 and Staff #2 were not licensed healthcare professionals. The personnel files for Staff #1 and Staff #2 did not have documented approval from the governing body to accept the delivery of narcotics and to possess keys to the locked narcotic cabinet.

An interview was conducted on 10/17/14, at 4:48 p.m., with Staff #2. Staff #2 agreed the job descriptions of Staff #1 and #2 failed to document they had been approved by the governing body to have access to the keys for the locked narcotic cabinet. Staff #2 verified their job descriptions did not include the responsibility for receiving and securing narcotic medications. Staff #2 acknowledged the governing body failed to ensure the facility had a policy, which allowed for non-licensed healthcare professionals to have access to the locked narcotic cabinet.

T 170 12 VAC 5-412-220 B Infection prevention

B. 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 already existing Administrator job description to appropriately authorize the Administrator/back up Administrator to have access to the keys for the locked narcotic cabinet and to receive and secure narcotic medications. This new job description was then approved by the Governing Authority, a copy of the description was placed in the two listed employees' files, and a copy was given to each of the two employees.
T 170  Continued From Page 2

indications for use of soap and water and use of alcohol-based hand rubs;
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 observations and interview the facility failed to ensure staff used safe injection practices for eleven of eleven prepared injections.

The findings included:

An observation was conducted on 10/17/2014 at approximately 6:40 p.m. with Staff #4 as he/she prepared Lidocaine/Vasopressin injections to be used during procedures. The observation revealed Staff #4 removed the caps covering the vial of Vasopressin and without disinfecting the vial's septum withdrew the medication. Staff #4 removed the cap from a multi-dose vial of Lidocaine and without disinfecting the vial's septum injected the Vasopressin into the vial of Lidocaine. Staff #4 did not change the needle on the syringe prior to injecting the Vasopressin into the Lidocaine vial. After injecting the Vasopressin into the Lidocaine vial Staff #4 used the same syringe to prepare a Lidocaine/Vasopressin dose for injection. Staff #4 removed the prepared syringe from the needle hub leaving the needle in engaged in preparations of injections have been individually advised of this policy, provided a copy of the deficiency report, and have formally agreed to follow this policy without deviation. Furthermore, these staff members were educated about the requirement of and method to disinfect the septum of all vials before withdrawing medication.
the vial of Lidocaine mixed with Vasopressin. Staff #4 attached four syringes in succession to the hub to prepare Lidocaine/Vasopressin injections to be used during the scheduled procedures. Staff #4 did not disinfect the hub of the needle, which protruded from the septum of the Lidocaine mixed with Vasopressin vial, prior to attaching each syringe. Staff #4 used the same manner of preparing Lidocaine/Vasopressin syringes as sited above; for a total of eleven injections.

An interview was conducted on 10/17/2014 at approximately 6:49 p.m., as Staff #4 prepared to begin procedures. The surveyor asked Staff #4 regarding his/her process for preparing syringes. Staff #4 reported all the connections between the needle and syringes were "sterile." Staff #4 reported the septum of the new vials were sterile.

An interview was conducted on 10/17/2014 at 7:40 p.m., with Staff #2. Staff #2 was informed of the findings during the observation. Staff #2 was informed of the standards for safe injection practices.

A second interview was conducted on 10/17/2014 at 7:43 p.m., with Staff #4. The surveyor provided Staff #4 with the current best practice guidelines for safe preparation of injections. Staff #4 acknowledged he/she had thought the septum of a newly opened vial was sterile and did not need to be disinfected. Staff #4 verified he/she had not used the best practice of "one needle, one syringe, one time."

According to the Association for Professionals in Infection Control and Epidemiology, Inc. American Journal of Infection Control 2010: "The transmission of bloodborne viruses and other microbial pathogens to patients during routine
health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication vial practices by health care professionals in various clinical settings throughout the United States. Breaches in safe injection, infusion, and medication vial practices continue to result in unacceptable and devastating events for patients.

Always use a new sterile syringe and new needle/cannula when entering a vial. Never enter a vial with a syringe or needle/cannula that has been previously used (eg, to inject a patient or access a medication vial).

Cleanse the access diaphragm of vials using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab. Allow the diaphragm to dry before inserting any device into the vial.

Never leave a needle, cannula, or spike device (even if it has a 1-way valve) inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination...

Use a new syringe and a new needle for each entry into a vial or IV bag...

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:
1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;

12 VAC 5-412-300 B Quality assurance

After our inspection and discussions with inspectors from the Department of Health, the Medical Director and Administrator called a meeting of the Quality Improvement Committee to discuss the findings. An assessment of the facility's Quality Assurance program revealed that some aspects were not
T 320 Continued From Page 5

5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

This RULE: is not met as evidenced by:
Based on document review and interview the facility's quality assurance program failed to perform the required evaluation of supervision appropriate to the level of service, Patient records, and infections, complications and other adverse events to identify unacceptable or unexpected trends.

The findings included:

Review of Patient #13's medical record revealed a note detailing a telephone call from the patient's family member. The note detailed Patient #13's visit to a local hospital's emergency department and treatment for an infection and possible incomplete abortion.

Review of the facility's "Complication Log" revealed information related to Patient #13's report of an infection and possible incomplete abortion.

An interview and review of the facility's quality program was conducted on 10/17/2014 at 5:15 p.m., with Staff #2. Staff #2 reviewed the data submitted to the facility's outside entity for quality purposes. The surveyor asked to review the data for the months of May 2014 and June 2014 to determine if Patient #13's infection/complications had been captured in the data. Review of April 2014 through June 2014 did not indicate the facility had documented any infections. Staff #2 and the surveyor reviewed Patient #13's medical record and the facility's "Complication Log." Staff #2 reported the physician had reviewed Patient adequate and appropriate to the level of services provided.

New policies regarding patient complication reporting and resolution were then drafted and implemented. The resulting process for gathering and documenting data related to the supervision of patient complications in our facility was installed. As a result, the Administrator and Medical Director will now have timely and more direct oversight of all reported patient complications.

Documentation was created for the Administrator to record all charts that are reviewed, the outcomes, or needed improvements/changes.

Quality indicator definitions were assessed, updated, and refined to ensure patient care appropriate to the level of services provided.

In addition to our current practice of timely consult and review with the M.D. of each patient problem, a Monthly assessment of all patient problems will be conducted and documented by the Medical Director and Administrator to identify unacceptable or unexpected trends in patient complications or other adverse events. In the event of unexpected trends in patient complications or other adverse events are identified, a meeting of the Quality Improvement Committee will immediately be called. The results of
T 320  Continued From Page 6

#13’s medical record and did not find anything out of the ordinary. Staff #2 acknowledged Patient #13’s medical record and the facility’s “Complication Log” offered detailed information regarding the patient having an infection. Staff #2 stated, “I think we may have just interpreted this wrong.” Staff #2 verified the facility failed to capture data regarding infections for its quality evaluation.

During the interview and review Staff #2 acknowledged he/she reviewed “100%” of the facility’s medical records but did not maintain a written document related to what was reviewed, the outcomes, or needed improvements/changes. Staff #2 verified the facility did not have a process or gather data related to supervision appropriate to the level of service.

T 340  12 VAC 5-412-310 Medical records

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:
1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist’s report of tissue, and radiologist’s report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;

T 340  12 VAC 5-412-310 Medical records

After our inspection and discussions with inspectors from the Virginia Department of Health, the facility created new progress notes in narrative form to document each patient’s progress from admission to discharge. All licensed staff were made aware that any signature must have the date and time documented. The layout of the new notes clearly demonstrate when the physician has seen and established the patient was stable for discharge. Furthermore, the new nurse’s progress notes in narrative form make clear the exact time of admission, the exact time of discharge, and all observations of the patient’s status while in recovery.
g. Physician and nurses' progress notes,

h. Condition at time of discharge,

i. Patient instructions, preoperative and
   postoperative, and

j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by:
Based on document review and interview the facility:

1. Failed to ensure physicians and nurses
   completed progress notes, which detailed the
   patient's progress from admission to discharge for
   twelve (12) of twelve (12) patients included in the
   survey sample. (Patients #1-#12) and

2. Failed to ensure direct care staff documented
   the date and time patients were discharged from
   the facility for twelve (12) of twelve (12) patients
   included in the survey sample. (Patients #1-#12)

The findings included:

1. Review of the medical records for Patients #1 -
   #12 did not reveal progress notes by the physician
   and the nursing staff, which detailed the patient's
   progress.

   Review of the medical records for Patients #1-
   #12 revealed a form titled "Recovery Room
   Notes." The form contained a section titled
   ObservationNote [Sic] the section was blank for all
   twelve patients (#1-#12). The recovery room
   nurse did not document observations of the
   patient's status while in the Recovery room.

An interview was conducted on October 17, 2014
at approximately 4:45 p.m., with Staff #2. Staff #2
acknowledged that he/she was not aware that
progress notes required a narrative of the patients'
status from post procedure until discharge.

2. Review of the medical records for Patients #1-#12 revealed a form titled "Recovery Room Notes." The lower portion of the form included medications prescribed and/or given to the patients at discharge. The "Recovery Room Notes" form did not indicate the time the patients had been discharged from the recovery area. The physician and nurse had signed the Recovery Room Notes" form under the area listing the discharge medications, but did not include the date and time of their signature. The surveyors could not determine when the physician had seen and established the patient was stable for discharge.

An interview was conducted on October 17, 2014 at approximately 4:45 p.m., with Staff #2. Staff #2 reviewed a sample of the twelve medical records included in the sample. Staff #2 was not able to determine when the patients had actually been discharged from the facility. Staff #2 reported he/she was not aware that licensed health care professionals’ signatures needed to be timed and dated.
An unannounced Licensure Biennial survey was conducted July 9, 2014 through July 10, 2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.

This RULE: is not met as evidenced by: Based on observation, interview, and document review the facility failed to have adequate personnel to meet the needs of patients.

The findings included:

Staff #4 (unlicensed) was observed handling narcotics in the procedure room on July 9, 2014 by a surveyor. Staff #4's employee file was reviewed on July 9, 2014 at approximately 3:00 pm. Staff #4 is unlicensed. Staff #4's job description was reviewed.

Staff #4 was interviewed on July 10, 2014 at approximately 10:30 am. Staff #4 confirmed he/she draws up narcotics for Staff #5. Staff #4 verified he/she is unlicensed. Staff #4 verified he/she works in the procedure room all the time. Staff #4 reported he/she has access to the narcotics in the above named facility and in the Richmond office.
**Department:** Patient Care Management  
**Policy Description:** Administration, Storage and Dispensing of Drugs

| Page: 1 of 1 | Replaces Policy Dated |
| Effective Date: 7/25/14 | Reference Number: 12VAC5-412-260 (Facility based) |

**Scope:** All licensed nursing and licensed medical personnel  
**Purpose:** To provide scope of responsibility for medication administration to patients  
**Policy:** All centers will follow established guidelines for the administration and documentation of medications.

**Procedure:**
1. All medications utilized in the facility will be administered only by licensed nurses or a physician.
2. Physician orders and patient allergies will be verified prior to medicating patients.
3. Each dose of any medication will be inspected for expiration date prior to preparing the medication for patient use.
4. When medicating patients the “5 rights” will be followed: right patient, right drug, right dose, right time, and right route.
5. Documentation will be done in the patient chart.
6. If a narcotic is administered the narcotic log will be used to record: the date; patient’s name; name of nurse preparing or administering the drug; dosage given; and the physician’s signature if he/she is administering the medication.
7. LPNs will neither prepare nor administer IV medications.
8. RNs may prepare IV medications for IV sedation prior to the actual start of the procedure: label the syringe with medication(s), dosage, and patient’s name, nurse initials who prepared the syringe, date and time; and store the medication in the “locked” narcotic storage box, in preparation for the procedure. In the event a RN/CRNA is not available to administer the IV medication the physician will do so.

**Reference:** 12VAC5-412-260
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<td>T 065</td>
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<tr>
<td>T 065</td>
<td>12 VAC 5-412-170 B Personnel</td>
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B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member.

This RULE is not met as evidenced by:
Based on documentation review and interview the facility failed to have evidence of education for one of eight employee files (Employee File #3).

The findings included:

Eight employee files were reviewed on July 9, 2014 at approximately 3:30 pm (Employee Files #1-#8). Employee file #3 had no documentation of education/resume. Employee file #3 has a job description for both a front desk receptionist and a counselor. Employee #3 had a documented hire date of 03/19/2014.

Staff #1 reported some of the employees were new and he/she had not reviewed the files.

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<th>T 090</th>
<th>PROVIDERS PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<td>T 090</td>
<td>12 VAC 5-412-170 G Personnel</td>
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G. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.
**T 090** Continued From Page 2

This RULE is not met as evidenced by:
Based on document review and interview the facility failed to have complete personnel files for four of eight employees (Employee Files #1, #3, #5, and #6).

The findings included:

Eight employee files were reviewed on July 9, 2014 at 3:30 pm (Employee Files #1-#8). The findings included:

1. Employee File #1 had no documentation of disaster preparedness training. Employee #1 has a documented hire date of 10/14/2013. Employee #1's job title is a recovery room assistant.

2. Employee File #3 had no documentation of education or a resume. Employee #3 has a documented hire date of 03/19/2014. Employee #3's job title is a counselor and front desk receptionist.

3. Employee File #5 has no documentation of Blood Borne Pathogen training on the orientation check list. Employee #5 had a documented hire date of 03/01/2013. Employee #5's job title is documented as alternate administrator.

4. Employee File #6’s orientation check list was not filled out. Employee #6 has a documented hire date of 06/25/2013. Employee #6's job title is documented as a recovery room nurse (LPN).

Staff #1 was interviewed on July 9, 2014 at approximately 3:30 pm. Staff #1 reported some of the employee files were new and he/she had not reviewed them.

**T 090**

Compliance officer has continued to review files and meet with staff to ensure training is complete and documentation is complete.

Compliance officer will review files of new hires but will also conduct periodic reviews of all personnel files for completion. Administrator is responsible for ensuring that personnel files are complete.
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No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian or other authorized person. If the emancipated minor elected not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

This RULE is not met as evidenced by:
Based on document review and interview the facility failed to provide proof of proper consent for an abortion for two of three minors (Patient #2 and Patient #3).

The findings included:

Seventeen patient records were reviewed on July 9, 2014 from 3:30 pm through 6:30 pm (Patient #1–#17). Three patient records reviewed were minors (Patient #1, #2, and #3). All three patients were under the age of eighteen at the time of the procedure (Patient #1, #2, and #3). The consents for a procedure for Patient #2 and Patient #3 were notarized but had no official notary seal.

Patient #2's date of birth is 08/17/98.
Patient #3's date of birth is 05/05/98.

Staff #1 was interviewed at the time of the finding. Staff #1 reported the signature on the form was Staff #4's. Staff #4 (administrator) was interviewed on July 10, 2014 at approximately 10:45 am. Staff #1 confirmed the forms did not have an official notary seal. Staff #4 reported he/she had left the official notary stamp in Richmond.
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<td>T 145</td>
<td>12 VAC 5-412-210 C Patients' rights</td>
<td>C. The facility shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgement of complaints; 2. Investigation of the complaint; 3. Review of the investigation findings and resolution for the complaint; and 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.</td>
<td>T 145</td>
<td>7/10/14</td>
<td>policy has been updated to include requirement that complaint be resolved within 30 days. Administrator is responsible for ensuring that complaints are handled appropriately.</td>
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<tr>
<td>T 170</td>
<td>12 VAC 5-412-220 B Infection prevention</td>
<td>B. 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</td>
<td>T 170</td>
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Scope: All stakeholders

Purpose: To establish a process for timely referral, prompt review, investigation and resolution of patient grievances and complaints.

DEFINITIONS:

Complaint is a concern represented by a patient or patient’s representative that can be addressed or resolved promptly by staff members who are present at the time of the complaint. “Staff present” includes those individuals close to the complaint situation or who can quickly be at the patient’s location to resolve the patient’s complaint. Generally, complaints can be resolved timely while the patient is still receiving care at the facility or in response to an issue raised after discharge from the facility.

Patient Grievance is a written or verbal complaint (when the verbal complaint about patient care is not resolved at the time of the complaint by staff present) by a patient, or the patient’s representative, regarding the patient’s care, abuse (verbal, mental, sexual or physical) or neglect, mistreatment, issues related to compliance to regulatory standards, or a Medicare beneficiary billing complaint.

A written complaint is always considered a grievance, whether from a patient or their representative. A written complaint also includes those complaints received via electronic mail or facsimile. Regardless of the form in which a complaint is received, whenever a patient or patient’s representative requests a response from the facility, the issue is defined as a grievance.

Information obtained on patient satisfaction surveys does not usually meet the definition of a grievance. If, however, the patient attaches a written complaint on the survey and requests resolution, then the complaint may meet the definition of a grievance. Written comments should be evaluated to determine if they constitute a complaint or a grievance.

A verbal complaint is a grievance if it cannot be resolved at the time of the complaint by staff present, if it is postponed for later resolution, if it is referred to other staff for later resolution, if it requires investigation, and/or if it requires further actions for resolution.

Policy: Each patient and/or the patient’s representative will be informed of the grievance process, including whom to contact to file a grievance or complaint. The patient will be informed that a grievance may be directly lodged with the State department of health or in the case of Medicare patients with the Medicare Beneficiary Ombudsman, regardless of whether he/she has first used the organization’s grievance process. Patient grievances are to be addressed in a timely, reasonable, and consistent manner. Notification to the complainant of the proposed resolution will occur within 30 days from the date of receipt of the complaint.

Dedication to providing quality care and service to patients requires an effective mechanism for resolving patient complaints. The goal is to be responsive and foster open communication with patients at all levels within the organization with the objective of resolving concerns expeditiously through appropriate problem solving actions. Presentation of a grievance or complaint...
will not compromise a patient’s future access to care nor subject the patient to coercion, discrimination, reprisal, or unreasonable interruption of care, treatment, or services.

The Governing Body approves and is responsible for the effective operation of the grievance process. The operational responsibility for reviewing and resolving grievances has been delegated to the Administrator. Data collected regarding patient grievances and complaints is incorporated in the quality assessment and performance improvement program with a quarterly report from the Quality Improvement Committee forwarded to the Governing Body for review. Confidential information will not be shared with the patient’s representative or any third party without appropriate written consent given by the patient.

The Facility Privacy Officer shall be responsible for overseeing the investigation and resolution of grievances related to the Health Insurance Portability and Accountability Act (HIPAA). The Risk Manager shall be responsible for grievances involving a request or demand for money or threatened litigation.

**Procedure:**

A. **Notification of Rights Regarding Complaint/Grievance Resolution**

1. Each patient and/or patient representative is informed of the rights and responsibilities afforded patients upon entry into the facility, and the process by which they may lodge a complaint. This information includes the designee of the organization, such as the Administrator, and the method of access to the designee to provide immediate assistance as needed.

2. Each patient receives information on how to lodge a grievance with the state agency upon entry to the facility. The state agency, Virginia Department of Health, 9960 Mayland Drive Suite 401 Richmond, VA 23223 or at (800) 955-1819, phone number, and address are provided in the event that the patient decides not to use the internal grievance process. The website is OLC-complaints@vdh.virginia.gov

B. **Complaint Resolution Process**

1. When a patient voices a complaint, the patient will be encouraged to discuss the complaint with the nursing staff and/or their physician. If the complaint is related to a particular department, a representative from that department may be invited to discuss the issue with the patient. The Administrator may be involved as needed to assist with prompt resolution.

2. Every effort will be made to resolve the complaint at the lowest level possible. Each staff member is empowered to respond and resolve promptly any complaint voiced by a patient and/or their representative. The staff member receiving the complaint will notify his/her supervisor when the issue cannot be immediately resolved. At each level of this process, the staff member will listen with concern to the patient’s complaint, consider the circumstances and context of the complaint, assure the patient that their complaint will be investigated and resolved as soon as possible.

3. At any point in the process, the complaint may become a grievance based on aforementioned criteria.

C. **Grievance Resolution Process**

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All grievances must be immediately reported to a person in authority when a facility employee is made aware of the grievance.

1. Grievances may be received written, verbally, via electronic mail or facsimile, or by telephone to any department. Upon receipt of a grievance, the Administrator shall confer with the appropriate personnel to review, investigate and resolve with the patient and/or patient representative within seven days of receipt of the grievance with the exception of complaints regarding situations in which patient safety may have been jeopardized, such as abuse or neglect. These grievances should be reviewed immediately given the seriousness of the allegations and the potential for harm to the patient. Medical staff leadership may be involved as needed to resolve physician delivery of care issues.

2. Occasionally, a grievance is complicated and may require an extensive investigation. If the grievance will not be resolved, or if the investigation is not or will not be completed within seven days, the complainant should be informed that the facility is still working to resolve the grievance and that the facility will follow-up with a written response within 21 days.

3. Regardless of the nature of the grievance, the substance of each grievance must be addressed while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

4. In resolution of the grievance, a written notice of the decision must be provided to the complainant that contains the name of the facility contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance investigation, and the date of completion.

5. The written notice must be communicated appropriately to the patient or the patient’s representative in a language and manner the patient or the patient’s representative understands. When a patient communicates a grievance via email, the response may be provided via email. However, the response must contain the aforementioned elements.

6. At the discretion of the person conducting the investigation, other mechanisms may be utilized to resolve a grievance. For example, conducting a meeting with the complainant may be very effective. However, in all cases a written notice of response with the aforementioned elements must be provided to each patient’s grievance.

7. A grievance is considered resolved when the patient and/or patient representative is satisfied with the actions taken on their behalf. There may be situations where the organization has taken appropriate and reasonable actions on the patient’s behalf in order to resolve the patient’s grievance and the patient or the patient’s representative remains unsatisfied with the actions taken by the organization. In these situations, the Quality Improvement Committee may consider the grievance closed. However, the organization must maintain documented evidence of compliance with all regulatory requirements.

8. Substantiated allegations of abuse, neglect, or other reportable events will be reported to state or local authorities.
D. Tracking, Trending, and Analysis of Data

1. A grievance/complaint log will be maintained by the Administrator or designated staff member. The documentation in the log will include date of complaint/grievance, location, summary of issue, how the issue was addressed, date resolved and response to complainant, and the individual responding to the grievance.

2. Documentation of the resolution process will include:
   - Name of person representing complaint/grievance and how to contact
   - Patient name
   - Nature of complaint/grievance
   - Date of service
   - Pertinent investigational information
   - Resolution/follow-up including written response for grievances
   - Signature of person addressing complaint/grievance

3. The above documentation will be maintained by the Administrator or forwarded to the designated staff member. Data will be aggregated, analyzed and reported to the Quality Committee and the Governing Body on a quarterly basis. Based on the QA/PI priorities of the Facility, the Governing Body shall give consideration to requiring the reporting of the following types of data analysis:
   - Reporting of individual cases deemed to be a serious grievance, as defined by the Facility (e.g., potential for causing harm, serious breach of policy, etc.), and any root cause analysis that might have been done in response, if necessary;
   - Total of all complaints/grievances, with analysis of nature/type of problem, frequency of each type, trends by seriousness of problem type, department(s) involved, type of staff involved (e.g., nursing, ancillary, physicians), type of patients involved (i.e. surgical, endoscopy, pain management), and actions taken in response to analysis of aggregate data;
   - Total of the subset of grievances only, with reporting of results of the investigations and actions taken, and the performance of follow-up and resolution, (e.g., number and percentage for which response to the patient was done timely, and included written response with all required information provided);
   - Status and success of any ongoing actions or other activities intended to reduce the number, frequency and/or seriousness of complaints and grievances.

Reference: 12VAC5-412-200 A-F
T 170

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;
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 observation, interview, and document review the facility failed to implement the policy relating to training all personnel in infection prevention techniques.

The findings included:

The facility's policy and procedure manual was reviewed on July 10, 2014 at approximately 4:00 pm. During the initial tour of the facility one bottle of opened undated normal saline was noted upstairs in the autoclave room. One open undated gallon bottle of distilled water was found in the same room. Staff #1 confirmed these solutions are used in the autoclave room.

Staff #1 was present during the initial tour and was aware of the findings.

Staff have been re-trained in the necessity of dating any opened solutions. Administrator is responsible for ensuring that any solutions are dated on their open date.

Administrator routinely inspects bottles for expiration date and opened date. Additionally, compliance officer conducts quarterly inspections. Administrator is responsible for ensuring opened solutions show the date they were opened.
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<td>T 200</td>
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<td>B. The abortion facility shall offer each patient, in a language or manner they understand, appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.</td>
<td>T 200</td>
<td>Proper documentation has been reviewed with current staff. Chart completion audits will be conducted on every chart to ensure proper charting. Staff have been advised to review charts in the process of seeing patients as well to catch any deficiencies at the time. Administrators are responsible for ensuring proper documentation.</td>
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<td>T 265</td>
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<td>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 (18 VAC 110-30).</td>
<td>T 265</td>
<td>This RULE: is not met as evidenced by: Based on observation, staff interview, and a</td>
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NAME OF PROVIDER OR SUPPLIER: CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN
STREET ADDRESS, CITY, STATE, ZIP CODE: 2321 COMMONWEALTH DRIVE, CHARLOTTESVILLE, VA 22901

STATE FORM 43U711

PRINTED: 07/16/2014
FORM APPROVED
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER: AF-0020

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
07/10/2014

NAME OF PROVIDER OR SUPPLIER
CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN

STREET ADDRESS, CITY, STATE, ZIP CODE
2321 COMMONWEALTH DRIVE
CHARLOTTESVILLE, VA 22901

(X4) ID
PREFIX
TAG

T 265 Continued From Page 7

T 265

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

review of the Code of Virginia § 54.1-3408. Professional use (of controlled substances) by practitioners, the agency failed to dispense controlled substances in accordance with federal and state laws.

The findings included:
An abortion procedure was observed by the surveyor on 07/09/14 at 6:10 p.m. with Patient #17. Upon entry to the procedure room the surveyor saw that Staff #4 was in the corner with medication in front of him/her. The surveyor approached Staff #4 and asked him/her to describe what he/she was doing. Staff #4 discussed the drawing up of Fentanyl (a narcotic analgesic) and Versed (also termed Midozolam, a benzodiazepine) into a syringe. Staff #4 labeled the syringe with a marker and then brought the syringe to the bedside. Staff #5 (physician) started the patient's intravenous line (IV) and then Staff #4 handed the syringe containing the Fentanyl and Versed to the physician, who then administered the medication. At no time were the contents of the syringe discussed between Staff #4 and Staff #5, nor was Staff #5 shown the vials from which the medications had been drawn.

Staff #5 was not in the corner with Staff #4 as the medication was being drawn up. An interview was conducted with Staff #4 on 07/10/14 at 11:15 a.m. Staff #4 was asked about his/her duties involving the administration of Fentanyl and Versed to patients prior to procedures. Staff #4 stated that he/she regularly "drew up" the Fentanyl and Versed for administration by the physician. Staff #4 stressed that he/she drew up the medication with the doctor in the room and that he/she was under the supervision of the physician. When asked how long Staff #4 had been drawing up medication for the doctor during procedures, Staff #4 stated that it has been for twenty (20) years. Staff #4 was asked if he/she was a licensed medical...
professional, and Staff #4 said, "no."
A review was done of the Code of Virginia § 54.1-3408 Professional use (of controlled substances) by Practitioners. There was no allowance for non-licensed persons to handle narcotic medications, even if under the supervision of a physician.

T 275 12 VAC 5-412-260 C Administration, storage and dispensing of drug
C. 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. 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 interview the facility failed to maintain drugs in the facility for daily use which are unexpired and to properly store and secure medications.

The findings included:
A tour of the facility was conducted on July 9, 2014 at approximately 2:00 pm with Staff #1. Four vials of Methergine (used for the control of hemorrhage) were found dated 04/14 in the unsecured laboratory refrigerator. The four vials of expired Methergine were removed by Staff #1.

One vial of opened Lidocaine (used for local anesthetics) and one vial of Pitocin (causes uterus to contract) were found in an unsecured cabinet in the procedure room on the first floor of the facility. This is an area where patients are present.
Staff #1 was present at the time of the finding and removed the expired medication. Staff #1 confirmed this is an area of the facility where patients would be present. Staff #1 confirmed the Lidocaine and Pitocin were unsecured. Staff #1 stated patients would never be alone in this room.

T 285 12 VAC 5-412-260 E Administration, storage and dispensing of drug

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.

This RULE is not met as evidenced by:

Based on document review, observation, and interview the facility failed to keep 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.

The findings included:

Seventeen patient records were reviewed on July 9, 2014 (Patients #1-#17). Six of seven patient records reviewed had consented to intravenous sedation (Patients #3, #5, #8, #11, #12, and #14). Each patient had documentation of having an intravenous line (IV) inserted into the vein by Staff #5. No documentation was found in the clinical records of any sedation being given to the patients.
Staff #1 was interviewed upon entry into the facility during the initial tour at approximately 2:30 pm. Staff #1 reported no narcotics are stored at the facility when asked to open the narcotic cabinet. Staff #1 reported the narcotics are brought from Richmond by Staff #4 and Staff #5. Staff #1 confirmed only patients who receive sedation have an IV (intravenous line which is inserted into the vein to receive fluids or medications) started prior to the procedure.

Staff #5 was interviewed on July 9, 2014 at approximately 8:50 pm. Staff #5 reported the narcotics are supplied by a local pharmacy in Richmond.

Staff #4 (administrator) was interviewed on July 10, 2014 at approximately 10:30 am. Staff #4 confirmed he/she is not licensed as a health professional. Staff #4 confirmed the narcotics are removed from the facility in Richmond and brought to the above named facility by him/her and Staff #5.

Staff #4 confirmed there would be no way to account for the narcotics given to patients at the above named facility unless documented in the patient's record. Staff #4 verified there was no documentation in Patient Records #3, #5, #9, #11, #12, and #14 of narcotics being administered. Staff #4 verified there was documentation in the patient's records of an intravenous being inserted by Staff #5. Staff #4 verified for a second time the only time a patient has an intravenous inserted is to receive sedation.

Staff #4 verified the narcotics are not counted at the above named facility. Staff #4 reported he/she counts the narcotics at the Richmond location when two licensed staff are not available. Staff #4 confirmed he/she has access to the narcotics. Staff #4 confirmed he/she is a non-licensed
**T 285 Continued From Page 11**

professional. Staff #4 confirmed he/she draws the narcotics up "under the supervision" of Staff #5. Staff #4 reported he/she has been "drawing up" narcotics for about twenty (20) years.

A review was done of the Code of Virginia § 54.1-3408 Professional use (of controlled substances) by Practitioners. There was no allowance for non-licensed persons to handle narcotic medications, even if under the supervision of a physician.

A review of the Practitioner’s Manual (by the US Department of Justice Drug Enforcement Administration an outline of the Controlled Substance Act) was reviewed on July 11, 2014 at 3:00 pm. According to the manual “a registered practitioner is not required to keep records of controlled substances unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services for substances so dispensed or administered.”

A review of the above named facility’s website was conducted on July 11, 2014 at 3:30 pm. The website list fees for services. The fee listed for the procedure with intravenous sedation (narcotics) is higher than the fee for local anesthesia (lidocaine).

A copy of the facility’s policy titled Administration Storage and Dispensing of Drugs-Controlled Substances Procedures was received and reviewed on July 9, 2014. The policy reads “an accurate, up to date ledger will be maintained by the facility nursing/anesthesia personnel. Upon receiving an order from the physician the nurse/CRNA (certified nurse anesthetist) administering the medication will record the date.
An abortion facility shall maintain medical equipment and supplies appropriate and necessary for the care of patients. 

An abortion facility shall maintain an inventory of medical equipment and supplies necessary for the care of patients. 

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<th></th>
<th>Versed</th>
<th>Fentanyl</th>
<th>Brevital</th>
<th>Dilaudid</th>
<th>T 3</th>
<th>Xanax</th>
<th>Signature and Date</th>
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T 290
Continued From Page 13

adequate to care for patients based on the level, scope and intensity of services provided, to include:
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.

This RULE: is not met as evidenced by:
Based on observation and interview the facility failed to maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:

1. Sterile suturing equipment and supplies.

The findings included:

During the initial tour of the facility on July 9, 2014 at 2:00 pm no sterile suture material was noted. On July 10, 2014 Staff #4 was asked if the facility had sterile suture material. Staff #4 was unable to locate any sterile suture material in the facility.

An interview was conducted with Staff #4 on July 10, 2014 at approximately 10:45 am. Staff #4 reported the suture material is in the red box (box which is brought by Staff #4 and Staff #5 from the Richmond facility) in Richmond. Staff #4 stated the suture material is here on procedure days. The red box was not present for verification of the
| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER IDENTIFICATION NUMBER: AF-0020 | (X2) MULTIPLE CONSTRUCTION A. BUILDING ___________________________ B. WING ___________________________ (X3) DATE SURVEY COMPLETED 07/10/2014 |
| NAME OF PROVIDER OR SUPPLIER CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN | STREET ADDRESS, CITY, STATE, ZIP CODE 2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901 |

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<th>(X5) COMPLETE DATE</th>
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<tbody>
<tr>
<td>T 290</td>
<td>Continued From Page 14 suture material on July 10, 2014. Staff #4 reported the red box was in Richmond. No access to the red box was obtained.</td>
<td>T 290</td>
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<tr>
<td>T 305</td>
<td>12 VAC 5-412-290 B Emergency services</td>
<td>T 305</td>
<td>T 305 9.1.14</td>
<td>A staff member (licensed) will become ACLS Certified administrator is responsible for ensuring that there is an ACLS certified staff if medications are given are given.</td>
</tr>
</tbody>
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This RULE: is not met as evidenced by: Based on document review and interview the agency failed to have an individual certified in Advanced Cardiac Life Support to provide services in the facility consistent with the current edition of American Heart Association's Guidelines for Advanced Cardiovascular Life Support.

The findings included:

Eight employee files were reviewed on July 9, 2014 at 3:30 pm (Employee Files #1-#8). No employee was found to be certified in Advanced Cardiac Life Support. One physician's credentials were reviewed. No documentation of being certified in ACLS was found in Staff #5's folder.

Staff #4 was interviewed on July 10, 2014 at approximately 10:45 am. Staff #4 confirmed the facility uses intravenous sedation. Staff #4 confirmed no staff at the facility have ACLS including the physician. Staff #4 reported some of the nurse anesthetists in Richmond have ACLS.
<table>
<thead>
<tr>
<th>T340</th>
<th>12 VAC 5-412-310 Medical records</th>
<th>T340</th>
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</table>
|      | An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:  
1. Patient identification;  
2. Admitting information, including a patient history and physical examination;  
3. Signed consent;  
4. Confirmation of pregnancy; and  
5. Procedure report to include:  
   a. Physician orders;  
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;  
   c. Anesthesia record;  
   d. Operative record;  
   e. Surgical medication and medical treatments;  
   f. Recovery room notes;  
   g. Physician and nurses' progress notes;  
   h. Condition at time of discharge;  
   i. Patient instructions, preoperative and postoperative; and  
   j. Names of referral physicians or agencies. |

This RULE: is not met as evidenced by:  
Based on document review the facility failed to have an accurate and complete patient record for twelve of seventeen patient records (Patient #1, #2, #3, #4, #5, #7, #9, #11, #12, #13, #14 and #16).  
The findings included:  
Seventeen patient records were reviewed on July 9, 2014 (Patients #1-#17). The review revealed the following information:
1. Six of seven patient records reviewed had consented to intravenous sedation (Patients #3, #5, #9, #11, #12, and #14). Each patient had documentation of having an intravenous line inserted into the vein (used to give fluids and medications) by Staff #5. No documentation was found in the clinical records of any sedation being given to the patients.

2. Seventeen of seventeen patient records reviewed had no nursing or physician's progress notes (Patients #1-17). All records reviewed had a recovery room record (nursing documentation) and a procedure record (medical doctor documentation). Previously cited for no nurses or physician's progress notes.

3. Eight of seventeen patient records had no documentation of the date or time on the patient's procedure record by the medical physician (Patient #1, #3, #4, #5, #7, #9, #12, and #13).

4. One of seventeen patient records reviewed had no documentation of vital signs being taken prior to the procedure (Patient #2).

5. One of seventeen patient records reviewed had no documentation the patient's history was reviewed by the physician prior to the procedure (Patient #4).

6. Six of seventeen patient records reviewed had no documentation of an order to discharge the patient from the procedure room to the recovery room (Patients #5, #7, #12, #13, #14, and #16).

7. One of seventeen patient records reviewed had no documentation of counseling prior to consenting to the procedure (Patient #3).

8. Four of seven patient records reviewed had
consented to intravenous sedation (Patients #5, #9, #12, and #14). No documentation was found on the pre-op notes except the history of the patients had been reviewed. No allergies, hemoglobin (blood count), Rh (inherited trait refers to a specific protein found on the surface of red blood cells) or current physical problems were documented on the physicians sheet. The hemoglobin and Rh factor were documented on a separate laboratory sheet.

Staff #1 and Staff #4 were interviewed on July 10, 2014 at approximately 11:00 am. Both Staff #1 and Staff #2 confirmed the only reason a patient would have an intravenous (IV) inserted would be to receive sedation for the procedure. Staff #1 and Staff #4 were shown the findings in the patient records relating to no documentation of the narcotics being given. Staff #4 reported the narcotics are brought in the red box from Richmond. Staff #4 verified the narcotics are not recorded or counted at the Charlottesville site. Staff #4 confirmed unless documented on the procedure record by Staff #5 there would be no record of the narcotics. Staff #4 reported there would be no other place these narcotics would be documented. Staff #1 and Staff #4 confirmed the findings in the patient records.

Staff #1 was made aware of the findings relating to no vital signs being taken on Patient #2 and no counseling being documented on Patient #3.

http://www.mayoclinic.org/tests-procedures/rh-factor/basics/definition/prc-20013476

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable
Continued From Page 18

federal and state law, including the Health Insurance Portability and Accountability Act (42 USC 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored.

This RULE: is not met as evidenced by:
Based on observation and interview the facility failed to store medical records in a safe manner.

The findings included:

During the initial tour of the facility on July 9, 2014 at approximately 2:10 pm several cardboard boxes were noted on the second floor of the facility in a room with a lock. The cardboard boxes had labeling on the outside of the boxes indicating the medical records were old. The cardboard boxes are not protected in the event of a fire in the building (cited last survey for having medical records in cardboard boxes).

Staff #1 was present during the finding and confirmed medical records were in the labeled cardboard boxes.

T 345

8. We must have documentation of procedure as well as on lab slip. Procedure rm. ass't will review chart to ensure proper documentation. Administrator will ensure all staff are aware of proper documentation. Chart completion audits will be conducted in every chart.

T 345

8-29-14

old files will be destroyed as allowed. Additional filing cabinets will be purchased to house old files that are not ready to be destroyed. Administrator is responsible for ensuring proper handling of files.
## Chart Completion Checklist

<table>
<thead>
<tr>
<th>Category</th>
<th>Action</th>
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<tbody>
<tr>
<td>Counseling Notes</td>
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<td>24 hr consent</td>
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<td>Ultrasound form</td>
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<tr>
<td>Pre-op Vital Signs</td>
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<td>Parental Consent if minor</td>
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<td>Local meds given</td>
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<td><strong>Physician</strong></td>
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<td>Admission time</td>
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<td>History review</td>
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<td>IV site</td>
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<td>Time for IV med</td>
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<td>O2 and Pulse</td>
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<td>Progress note</td>
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<td>Discharge time to Recovery</td>
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<td><strong>Recovery</strong></td>
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<td>Time admitted</td>
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<td>Vitals</td>
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<td>Progress note</td>
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<td>Pt understanding Of information</td>
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<td>Discharge criteria Met</td>
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<td>Physician sig</td>
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Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted an unannounced Licensure Revisit survey to the Initial survey performed July 31, 2012 through August 1, 2012. The Revisit survey was conducted December 11, 2012 through December 12, 2012.

The following regulations were not cleared from the initial survey and were re-cited:
12 VAC5-412-170 (B) (C) (E) (F) (G) - Personnel (with new findings included)
12 VAC5-412-220 (C) and (E) - Infection Prevention
12 VAC5-412-240 (A) - Medical Testing, patient counseling and laboratory services (new finding included)
12 VAC5-412-250 (C) (H) - Anesthesia Services
12 VAC5-412-300 (A) (B) (D) - Quality Assurance (new findings included)

New findings were cited in the following areas:
12 VAC5-412-140 (A) - Governing Body
12 VAC5-412-150 - Policy and Procedure Manual
12 VAC5-412-180 (C) - Clinical Staff
12 VAC5-412-310 - Medical Records

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics (effective 12/29/2011). Deficiencies cited follow in this report.

A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility.
This RULE is not met as evidenced by:
Based on facility document review, clinical record review, staff interview and revisit survey findings, the governing body failed to ensure the facility plan of correction was implemented and that the facility was in compliance with state regulations.

The findings included:
Based on the revisit survey conducted 12/11/12 through 12/12/12, and review/validation of the plan of correction submitted by the facility, the facility did not implement its plan of correction and new findings were also cited by the survey team.

The following regulations were not cleared and were re-cited:
12 VAC5-412-170 Personnel (with new findings included)
12 VAC5-412-220 Infection Prevention
12 VAC5-412-240 - Medical Testing, patient counseling and laboratory services (new finding included)
12 VAC5-412-250 - Anesthesia Services
12 VAC5-412-300 - Quality Assurance (new findings included)
12 VAC5-412-380 - Local and State codes and standards

New findings were cited in the following areas:
12 VAC5-412-140- Governing Body
12 VAC5-412-150 - Policy and Procedure Manual
12 VAC5-412-180 - Clinical Staff
12 VAC5-412-310 - Medical Records

On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee #4.
Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics:

1. Personnel;
2. Types of elective and emergency procedures that may be performed in the facility;
3. Types of anesthesia that may be used;
4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
5. Obtaining written informed consent of the patient prior to the initiation of any procedures;
6. When to use ultrasound to determine gestational age and when indicated to assess patient risk;
7. Infection prevention;
8. Risk and quality management;
9. Management and effective response to medical and/or surgical emergency;
10. Management and effective response to fire;
11. Ensuring compliance with all applicable federal, state and local laws;
12. Facility security;
13. Disaster preparedness;
14. Patient rights;
15. Functional safety and facility maintenance; and
16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable. These policies and procedures shall be based on recognized standards and guidelines.
This RULE: is not met as evidenced by:
Based on staff interview, clinical and employee record review, and facility document review, the facility staff failed to ensure the implementation of policies and procedures.

The findings included:

During the revisit survey conducted 12/11/12 through 12/12/12, it was found the facility developed policies and procedures, however failed to implement the following:
1. Personnel
2. Criteria for evaluating the patient before admission and before discharge.
3. Infection prevention related to training and education of staff.
4. Quality/Risk Management

---

**Governing Body has been informed.**

**Administrator is responsible for implementing policies & procedures.**

**Administrator is delegating tasks to other staff to ensure completion of personal files.** Chart forms have been revised to reflect admission & discharge criteria.

**Training & education of staff has been brought up to date, with new staff.**

**Training is ongoing.**

**Quality/Risk Management is ongoing.**

Jan 10, 2013
On 12/11/12 at 12:30 p.m., the survey team discussed the findings with Employee #1.

On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee # 4.

T 065 12 VAC 5-412-170 B Personnel

B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member.

This RULE is not met as evidenced by:
Based on observations, interviews and record reviews the facility failed to ensure employee records contained a written application, verification of training, experience or education for five of six employees. (Employee record #2 - #6)

The finding included:

During an interview conducted on December 11, 2012 at 10:25 a.m. with Staff #1, he/she reported the facility had less than ten (10) employees. Staff #1 presented six employee records for current staff.

Observation and review of the six (6) employee records revealed five of the employee records did not contain an application. The five employee records did not contain documentation of the employee's educational background or previous work experience. The five employee records did not contain documentation the employees meet...
Qualifications for their position through verification of training

Review of the facility's policy "Personnel Policies" read "Purpose: To ensure personnel are hired, trained, and reviewed appropriately so that the center may function optimally to the satisfaction of the patients, the governing authority, and other staff... Procedure: ...When filling a position, the new employee form will be utilized to ensure verification of qualifications for the position. An application will be obtained from all staff..."

An interview was conducted on December 11, 2012 at 12:06 p.m., with Staff #1. Staff #1 verified the information presented as the employees' records were their complete employee record and health file. Staff #1 was informed that five of the employee records did not contain applications, verification of previous experience, education or training that qualified them for their position. Staff #1 reported there was no other information available.

E. The facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.

This RULE is not met as evidenced by:
Based on record review and interview the facility failed to implement their policies related to
orientation and training specific to staff duties for five of six employees. (Employee record #2 - #6)

The findings included:

During an interview conducted on December 11, 2012 at 10:26 a.m. with Staff #1, he/she reported the facility had less than ten (10) employees. Staff #1 presented six employee records for current staff.

Observation and review of the six (6) employee records revealed five of the employee records did not contained documentation of the employee's orientation or ongoing training specific to their duties.

Review of the facility's policy "Personnel Policies" read "Purpose: To ensure personnel are hired, trained, and reviewed appropriately so that the center may function optimally to the satisfaction of the patients, the governing authority, and other staff ... Procedure: ... Orientation checklist will be completed ... Staff will participate in initial and ongoing training directly related to staff duties. Documentation of training will be kept in the personnel file as well as in the training manual ..."

An interview was conducted on December 11, 2012 at 12:06 p.m., with Staff #1. Staff #1 verified the information presented was the employees' complete record. The surveyor informed Staff #1 five employee records did not contain documentation of initial/orientation or other training specific to each employee's duties. Staff #1 reported there was no other information available.

| T 080 | Continued From Page 6 |
| T 080 |

| Orientation checklist has been completed for staff. |
| Completion date:

January 10, 2013. |

Administrator is responsible for ensuring that new staff is properly trained and oriented. Administrator is responsible for maintaining personnel files. |
F. Job descriptions.
1. Written job descriptions that adequately describe the duties of every position shall be maintained.
2. Each job description shall include: position title, authority, specific responsibilities and minimum qualifications.
3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.

This RULE: is not met as evidenced by: Based on record review and interview the facility failed to ensure employee records contained job descriptions and documentation the employee received a current job description for three of six employees. (Employee records #2, #3 and #5)

The findings included:

Observation and review of the six (6) employee records revealed two of the employee records did not contain a job description or documentation the employees received their job description. An additional employee did not have documentation of qualifications and/or job description for his/her position appointed by the governing body/board.

Review of the facility's policy "Personnel Policies" read "Purpose: To ensure personnel are hired, trained, and reviewed appropriately so that the center may function optimally to the satisfaction of the patients, the governing authority, and other staff. Procedure:... A job description will be part of each personnel file. The staff member will sign and date the job description to indicate that she is aware of her responsibilities. Job descriptions will
T 085 Continued From Page 8

be reviewed annually. A copy will be given to each staff member initially and on review ."

An interview was conducted on December 11, 2012 at 12:06 p.m., with Staff #1. Staff #1 verified the information presented was the employees' complete record. The surveyor informed Staff #1 three of the employee records did not contain their job description or information the employee was aware of their duties. Staff #1 reported the job descriptions should have been in their employee's record. Staff #1 reported there was no additional information available.

T 090 12 VAC 5-412-170 G Personnel

G. A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable.

This RULE is not met as evidenced by:
Based on record review and interview the facility failed to maintain complete and accurate employee records for five of six employees.
(Employee records #2 - #6)

The findings included:

During an interview conducted on December 11, 2012 at 10:26 a.m. with Staff #1, he/she reported the facility had less than ten (10) employees. Staff #1 presented six employee records for current staff.
Observation and review of the six (6) employee records revealed:

Five employee records (Employee record #2 - #6) did not contain the employee’s application for employment. The records did not contain documented orientation or initial training to ensure the employee’s capabilities/competency to perform their job/position duties. The records did not document the facility’s verification of the employees’ previous employment, education or training, which qualified the employee for his/her position. Employee records #2 through #6 did not contain documentation of on-going training related to the employee’s specific job duties.

Three employee records (Employee #2, #3, and #5) did not contain current job descriptions or provide documentation the employee had received their job descriptions.

Five employee records (Employee #2 - #6) did not contain the employee’s date of hire.

Review of the facility’s policy "Personnel Policies" read "Purpose: To ensure personnel are hired, trained, and reviewed appropriately so that the center may function optimally to the satisfaction of the patients, the governing authority, and other staff... Procedure: ... When filling a position, the new employee form will be utilized to ensure verification of qualifications for the position. An application will be obtained from all staff... Orientation checklist will be completed... Staff will participate in initial and ongoing training directly related to staff duties. Documentation of training will be kept in the personnel file as well as in the training manual... A job description will be part of each personnel file. The staff member will sign and date the job description to indicate that she is aware of her responsibilities. Job descriptions will be reviewed annually. A copy will be given to each staff member initially and on review..."
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An interview was conducted on December 11, 2012 at 12:06 p.m. with Staff #1. Staff #1 verified the employees’ records were not accurate and complete. Staff #1 verified the facility failed to implement its personnel policies. Staff #1 stated, “We still have work to do.”

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<th>12 VAC 5-412-180 C Clinical staff</th>
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C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The facility shall develop, implement and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the facility.

This RULE: is not met as evidenced by:
Based on clinical record review and staff interview, the facility staff failed to ensure discharge orders were signed after an assessment of the patient indicating the patient was safe for discharge for 8 (eight) of 8 (eight) patient records reviewed.
Patient #1 through 8.

The findings included:
Review of the clinical records for eight (8) patients...
T 115. Continued From Page 11

who received services from the facility revealed no discharge order signed by the physician. There was no evidence an assessment had been performed by the physician or that the physician had been given a report by a trained health care practitioner which indicated the patient(s) were safe for discharge.

On 12/11/12 at 12:30 p.m., the survey team discussed the findings with Employee #1. Employee #1 stated she was unable to find that a discharge order was written for the records reviewed.

On 12/12/12 at 7:30 p.m., the survey team reviewed the survey findings with Employee #1 and Employee #4.

T 175. 12 VAC 5-412-220 C Infection prevention

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);
4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing...
and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
   (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization), and
   (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE is not met as evidenced by:
Based on observations, record review and interviews the facility failed to implement necessary controls to prevent the transmission of infections. The facility failed to perform weekly spore testing for one of one autoclave.

The findings included:
Review of the facility's policy regarding performance of spore testing of the autoclave
indicated the testing would occur weekly.

A review conducted on December 11, 2012 at 9:08 a.m. of the facility's log for spore testing revealed:
No documented performance of spore testing for the weeks (Thursday begin date) of August 9, 2012 and August 16, 2012. The log did not document spore testing for the weeks of September 5, 2012 and September 26, 2012. Documentation for the week of September 13, 2012 indicated the test was "Invalid". The facility's log did not document the facility's follow-up actions.

Review of the facility's policy titled "Infection Control: Spore testing of autoclave" read "Purpose: To ensure that the autoclave is operating in a manner that materials being placed in the autoclave are being sterilized. Procedure: ... Weekly spore testing will be conducted on each autoclave in operation ... immediately notify site administrator in the event of a failed sterilization cycle ..." [The weekly spore test failure would provide evidence of a failed cycle.]

An interview was conducted on December 11 at 11:17 a.m. with Staff #1. Staff #1 reviewed the information in the spore testing log. Staff #1 reported the indicators were transported to another facility for processing and the results were faxed back to this facility. Staff #1 verified the log did not have documentation that the spore testing had been done weekly. When asked for the follow-up action related to the "Invalid" test for September 13, 2012; Staff #1 reported there was no additional information. Staff #1 acknowledged if the autoclave had failed its spore test during that week any instruments processed in the autoclave would not be sterile. Staff #1 stated, "I see where you are going with this. We need to tweak that."
Spore Test Report

Date of Test: ____________________________________________

Location: ________________________________________________

Result(s): Autoclave _______________________________________

Autoclave ________________________________________________

Control _________________________________________________

Technician: ______________________________________________

Corrective Action: NA As below

________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
T 175  Continued From Page 14

Observations during tour on December 11, 2012 at 12:06 p.m., with Staff #1 revealed the facility had only one autoclave available for use.

T 185  12 VAC 5-412-220 E Infection prevention

E. The facility shall develop, implement and maintain policies and procedures for the following patient education, follow-up, and reporting activities:
1. Discharge instructions for patients, to include instructions to call or return if signs of infection develop;
2. A procedure for surveillance, documentation and tracking of reported infections; and
3. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12 VAC 5-90), including outbreaks of disease.

This RULE is not met as evidenced by:
Based on clinical record review and staff interview, the facility staff failed to implement policies and procedures regarding patient education for 8 (eight) of 8 (eight) patient records reviewed (Patient’s #1 through 8) and failed to implement infection monitoring and reporting activities.

The findings included:

Review of the clinical records for Patient’s #1 through 8 revealed no documented discharge instructions which included instructions to call or to return if signs or symptoms of infection develop and education regarding the signs and symptoms of infection.

On 12/11/12 at 11:45 a.m., the surveyor requested
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To review the facility infection tracking and surveillance documentation. Employee #1 stated, "I can't put my hands on it right now." Employee #1 provided the surveyor a copy of a document from another facility with tracking information but stated, "I cannot find the one for this office right now."

At 12:30 p.m. on 12/11/12, the surveyor discussed the findings with Employee #1.

On 12/12/12 at 7:30 p.m., the survey team reviewed the survey findings with Employee #1 and Employee #4.

T195  12 VAC 5-412-240 A Medical testing, patient counseling and labor

A. Prior to the initiation of any abortion, a medical history and physical examination, to include confirmation of pregnancy, shall be completed for each patient.
1. Use of any additional medical testing, including but not limited to ultrasonography shall be based on an assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.
2. Medical testing shall include a recognized pregnancy test and determination on Rh factor.
3. The facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test.
4. A written report of each laboratory test and examination shall be a part of the patient's record.
This RULE is not met as evidenced by:
Based on clinical record review and staff interview, the facility staff failed to ensure a medical history and physical examination was completed for 8 (eight) of 8 (eight) patient records reviewed, Patient’s #1 through #8.

The findings included:

The clinical records for Patients #1 through #8 were reviewed on 12/11/12 and revealed no documentation that a history and physical was completed and signed by the physician.

On 12/11/12 at 12:30 p.m., the findings were discussed with Employee #1. Employee #1 stated the patients complete the history portion but she was not able to locate an physical assessment by the physician or that the physician reviewed the history as completed by the patient.

This RULE is not met as evidenced by:
Based on clinical record review, staff interview, and facility document review, the facility staff failed to implement their policy regarding criteria for discharge from anesthesia care for 8 (eight) of 8 (eight) records reviewed who received anesthesia (2 (two) patients #2 and #4 had documented IV sedation, but 6 (six) patients #1, 3, and 5 through...
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLINIC IDENTIFICATION NUMBER:

FTAF-0018

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
12/12/2012

NAME OF PROVIDER OR SUPPLIER
CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN

STREET ADDRESS, CITY, STATE, ZIP CODE
2321 COMMONWEALTH DR
CHARLOTTESVILLE, VA 22901

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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8. Did not have documentation designating the
pro / operative medications administered during
their procedure. (It was difficult to establish from
the clinical record of the patients who had
received moderate / intravenous sedation, as there
was no documentation of intravenous access
being initiated, and no documentation of
medications / dosages of intravenous sedation
medications.)

The findings included:

Review of the clinical records for Patients #1
through #8 revealed no documentation of the
responsiveness, orientation, ability to respond and
move voluntarily, pain under control, and the
presence / absence of nausea and / or vomiting
occurring, or after their procedures. There was
minimal documentation during the recovery phase
consisting of a blood pressure, bleeding
(light / moderate / heavy) and cramping / pain
(light / moderate / heavy). There was no
documentation at the time of discharge from
anesthesia or recovery of the condition of the
patient, whether they met the criteria for discharge
as outlined in the facility policy and state
regulations. (There was no documentation how
the patient left the facility, whether with a driver or
driving themselves.)

Employee #1 was interviewed regarding this on
12/1/12 at 12:15 p.m., and stated, "There is
some documentation here but, no, there is no
documentation of the condition on discharge."

On 12/12/12 at 7:30 p.m., the survey team
reviewed the survey findings with Employee #1
and Employee #4.

T 230

Forms have been revised
and staff trained to
improve documentation
of medications given.

Additionally, forms now
better reflect that
the criteria for
discharge have been
met.

Completion date
January 10, 2013

Staff is responsible for
proper documentation.
Administrator is responsible
for training and
continually evaluating
plan / care / documenta-
T 255. Continued From Page 18

T 255  12 VAC 5-412-250 H Anesthesia service

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.

This RULE: is not met as evidenced by; Based on clinical record review, facility document review and staff interview the facility staff failed to ensure 6 (six) of 6 (six) patients who underwent procedures for the termination of pregnancy were discharged after meeting physician-defined criteria for discharge. Two (2) of two (2) patients, #2 and #4, had documented IV sedation, but 6 (six) patients #1, 3, and 5 through 8, did not have documentation designating the preoperative medications administered) during their procedure. (It was difficult to establish from the clinical record of the patients who had received moderate/intravenous sedation, as there was no documentation of intravenous access being initiated, and no documentation of medications/dosages of intravenous sedation medications.)

The findings included:

Review of the clinical record of six patients who underwent procedures for the termination of pregnancy did not reveal any documentation that these patients had met the criteria for discharge which were outlined as follows:

1. Alert and oriented
2. Vital signs stable
3. Voided prior to discharge, if required by physician
4. Instructed to call physician if unable to void within 8 hours
5. Nausea, vomiting, dizziness minimal
T 255 Continued From Page 19

6). Able to ambulate
7). Tolerates liquids well
8). Responsible adult to escort home if IV or moderate
9). Prescriptions given
10). Patient given follow-up instruction sheet which includes instructions to call center if signs of infection develop.
11). Pain on discharge recorded; pain controlled
12). Menstrual pad checked (a) patient will have no unusual bleeding at time of discharge.

There were no notes written by the licensed health care practitioner regarding the condition of the patients at discharge, nor were there areas checked on the patient's record which reflected the above criteria was met.

On 12/11/12 at 12:15 p.m., the survey team discussed the findings with Employee #1.

On 12/12/12 at 7:30 p.m., the survey team reviewed the survey findings with Employee #1 and Employee #4.

T 315 12 VAC 5-412-300 A Quality assurance

A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.

This RULE is not met as evidenced by:
Based on facility document review, staff interview,
and survey revisit findings, the facility staff failed to ensure an ongoing, comprehensive, integrated, self-assessment Quality Assurance program was implemented.

The findings included:

During the revisit survey multiple areas of concern were found in the areas of:
Personnel, implementation of policies and procedures related to patient care and safety, patient medical record documentation, employee records, infection control, medical testing, anesthesia services, and local and state codes and standards.

There were also new findings in addition to areas previously cited that had not been cleared indicating the facility failed to follow/complete their submitted plan of correction.

On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee #4.

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:
1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.
This RULE is not met as evidenced by:
Based on facility document review and staff interview, the facility staff failed to implement a Quality Assurance Program which evaluated the adequacy and appropriateness of services to identify trends and occurrences.

The findings included:
On 12/11/12 at 11:45 a.m., the surveyor asked to review the Quality Assurance (QA) meeting minutes for the facility. Employee #1 presented the surveyor with a hand-written document for September 2012 which revealed the QA committee had done a review of patient medical records for completeness. Based on the revisit survey and citation regarding the incompleteness of the medical records, it was evident the QA committee had not thoroughly implemented and evaluated the program. There was also no evidence the QA committee had addressed any of the required elements to identify trends and occurrences in the areas of:
1. Staffing patterns and performance
2. Supervision appropriate to the level of service
3. Patient records
4. Patient satisfaction
5. Complaint resolution
6. Infections, complications and other adverse events and
7. Staff concerns regarding patient care.

On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee #4.

T 330 12 VAC 5-412-300 D Quality assurance
D. Measures shall be implemented to resolve
problems or concerns that have been identified.

This RULE: is not met as evidenced by:

Based on the results of the revisit survey conducted 12/11/12 through 12/12/12, the facility staff failed to ensure their Quality Assurance (QA) program implemented measures to resolve problems and identified concerns.

The findings included:

During the revisit survey the following regulations were not cleared and were re-cited by the survey team:

12 VAC5-412-170 (B) (C) (E) (F) (G) - Personnel (with new findings included)
12 VAC5-412-220 (E ) - Infection Prevention
12 VAC5-412-240 (A) - Medical Testing, patient counseling and laboratory services (new finding included)
12 VAC5-412-250 (C) (H) - Anesthesia Services
12 VAC5-412-300 (A) (B) (D) - Quality Assurance (new findings included)
12 VAC5-412-380 - Local and State codes and standards

New findings were cited in the following areas:

12 VAC5-412-140 (A)- Governing Body
12 VAC5-412-150 - Policy and Procedure Manual
12 VAC5-412-180 (C) - Clinical Staff
12 VAC5-412-310 - Medical Records

On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee # 4.
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<td>T 340 12 VAC 5-412.310 Medical records</td>
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An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:
1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses' progress notes;
   h. Condition at time of discharge;
   i. Patient instructions, preoperative and postoperative, and
   j. Names of referral physicians or agencies.

This RULE is not met as evidenced by:
Based on review and interview the facility failed to maintain accurate and complete clinical records for eight of eight patients in the survey sample.
(Patients #1 through #8)

The findings included:
Review of clinical records of the survey sample revealed:
Eight of eight clinical records did not have a physician's physical examination documented.

T 340 Addendum
Chart completion audits to be performed at least quarterly.
The eight clinical records did not have documentation the physician had discussed or reviewed the patient's medical history with the patient prior to the procedure.

Eight of eight clinical records did not have documented signatures by the facility's staff, which provided a witness to the patient's acknowledgement of reviewing required information twenty-four hours prior to their procedure.

Eight of eight clinical records failed to have physician orders for medications documented as administered "pre-op" (pre-operative), operative, and "post-op" (post[after] operative). Eight of eight clinical records failed to have physician discharge orders.

Two of two clinical records, which indicated the administration of Fentanyl and Versed, did not specify the route or dosage of the medications. The two clinical records did not have documentation related to which facility staff administered the narcotics.

Eight of eight clinical records did not document, which licensed staff had administered the medications, what time the medications were administered, which route the medications were administered and documentation of the patient's outcome after on-site medications were administered.

Eight of eight clinical records had incomplete recovery room notes. The clinical records did not consistently have the patient's vital signs documented post procedure and prior to discharge.

Eight of eight clinical records failed to have physician and nurses' progress notes to document the patients' progress or status operatively and post operative. The eight clinical records did not document that the patients' met the facility's criteria for discharge as establish by a physician.

Eight of eight clinical records failed to have
T 340. Continued From Page 25

documented physician assessment prior to discharge. Eight of eight clinical records failed to have documented assessments by nursing, the information entered within the clinical record failed to have authentication of which staff entered the data.
Eight of eight clinical records failed to document the patients' condition at the time of discharge. On eight of eight clinical records, the pre-documented "Disposition" items were left blank.
Eight of eight clinical records failed to indicate the patients had received discharge instructions.

According to Healthline.com FENTANYL (FEN ta nil) is a synthetic opioid narcotic analgesic, a pain reliever. It is used to treat pain before, during, and after surgery. This medicine is also used before, with, and in place of other medicines for sleep during a medical procedure.

According to Drugs.com Midazolam hydrochloride (midâz'ol'am), [Versed] is a short-acting benzodiazepine central nervous system depressant, a benzodiazepine anxiolytic. It is prescribed for preoperative sedation and impairment of memory of preoperative events and for conscious sedation before short diagnostic endoscopic or dental procedures.

An interview was conducted on December 11, 2012 at 10:35 a.m., with Staff #1. Staff #1 reviewed the findings. After reviewing Patient #1's clinical record, Staff #1 stated, "I think she had an IV (termination) and we just didn't check the boxes." Staff #1 reported the physician at present did not have a separate paper to document progress notes. Staff #1 stated, "The 24 hour consent is a problem. The patients call into the [name of another facility] to listen to the audio tape. The staff here call the [name of another
<table>
<thead>
<tr>
<th>T 340</th>
<th>Continued From Page 26</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>facility to check if the patient has called and recorded their name verifying they [the patient] has listened. The staff here places the time, date, and the patient's name on a blank form. But the patient fills out another form (attestation) that they listened when they arrive for the procedure.&quot; Staff #1 verified the staff that checks whether the patient had called 24 hours prior to the procedure did not enter their name as the person witnessing or verifying the patient's call. Staff #1 stated, &quot;I see your point.&quot; Staff #1 verified the eight clinical records did not have the required information.</td>
</tr>
<tr>
<td>ID PREFIX TAG</td>
<td>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(T 000)</td>
<td>An unannounced Licensure Revisit survey to the facility's July 2014 biennial survey for a First Trimester Abortion Facility was conducted on October 8, 2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the revisit survey. The agency was not in compliance with the provisions of the Code of Virginia, and the State Board of Health 12 VAC 5-381 Regulations for the Licensure of Abortion Facilities. (Rev. 06/20/2013). Two citations (0275 and 0340) cited during the July 2014 biennial survey were re-cited and one new finding (0175) observed during the initial tour on October 8, 2014.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T 175</th>
<th>12 VAC 5-412-220 C Infection prevention</th>
<th>T 175</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:</td>
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<tr>
<td>1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);</td>
<td></td>
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<tr>
<td>2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;</td>
<td></td>
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<tr>
<td>3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);</td>
<td></td>
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<tr>
<td>4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;</td>
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<tr>
<td>5. Procedures for handling/temporary storage/transport of soiled linens;</td>
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</tbody>
</table>
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;

7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
   (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
   (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;

8. Procedures for appropriate disposal of non-reusable equipment;

9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;

10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;

11. An effective pest control program, managed in accordance with local health and environmental regulations; and

12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: is not met as evidenced by: Based on observations, interviews, and document review the facility failed to ensure the recliners utilized in the recovery area were disinfected between patients to prevent the spread of infection for four of four recliners.

The findings included:

Observations were conducted in the facility's
recovery area on October 8, 2014 at approximately 5:21 p.m., with Staff #2 and two surveyors. The observations revealed four recliners. All four recliners had non-intact metal surfaces along the front lower rails and rust build up at the connection of the rails and wheel housings. One pink recliner had bilateral tears on the lateral sides where the arm rests met the back cushion. The same pink recliner had tape residue on the rail under the arm rest on the left side and the metal surface of the rail was not intact (a rust area approximately 1.5 inches) under the right arm rest.

An interview was conducted on October 8, 2014 at approximately 5:21 p.m., with Staff #2 during the observations. Staff #2 verified the findings. Staff #2 agreed the recliners could not be disinfected between patients if the surface areas were not intact. Staff #2 verified the tape residue indicated the arm rest railing had not been disinfected between patients.

Review of the facility's policy titled "Processing of Reusable Medical Equipment" read in part "Purpose: Reusable equipment shall be cleaned, disinfected, and sterilized to prevent infection from spreading from patient to patient to staff ... 3. Procedure c) Table: wipe off any visible blood with absorbent material and discard in red bag. Spray with disinfecting spray or use disinfecting wipes. Allow to remain wet for 3 minutes. See manufacturer's recommendations [Sic] ... 4. Recovery c) Recliners: treat same as tables."

C. Drugs maintained in the facility for daily administration shall not be expired and shall be
Continued From Page 3

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 observations, interviews and document review the facility failed to ensure two multidose vials of Lidocaine were stored properly and that one bottle of normal saline was discarded after being opened for thirty (30) days.

The findings included:

1. Observations were conducted in the facility's laboratory area on October 8, 2014 at approximately 5:08 p.m., with Staff #2 and two surveyors. The observation revealed a bottle of Normal Saline USP with an opened date documented as "9/13/14."

Review of the facility's policy titled "Administration, Storage and Dispensing of Drugs- Overall policy; Use of multi-dose vials; Disposition of Expired Drugs" read in part "Procedure: All components of State regulations shall be followed. In addition the following 3 components are delineated. 1. B) Unless contamination of the multi-dose vials is apparent or suspected, the vial may be used for 30 days for opened or entered vials provided this is in accordance with manufacturer's recommendations [sic] ... E) Discard times for: 3. Irrigating solutions 24 hours;"

An interview was conducted on October 8, 2014 at 5:10 p.m., with Staff #2. Staff #2 verified the date on the opened bottle of Normal Saline USP. Staff #2 stated, "It should have been discarded within thirty days of being opened."
Continued From Page 4

An interview conducted on October 8, 2014 at 8:24 p.m., with Staff #3. Staff #3 reported the opened bottle of Normal Saline USP was used in the laboratory area only. A second observation was conducted in the laboratory area with Staff #3 and two surveyors. Staff #3 verified the opened bottle of Normal Saline USP was dated “9/13/14” with the indication for use “wound irrigation...” Staff #3 verified the opened bottle of Normal Saline USP did not have a designation of use in laboratory area only and was available for potential patient use.

[According to www.drugs.com: Sodium Chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water. This irrigation solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose, short procedure irrigation or cell washing fluid. When smaller volumes are required the unused portion should be discarded. It may be classified as a sterile irrigant, rinse, diluent, cell wash and pharmaceutical vehicle.]

2. Observations were conducted in the facility’s autoclave area on October 8, 2014 at approximately 5:31 p.m., with Staff #2 and two surveyors. The observation revealed two 50 milliliter (ml) multidose vials of Lidocaine 1% inside an unlocked cabinet near the autoclave. The two multidose vials of Lidocaine were accessible to any individual or staff on the second floor.

An interview was conducted on October 8, 2014 at 5:33 p.m., with Staff #2. Staff #2 verified the observation. Staff #2 stated, “There is no reason these (the two multidose vials of Lidocaine 1%) should be here.” Staff #2 acknowledged the two multidose vials of Lidocaine should have been in
Continued From Page 5

the locked medication cabinet and not freely accessible to any staff or other individuals on the second floor.

Review of the facility's policy titled "Administration, Storage and Dispensing of Drugs - Overall policy, Use of multi-dose vials; Disposition of Expired Drugs" read in part "C. 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 ...." [According to www.drugs.com: Lidocaine is a local anesthetic (numbing medication). It works by blocking nerve signals in your body. Lidocaine injection is used to numb an area of your body to help reduce pain or discomfort caused by invasive medical procedures such as surgery, needle punctures, or insertion of a catheter or breathing tube.]

This is a re-citing of deficient practice.

12 VAC 5-412-310 Medical records

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:
1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
a. Physician orders;
b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
c. Anesthesia record;

T75 cont'd.
Lidocaine will be kept in locked cabinet only. Administrator is responsible for ensuring proper storage of medications.
10-9-14
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

Provider/Supplier/Clinical Identification Number: AF-0020

MULTIPLE CONSTRUCTION
A. Building ____________________________
B. Wing ________________________________

DATE SURVEY COMPLETED: 10/08/2014

NAME OF PROVIDER OR SUPPLIER:
CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN

STREET ADDRESS, CITY, STATE, ZIP CODE:
2321 COMMONWEALTH DRIVE
CHARLOTTESVILLE, VA 22901

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)

COMPLETE DATE

(T 340): Continued From Page 6

- Operative record;
- Surgical medication and medical treatments;
- Recovery room notes;
- Physician and nurses' progress notes;
- Condition at time of discharge;
- Patient instructions, preoperative and postoperative; and
- Names of referral physicians or agencies.

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to ensure physicians and nurses completed details related to the patient's progress and maintained progress notes for six (6) of six (6) patient records reviewed during the revisit survey (Patients #1 - #6)

The findings included:

The facility provided a list of patients, who had procedures after the facility's allegation of compliance date of August 6, 2014. The surveyors selected six patients from the list to review medical records.

Review of medical records revealed a page titled "Physician Progress Note" and a page titled "Nurse's Progress Note." The "Physician Progress Note" and "Nurse's Progress Note" in all six medical records were blank.

Review of the medical records for Patients #1 - #6 revealed a form titled "Recovery Room Notes."
The form contained a section titled ObservationNote [sic] the section was blank for all six patients. The recovery room nurse did not document observations of the patient's status.

Staff has been trained to elaborate on the documentation of pt's progress.
Administrator will review files for proper documentation.
Administrator is responsible for ensuring proper documentation.

10-22-14

Americans United for Life

STATE FORM
43U712
021183

RECEIVED
OCT 20 2014
VDH/OLC

04/21/2010 16:56:56 Fax
Review of the medical records for Patients #1 - #6 revealed a form for the physician to document pre-operative through discharge to recovery information. The form contained a section titled "Notes" for all six patients the physician left the section blank.

An interview was conducted on October 8, 2014 at approximately 6:33 p.m., with Staff #3. Staff #3 verified "Physician Progress Note" and "Nurse's Progress Note" pages for the reviewed patients were blank. Staff #3 verified the sections for the physician and recovery room nurses to document patient care or observations were left blank. Staff #3 reported the staff "probably did not see anything they needed to write." Staff #3 agreed the patient's status should change from admission to discharge.

This is a re-citing of deficient practice.
To: All medical staff
From: Jill Abbey
Date: October 20, 2014
Re: Progress Notes

Our recent survey by the inspectors with the Office of Licensure and Certification revealed a deficiency that we have had trouble with in the past as well. That deficiency is the documenting of a progress note for each patient. After the last survey, we inserted a new progress note form with the intention that it would be present in the event that a note needed to be written. Unfortunately, that was not the spirit of the deficiency. It is not satisfactory to have a form but not have anything written. The space on the procedure and the recovery forms is satisfactory but must have some indication that the patient’s progress has been noted. Please review the attached recovery forms for examples of what other staff has written in the observation note section.

The longer form may be needed in the event that there is a longer note needed (for example, if a complication has occurred).

Thank you for taking good care of our patients. Now we must make sure that our documentation reflects that.
Recovery Room Notes

Date: 10/17/14

Patient’s Name: [Redacted]

Allergies: [Redacted]

Arrival Time to RR: 5:35

Received from OR via Stretcher ✓

Condition (Pain 0–10): 0

Measures taken for pain:
- Ice Pack
- NA

Blood Pressure: 120/84

O2 Sats if MAC patient:

Pulse: 81

Bleeding: Light

Prescriptions with Instructions:

- Doxycycline 100 mg #14 b.i.d. refill 0 ✓
- Methergine 0.2 mg #10 i.d. refill 0
- Tylenol 3 q 4 hr prn pain #12 refill 1 ✓
- Ultram 50 mg 1 q 4 hr prn pain #12 refill 1

Other:

Medications given in RR:

- Methergine 0.2 mg IM
- Tocolytics 50 mg IV
- Phenergan 25 mg IM

Birth Control Action/Plan: OC (specify type):

Nuva Ring (Rx for 1 ring with 5 refills); after procedure insertion by [Redacted]

Depo Provera 150 mg IM (site): [Redacted]

IUD/Implanon at follow up:

Diaphragm at follow up:

Sterilization:

Condoms

Observation Notes:

5:45 PM: Fetal heart rate checked.

6:00 PM: Tocolytics given.

No IV disconnection.

IV d/c: Time 12/18/14 Site: [Redacted]

Bleeding: [Redacted]

Discharge Criteria:

- Yes: Alert and oriented
- Yes: Vital signs stable
- Yes: Dizziness minimal
- Yes: Able to ambulate
- Yes: Responsible adult to escort if IV or MAC
- Yes: Prescriptions given
- Yes: Follow-up instructions given

Patient verbalizes understanding of discharge medications and instructions: [Redacted]

Pain scale: 0 (none) to 10 (severe)

Bleeding: [Redacted]

Nausea: [Redacted]

Discharge Time/Date: 10/17/14 6:15 PM

Nurse: [Redacted]
**Recovery Room Notes**

**Date:** 10/11/14  
**Patient's Name:** [Redacted]  
**Nurse:** [Redacted]  
**Rh:** Rh+  
**Allergies:** [Redacted]  

<table>
<thead>
<tr>
<th>Arrival Time to RR:</th>
<th>Received from OR via Stretcher</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:10 P.M.</td>
<td>Ambulated from OR with nursing assistance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition (Pain 0-10)</th>
<th>Measures taken for pain:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/10</td>
<td>Ice Pack, Positioning, Relaxation Breathing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blood Pressure:</th>
<th>93/58, 78</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse:</td>
<td>O2 Sats IF MAC patient:</td>
</tr>
<tr>
<td>Light</td>
<td>Moderate</td>
</tr>
<tr>
<td>Clots</td>
<td>No Clots</td>
</tr>
</tbody>
</table>

**Prescriptions with Instructions:**

- Doxycycline 100 mg #14 b.i.d. refill 0
- Methotrexate 0.2 mg #10 i.d. refill 0
- Tylenol 3 q 4 hr pm pain #12 refill 1
- Ultram 50 mg 1 q 4 hr pm pain #12 refill 1
- Other

**Medications given in RR:**

- Microlimus Lot #  
- Exp  
- Site given  
- Time  
- Initials  
- Ampicillin 1 gr  
- PO  
- IV  
- Other

**Postpartum Care Action/Plan:**

- OC (specify type): Spontaneous  
- Nuva Ring (Rx for 1 ring with 5 refills); after procedure insertion by [Clinician Initials]  
- Depo Provera 150 mg IM (site): [Clinician Initials]  
- IUD/Implanon at follow up: Diaphragm at follow up  
- Sterilization: Condoms  
- None

**Observation Notes:**

- Patient alert and oriented 4:30 P.M.  
- Patient able to ambulate to chair w/ assistance. Patient then able to tolerate 30 cc of fluids and crackers. Reassured  
- Patient, 3:15 P.M., 4 cm pain scale. Patient able to ambulate to bathroom and void.

**IV d/c:**

- Time: 4:16 P.M.  
- Site: bleeding  
- redness  
- normal  

**Discharge Criteria:**

- Yes  
- No  
- Alert and oriented  
- Vital signs stable  
- BP & P  
- Dizziness minimal  
- Able to ambulate  
- Responsible adult to escort home if IV or MAC  
- Prescriptions given  
- Follow-up instructions given

Patient verbalizes understanding of discharge medications and instructions

Follow up (2-3 weeks) will be done at: RMCW  
Health Dept  

**Pain scale:**

- 0 (none) to 10 (severe)  
- [Redacted]

**Discharge Time/Date:**

- [Redacted]

- [Redacted]
Recovery Room Notes

<table>
<thead>
<tr>
<th>Date: 10/18/2014</th>
<th>Nurse:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's Name:</td>
<td></td>
</tr>
<tr>
<td>Allergies: NKA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arrival Time to RR: 4:00 PM</th>
<th>Received from OR via Stretcher</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ambulated from OR with nursing assistance</td>
</tr>
<tr>
<td>Condition (Pain 0 - 10): 6</td>
<td>Measures taken for pain:</td>
</tr>
<tr>
<td></td>
<td>Ice Pack</td>
</tr>
<tr>
<td>Blood Pressure: 97/63</td>
<td>O2 Sats IF MAC patient:</td>
</tr>
<tr>
<td>Pulse: 100</td>
<td>Light</td>
</tr>
<tr>
<td>Bleeding:</td>
<td></td>
</tr>
</tbody>
</table>

**Prescriptions with Instructions:**
- Doxycycline 100 mg #14 b.i.d. refill 0
- Methergine 0.2 mg #10 t.i.d. refill 0
- Tylenol 3 q 4 hr prn pain #12 refill 1
- Ultram 50 mg 1 q 4 hr prn pain #12 refill 1
- Other

**Medications given in RR:**
- Mic hogam Lot # Exp
- Site given Time | Initials
- Amoxicillin 1 gr | PO | IV
- Other Rhogam Lot # 434540008

**Birth Control Action/Plan:** OC (specify type):
- Nurse Ring (Rx for 1 ring with 5 refills); after procedure insertion by
- Depo Provera 150 mg IM (site):
- IUD/ Implanon at follow up:
- Sterilization:
- Condoms:
- None

**Observation Notes:**

| 11/17/14 0946 Site: bleeding redness normal |
| -------------------------------------------- |-------------------------------------------|
| Time  | 4:40 | Action: |
| Site:  |     | Alert and oriented |
| Site:  |     | Vital signs stable |
| Site:  |     | BP & P 117/66 HR 69 |

**Discharge Criteria:**
- Yes No
- Vital signs stable
- Dizziness minimal
- Able to ambulate
- Responsible adult to escort home if IV or MAC
- Prescriptions given
- Follow-up instructions given

**Patient verbalizes understanding of discharge medications and instructions**
- Follow up (2-3 weeks) will be done at: RMCW PMD Health Dept Other
- Pain scale 0 (none) to 10 (severe)
- Pain scale 2/10 Bleeding None Nausea Done

**Discharge Time/Date:** 10/18/2014 5 PM
- Nurse MD
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER
FALLS CHURCH HEALTHCARE CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

STATE OF VIRGINIA

ADDRESS, CITY, STATE, ZIP CODE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

AF-0017

(X2) MULTIPLE CONSTRUCTION NUMBER
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
11/17/2016

(X4) ID PREFIX
TAG
T 000
T 080

T 000
12VAC5-412 Initial Comments

An unannounced Biennial Licensure Inspection was conducted 11/14/16 through 11/17/16 by two (2) Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health.

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics (amended 2013). Deficiencies cited follow in this report.

T 080
12VAC5-412-180 D Personnel

The abortion facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.

This RULE: is not met as evidenced by;
Based on staff interview and document review, the facility staff failed to ensure all employees participated in annual infection control training for 13 of 13 staff members, 2 of 2 Anesthesia Providers, and 5 of 5 physicians. There was also no documentation that 1 Anesthesia Provider had annual fire safety training.

The findings included:

During a review of the training provided for staff, there was no evidence of annual training for infection control contained in the staff records.

On 11/17/16 at 12:10 p.m., Staff Member # 9
Continued From Page 1

stated, "We had our last Infection Control training in July of 2105. I have been trying to get (name of person) back to do training, but haven't been able to because of his/her schedule."

Review of the personnel and training record for Staff Member #5 (Anesthesia Provider) revealed no evidence of participation in fire safety or emergency/disaster training.

On 11/17/16 at 12:50 p.m., the inspectors discussed the findings with Staff Member #1 and #4.

No further evidence was provided by the end of the inspection.

Please refer to tag T 195 for more information on infection control observations during the inspection.

12VAC5-412-220 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;

4. Use of standard precautions;
<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
</tr>
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<td>T 195</td>
<td>Continued From Page 2</td>
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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 observation, staff interview, and facility document review, the facility staff failed to ensure that medications were administered using aseptic technique, that reusable non-critical medical equipment was cleaned appropriately prior to use on another patient, proper PPE (personal protective equipment) was used, and that manufacturer's recommendations for use of cleaning and disinfection products was followed. Also the facility staff failed to ensure all employees participated in annual infection control training for 13 of 13 staff members, 2 of 2 Anesthesia Providers, and 5 of 5 physicians.

The findings included:
# Statement of Deficiencies and Plan of Correction

**State of Virginia**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
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<tr>
<td>AF-0017</td>
<td>A. BUILDING ____________________________</td>
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<td>B. WING ____________________________</td>
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**NAME OF PROVIDER OR SUPPLIER**

**FALLS CHURCH HEALTHCARE CENTER**

**STREET ADDRESS, CITY, STATE, ZIP CODE**

**900 SOUTH WASHINGTON ST SUITE 300**

**FALLS CHURCH, VA  22046**

**DATE SURVEY COMPLETED**

11/17/2016

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**SUMMARY STATEMENT OF DEFICIENCIES**

(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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<tr>
<th>ID</th>
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1. Consent was obtained, and the surveyor observed the following during the surgical procedure for Patient #17 on 11/15/16 between 4:25 PM and 4:50 PM:

   A) Staff Person #5, a CRNA (Certified Registered Nurse Anesthetist) placed a plastic caddy containing IV (intravenous) supplies, including syringes which had been removed from the protective covering, on the exam table beside Patient #17’s head. Staff Person #5 retrieved supplies, and started an IV for Patient #17, and then set the plastic caddy on a cart with the emergency portable respiratory suction machine. Staff Person #5 did not clean or disinfect the caddy prior to placing it on the cart.

   B) Prior to the start of the procedure, three (3) 250 ml (milliliter) IV bags of LR (Lactated Ringers) , which were spiked with IV tubing, were observed hanging on an IV pole in the exam room.

   Staff Person #5 touched the IV pole wearing gloves he/she wore while starting Patient #17’s IV and connected the bag of LR to the IV; the other two (2) bags were left hanging on the IV pole during the procedure.

   C) The surveyor observed Staff Member #5 withdraw two (2) medications for sedation into two (2) syringes without wiping off the septum with alcohol prior to withdrawing the medication.

   At approximately 4:29 PM, Staff Member #5 injected the first medication via a port in the IV line without wiping the port with alcohol prior to puncturing the septum. After administering the first medication, Staff Member #5 administered the second medication, in divided doses, accessing the port multiple times without using alcohol to disinfect the port before or after medication administration between approximately...
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**
FALLS CHURCH HEALTHCARE CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

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<tr>
<td></td>
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<td>4:30 PM and 4:31 PM.</td>
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<td></td>
<td>D) After Patient #17 was transferred to a stretcher and moved to recovery, Staff Member #5 picked up the IV caddy from the cart and left the room.</td>
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<td>E) The surveyor interviewed Staff Member #7 regarding the three (3) IV bags of LR spiked with IV tubing and hanging on the IV pole in the room labeled &quot;Exam Room&quot; and two (2) bags on an IV pole in the room labeled &quot;Surgery I&quot; at 4:00 PM on 11/15/16, and he/she stated &quot;We have 3 patients scheduled in the exam room and 2 in the surgery room, so we do one for each&quot;.</td>
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<td>2. Neither Staff Member #3, who assisted with the procedure, nor Staff Member #6, the physician, wore goggles during the procedure. Staff Member #3 did not wear eyeglasses; Staff Member #6 was wearing prescription eyeglasses during the procedure.</td>
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<td>The CDC (Centers for Disease Control) &quot;Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care&quot; states in part the following: &quot;...The selection of PPE is based on the nature of the patient interaction and potential for exposure to blood, body fluids or infectious agents. Examples of appropriate use of PPE for adherence to Standard Precautions include: use of gloves in situations involving possible contact with blood or body fluids, mucous membranes, non-intact skin or potential infectious material; use of a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated; use of mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids...&quot;. The facility's Infection Control manual included a</td>
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copy of the above mentioned CDC document.

3. Staff Member #3 used running water from the hand washing sink to clear the vacuum line from the vacuum suction machine used during the surgical procedure. During an interview with Staff Member #3 on 11/15/16 at 4:40 PM, he/she told the surveyor that the sink was the "clean sink used for handwashing".

4. Staff Member #3 cleaned the room after the procedure using an unlabeled spray bottle of liquid, which Staff Member #3 stated was Terg-o-cide.

Staff Member #3 applied the liquid from the spray bottle on the surface of the exam table, including the vinyl stirrup covers, and the vacuum suction machine so that it was dripping from the surfaces. The equipment was wiped off by Staff Member #3 immediately, without allowing the liquid to remain wet on the surfaces.

Staff Member #3 did not clean or disinfect the IV pole, the rolling exam light used during the procedure, the sharps container, the cart with the respiratory suction machine, or the BP (blood pressure) cuff which was used to monitor Patient#17's vital signs during the procedure.

Staff Member #3 provided the surveyor with manufacturer's directions and guidelines for Terg-o-cide dilution for general cleaning, sono rinse bucket, and small spray bottles located in every patient service area use. The directions state in part the following: "...As possible area cleaned should remain wet 5-10 minutes; use in cleaning exam tables, floor spills, and any non-porous surface...". The label on the original container of Terg-o-cide included the following in part: "...cleaning procedure-blood/body fluids
**Findings were reviewed with Staff Persons #1 and #4 on 11/17/16 between 12:30 PM and 1:30 PM.**

5. During a review of the training provided for staff, there was no evidence of annual training for infection control contained in the staff records.

On 11/17/16 at 12:10 p.m., Staff Member # 9 stated, "We had our last Infection Control training in July of 2105. I have been trying to get (name of person) back to do training, but haven't been able to because of his/her schedule."

On 11/17/16 at 12:50 p.m., the inspectors discussed the findings with Staff Member #1 and #4.

No further evidence was provided by the end of the inspection.

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**Summary Statement of Deficiencies**

**T 195** Continued From Page 6

must be thoroughly cleaned before application of this product. Treated surfaces must remain wet for at least 10 (ten) minutes for proper disinfection...".

Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy based on an appropriate clinical estimate by a licensed physician.

This RULE: is not met as evidenced by:

Based on staff interview and clinical record review, it was determined the facility staff failed to ensure that medications administered to terminate pregnancy were not administered prior to the...
The findings included:
A record review of Patient #3's medical record revealed that an ultrasound performed at the facility on 1/14/16 documented gestational age as 13 weeks 5 days with a CRL (crown rump length of 77.5 mm (millimeters)). On 1/15/16, the day that Patient #3 returned to the facility for a procedure, a repeat ultrasound at 2:35 PM documented a gestational age of 14 weeks 5 days +/- (plus or minus) 6 days, with a BPD (biparietal diameter) of 28.8 mm.

Medical record documentation dated 1/15/16 for Patient #3 under the section "Aspiration D&C (dilation and curettage) Patients DOP (day of procedure) it was noted that Staff Person #1 had initialed that Pre-operative Misoprostol 200 mcg (micrograms)-2 tablets PO (by mouth) time 1330 (1:30 PM) was given, a pad was placed, and Pt (patient) was advised: C & B (cramping and bleeding) & Nausea. Pre-operative anti-anxiety: Librium 10 mg (milligrams) #2 PO time 1330 (1:30 PM). The space for M.D. (medical doctor) signature, was blank.

The surveyor also noted a handwritten note by Staff Member #1 on the same page to "1) refer pt to (facility name) return 2 wks (weeks) FU (follow-up) OC's (oral contraceptives) generic @ FU".

An interview was conducted with Staff Member #1 on 11/15/16 between approximately
### Statement of Deficiencies and Plan of Correction

**State of Virginia**

**AF-0017**

**Name of Provider or Supplier**

FALLS CHURCH HEALTHCARE CENTER

**Street Address, City, State, Zip Code**

900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

**State of Virginia**

**Printed:** 12/07/2016

**Printed:** 12/07/2016

**Form Approved:**

<table>
<thead>
<tr>
<th>ID Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID Prefix Tag</th>
<th>Provider’s Plan of Correction (Each Corrective Action Should Be Cross-referenced to the Appropriate Deficiency)</th>
<th>Complete Date</th>
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<td>T 215</td>
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<tr>
<td>2:30 PM and 3:45 PM. Staff Member #1 was asked if he/she gave Misoprostel to Patient #3 who did not have a procedure that day, but was referred to another facility. Staff Person #1 stated &quot;Yes, I gave it. That is in our standing orders. (He/She (the doctor)) decided (he/she) was not comfortable doing her after repeating her sono and referred her out. (He/She) was aware she got it. We go from their LMP (last menstrual period) not EDC (estimated date of conception). Most physicians talk LMP. It's different with each physician what they are comfortable doing. Our limit is 13 weeks 6 days&quot;. The package insert for Misoprostol states the following in part &quot;...CYTOTEC (MISOPROSTOL) ADMINISTRATION TO WOMEN WHO ARE PREGNANT CAN CAUSE BIRTH DEFECTS, ABORTION, OR PREMATURE BIRTH. UTERINE RUPTURE HAS BEEN REPORTED WHEN CYTOTEC WAS ADMINISTERED IN PREGNANT WOMEN TO INDUCE LABOR OR TO INDUCE ABORTION BEYOND THE EIGHTH WEEK OF PREGNANCY...&quot;. (<a href="http://druginserts.com">http://druginserts.com</a>; accessed 11/29/16 3:14 PM). It was documented that Patient #3 had a follow-up visit on 2/1/16. The record did not include documentation that Patient #3 followed up with the facility she was referred to on 1/15/16 to complete the procedure. Documentation did note that a urine pregnancy test was negative at the follow up appointment.</td>
<td>T 355</td>
<td>12VAC5-412-300 Health Information Records</td>
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<tr>
<td>T 355</td>
<td>An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:</td>
<td>T 355</td>
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER
FALLS CHURCH HEALTHCARE CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
900 SOUTH WASHINGTON ST SUITE 300 FALLS CHURCH, VA 22046

T 355 Continued From Page 9

1. Patient identification;
2. Admitting information, including patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy;
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses' progress notes,
   h. Condition at time of discharge,
   i. Patient instructions, preoperative and postoperative; and
   j. Names of referral physicians or agencies.
6. Any other information required by law to be maintained in the health information record.

This RULE: is not met as evidenced by:
Based on clinical record review and staff interview, the facility staff failed to ensure a complete and accurate medical record was maintained for each patient and corrections made to the clinical record were done legibly. The facility staff also failed to ensure medication dosages administered during the procedures were documented in the clinical record. This involved 3 of 23 patients in the inspection sample, Patients #13, #20 and #22.

The Findings included:
During a review of the clinical record for Patient #
13. In the area for the documentation of "pre-med standing orders" the staff had entered a time for the administration of the medication Misoprostol and Librium and then had scribbled through the time and wrote a different time on the record. A date underneath this documentation had also been entered and written over causing the date to be illegible. The date documented for the physician review of the sonogram had also been written over making it difficult to tell when the review was actually done. Under the section for "Health Education" the time for the administration of the Misoprostol was again scribbled through and another time written as well as the same for the Librium. The date was also overwritten making it difficult to discern the date documented.

Misoprostol is a medication used to start the abortion process. Librium is an medication used to treat anxiety. (www.drugs.com accessed 11/28/16 at 1:41 p.m.)

Review of the clinical record for Patient #20 revealed a document "Recovery". At the bottom of the document the date for the patients discharge status was overwritten to the point the actual date was not identifiable. The "Follow-up" date was also overwritten and illegible.

Patient #22 received the medication Lidocaine as a numbing/local anesthetic agent during the procedure on 5/21/16. The amount/dose of Lidocaine administered was not documented in the clinical record. The clinical record documented "... block using 1% (one percent) Lidocaine", however no dose was documented anywhere within the clinical record.

On 11/17/16 at 12:10 p.m., the inspectors discussed the findings with Staff #1 and #4. Staff #1 stated, "We will re educate the staff regarding..."
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

- **(X1) PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER:** AF-0017
- **(X2) MULTIPLE CONSTRUCTION** A. BUILDING ____________________________
- **B. WING ____________________________**
- **(X3) DATE SURVEY COMPLETED:** 11/17/2016

**NAME OF PROVIDER OR SUPPLIER:** FALLS CHURCH HEALTHCARE CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE:**
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

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<td>T 355</td>
<td>Continued From Page 11 making corrections in the record...the Lidocaine is on our new forms and we will document that...&quot;</td>
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<tr>
<td>T 415</td>
<td>12VAC5-412-350 B Maintenance</td>
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This RULE: is not met as evidenced by:
Based on observation, review of facility documentation, and staff interview, the facility staff failed to ensure that annual PM (preventative maintenance) was performed on one vacuum suction machine.

Findings include:

While touring the facility on 11/15/16 between 11:30 AM and 12:00 PM, the surveyor noted that the vacuum suction machine in Surgery Room I did not have a PM sticker. The surveyor asked Staff Member #1 if there was a PM log that might have information as to when the PM had been done on the machine. A PM log for equipment was provided to the surveyors; however, the vacuum suction machine was not included in the document.
At the exit meeting on 11/17/16 at 11:55, Staff Person #1 was asked again about documentation of annual PM for the vacuum suction machine, and he/she stated "It may be that we replaced that suction machine. We have many suction machines. If it was replaced, it probably has not had a PM. We will have to call and have them check it".

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T 415
Two (2) Medical Facilities Inspectors from the Virginia Department of Health's Office of Licensure and Certification conducted an unannounced First Trimester Abortion Facility (FTAF) biennial licensure inspection and complaint investigation on June 11, 2018 and June 12, 2018. The surveyors conducted observations, interviews and document reviews during the investigation process to determine compliance.

The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Amended 3/22/2017). The deficiencies cited follow in this report.

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<td>Initial Comments</td>
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<tr>
<td>T 035</td>
<td>12 VAC5-412-160 A Policy and Procedures</td>
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Each abortion facility shall develop, implement and maintain documented policy and procedures, which shall be readily available on the premises and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but not limited to the following topics:

1. Personnel;
2. Types of elective services performed in the abortion facility;
3. Types of anesthesia that may be used;
4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
5. Obtaining informed written consent of the patient pursuant to § 18.2-76 of the Code of Virginia prior to the initiation of any procedures;
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6. When to use sonography to assess patient risk;
7. Infection prevention;
8. Quality and risk management;
9. Management and effective response to medical and/or surgical emergency;
10. Management and effective response to fire;
11. Ensuring compliance with all applicable federal, state, and local laws;
12. Abortion facility security;
13. Disaster preparedness;
14. Patient rights;
15. Functional safety and abortion facility maintenance; and
16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable.

This RULE: is not met as evidenced by:

Based on document review and interview, it was determined the governing body failed to review annually and update as necessary the facility's policies and procedures.

The findings included:

The need to review the facilities policies and procedures was discussed, with Staff Member #1,
During the entrance conference on June 11, 2018 at 12:07 p.m. While conducting that review, surveyors asked Staff Member #1 on several occasions for official documentation of an annual review of the facility's policy and procedures by the governing body as provided in this regulation. Surveyors asked one last time on June 12, 2018 at 6:37 p.m. prior to the exit conference.

During the exit conference on June 12, 2018 at 6:47 p.m., Staff Member #1 provided an email from a member of the governing body that advised the required documentation of the annual review is not onsite.

12 VAC5-412-170 A Administrator

The governing body shall select an administrator who shall be responsible for the managerial, operational, financial, and reporting components of the abortion facility including but not limited to:

1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;

2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation;

3. Ensuring the accuracy of public information materials and activities;

4. Ensuring an effective budgeting and accounting system is implemented; and

5. Maintaining compliance with applicable laws and regulations and implementing corrective action.
This RULE: is not met as evidenced by:
Based on document review and interview, it was determined the facility administrator failed to ensure the completion of appropriate training for all staff members, namely, annual fire safety training for two (2) out of twenty-two (22) staff members.

The findings included:

On June 12, 2018 surveyors provided Staff Member #1 with a form to document clinic personnel medical licensure, privileges, required training, etc. to include annual annual fire safety training. That same day at 4:19 p.m., Staff Member #1 returned the completed form to surveyors. Surveyors reviewed the document with Staff Member #1 and noticed blank spaces in the fire drill training section for several clinic employees. Staff Member #1 advised they would be deficient in annual fire drill training because some members have not completed the required training. Staff Member #1 identified two persons based on their tenure at the clinic who did not complete the fire safety training as required, Staff Member #7 and Staff Member #8. Staff Member #1 further advised that Staff Member #8 is a part-time employee but advised there is no reason why Staff Member #7 did not complete the training.

Surveyors requested the facility's policy and procedure that outlines the requirement for annual fire safety training during the meeting above. Additionally, later that evening at 6:37 p.m., surveyors asked again for the policy and procedure that outlines the requirement for annual fire safety training. Prior to the entrance conference at 6:47 p.m. Staff Member #2 advised
**Summary Statement of Deficiencies**

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<tr>
<td>T 080</td>
<td>12 VAC5-412-180 D Personnel</td>
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**T 045** continued from Page 4

They could not locate a document that details the protocol for this training requirement.

**T 080**

12 VAC5-412-180 D Personnel

The abortion facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.

This RULE: is not met as evidenced by:

Based on interview and document review, it was determined the facility failed to develop, implement and maintain a policy and procedure for annual participation of fire safety training for all clinic employees.

The findings included:

On June 12, 2018, surveyors provided Staff Member #1 with a form to document clinic personnel medical licensure, privileges, required training, etc. to include annual annual fire safety training. That same day at 4:19 p.m., Staff Member #1 returned the completed form to surveyors. Surveyors reviewed the document with Staff Member #1 and noticed blanks in the fire drill training section for several clinic employees. Staff Member #1 advised they would be deficient in annual fire drill training because some members have not completed the required training. Staff Member #1 identified two persons based on their tenure at the clinic who did not complete the fire safety training as required, Staff Member #7 and Staff Member #8. Staff Member #1 further advised...
that Staff Member #8 is a part-time employee but advised there is no reason why Staff Member #7 did not complete the training.

Surveyors requested the facility's policy and procedure that outlines the requirement for annual fire safety training during the meeting above. Additionally, later that evening at 6:37 p.m., surveyors asked again for the policy and procedure that outlines the requirement for annual fire safety training. Prior to the entrance conference at 6:47 p.m. Staff Member #2 advised they could not locate a document that details the protocol for this training requirement.

The abortion 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 document review and interview, it was determined the facility failed to maintain complaint handling procedures, namely; logging of the receipt, investigation and resolution of each complaint.

The findings included:

On June 12, 2018 at 3:07 p.m. surveyors requested to review the facility’s complaint log.
Staff Member #2 provided a complaint log with the last entry dated one and a half years ago in December, 2016. Staff Member #2 advised that her training at the facility included entering complaints into the log but the facility has not been logging complaints as required. Additionally, Staff Member #1 advised she usually just "takes care" of complaints and they are not placed in the complaint log.

A review of the facility's policy titled "Rights and Complaint Process" states in part:

"1. A patient complaint log shall be created and kept in the assistant administrator's office....

All Actions are documented on the Compliment and Complaint Log and noted in the patient's chart. All complaints are reported to the QAC."

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;

4. Use of standard precautions;
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER
FALLS CHURCH HEALTHCARE CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL
REGULATORY OR LSC IDENTIFYING INFORMATION)

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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 observation, interview and document review it was determined:

1. A physician utilized single dose medication vials for more than one patient.

2. A Certified Registered Nurse Anesthetist (CRNA) utilized the procedure table, within the patient's personal space, to keep and draw up medications during procedures.

3. The facility staff used a recommended single patient Ventolin HFA inhaler for more than one patient.

The findings included:
Observations conducted during the initial tour on June 11, 2018 at 11:22 a.m., with Staff Members #1 and #2 revealed a plastic container within the locked controlled medication area. Staff Member
#1 opened the plastic container and identified the contents as two (2) opened vials of Fentanyl Citrate. Staff Member #1 stated, “[Staff Member #6’s name] takes two vials out at a time and [he/she] reuses the vials until [he/she] needs more.” The surveyor questioned regarding the facility’s accounting for the controlled narcotics in the plastic container. Staff Member #1 reported once the Fentanyl Citrate vials were signed out to Staff Member #6 then Staff Member #6 was accountable by placing whatever was not used in the plastic container and returning the plastic container to the safe for storage. Staff Member #1 reported once the Fentanyl was removed from the facility’s narcotic count it was not added back in when the plastic container was returned to the safe.

The surveyor and Staff Member #2 inspected the two (2) opened vials of Fentanyl Citrate. The vial’s label read in part “Fentanyl Citrate Injectable, 2 mL (milliliter) vial, 100 mcg (microgram), 50 mcg /mL, single dose vial”, and the manufacturer’s name. Staff Member #2 verified both vials of Fentanyl did not have a dated written to indicate when the vials had been opened. Staff Member #2 verified both vials were slightly less than half-full. Staff Member #2 verified the Fentanyl label read "single dose vial."

Staff Member #1 reported Staff Member #6 maintained a log with each patient’s name, date and the dose of Fentanyl, Propofol or other medications administered during each procedure. Staff Member #1 presented a red binder. Staff Member #1 reported he/she had “clipped together” Staff Member #6’s log pages.

Review of Staff Member #6’s log sheet spanned from December 14, 2017 to June 6, 2018. An overview of Staff Member #6’s documentation...
An interview was conducted on June 12, 2018 at approximately 4:48 p.m., with Staff Members #1 and #2. The surveyor informed Staff Members #1 and #2 of the findings. The surveyor inquired regarding the possibility that Staff Member #6 wasted the additional 75 mcg Fentanyl Citrate in each single dose vial. Staff Member #1 reported the facility did not have a narcotics waste log for the number of entries on Staff Member #6's log of administrations by Staff Member #6 of only 25 mcg of Fentanyl Citrate, because "[Staff Member #6’s name] splits the vials". Staff Member #1 verified the Fentanyl Citrate utilized by the facility were single dose vials that contained 100 mcg/2 mL. The surveyor requested the facility’s policy, procedure, and best practice standard that allowed for utilizing a single dose vial for multiple patients.

An interview was conducted on June 12, 2018 at 6:29 p.m., with Staff Member #1 related to the requested policies, procedure, or best practice standard for multiple medication administrations to different patients from a single dose vial. Staff Member #1 reported the facility did not have a policy, procedure or nationally recognized best practice standard, which allowed for using single dose vials as multi-dose vials.

According to the Safe Injection Practice Coalition (SIPC) in conjunction with the Centers for Disease Control and Prevention (CDC) regarding safe injection practices. "IV.H.5. Do not administer medications from single-dose vials or ampules to
multiple patients or combine leftover contents for later use...CDC guidelines call for medications labeled as "single-dose" or "single-use" to be used for only one patient.

2. Observations were conducted on June 12, 2018 from 4:08 p.m. through 4:20 p.m., with Staff Member #4. Staff Member #4 asked Staff Member #9 for the number of patients scheduled to receive monitored anesthesia care (MAC). Staff Member #9 reported five (5) patients. Staff Member #4 retrieved a plastic container from a cabinet at the nurse’s station. Staff Member #9 handed a staff member a box containing Propofol vials. Staff Member #9 placed the box inside the plastic container. Staff Member #4 placed additional supplies: needles, syringes, and a specialized insert for the Propofol vials in the plastic container. Staff Member #4 requested that Staff Member #1 assist in the retrieval of the controlled narcotics from the area where such medications were stored. Staff Member #4 placed five vials of Fentanyl Citrate 100 mcg/2 mL inside the plastic container. Staff Member #4 and the surveyor waited for the first scheduled MAC patient.

An observation starting at 4:20 p.m. on June 12, 2018, as Staff Member #4 and the surveyor entered the Procedure Room. Staff Member #4 introduced him/herself to the patient. Staff Member #4 attempted to place the plastic container on the top of a cart next to the suction machine, but there was not enough room. Staff Member #4 positioned the plastic container on the procedure table with Patient #12. Patient #12 was positioned on the procedure table in a manner, which allowed her head to rest on and her hair to cover the entire roll of protective paper used to cover the procedure table. Staff Members #5 and #9 assisted in re-positioning Patient #12. Staff
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Member #4 re-positioned his/her plastic container with medications and supplies onto the paper next to Patient #12's head. Staff Member #4 interviewed and performed Patient #12's physical examination. Staff Member #4 obtained supplies and placed Patient #12's intravenous (IV) catheter. Staff Member #4 obtained a vial of Fentanyl Citrate plastic container and utilizing Patient #12's procedure table prepared the patient's dose of Fentanyl. Staff Member #4 also utilized Patient #12's procedure table to prepare the patient's dose of Propofol. Staff Member #4 continued to store the plastic container with medications and supplies at the head of Patient #12's procedure table as he/she monitored the patient's sedation and maintained a patent airway for Patient #12.

At the end of Patient #12's procedure Staff Member #4 placed the plastic container between his/her arm and body then entered the recovery area to monitor Patient #12. After Patient #12 gained consciousness, Staff Member #4 left the recovery area. Staff Member #4 entered the next procedure with the same plastic container, increasing the risk of spreading infectious agents to the next patient.

An interview was conducted on June 12, 2018 at approximately 5:36 p.m., with Staff Member #4. The surveyor discussed the potential cross contamination of supplies and medications when placed in the plastic container and carried from procedure to procedure. The surveyor also discussed the best practice standard of drawing up/preparing a medication for administration in a clean area. Staff Member #4 acknowledged the procedure table with the patient on the table would not be considered a clean area. Staff Member #4 stated, "I will have to find a better place to draw up meds, the room has little extra..."
### Summary Statement of Deficiencies

**3.** An observation was conducted on June 11, 2018 at approximately 11:11 a.m., with Staff Members #1 and #2. Staff Member #1 and the surveyors reviewed the content of the facility's emergency cart. The emergency cart included an opened box with a Ventolin HFA inhaler. The inhaler box nor the inhaler had a documented date when the medication was opened. Staff Member #1 reported the inhaler was kept in case it was needed for a patient. The Ventolin HFA box indicated the inhaler initially had sixty metered doses. The counter on the inhaler indicated the inhaler had forty-one metered doses left. Staff Member #1 reported the inhaler was "cleaned off" after each use. The surveyor requested the policy and the Ventolin HFA package insert.

Review of the package insert did not provide information the inhaler was recommended for use by multiple patients.

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According to the Safe Injection Practice Coalition (SIPC) in conjunction with the Centers for Disease Control and Prevention (CDC) regarding safe injection practices. "...Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment ... In this context, aseptic technique refers to the manner of handling, preparing, and storing of medications and injection equipment/supplies (e.g., syringes, needles and IV tubing) to prevent microbial contamination ...

Medications should be drawn up in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. ...

---
An interview was conducted on June 12, 2018, at 6:29 p.m., with Staff Member #1. The surveyor made a second request for the facility's policy for use and cleaning of the inhaler, a best practice standard, or evidence of the manufacturer's recommendation for multiple patient use of a single inhaler. Staff Member #1 reported the facility did not have a policy or best practice standard regarding the use of the inhaler for multiple patients.

The surveyor contacted the manufacturer of the Ventolin HFA inhalers for recommended use of a single inhaler. The manufacturer emailed the surveyor the following information: "SUMMARY: Individual MDIs [Metered Dose Inhalers] manufactured by [Name of Manufacturer] including ... Ventolin HFA are intended for use by individual patients. Administering inhalations from a single MDI to multiple patients, often referred to as common MDI canister protocol (CCP), is outside the recommended labeling for MDIs manufactured by [Name of the Manufacturer] ..."

The abortion facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting. 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, and those criteria have been documented within the patient's medical record.
This RULE: is not met as evidenced by:
Based on interviews and document reviews, it was determined the anesthesia service providers failed to document the patient's stability for discharge from the Recovery Area to the "Lounge" for three (3) of five (5) surgical abortion patients. (Patients #2, #3, #10)

The findings included:

1. Review of Patient #2's medical record indicated she was admitted to the facility on February 2, 2018 for a monitored anesthesia care (MAC) surgical abortion. The anesthesia service provider did not document, by check box, clearance for Patient #2 to move from the Recovery area to the secondary monitoring area in the "Lounge."

An interview conducted at 12:13 p.m. on June 12, 2018, Staff Member #1 verified the anesthesia provider failed to check the box "Cleared for the Lounge." The surveyor requested the facility's policy for post anesthesia care.

2. Review of Patient #3's medical record indicated she was admitted to the facility on January 6, 2018 for a MAC surgical abortion. The anesthesia service provider did not document, by check box, clearance for Patient #3 to move from the Recovery area to the secondary monitoring area in the "Lounge."

3. Review of Patient #10's medical record indicated she was admitted to the facility on December 15, 2017 for a MAC surgical abortion. The anesthesia service provider did not document, by initial, in the space provided for the
## Statement of Deficiencies and Plan of Correction

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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<td>T 300</td>
<td>Continued From Page 15 sedation provider, to discharge the patient from anesthesia care.</td>
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<td>During an interview at 12:23 p.m. on June 12, 2018, regarding Patient #10, Staff Member #1 advised the block requiring an initial for the sedation provider to discharge the patient from anesthesia care should not be on the form. Additionally, at 12:27 p.m., Staff Member #1 verified the findings for Patient #2 and Patient #3.</td>
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<td>Staff Member #1 presented the facility's policy titled &quot;First Stage Recovery Attendant&quot; on June 12, 2018. The policy documented the duties of the &quot;Recovery Attendant&quot; but included &quot;RN/CRNA (Registered Nurse/Certified Registered Nurse Anesthetist) directs ALL actions ... Assist RN/CRNA as needed while [he/she] monitors the first minutes of first recovery...&quot; The surveyor requested Staff Member #1’s assistance regarding the inability to find information within the policy related to the responsibilities of the anesthesia provider's responsibilities. Staff Member #1 provided two (2) additional policies &quot;12. Post-Procedure Care&quot; and &quot;Post-Operative Care.&quot; Review of these policies documented the responsibilities of the &quot;nurse,&quot; the training requirements for non-licensed staff, and post-procedure discharge process. No additional information was provided prior to exit on June 12, 2018.</td>
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<td>T 315</td>
<td>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</td>
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### SUMMARY STATEMENT OF DEFICIENCIES

**T 315** Continued From Page 16

Temperatures in accordance with definitions in 18 VAC 110-20-10.

This RULE is not met as evidenced by:

Based on observations, interviews and document review it was determined the facility staff failed to ensure expired medications were not available for use in one (1) of one (1) emergency cart and one (1) of two (2) procedure rooms.

The findings included:

1. Observations and interview were conducted during the initial tour on June 11, 2018 at approximately 11:11 a.m., with Staff Members #1 and #2. The observation revealed the emergency medication cart was housed in a storeroom. Staff Member #1 stated, "We follow a no expiration policy." Staff Member #1 reported the facility had documentation that expiration date did not matter. The surveyor attempted to clarify if the "no expiration date" practice was for supplies or medications. Staff Member #1 reported for supplies and medications. The surveyors discussed the concern that not all medications had preservatives, which allowed extension past the manufacturer's date of expiration. The surveyors requested to review the facility's documentation regarding not needing to abide by the manufacturer's expiration date for medications and supplies. Staff Member #1 inspected the medications with the surveyor. The observation revealed the following expired medications within the facility's emergency cart:
   - One (1) bag of 5% Dextrose 250 mL (milliliter) Intravenous Solution (IV) - with an expiration date "Nov 2015"
   - One (1) bag of 9% Sodium Chloride 250 mL not within a protective outer cover - with an expiration date "May 2018"
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

A. PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0017

B. WING _____________________________

STATE OF VIRGINIA

NAME OF PROVIDER OR SUPPLIER
FALLS CHURCH HEALTHCARE CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

DATE SURVEY COMPLETED
06/12/2018

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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Four (4) bags of 5% Dextrose 500 mL IV Solution - with an expiration date: "Jan 2016"
Two (2) packages of Lidocaine HCL 2% injectable - with an expiration date: "May 2018"
One (1) bottle of Nitrostat 0.4 mg (milligram) - with an expiration date: "04/18"
Three (3) vials Dopamine HCL 5 mL single dose 200 mg (40 mg/mL) - with an expiration date: 1 June 2018.

2. The same tour also revealed the following expired medications available for patients in procedure room #2. Staff Member #1 provided the same explanation as above that the facility follows a no expiration policy.

One (1) bag of 5% Dextrose 250 mL (milliliter) Intravenous Solution (IV) - with an expiration date "Jan 2015"
One (1) bag of Lactated Ringers 250 mL (milliliter) Intravenous Solution (IV) - with an expiration date "April 2015"

On June 11, 2018, Staff Member #1 presented the facility's policy titled "Expiration of items to be used for patient care" for the surveyors to review. The policy read in part "Purpose: To provide safe and appropriate patient care consistent with Infection Control and Quality Assurance policies. All staff and healthcare workers will help to ensure suitability of medications, solutions, reagents, supplies and equipment used in patient care. Policy: Staff will provide best practices to monitor medications, solutions, reagents, supplies and equipment used in patient care and ensure sequence cross checks for rotation of stock and dated items ... Before patient use or administration all medications, IV solutions, equipment, and supplies will be rechecked at point of use for expirations and condition in accordance with expiration and maintenance procedures ... 4. Sterile items will no longer have an expiration date.
...All medical devices and instruments will be cleaned and/or sterilized, dated, and initialed by instrument tech who prepared the items...
Event-related shelf life for sterilized items recognizes that autoclaved medical instruments or those received from the manufacturer sterile would remain sterile indefinitely, unless an event caused them to be contaminated...
5. All medical supplies such as gloves, syringes, IV solutions, needles, cannulas will follow event related shelf-life guidelines recognizing they would remain sterile indefinitely, unless an event causes them to become contaminated e.g., torn or wet packaging or if the manufacturer specifies otherwise...

Attachments to the facility's policy included a document regarding "self-life for sterilized materials" and a document with Centers for Disease Control and Prevention (CDC) guidelines for event-related management of sterilized/processed instruments.

On June 12, 2018, the surveyor discussed the facility's policy with Staff Member #1. The surveyor discussed the facility's policy titled "Expiration of items to be used for patient care" primarily focused on management of sterilization medical equipment. Staff Member #1 reported the policy's inclusion of "all medications" and "IV solution." The surveyor discussed with Staff Member #1 the policy also directed cross checks for expiration dates and following manufacturers' specified expiration recommendation. Staff Member #1 stated, "I have other proofs, articles for no expiration and indefinite shelf life for medications." The surveyor requested the additional information and best practice standard for utilizing medication beyond the manufacturer's documented expiration date. No additional information was presented to the surveyors prior to exit.
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<td>T 355</td>
<td>12 VAC5-412-300 Health Information Records</td>
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According to CDC's Frequently Asked Questions (FAQ): "If a single-dose or single-use vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date."

According to drugs.com, "The expiration date is the final day that the manufacturer guarantees the full potency and safety of a medication. Drug expiration dates exist on most medication labels, including prescription, over-the-counter (OTC) and dietary (herbal) supplements. U.S. pharmaceutical manufacturers are required by law to place expiration dates on prescription products prior to marketing. For legal and liability reasons, manufacturers will not make recommendations about the stability of drugs past the original expiration date ..."

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. If medically indicated, it shall include, but not be limited to the following:

1. Patient identification;
2. Admitting information, including patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy;
5. Procedure report to include:
   a. Physician orders;
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**
FALLS CHURCH HEALTHCARE CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

**STATE FORM 021199**

**AF-0017**

**STATE OF VIRGINIA**

**STATE FORM**

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- Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
- Anesthesia record;
- Operative record;
- Surgical medication and medical treatments;
- Recovery room notes;
- Physician and nurses' progress notes;
- Condition at time of discharge;
- Patient instructions (preoperative and postoperative);
- Names of referral physicians or agencies; and

6. Any other information required by law to be maintained in the health information record.

This RULE: is not met as evidenced by:

Based on interview and document review, it was determined the facility staff and physicians failed to ensure patient's medical records were complete and accurate, including progress notes, the doses of administered medications, the authentication of signatures and administration of medications with dates and/or times, discharge orders and patient consents/notifications for eleven (11) out of eleven (11) patients included in the survey sample.

(Patients #1, #2, #3, #4, #5, #6, #7, #8, #9, #10, and #11)

The findings included:

1. Review of Patient #1's medical record documented the patient was admitted to the facility on February 3, 2018 for a monitored anesthesia care (MAC) procedure. Staff Member #1 reviewed the medical record with the surveyor at 1:06 p.m. on June 12, 2018. Staff Member #1 verified the informed consent form dated January 23, 2018 did not have the patient's initials acknowledging her right to speak with a physician about the abortion services. Staff Member #1 also verified no physician notes were present on the
“Physician Progress Notes” and he/she advised that form should not be in the file. Staff Member #1 verified Patient #1's medical record did not have a start and stop time for the patient’s surgical procedure. Staff Member #1 advised the facility gave all notes relating to the patient transfer to the EMS crew and thus the facility has an incomplete medical file.

2. Review of Patient #2's medical record documented the patient was admitted to the facility on February 2, 2018 for a monitored anesthesia care (MAC) procedure on February 3, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:13 p.m. June 12, 2018. Staff Member #1 verified Patient #2's medical record did not have a start and stop time for the patient's surgical procedure. Staff Member #1 verified the medical record did not include a documented discharge order by a physician and did not have progress notes by the physician and nursing staff. Staff Member #1 reported the top of the page was dated, but verified the line associated with the administration of Misoprostol indicated a "Date/Time" requirement. Staff Member #1 verified staff failed to date the administration of the medication.

3. Review of Patient #3 medical record documented the patient had a MAC procedure on January 13, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:27 p.m. June 12, 2018. Staff Member #1 verified Patient #3's medical record did not have a physician discharge order and progress notes by nursing staff and the physician. Patient #3 was returned to the facility on February 14, 2018 for a re-evacuation. Patient #3's re-evacuation procedure was performed utilizing a peri-cervical block with lidocaine. Staff Member #1 verified the physician failed to document the amount of
lidocaine used within the operative note. Staff Member #1 verified the documentation for Patient #3's procedure on February 14, 2018 did not include nursing progress note and a discharge order by the physician. Staff Member #1 acknowledged the form utilized for re-evacuations did not have a line or check-off box for the patient's discharge home when stable.

4. Review of Patient 4's medical record documented the patient had a surgical abortion with local anesthesia (peri-cervical block) on February 13, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:31 p.m. June 12, 2018. Staff Member #1 verified Patient #4's medical record did not have progress notes by nursing staff and the physician. Staff Member #1 verified the line associated with the discharge per sedation provider related to "Lidocaine"/local procedures was blank. Staff Member #1 crossed through the line and stated, "That's an error on the form. We don't require the anesthesiologist to review these." Staff Member #1 verified the Misoprostol administered prior to the February 13, 2018 procedure did not have a date associated with the time of administration.

5. Review of Patient 5's medical record documented the patient was had a surgical abortion with local anesthesia on November 21, 2017. Staff Member #1 reviewed the medical record with the surveyor at 12:39 p.m. June 12, 2018. Staff Member #1 verified the physician failed to document the amount of lidocaine used within the operative note. Staff Member #1 verified the "Recovery" section was blank and did not include documentation of vitals sign, nor an indication if the patient was post-operative for a lidocaine or MAC procedure. Staff Member #1 verified Patient #5's medical record did not have a nursing progress note. Staff Member #1 verified
the Misoprostol administered on November 21, 2017 did not have a date associated with the time of administration.

6. Review of Patient #6 medical record documented the patient was scheduled for a medical abortion on January 24, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:42 p.m. June 12, 2018. Staff Member #1 verified the physician that administered the Mifepristone failed to document the date and time. [According to the FDA, "Mifepristone/Mifeprex is used, together with another medication called misoprostol, to end an early pregnancy."]

7. Review of Patient #7's medical record documented the patient was scheduled for a MAC procedure on March 8, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:56 p.m. June 12, 2018. Staff Member #1 verified the physician's documented observation of Patient #7's product of conception (POC) did not include whether the POC was "Normal" or "Abnormal." Staff Member #1 verified the "Recovery" section did not document whether the patient was post-operative for a lidocaine or MAC procedure. Staff Member #1 verified Patient #7's medical record did not have a physician's discharge order, physician progress note and nursing progress note. Patient #7 returned to the facility on March 22, 2018 for a re-evacuation procedure under MAC. Staff Member #1 verified nursing staff failed to document whether the patient was allowed to leave the facility on her own after sedation or accompanied by another person. Staff Member #1 verified nursing staff failed to make a progress note associated with the March 22, 2018 re-evacuation procedure. Staff Member #1 acknowledged the form utilized for re-evacuations did not have a line or check-off box...
for the physician's order to discharge the patient to home when stable. Staff Member #1 verified the Misoprostol administered on March 8, 2018 and March 22, 2018 did not have a date associated with the time of administration.

8. Review of Patient #8's medical record on June 12, 2018 at 9:44 a.m., revealed the patient was scheduled for a MAC procedure on March 21, 2018. On the surgical record, the physician failed to check the box denoting the patient's discharge when stable. Additionally, in the sedation record, no times were recorded for the surgical procedure.

9. Review of Patient #9's medical record documented the patient was scheduled for a medication abortion on November 14, 2017. Staff Member #1 reviewed the medical record with the surveyor at 1:00 p.m. June 12, 2018. Staff Member #1 verified the physician that administered the Mifepristone failed to document the date and time. [According to the FDA, "Mifepristone/Mifeprex is used, together with another medication called misoprostol, to end an early pregnancy."] Staff Member #1 also verified on a prescription for Vicoden ES #8, the 8 is crossed out and a 12 is written. No notation is made regarding who altered the record and when. Staff Member #1 verified two inaccuracies on the form documenting the required ultrasound. The first inaccuracy is in the area for a patient exception (lives more than 100 miles from the clinic) where the box is checked but it is not applicable to the patient. The second inaccuracy is in the area where the clinic offers the patient the ability to view the ultrasound or listen to fetal heart tones. In this section both the decline and I choose box is checked for listen to fetal heart tones.

10. Review of Patient #10's record documented

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<th>PROVIDER'S PLAN OF CORRECTION</th>
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the patient was scheduled for a MAC procedure on December 15, 2017. Staff Member #1 reviewed the medical record with the surveyor at 1:02 p.m. Staff Member #1 verified none of the boxes are checked on the ultrasound verification form indicating if the patient requested or declined to view the ultrasound or listen to fetal heart tones. Additionally on that form, the patient signed the area denoting an exception to the ultrasound waiting period although she did not live more than 100 miles from the facility. Lastly, a staff member did not provide a review date on that form. Staff Member #1 advised the physician made an error in this case because they were supposed to complete the form once a cervical exam was completed. Staff Member #1 verified Patient #10’s medical record did not have a start and stop time for the patient’s surgical procedure. Staff Member #1 also verified the sedation provider did not initial the area denoting release of the patient from sedative care.

11. Review of Patient #11’s medical record documented the patient was admitted to the facility on May 25, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:58 p.m. on June 12, 2018. The physician’s operative note, for May 29, 2018 indicated, by circle, the procedure was performed under MAC. Patient #11’s medical record did not include an anesthesia record. Staff Member #1 reviewed the record and stated, "This is a local not a MAC." Staff Member #1 verified the physician failed to indicate in the operative note an amount of lidocaine administered, if a peri-cervical block procedure was performed. Staff Member #1 verified Patient #11’s medical record did not include a physician's progress note, or explanation the patient had initially requested a MAC and changed to a procedure managed under local anesthesia. Staff Member #1 verified the
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

**NAME OF PROVIDER OR SUPPLIER**
FALLS CHURCH HEALTHCARE CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<tr>
<td>T 355</td>
<td>Continued From Page 26 Misoprostol administered on May 29, 2018 did not have a date associated with the time of administration. Staff Member #1 presented the facility's policy titled &quot;Guidelines for Maintaining the Medical Record as a Medicolegal Document&quot; on June 12, 2018 for the surveyor's review. The policy read in part, &quot;3 ... Documentation should always be precise, objective, accurate and complete ... The medical record will minimally include ... pre, intra, and post phases of the patient's visit ... physician's SOAP (an acronym for subjective, objective, assessment, and plan) notes; ... 7. All blanks and check boxes should be completed on assessment forms and consent forms ... 18. For surgery patients recovery room discharge notes should include, but not limited to: a. With whom the patient is discharged. b. Patient ambulatory by self status. c. When the patient is discharged ... f. Basic vitals ...&quot; The policy did not address the need for a physician's order for discharging the patient once the patient had meet discharge criteria. The surveyors requested the facility's policy for discharge criteria. Staff Member #1 presented the facility's policy titled &quot;Patient Admission and Discharge&quot; on June 12, 2018. The policy read in part, &quot;Patients shall be discharged only on order of the Medical Staff physician which order shall be recorded on the patient's medical record ... [Sic]&quot; The surveyors and Staff Member #1 reviewed the regulatory requirements related to the missing medical record components for the patients included in the survey sample. The facility staff presented no additional information prior to the survey completion on June 12, 2018.</td>
<td>T 355</td>
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T 370 Continued From Page 27

12 VAC5-412-320 B Required Reporting

The abortion facility shall report the following events to OLC:

1. Any patient, staff or visitor deaths.
2. Any serious injury to a patient.
3. Medication errors that necessitate a clinical intervention other than monitoring; and
4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds;

This RULE: is not met as evidenced by:
Based on document review, interview, and complaint investigation, it was determined the facility failed to report a serious injury to a patient to Office of Licensure and Certification (OLC).

The finding included:

During the entrance conference on June 11, 2018 at 12:07 p.m., the facility administrator advised a transfer from the clinic to a hospital did occur in 2018. The administrator further advised the medical file relating to that transfer was located in his/her desk and available for surveyor review. Surveyors examined the medical file and learned the patient arrived at the clinic on February 3, 2018 for a surgical procedure to terminate pregnancy. This date aligned with the date provided in the complaint. The procedure utilized moderate sedation, and thus a CRNA (Certified Registered Nurse Anesthetist) attended the procedure for the administration and management of sedation while a medical doctor performed the surgical procedure.
The physician notes contained in part: "Aspirate the uterine without difficulty." "Estimated blood loss 80 ml." "Patient sent to recovery in excellent condition."

The physician notes did not contain a start or stop time for the procedure. Additionally, the physician notes ended after a brief notation on pathology. The brief pathology report also did not include a time.

The CRNA notes contained in part: The CRNA noted a series of hypotensive blood pressure readings and actions taken for patient management to include the administration of 1,000 ml of normal saline. The anesthesia record further noted "blood loss" "EMS Called 9:29 am" and "to stretcher 9:53 am."

The medical record provided no other information on the presentation and management of the bleeding. Additionally, the record did not contain documentation regarding the patient transfer, name of the receiving hospital, or if and what relevant medical information the facility provided to the hospital.

On June 11, 2018 at 2:59 p.m., surveyors spoke to the physician who performed the surgical procedure, via telephone. The physician advised the interns at the receiving hospital believed the bleeding occurred due to a perforation. The physician advised he/she believed the bleeding occurred due to previous injury from repeated C-sections. The physician advised he/she rode in the ambulance with the patient to the hospital and waited in the emergency room with her. He/she also advised the receiving hospital moved the patient to a surgical suite, and he/she attempted to go into the operating room with the patient but
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

A. BUILDING ________________________
   PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: (X1)

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

AF-0017

NAME OF PROVIDER OR SUPPLIER
FALLS CHURCH HEALTHCARE CENTER

STATE FORM

STREET ADDRESS, CITY, STATE, ZIP CODE
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

(T1) ID
 PREFIX
 TAG

T 370

Continued From Page 29

the receiving hospital staff would not allow him/her to do so.

On June 12, 2018 at 4:58 p.m., surveyors spoke with the CRNA. in person. at the facility. The CRNA advised he/she and the physician made the decision together to transfer the patient because of bleeding. The CRNA described the bleeding as "not excessive" but more than usual. The CRNA advised he/she noticed a drop in blood pressure before the discovery of the unusual bleeding, and administered 1,000 ml of normal saline. He/she further advised the patient was stable when EMS arrived and additionally the patient spoke with her family member on the telephone.

On June 12, 2018 at 1:06 p.m., surveyors spoke to the facility administrator who is also a registered nurse. The administrator advised the patient never made it to the recovery area. Instead, with the physician in pathology, the staff notified him/her the patient continued to bleed and the facility then called EMS. The administrator advised the facility gave all notes relating to patient management and transfer during the bleeding to the EMS crew. He/she advised the facility had no additional medical documentation outside of that contained in the file. The facility administrator advised the physician rode in the ambulance with the patient and it is his/her understanding the receiving hospital performed a surgical procedure to identify and fix the source of the bleeding.

The facility administrator assisted surveyors in reading a note placed on the front of the medical file. He/she advised the note contained documentation of the facility's attempts to contact the patient by telephone after the transfer. The notes indicated two failed attempts and a third call where the administrator did speak with the patient on the telephone. The patient advised, according

(T4) ID
 PREFIX
 TAG

T 370

(ID)
 PREFIX
 TAG

(T5) COMPLETE
 DATE

06/12/2018
to the note, of a discharge from the receiving hospital on Monday February 5, 2018. Lastly, the administrator advised the clinic did not contact the OLC because they believed they were not required to. He/she further explained the facility has had patients transferred out in the past but the clinic did not notify OLC during those events either.

Surveyors examined the facility's complications log and determined that no other transfers occurred during the review period for this survey (2017 or 2018).

A review of the facility's policy titled "Serious incidents/injuries/death at FCHC" states in part:

"reports [sic] all serious incidents/injuries/death that may occur in the center. In the event of a serious incident/injury/death a "Serious/Injury/Death Report Form" will be submitted to VDH/OLC within 24 hours."

Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the following:

1. Abortion facility name;
2. Type and circumstance of the events being reported;
3. Date of the event; and
4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.
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<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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<td>T 375</td>
<td>Continued From Page 31</td>
<td>T 375</td>
<td>This RULE: is not met as evidenced by: Based on document review, interview, and complaint investigation, it was determined the facility failed to report a serious injury to a patient to Office of Licensure and Certification (OLC) within twenty four hours of occurrence. The finding included: During the entrance conference on June 11, 2018 at 12:07 p.m., the facility administrator advised a transfer from the clinic to a hospital did occur in 2018. Surveyors examined the medical file and learned the patient arrived at the clinic on February 3, 2018 for a surgical procedure to terminate pregnancy. The procedure utilized moderate sedation, and thus a CRNA (Certified Registered Nurse Anesthetist) attended the procedure for the administration and management of sedation while a medical doctor performed the surgical procedure. The CRNA notes contained in part: The CRNA noted a series of hypotensive blood pressure readings and actions taken for patient management to include the administration of 1,000 ml of normal saline. The anesthesia record further noted &quot;blood loss&quot; &quot;EMS Called 9:29 am&quot; and &quot;to stretcher 9:53 am.&quot; The medical record provided no other information on the presentation and management of the bleeding. Additionally, the record did not contain documentation regarding the patient transfer, name of the receiving hospital, or if and what relevant medical information the facility provided.</td>
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Continued From Page 32

The facility administrator advised the clinic did not contact the Office of Licensure and Certification (OLC) because they believed they were not required to. He/she further explained the facility has had patients transferred out in the past but the clinic did not notify OLC during those events either.

A review of the facility’s policy titled "Serious incidents/injuries/death at FCHC" states in part:

"reports [sic] all serious incidents/injuries/death that may occur in the center. In the event of a serious incident/injury/death a "Serious/Injury/Death Report Form" will be submitted to VDH/OLC within 24 hours."

Refer to T 0370 for additional information.
T 000  12 VAC 5-412 Initial comments

An unannounced Licensure Biennial survey was conducted 10/27/2014 through 10/29/2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey.

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

T 035  12 VAC 5-412-150 Policy and procedure manual.

Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the license. The manual shall include provisions covering at a minimum, the following topics:

1. Personnel;
2. Types of elective and emergency procedures that may be performed in the facility;
3. Types of anesthesia that may be used;
4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;
5. Obtaining written informed consent of the patient prior to the initiation of any procedures;
6. When to use ultrasound to determine gestational age and when indicated to assess patient risk;
7. Infection prevention;
8. Risk and quality management;
9. Management and effective response to medical and/or surgical emergency;
10. Management and effective response to fire;
11. Ensuring compliance with all applicable federal, state and local laws;
12. Facility security;
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA
IDENTIFICATION NUMBER:

AF-0017

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY
COMPLETED
10/29/2014

NAME OF PROVIDER OR SUPPLIER
FALLS CHURCH HEALTHCARE CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

(X4) ID
PREFIX
TAG

T 035  Continued From Page 1

13. Disaster preparedness;
14. Patient rights;
15. Functional safety and facility maintenance;
and
16. Identification of the person to whom
responsibility for operation and maintenance of
the facility is delegated and methods established
by the licensee for holding such individual
responsible and accountable. These policies
and procedures shall be based on recognized
standards and guidelines.

T 035

Policy and procedure manual
12 VAC 5 – 412-150
Correction: Notation of the Governing Body’s
December 2013 review of over 1000 pages of the 5
Policy Manuals is now posted in the Annual
Review Documentation. Not been posted due to
clerical issue of the form being revised to multiyear
and new form not returned to the Manual.
Notation of the Governing Body’s December 2013
review of over 1000 pages of the 5 Policy Manuals
is posted in the Annual Review Documentation.
Prevent recurrence of Deficiency: The corrective
actions taken will prevent recurrence of deficiency.
Revised Annual Review Documentation form
reviewed with QAC and Co-Administrator.
Measures to maintain compliance: Governing
Body will review annually and address any

This RULE: is not met as evidenced by:
Based on document review and interview the
facility failed to implement their policies and
procedure to annually update the policy and
procedure manual.

The findings included:

STATE FORM 021199
OS4L11
RECEIVED
DEC 15 2014
VDH/OLC

American
United for Life

Printed sheet 1 of 2
Review of the facility's policies and procedures on 10/27/2014 through 10/29/2014 did not contain evidence the policy and procedure manual had been reviewed and updated since 2012.

Review of the policy/procedure manual did not include policies for when to use ultrasound to determine gestational age and when indicated to assess patient risk.

An interview was conducted on 10/28/2014 at 6:30 p.m., with Staff #1. The surveyor requested documentation that the governing body or the administrator had reviewed the facility's policy and procedure manual annually. Staff #1 stated, "I didn't realize they needed to be reviewed annually. On 10/29/2014, Staff #1 reported the facility did not have policies and procedures to reflect the updated State licensure requirements for ensuring when to use ultrasound to determine gestational age and when indicated to assess patient risk and evidence the manual is annually reviewed and updated.

This RULE: is not met as evidenced by:
Based on interview and document review it was determined the facility failed to notify the Office of Licensure and Certification of the appointment of a new administrator.

The Findings Included:

The Surveyors were informed on entering the
T 050 Continued From Page 3

facility on 10/27/14, that a new Administrator had been appointed.

During an interview on 10/29/14 at approximately 12:30 PM, Staff #1 was unable to provide evidence that notification was sent to the Office of Licensure and Certification of a change in Administrator.

T 065 12 VAC 5-412-170 B Personnel

B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member.

This RULE: is not met as evidenced by:
Based on interview and document review, it was determined the facility failed to implement a mechanism to verify professional licensure of three (3) of three (3) staff licenses in the survey sample. (Employee file #1, #8, #13).

The findings included:

Review of personnel records on 10/28/14, revealed that the agency failed to provide evidence of license verification for three (3) of three (3) licensed employees. (Employee file #1, #8, and #13).

During an interview on 10/28/14, at approximately 6:00 PM, Staff #1 acknowledged that professional licenses had not been verified, and that they were not aware this was required.
T 095 Continued From Page 4

T 095 12 VAC 5-412-170 H Personnel

H. Personnel policies and procedures shall include, but not be limited to:
   1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;
   2. Process for verifying current professional licensing or certification and training of employees or independent contractors;
   3. Process for annually evaluating employee performance and competency;
   4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and
   5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.

This RULE: is not met as evidenced by:
Based on interview and document review, it was determined that the agency did not have required personnel policies and procedures.

The findings included:

Review of the policies and procedures on 10/28/14 and 10/29/14 revealed that there were no personnel policies and procedures for:

1. Verifying current professional licensing or certification
2. Process for annually evaluating employee performance
3. Process for verifying that contractors and their employees meet the personnel qualifications of the facility
4. Process for reporting licensed and certified health care practitioners for violations of their
Patients' rights
12 VAC 5 – 412-210 A
Correction: Background: Patients, as noted, are given a summary copy of Patients' Rights and Responsibilities including the complaint processes when they check in. They sign acknowledging they have reviewed and had opportunity to read the more detailed information on the clipboard. The full 7 page text is available in binders in the waiting room. The full 7 page text is available at the front desk to take if they want. Additionally, the Patient Rights are published on our website which an estimated 80% of our patients utilize. The patient signs the handout and it is included in her medical record (chart).

PLAN OF CORRECTION:
The Patient Rights Handout will be revised to include a check off box for the patient to request or decline taking home a copy of the Patient Rights. It also includes a reminder that the full text of our Patient Rights Policies is on our website (see attached). Additionally, the receptionist will ask if patient wants a copy. Copies of the “How to file compliments or complaints” portion of the Patient Rights will be available on the reception counter for patients to take home. Our brochure of Patients' Rights and Responsibilities is also available in the waiting room and patient lounge.

Prevent Recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency. The chart now evidences that patients receive and could have selected to take home a copy upon admission.

Measures to maintain compliance: The various Expanded forms and Staff training to Policies will maintain compliance.

No patients were affected by this deficiency
T 135  Continued From Page 6

room. Staff #1 acknowledged that patients were not given a copy and did not know that this was required.

T 150  12 VAC 5-412-210 D Patients' rights

D. The patient shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service.

This RULE: is not met as evidenced by:
Based on interview and document review, it was determined that 12 of 12 patient files (#1-#12) did not provide evidence that a copy of the complaint procedure was given at the time of admission to service.

The findings include:

Review of patient records for 12 of 12 patients (#1-#12) on 10/27/14 and 10/28/14, it was revealed there was no evidence that patients had received a copy of the complaint procedure on admission. The admission packet provided to the surveyors did not contain a copy of the complaint procedure.

During an interview on 10/28/14, at approximately 5:00 PM, Staff #1 stated that patients were given a laminated copy of the complaint procedure upon admission to review. Staff #1 acknowledged that patients were not given a copy.

T 165  12 VAC 5-412-220 A Infection prevention

A. The abortion facility shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the provisions of the current

Patient's rights

12 VAC 5–412-210 D
Correction: Background: Patients, as noted, are given a summary copy of Patients' Rights and Responsibilities including the complaint processes when they check in. They sign acknowledging they have reviewed and had opportunity to read the more detailed information on the clipboard. The full 7 page text is available in binders in the waiting room. The full 7 page text is available at the front desk to take if they want. Additionally, the Patient Rights are published on our website which an estimated 80% of our patients utilize. The patient signs the handout and it is included in her medical record (chart). Additionally the Complaint process is posted on bulletin boards in the waiting room and patient lobby.

PLAN OF CORRECTION:
The Patient Rights Handout will be revised to include a check off box for the patient to request or decline taking home a copy of the Patient Rights. It also includes a reminder that the full text of our Patient Rights Policies is on our website (see attached). The receptionist additionally will ask if patient wants a copy. Copies of the “How to file compliments or complaints” portion of the Patient Rights will be stacked on the reception counter available for patients to take home. Our brochure of Patients’ Rights and Responsibilities is also available in the waiting room and patient lounge.

Prevent recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency. The chart now evidences that patients receive and could have selected to take home a copy upon admission.

Measures to maintain compliance: The various Expanded forms and Staff training to Policies will maintain compliance.

No patients were affected by this deficiency.
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edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.

1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.

2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.

3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to ensure all infection prevention policies and procedures are reviewed annually and the designated person shall participate in the annual review.

Note: This is a re-cite from 2012 related to staff’s failure to ensure infection prevention policies and procedures will be reviewed annually with documented recommendations changes and updates.

The findings included:

An interview and review of the facility’s infection prevention plan was conducted on 10/28/2014.
Beginning at 12:30 p.m., with Staff #5. Staff #5 acknowledged the infection prevention plan did not include the administrator, appropriate members of the clinical staff and the designated qualified person would review the infection prevention policies and procedures annually as required in the Virginia licensure regulations.

Review of the facility's policies and procedures on 10/27/2014 through 10/29/2014 did not contain evidence the policy and procedure manual had been reviewed and updated since 2012.

An interview was conducted on 10/28/2014 at 6:30 p.m., with Staff #1. The surveyor requested documentation that demonstrated the governing body or the administrator had reviewed the facility's policy and procedure manual annually. Staff #1 stated, "I didn't realize they needed to be reviewed annually. On 10/29/2014, Staff #1 reported the facility did not have policies and procedures to reflect the updated State licensure requirements for ensuring the manual is annually reviewed and updated by the administrator, appropriate members of the clinical staff and designated qualified person.

12 VAC 5-412-220 C Infection prevention

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
   1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);
   2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
   3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for
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<td>cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);</td>
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<td>4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;</td>
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<td>5. Procedures for handling/temporary storage/transport of soiled linens;</td>
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<td>6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;</td>
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<td>7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:</td>
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<td>(i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,</td>
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<td>(ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and</td>
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<td>(iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;</td>
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<td>8. Procedures for appropriate disposal of non-reusable equipment;</td>
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<td></td>
<td>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;</td>
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<td>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;</td>
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<td>11. An effective pest control program, managed in accordance with local health and environmental regulations; and</td>
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<td>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.</td>
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This RULE: is not met as evidenced by: Based on observations, interview and document
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<td>review it was determined that the facility failed to:</td>
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<tr>
<td>1. Ensure linens and other items were handled in a manner to prevent contamination and were washed at the correct temperature to prevent the spread of infections;</td>
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<td>2. Develop policies and procedures that encompassed the procedures for handling, storing and transporting clean and soiled linens;</td>
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<td>3. Ensure the process of cleaning, disinfecting, and sterilizing has been achieved according to the recommended level of disinfection/sterilization; and</td>
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<tr>
<td>4. Perform appropriate infection prevention procedures necessary to prevent/control transmission of an infectious agent.</td>
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Note: This is a re-cite from 2012 related to staff's failure to ensure linens and other items were handled in a manner to prevent contamination and to prevent the spread of infections; and infection prevention polices and procedures are developed and implemented.

The findings included:

1. Observations and interviews were conducted on 10/27/2014 from 12:50 p.m. to 1:30 p.m., with Staff #1 and Staff #3. An observation at 1:05 p.m. with Staff #1 in the "Surgical Suite - Local" procedure room revealed an oxygen tank with a piece of gauze strip attached to the cylinder wrench (metal cylinder key to open the oxygen tank). Staff #1 stated, "They tie this gauze to the key so it won't get lost." In the "Surgical Suite - IV Sedation" procedure room a second oxygen tank was observed with a gauze strip attached to the cylinder wrench. The observation revealed gauze strip attached to two (2) cylinder wrenches. Staff #1 verified the findings. Staff #1 affirmed the gauze strip could not be disinfected and that it would present a mode of cross-contamination and

Infection prevention
12 VAC 5 – 412-220 C
Correction:
1. The small gauze tie was removed from O2 tanks. Only items that can be cleaned according to existing FCHC policies in order to minimize cross contamination will be used in the surgical suites. 10/29/14
2. All PPE will be stored in the cabinets or in protective plastic bags. This will minimize cross contamination from environmental sources. 01/01/15
3. The metal cart in the clean autoclave alcove has been removed. A cart with an intact surface that can be disinfected has replaced it. Personnel entering the clean autoclave alcove will don full PPE including gown, gloves, mask, head cover and shoe cover. This will minimize contamination from environmental sources. 12/10/14
4. The surgical straps in the surgical suites are to be replaced with ones that can be disinfected between patients or disposable straps. The Nursing Administrator is investigating different options to assist in immobilizing the patients for their safety and which would meet infection control protocols without jeopardizing patient health. 01/01/15
5. The soiled linen container will be replaced. 01/01/15
a means for transmission of potentially infectious agents.

2. Observations and interviews were conducted on 10/27/2014 at 1:00 p.m. to 1:30 p.m., with Staff #1. The observations revealed the following personal protective equipment (PPE) stored on an open shelf un-protected from environmental contamination:

A stack of head covers, face mask and shoe covers in the "Surgical Suite - Local" procedure room and main hallway by the entrance door into the "Surgical Suite - IV Sedation" procedure room. An interview conducted on 10/27/2014 at 1:15 p.m., with Staff #1 revealed he/she was not aware this supply of PPE on the shelf should be covered to prevent contamination from environmental sources until it was brought to his/her attention by the surveyor. The main supply of PPE are stored in cabinets.

3. On 10/29/2014 at 10:45 a.m. an observation was conducted in the "Clean" scrub room (where instruments are packaged and sterilized as appropriate for use again) with Staff #9. The observation revealed a metal cart with shelf #1 and #2 covered in shelf contact paper and metal instruments placed on shelf #1. Multiple tears were observed in the contact paper on shelf #2. Staff #9 failed to don full PPE including: gown, gloves, mask, head cover and shoe covers prior to entering into a clean environment. Staff #9 reported the sterilized instruments were ready to be removed from the autoclave machine (pressure chamber used to sterilize equipment and supplies by subjecting them to high pressure saturated steam). An interview conducted with Staff #9 revealed he/she was not aware full PPE should be donned before entering the "Clean" scrub room to prevent contamination from environmental sources. Staff #9 reported he/she

with one that is labeled, has a cover, and a disposable transport bag. Soiled laundry will be transferred to the janitor's room in this closed disposable bag. This policy will be updated in the Policy for processing laundry and Guidelines for Best Practices manual. A thermometer will be purchased to monitor the hot water temperature. The temperature is maintained at 160 degrees by the landlord. A temperature log will be maintained and reviewed by the MA staff. Any deviations from the 160 degree temperature will be reported to the Nursing Administrator and corrective actions will be taken. Offsite laundry services and disposable supplies are being explored as an alternative. Prevention Recurrence Deficiency:
The corrective action will prevent any reoccurrence. The Nursing Administrator will monitor and report to the Governing Body any emergent issues that need corrective action. Measures to maintain Compliance:
Update to laundry manual to reflect changes. Staff trained/retrained to new process/procedure. Governing Body will review infection prevention policy annually, address any emergent issues and take corrective actions. Documentation will be shared with QAC as part of their annual review. No patients were affected evidenced by no increase in adverse events during the period of deficiency.
was only aware gloves were to be donned while working in that area. An interview was conducted with Staff #1 on 10/29/2014 at approximately 11:00 a.m. Staff #1 acknowledged the non-intact surface prevented disinfection of the cart; however the cart really had no purpose in this area and could be moved. Staff #1 reported the cart could not be cleaned and could see why this could be a means for transmission of potentially infectious agents. Staff #1 reported it was not the facility's policy to don full PPE during the removal of sterilized instruments from the autoclave.

4. Observations and interviews were conducted on 10/28/2014 from 5:10 p.m. to 5:40 p.m. during an abortion procedure in the "Surgical Suite-IV Sedation" procedure room with Staff #3, Staff #5 and Staff #6. The observation revealed two (2) blue cloth strips attached to the procedure table used to hold the patient's legs stable. Staff #1 verified the findings. Staff #1 affirmed the blue cloth strips could not be disinfected and cleaned between patients.

5. Observations and interviews were conducted on 10/28/2014 from 5:05 p.m. to 6:00 p.m., with Staff #5. An observation at approximately 5:30 p.m. revealed a vertical storage container with no label and several pieces of linen uncovered located in the hallway by the entrance door of the "Surgical Suite-IV Sedation" procedure room. The observation revealed soiled linen from a post procedure in the "Surgical Suite-IV Sedation" procedure room. Staff #5 reported the soiled linen items included: a sheet from "Recovery Room #1," a patient cloth gown; and a pillowcase that is placed under the patient during the procedure to assist staff with transferring the patient post procedure from the procedure table to a stretcher. Staff #5 reported at the end of the procedures or when the container is full, it is then transported to

T 175 Continued From Page 12
the closet marked janitor. Staff #5 reported that all linens were washed on site. The observation revealed a standard washer/dryer combination unit. Staff #5 reported the linens were washed on the appropriate setting for the material. Staff #5 reported the washer was connected to the general hot water supply for the building and he/she thought it was set to the required hot water temperature of 160 degrees Fahrenheit. Staff #5 reported the washer did not currently have a thermometer to verify the required temperature. An interview conducted on 10/28/2014 with Staff #1 revealed he/she was not aware the soiled linen container should be covered to prevent contamination. Staff #1 reported the facility did not have a written policy and procedure related to handling, storing and transporting clean and/or soiled linen.

An exit interview was conducted on 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 stated, "I didn't realize the soiled linen container needed to be covered. Staff #1 reported the facility needed to address the issues found by the survey team.

D. The facility shall have an employee health program that includes:
1. Access to recommended vaccines;
2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;
3. An exposure control plan for blood-bourne pathogens;
4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or
T 180

Continued From Page 14

recommends of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine; 5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.

This RULE: is not met as evidenced by:
Based on documentation and interview, it was determined that the facility failed to provide evidence that screening and immunizations were offered/received by 11 of 13 employees.

(Employee files #1, #4, #6-#8, and #11-#13)

The findings included:

Document review and staff interviews reveal the facility failed to documented screenings and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities for 11 of 13 employees.

During an interview on 10/28/18, at approximately 6:00 PM, Staff #1 stated "Screening for tuberculosis and immunization for Hepatitis B and flu are offered to all employees, once when hired and annually thereafter." Staff #1 stated that the immunization information is kept in the employee health file, but has been misplaced and cannot be located at this time.

T 290

12 VAC 5-412-270 Equipment and supplies

An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:

T 290

Infection prevention

12 VAC 5 – 412-220 D

Correction: Background: our SSHP (Staff Safety and Health Program) staff medical files are renewed each September – October or within the Orientation Program for new Staff. That renewal was completed. But as noted in the deficiency report the “files” were misplaced. NOTE: the staff member #13 was cited but there was not a staff #13. Staff member #6 is a new employee and still in orientation. Staff #8 and #11 are consultants.

PLAN OF CORRECTION:
The staff file of their various testing’s and/or declinations have been located. The staff medical files have been updated and are current. The new Staff member’s SSHP orientation is now scheduled. The Consultants medical files will be completed and brought to consistency with staff policies. Prevent recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency. Measures to maintain compliance: The various steps for the staff medical charts have been consolidated to the activity of one staff person. Our Gynecology Coordinator. No patients were affected by this deficiency.
T 290

Continued From Page 15

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.

This RULE: is not met as evidenced by:
Based on observation and interview, the facility failed to ensure that equipment and medical supplies were appropriately maintained.

The findings included:
1. Observation of Surgical Suite-Local Room, on 10/27/14, from 12:50 PM to 1:30 PM with Staff #1 and Staff #3, revealed tears on the left and right sides of the padding on the procedure table. Tears in vinyl restrict the ability to disinfect and can harbor bacteria. Staff #1 stated that the padding had recently replaced. An oxygen mask, not in a bag or packaging, was placed on the oxygen tank. Staff #1 acknowledged that the oxygen mask should be inside a bag and not open to air. Inspection of the container of emergency supplies revealed two (2) of two (2) 18 gauge needles had an expiration date of 6/2008, and one (1) 20 ml syringe had an expiration date of 5/2012. Staff #1 acknowledged the findings.
2. Observation of Recovery Room one (1) on 10/27/14, from 1:55 PM to 2:10 PM, with Staff #1, revealed tape on the vinyl pad and on the metal plate under the pad on the first gurney when entering the room. Tape was wrapped around the metal joints on both sides at the foot of the

Equipment and supplies
12 VAC 5 – 412-270

Correction:
1. The vendor for the surgical procedure table will be contacted to repair the small tears on the recently recovered procedure table. All oxygen masks are in a bag or packaged and not open to air. Consistent with our approved event related expiration policy. See attached. All medical supplies such as gloves, syringes, IV solutions, needles, cannulas, will follow event related shelf-life guidelines recognizing sterile indefinitely, unless an event causes them to become contaminated, e.g., torn or wet packaging or if the manufacturer specifies otherwise. Sterile items will no longer be evaluated by manufacturers’ expiration date.
2. The tape on the gurney was removed. The pillow roll stored under the gurney was discarded. The suction catheter attached to an aspirator was bagged and not open to air.
3. All oxygen masks are in a bag or packaged and not open to air.
4. The soiled linen container will be replaced with one that is labeled, has a cover, and a disposable transport bag. Soiled laundry will be transferred to the janitor’s room in this closed disposable bag. This policy will be updated in the Policy for processing laundry and Guidelines for Best Practices manual.

Prevent recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency and ensure that all items used in patient care will be cross checked at point of use before patient care.

Measures to maintain compliance: Staff trained to new process/procedure. Governing Body and Co-Administrator will review annually and address any emergent issues and take corrective actions. Patients were affected evidenced by no increase in adverse events during the period of deficiency.
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<th>T 290</th>
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<td>gurney. Staff #1 stated that the tape was used to hold it down. The rough surface of tape restricts the ability to disinfect and can harbor bacteria. A pillow roll was stored under the gurney had tears and was dusty. Staff #1 stated that this pillow was no longer used. The end of a catheter attached to an aspirator, was placed in the original packaging that was open to air, not bagged. Staff #1 acknowledged the findings.</td>
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3. Observation of Surgical Suite-Sedation on 10/27/14, from 2:15 PM to 2:25 PM, with Staff #1, revealed an oxygen mask placed on the anesthesia equipment was open to air, not bagged. Staff #1 acknowledged the findings.

4. Observations and interviews were conducted on 10/28/2014 from 5:05 p.m. to 6:00 p.m., with Staff #5. An observation at approximately 5:30 p.m. revealed a vertical storage container with no label and several pieces of linen uncovered located in the hallway by the entrance door of the "Surgical Suite-IV Sedation" procedure room. The observation revealed soiled linen from a post procedure in the "Surgical Suite-IV Sedation" procedure room. Staff #5 reported the soiled linen items included: a sheet from "Recovery Room #1," a patient cloth gown; and a pillowcase that is placed under the patient during the procedure to assist staff with transferring the patient post procedure from the procedure table to a stretcher. Staff #5 reported at the end of the procedures or when the container is full, it is then transported to the closet marked janitor. Staff #5 reported that all linens were washed on site. The observation revealed a standard washer/dryer combination unit.

An interview conducted on 10/28/2014 with Staff #5 revealed he/she was not aware the soiled linen container should be covered to prevent...
T 290  Continued From Page 17

contamination.

An interview was conducted on 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 stated, "I didn't realize the soiled linen container needed to be covered. Staff #1 reported the facility needed to address the issue found by the survey team.

T 320  12 VAC 5-412-300 B Quality assurance

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:
1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

This RULE: is not met as evidenced by:
Based on document review and interview the quality committee failed to ensure an evaluation of the adequacy and appropriateness of services as required by the State licensure regulations.

Note: This is a re-cite from 2012 related to staff's failure to ensure all subjects of the quality improvement committee would be addressed.

The findings included:

An interview and review of the facility's quality program documents were conducted on 10/28/2014 at 12:15 p.m., with Staff #2. Staff #2
and the surveyor reviewed the facility's quality program documentation. The facility's documentation did not include the required seven (7) elements of:
- staffing patterns and performance;
- supervision appropriate to the level of service;
- patient records;
- patient satisfaction;
- complaint resolution;
- infections, complications and other adverse events; and
- staff concerns regarding patient care. Staff #2 reported the quality committee had collected data but had not evaluated data for the seven required areas or identified unacceptable or unexpected trends or occurrences.

During an interview conducted on 10/28/2014 at 1:30 p.m. the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 denied awareness of the updated State licensure regulations. Staff #2 reported the quality committee had collected data, but had not analyzed or trended data for the required areas to identify unacceptable or unexpected outcomes.

D. Measures shall be implemented to resolve problems or concerns that have been identified.

This RULE: is not met as evidenced by:
Based on document review and interview the quality committee failed to ensure measures were implemented to resolve identified problems and concerns.

Note: This is a re-cite from 2012 related to staff's failure to ensure how problems would be resolved.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
<th>(X2) MULTIPLE CONSTRUCTION IDENTIFICATION NUMBER:</th>
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<tr>
<td>AF-0017</td>
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| (X3) DATE SURVEY COMPLETED: | 10/29/2014 |

**NAME OF PROVIDER OR SUPPLIER**
FALLS CHURCH HEALTHCARE CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**
900 SOUTH WASHINGTON ST SUITE 300
FALLS CHURCH, VA 22046

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<thead>
<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>(X5) COMPLETE DATE</th>
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<tr>
<td>T 330</td>
<td>Continued From Page 19 by the quality improvement committee. The findings included: An interview and review of the facility's quality program was conducted on 10/28/2014 at 12:15 p.m., with Staff #2. Staff #2 initially acknowledged the quality improvement committee did discuss concerns/problems that had been identified by services provided, appropriateness of care including reports from staff, patients, performance patterns, or any other sources of data collected. The review revealed documents titled &quot;Quality Meeting,&quot; which listed items discussed as part of the facility's quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were implemented. An interview was conducted on 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 reported the facility's quality program needed to address the issues found by the survey team. Staff #1 acknowledged the quality program's failure to implement measures to resolve problems or concerns that have been identified.</td>
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**T 335 2 VAC 5-412-300 E Quality assurance**

E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon.
T 335 Continued From Page 20

by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

This RULE: is not met as evidenced by:
Based on document review and interview the quality committee failed to compile results of deficient practices or corrective action implemented to the governing body.

Note: This is a re-cite from 2012 related to staff’s failure to ensure results of the quality improvement program would be reported to the licensee at least annually and deficiencies identified, recommendations and improvements were being acted upon by the governing body and the facility.

The findings included:

An interview and review of the facility’s quality program was conducted on 10/29/2014 at 12:15 p.m., with Staff #2. Staff #2 initially acknowledged the quality improvement committee did discuss concerns/problems that had been identified by services provided, appropriateness of care including reports from staff, patients, performance, patterns, or any other sources of data collected.

The review revealed documents titled “Quality Meeting,” which listed items discussed as part of the facility’s quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not

Quality Assurance
12 VAC 5 - 412-300 E
Correction: A report for the governing body is compiled annually on the Annual Review Document and any details of corrective actions noted in QAC minutes. As per existing policy, this report is part of the QAC minutes that includes any deficiencies, recommendations, and/or improvements. The corrective actions taken will prevent recurrence of deficiency. We will submit a report to the governing body annually as documentation on the Annual Review Document. Measures to maintain compliance: The QAC will review all documentation annually, address any emergent issues, take corrective actions as outlined in existing policies, and document all corrective actions, deficiencies, recommendations, and/or improvements. With the following information, the QAC will compile a report for the governing body to review annually through the QAC minutes. No patients were affected by this deficiency.
<table>
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<th>T 335</th>
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<tr>
<td>Document any corrective actions that were implemented. Staff #2 reported the quality committee did not compile a report for the governing body to review at least annually.</td>
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<tr>
<td>An interview was conducted on 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 reported the facility’s quality program needed to address the issues found by the survey team. Staff #1 acknowledged the quality program’s failure to report the deficiencies identified and recommendations for corrections and improvements.</td>
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<tr>
<th>T 345</th>
<th>12 VAC 5-412-320 Record storage</th>
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<td>Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored.</td>
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<tr>
<td>This RULE: is not met as evidenced by: Based on document review and interview the facility failed to provide provisions for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law. In the event of closure of the facility, the facility shall notify Office of Licensure and Certification (OLC) concerning the location where patient medical records are stored.</td>
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<p>| The findings included: |</p>
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<th>T 345</th>
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<td>Review of the facility's policies and procedures on 10/27/2014 through 10/29/2014 did not contain evidence the policy and procedure manual had been reviewed and updated since 2012. The facility failed to have evidence that provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law. In the event of closure of the facility, the facility shall notify Office of Licensure and Certification (OLC) concerning the location where patient medical records are stored. An interview was conducted on 10/28/2014 at 10:30 a.m., with Staff #1. The surveyor requested documentation that records were being stored according to applicable federal and state law. Staff #1 stated, &quot;I'm not sure where the owner of the facility has them located, but I will look into that matter.&quot; On 10/29/2014 at 11:30 a.m., Staff #1 reported he/she did not have any further information for the surveyor regarding the provisions of the safe storage of medical records because he/she has been busy with other responsibilities and duties regarding the survey.</td>
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<th>T 355</th>
<th>12 VAC 5-412-330 B Reports</th>
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<tr>
<td>B. Abortion facilities shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence.</td>
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This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to develop policies and procedure for reporting to the Office of Licensure and Certification (OLC) within 24 hours any occurrences, which involved:

1. Serious patient injury, medication errors, death | Record Storage |

**12 VAC 5 – 412-320**
Correction: Notation of the governing Body’s December 2013 review of over 1000 pages of the 5 Policy Manuals is now posted in the Annual Review Documentation. It was not posted due to clerical issue of the form being revised to multiyear. The new form was not returned to the Manual by the time of the unannounced inspection. Notation of the Governing Body’s scheduled December 2014 review of over 1000 pages of the 5 Policy Manuals is posted in the Annual Review Documentation. See attached form. Safe and secure storage of Patient Records has been continually maintained on and off site according to FCHC’s record retention and destruction policy. Revising storage of archived medical records is part of FCHC’s ongoing administrative transition that began in September 2014. Since May of 2014, we entered into and are presently in final stages of negotiations with the landlord to obtain additional storage space. This will facilitate full on-site record storage. As well, initial planning to make electronic copies of archived files is underway. Staff is currently consolidating the archived records on site in a secure locked auxiliary room. The new procedure will be reviewed by GB and reported to QAC at their next meeting. Prevent recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency. Measures to maintain compliance: Governing Body will review annually and address any emergent issues and take corrective actions as outlined in existing policies. Policies will be clarified as needed. Staff will be trained in the new procedures including assisting with making electronic copies. No patients were affected by this deficiency. |

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STATE FORM 021199

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VDH/OLC
or significant injury resulting from a physical assault, any other incident reported to the malpractice insurance carrier;
2. What the notification to OLC should include;
3. The facility's responsibility to report occurrences to law enforcement and the failure to develop policies and procedures to ensure compliance with; and
4. Confidentiality of records shared with OLC.

The findings included:

1. Review of the facility's policy and procedure manual on 10/27/2014 through 10/29/2014 did not reveal the following policy and procedures:

(B). The abortion facility shall report the following events to OLC:

1. Any serious injury to a patient;
2. Medication errors that necessitate a clinical intervention other than monitoring;
3. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and
4. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990.

2. Review of the facility's policy and procedure manual on 10/27/2014 through 10/29/2014 did not reveal the following policy and procedures:

(C). Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the following:

1. Abortion facility name;
2. Type and circumstance of the events being reported;

Reports

12 VAC 5 – 412-330 B
Correction: NOTE: There have been no events of serious injury to a patient, medication errors that necessitate clinical intervention, death or significant injury resulting from assault at FCHC or incident reported to malpractice insurance. The reporting of NO incidents will be included as requested to OLC. The existing Policy for reporting deaths to the Office of Licensure within 24 hours will be expanded to clarify reporting sequence and process. An additional line for Reports to OLC will be added to the Annual Review Documentation. The current policies previously approved by OLC are attached.

Prevent recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency. Measures to maintain compliance: GB will report annually in December to OLC as requested even if no reportable events were experienced. GB will continue to review the OLC website to see any noticed changes. The GB will also review for licensure regulations that may have changed without notification from the OLC. No patients were affected by this deficiency.
T 355  Continued From Page 24

3. Date of the event; and
4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.

(D). Compliance with 12VAC5-412-320 does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law enforcement or professional regulatory agencies.

(E). Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC except as required or permitted by law.

An interview was conducted on 10/28/2014 at approximately 6:30 p.m. with Staff #1. A request was made for any information related to reporting events to the OLC. Staff #1 reported he/she was not aware of a requirement related to reporting the events to the OLC within 24 hours of occurrence. The surveyor inquired if Staff #1 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #1 reported they had not received notification that the regulations had been revised. The surveyor informed Staff #1 that the State licensure office did not send out notices to each facility related to changes in the licensure regulations. The surveyor informed Staff #1 that it was the facility's responsibility to occasionally check the State's website for updated licensure regulations. Staff #1 reported the facility had not developed the additional policies, procedures, or processes to encompass the new reporting requirements to comply with the required reporting events to the OLC.
### Statement of Deficiencies

**Provider/Supplier/CLIA Identification Number:** AF-0004

**Multiple Construction**

- **Building:**
- **Wing:**

**Date Survey Completed:** 06/04/2019

**Name of Provider or Supplier:** A Tidewater Women's Health Clinic

**Street Address, City, State, Zip Code:**

891 Norfolk Square
Norfolk, VA 23502

<table>
<thead>
<tr>
<th>ID Prefix Tag</th>
<th>Summary Statement of Deficiencies</th>
<th>D Prefix Tag</th>
<th>Provider's Plan of Correction</th>
<th>Complete Date</th>
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| T 000         | Initial Comments

An unannounced complaint survey was conducted June 4, 2019 by two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey.

Complaint #2019-AC042 was investigated. The complaint was unsubstantiated, lack of sufficient evidence.

The agency was found to be in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective February 22, 2019).
An unannounced Licensure Biennial survey was conducted August 28, 2014 by two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey.

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

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 record review and interview the facility staff failed to ensure their system of complaint handling procedures was followed for 4 of 4 complaints reviewed.

The findings include:

On 8/28/14 at approximately 10:20 A.M. the complaint log was reviewed. There were complaints dated 9/13/12, 3/26/13, 4/4/13 and 7/3/14. Complaint dated 9/13/12 did not contain an investigation or outcome; Complaint dated 3/26/13 did not have an investigation or outcome; Complaint dated 4/4/13 did not have a documented outcome and Complaint dated 7/3/14 did not have a documented outcome.

The Staff member #1 was interviewed on 8/28/14 at approximately 4 P.M. and stated, "I do not have
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER
PENINSULA MEDICAL CENTER FOR WOMEN

STREET ADDRESS, CITY, STATE, ZIP CODE
10758 A JEFFERSON AVENUE
NEWPORT NEWS, VA 23601

<table>
<thead>
<tr>
<th>(X4) ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREFIX</td>
<td>(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
<td>PREFIX</td>
<td>(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
</tr>
<tr>
<td>TAG</td>
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<tr>
<td>T 140</td>
<td>Continued From Page 1</td>
<td>T 140</td>
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<td>the documentation.&quot;</td>
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<tr>
<td>T 155</td>
<td>12 VAC 5-412-210 E Patients' rights</td>
<td>T 155</td>
<td></td>
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<tr>
<td></td>
<td>E. The facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:</td>
<td></td>
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<tr>
<td></td>
<td>1. Facility contact person; and</td>
<td></td>
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<tr>
<td></td>
<td>2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The facility shall display a copy of this information in a conspicuous place.</td>
<td></td>
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</tr>
</tbody>
</table>

This RULE: is not met as evidenced by:
Based on document review and interview the facility staff failed to ensure each patient was provided the name, mailing address and phone number of OLC (Office of Licensure and Certification).
The findings included:

Upon entering the facility on 8/28/14 a copy of the patient rights was posted on the wall. The posting did not include the address of the OLC. As each patient was checked in they were handed a clipboard with the same information as posted on the wall taped to the front of the clipboard.

Staff Member #1 stated, "I didn't realize we didn't have the address on the information."

T 160  12 VAC 5-412-210 F Patients' rights
The facility shall maintain documentation of all complaints received and the status of each
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**AF-0003**

**NAME OF PROVIDER OR SUPPLIER**
PENINSULA MEDICAL CENTER FOR WOMEN

**STREET ADDRESS, CITY, STATE, ZIP CODE**
10758 A JEFFERSON AVENUE
NEWPORT NEWS, VA 23601

**ID PREFIX TAG**

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<th>COMPLETE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T 160</strong></td>
<td>Continued From Page 2 complaint from the date of receipt through its final resolution. Records shall be maintained for no less than three years.</td>
<td><strong>T 160</strong></td>
<td><strong>T 160</strong> The administrator has reviewed the policy to ensure in the future that all compliant forms are completed in its entirety. The compliance officer will review complaints during the quarterly inspection.</td>
<td><strong>9/10/14</strong></td>
</tr>
</tbody>
</table>

**This RULE** is not met as evidenced by:
Based on record review and interview the facility staff failed to ensure their system of complaint handling procedures was followed for 4 of 4 complaints reviewed.

The findings include:

On 8/28/14 at approximately 10:20 A.M. the complaint log was reviewed. There were complaints dated 9/13/12, 3/26/13, 4/4/13 and 7/3/14. Complaint dated 9/13/12 did not contain an investigation or outcome; Complaint dated 3/26/13 did not have an investigation or outcome; Complaint dated 4/4/13 did not have a documented outcome and Complaint dated 7/3/14 did not have a documented outcome.

The Staff member #1 was interviewed on 8/28/14 at approximately 4 P.M. and stated, "I do not have the documentation."

**T 165**

12 VAC 5-412-220 A Infection prevention

A. The abortion facility shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall

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SEP 6 2019

VDH/OLC
review them to assure they comply with applicable regulations and standards.

1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.

2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.

3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

This RULE: is not met as evidenced by:

Based on observations and interviews the facility staff failed to ensure they followed their infection control plan. During the initial tour of the facility and during observations of patient care items were identified that did not appear to have been cleaned; exam rooms and tables were dirty and stained, sonogram machines were dirty, had hair in the crevices, 3 of 3 pillow cases on the pillows ready for use were stained with make-up, the air condition vents/intake vents were dusty, stirrups had peeling paint, one of 4 cots used for recovery had tears, corrugated boxes were stored in patient care areas, three counter tops had missing or broken pieces. Blood pressure cuffs were not cleaned between each patient use. And they failed to date when items were opened.

The findings include:

On 8/28/14 during the initial tour and during patient care with Staff Member #1 the following observations were noted;

1. Sonogram room #1 had a dirty exam table, and

The licensee by the quality improvement committee.

This RULE is not met as evidenced by: Based on document review and interview the facility staff failed to ensure the quality improvement program reported to the licensee at least annually deficiencies identified, recommendations for corrections and improvements.

The findings included:

On 8/28/14 the quality improvement program and the information forwarded to the governing body was reviewed. There was no evidence information collected, problems identified or corrective actions or recommendations were forwarded to the governing body to act on. The information revealed data had been collected, improvements recommended but no evidence the governing body was made aware of the information. There was no evidence of a formalized plan demonstrating an assessment had been made of areas that may need improvement for the current 12 months.

On 8/28/14 at approximately 1:30 P.M. the quality improvement program was reviewed with Staff Member #2. Staff Member #2 stated, "You are correct, I never sent a report to the governing body. We did find some issues to work on. We did not complete a formalized plan. I can see the benefit of that now."

12 VAC 5-412-310 Medical records

An accurate and complete clinical record or chart shall be maintained on each patient. The record...
or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:
1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses' progress notes;
   h. Condition at time of discharge;
   i. Patient instructions, preoperative and postoperative; and
   j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by:
Based on document review and interview the facility staff failed to ensure the medical record for 2 of 9 records (Record #6 and 7) reviewed were complete and accurate.

The findings include:

On 8/28/14 at approximately 1:15 P.M. records were reviewed and the following was noted:
Record #6 the physician failed to a time when the operative report was signed and failed to indicate a time of discharge.
Record #7 the physician failed to indicate the time on the operative report and failed to provide an order for discharge to recovery.

T 340
Continued From Page 6

T 340

WILL BE CONDUCTED ON EVERY CHART BY ADMINISTRATOR. ADMINISTRATOR WILL MONITOR TO ENSURE CONTINUOUS PROPER DOCUMENTATION. PHYSICIAN HAS BEEN REMINDED OF PROPER DOCUMENTATION REQUIREMENTS.
Continued From Page 7

Staff Member #2 stated, "Documentation is something we are trying to work on."

T 375 12 VAC 5-412-360 A Maintenance

A. The facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be all be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

This RULE: is not met as evidenced by:
Based on observation and interview the facility failed to provide patients with a means of calling for assistance from the bathroom used by the patients after a procedure.

The findings included:

The facility was toured on August 28, 2014 at approximately 9:30 A.M. with Staff Member #1. No call light or means of calling for assistance from the facility's staff was found in the patient bathroom used by patients who have had procedures. This bathroom is located directly across from the recovery room area and is used by patients in the recovery room.

Staff Member #1 stated, "Well I am right there and pointed to the counter in the recovery area. And the people who are doing the cleaning of the equipment and in this area (Staff Member #1 pointed to an open area between the procedure room and the soiled and clean rooms)."
At approximately 1:30 P.M. during the observations of patients in the recovery room one patient complained of "feeling like I am going to throw up". The surveyor look for and called by name Staff Member #1. Staff Member #1 was in the bathroom assisting another patient. As Staff Member #1 was exiting the bathroom she was asked if she heard her name being called and she stated, "No".

**Table:**

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</table>
Policy Description: Patients' Rights: Grievance and Complaint Management

Replaces Policy Dated:

Reference Number: 12VAC5-412-200 A-F

Approved: 01/12

Scope:
All stakeholders

Purpose:
To establish a process for timely referral, prompt review, investigation and resolution of patient grievances and complaints.

DEFINITIONS:

Complaint is a concern represented by a patient or patient’s representative that can be addressed or resolved promptly by staff members who are present at the time of the complaint. “Staff present” includes those individuals close to the complaint situation or who can quickly be at the patient’s location to resolve the patient’s complaint. Generally, complaints can be resolved timely while the patient is still receiving care at the facility or in response to an issue raised after discharge from the facility.

Patient Grievance is a written or verbal complaint (when the verbal complaint about patient care is not resolved at the time of the complaint by staff present) by a patient, or the patient’s representative, regarding the patient’s care, abuse (verbal, mental, sexual or physical) or neglect, mistreatment, issues related to compliance to regulatory standards, or a Medicare beneficiary billing complaint.

A written complaint is always considered a grievance, whether from a patient or their representative. A written complaint also includes those complaints received via electronic mail or facsimile. Regardless of the form in which a complaint is received, whenever a patient or patient’s representative requests a response from the facility, the issue is defined as a grievance.

Information obtained on patient satisfaction surveys does not usually meet the definition of a grievance. If, however, the patient attaches a written complaint on the survey and requests resolution, then the complaint may meet the definition of a grievance. Written comments should be evaluated to determine if they constitute a complaint or a grievance.

A verbal complaint is a grievance if it cannot be resolved at the time of the complaint by staff present, if it is postponed for later resolution, if it is referred to other staff for later resolution, if it requires investigation, and/or if it requires further actions for resolution.

Policy:
Each patient and/or the patient’s representative will be informed of the grievance process, including whom to contact to file a grievance or complaint. The patient will be informed that a grievance may be directly lodged with the State department of health or in the case of Medicare patients with the Medicare Beneficiary Ombudsman, regardless of whether he/she has first used the
organization's grievance process. Patient grievances are to be addressed in a timely, reasonable, and consistent manner. Notification to the complainant of the proposed resolution will occur within 30 days from the date of receipt of the complaint.

Dedication to providing quality care and service to patients requires an effective mechanism for resolving patient complaints. The goal is to be responsive and foster open communication with patients at all levels within the organization with the objective of resolving complaints expeditiously through appropriate problem solving actions. Presentation of a grievance or complaint will not compromise a patient's future access to care nor subject the patient to coercion, discrimination, reprisal, or unreasonable interruption of care, treatment, or services.

The Governing Body approves and is responsible for the effective operation of the grievance process. The operational responsibility for reviewing and resolving grievances has been delegated to the Administrator. Data collected regarding patient grievances and complaints is incorporated in the quality assessment and performance improvement program with a quarterly report from the Quality Improvement Committee forwarded to the Governing Body for review.

Confidential information will not be shared with the patient's representative or any third party without appropriate written consent given by the patient.

The Facility Privacy Officer shall be responsible for overseeing the investigation and resolution of grievances related to the Health Insurance Portability and Accountability Act (HIPAA). The Risk Manager shall be responsible for grievances involving a request or demand for money or threatened litigation.

<table>
<thead>
<tr>
<th>Procedure:</th>
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<tbody>
<tr>
<td><strong>A. Notification of Rights Regarding Complaint/Grievance Resolution</strong></td>
</tr>
<tr>
<td>1. Each patient and/or patient representative is informed of the rights and responsibilities afforded patients upon entry into the facility, and the process by which they may lodge a complaint. This information includes the designee of the organization, such as the Administrator, and the method of access to the designee to provide immediate assistance as needed.</td>
</tr>
<tr>
<td>2. Each patient receives information on how to lodge a grievance with the state agency upon entry to the facility. The state agency, Virginia Department of Health, 9960 Mayland Drive Suite 401 Richmond, VA 23223 or at (800) 955-1819, phone number, and address are provided in the event that the patient decides not to use the internal grievance process. The website is <a href="mailto:OLC-compliants@vdh.virginia.gov">OLC-compliants@vdh.virginia.gov</a></td>
</tr>
<tr>
<td><strong>B. Complaint Resolution Process</strong></td>
</tr>
<tr>
<td>1. When a patient voices a complaint, the patient will be encouraged to discuss the complaint with the nursing staff and/or their physician. If the complaint is related to a particular department, a representative from that department may be invited to discuss the issue with the patient. The Administrator may be involved as needed to assist with prompt resolution.</td>
</tr>
</tbody>
</table>
| 2. Every effort will be made to resolve the complaint at the lowest level possible. Each staff member is empowered to respond and resolve promptly any complaint voiced by a patient and/or their representative. The staff member receiving the complaint will notify his/her supervisor when the issue cannot be immediately resolved. At each level of this process, the staff member will listen with concern to the
patient’s complaint, consider the circumstances and context of the complaint, assure the patient that their complaint will be investigated and resolved as soon as possible.

3. At any point in the process, the complaint may become a grievance based on aforementioned criteria.

C. Grievance Resolution Process

All grievances must be immediately reported to a person in authority when a facility employee is made aware of the grievance.

1. Grievances may be received written, verbally, via electronic mail or facsimile, or by telephone to any department. Upon receipt of a grievance, the Administrator shall confer with the appropriate personnel to review, investigate and resolve with the patient and/or patient representative within seven days of receipt of the grievance with the exception of complaints regarding situations in which patient safety may have been jeopardized, such as abuse or neglect. These grievances should be reviewed immediately given the seriousness of the allegations and the potential for harm to the patient. Medical staff leadership may be involved as needed to resolve physician delivery of care issues.

2. Occasionally, a grievance is complicated and may require an extensive investigation. If the grievance will not be resolved, or if the investigation is not or will not be completed within seven days, the complainant should be informed that the facility is still working to resolve the grievance and that the facility will follow-up with a written response within 21 days.

3. Regardless of the nature of the grievance, the substance of each grievance must be addressed while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

4. In resolution of the grievance, a written notice of the decision must be provided to the complainant that contains the name of the facility contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance investigation, and the date of completion.

5. The written notice must be communicated appropriately to the patient or the patient’s representative in a language and manner the patient or the patient’s representative understands. When a patient communicates a grievance via email, the response may be provided via email. However, the response must contain the aforementioned elements.

6. At the discretion of the person conducting the investigation, other mechanisms may be utilized to resolve a grievance. For example, conducting a meeting with the complainant may be very effective. However, in all cases a written notice of response with the aforementioned elements must be provided to each patient/grievance.

7. A grievance is considered resolved when the patient and/or patient’s representative is satisfied with the actions taken on their behalf. There may be situations where the organization has taken appropriate and reasonable actions on the patient’s behalf in order to resolve the patient’s grievance and the patient or the patient’s representative remains unsatisfied with the actions taken by the organization. In these situations, the Quality Improvement Committee may consider the
grievance closed. However, the organization must maintain documented evidence of compliance with all regulatory requirements.

8. Substantiated allegations of abuse, neglect, or other reportable events will be reported to state or local authorities

D. Tracking, Trending, and Analysis of Data

1. A grievance/complaint log will be maintained by the Administrator or designated staff member. The documentation in the log will include date of complaint/grievance, location, summary of issue, how the issue was addressed, date resolved and response to complainant, and the individual responding to the grievance.

2. Documentation of the resolution process will include:
   - Name of person representing complaint/grievance and how to contact
   - Patient name
   - Nature of complaint/grievance
   - Date of service
   - Pertinent investigational information
   - Resolution/follow-up including written response for grievances
   - Signature of person addressing complaint/grievance

3. The above documentation will be maintained by the Administrator or forwarded to the designated staff member. Data will be aggregated, analyzed and reported to the Quality Committee and the Governing Body on a quarterly basis. Based on the QA/PI priorities of the Facility, the Governing Body shall give consideration to requiring the reporting of the following types of data analysis:
   - Reporting of individual cases deemed to be a serious grievance, as defined by the Facility (e.g., potential for causing harm, serious breach of policy, etc.), and any root cause analysis that might have been done in response, if necessary;
   - Total of all complaints/grievances, with analysis of natural type of problem, frequency of each type, trends by seriousness or problem type, department(s) involved, type of staff involved (e.g., nursing, ancillary, physicians), type of patients involved (i.e. surgical, endoscopy, pain management),
Peninsula Medical Center for Women
10758A Jefferson Avenue
Newport News, Virginia  23601
(757) 599-6389 – phone (757) 599-0347
Patient Complaint

Date: ____________________________  Time: ____________________________

Name of Patient: __________________________________________________________

Nature of Complaint: ______________________________________________________

Brief description of what happened:
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Date and Time of Occurrence:
____________________________________________________________________

Contact telephone # for problem resolution: ________________________________

Employee taking report: _________________________________________________

Complaint reported to: _________________________________________________

Date: ____________________________  Time: ____________________________

__________________________________________ [office use below this line]

Date and time complaint received: _______________________________________

Complaint reviewed: YES  NO

Employees interviewed: YES  NO

Patient interviewed: YES  NO

If yes, when ____________________________  By Phone  In person

Investigation completed: YES  NO

Outcome of Investigation: ______________________________________________

____________________________________________________________________

Person completing investigation: __________________________________________

Date: ____________________________  Time: ____________________________

Was the patient satisfied with the outcome?: ______________________________

What can be done to avoid similar complaints?: ___________________________
Richmond Medical Center for Women  
Peninsula Medical Center for Women  
Clinical Policies and Procedures Manual

<table>
<thead>
<tr>
<th>Department:</th>
<th>Quality Assurance</th>
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<tbody>
<tr>
<td>Policy Description:</td>
<td>Quality Management, Quality Assurance and Process Improvement, QAPI</td>
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<tr>
<td>Page:</td>
<td>1 of 2</td>
</tr>
<tr>
<td>Replaces Policy Dated:</td>
<td>4/1/12; 6/5/12 (300 A, B, C, D, E)</td>
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<tr>
<td>Effective Date:</td>
<td>7/15/13</td>
</tr>
<tr>
<td>Reference Number:</td>
<td>12VAC5-412-210 A, B, C, D, E</td>
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<td>Approved:</td>
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**Scope:**
All facility personnel

**Purpose:**
To establish a QAPI program to achieve optimal care for the consumer as well as provide for patient and employee safety.

**Policy:**
QAPI is a program which allows both administrative personnel and staff to identify real or potential problems, document findings, and use methodology to improve processes to improve outcomes in various areas as noted below.

**Procedure:**

A. QAPI for the facility serves as an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program includes process design, data collection/analysis, assessment and improvement and evaluation. The findings are used to correct identified problems and revise policies and practices.

B. To ensure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences the following shall be evaluated:
1. Staffing patterns and performance, done annually and as needed.
2. Supervision appropriate to the level of service, done annually and with position vacancies.
3. Patient records; with one record checked weekly by site administrator; and full audit of all records current with procedure day every other month; and as determined by chart errors found through audits.
5. Complaint resolution; through audits for trends. See also policy on patient rights (12VAC5-412-200, B, C, & D.)
6. Infections, complications and other adverse events; audits done and occurrences sent to Regional Director for trending.
7. Staff concerns regarding patient care.
8. Periodic safety checks on all equipment

C. The quality improvement (QI) committee is responsible for the oversight and supervision of the program and shall consist of:
1. A physician
2. A non-physician health care practitioner
3. A member of the administrative staff
4. An individual with demonstrated ability to represent the rights and concerns of patients. This may be a member of the facility’s staff.

5. There may be coordination between the Regional Director’s multiple sites of responsibility to provide a range of insight helpful to the improvement process.

D. When problems are identified measures shall be implemented to resolve the problems and concerns that have been identified.

E. Results of the quality improvement program will be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrections actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

F. Quarterly inspections assessing facility quality audits on documentation, infection prevention and other subjects as the need arises, and including a tour of the facility for compliance of State Regulations are to be done by the Compliance Officer who shall review findings with the Administrator of the facility for quality improvement and corrections. The quarterly inspections will be sent to the Governing Body and the Administrator of the facility will advise the Governing Body within fifteen working days of corrections made, and if ongoing monitoring is needed.

Reference: 12 VAC5-412-210-A, B, C, D, E; & 12 VAC5-412-200 B, C, D

Richmond Medical Center for Women
Peninsula Medical Center for Women
Clinical Policies and Procedures Manual

Charlottesville Medical Center for Women
Roanoke Medical Center for Women

Americans United for Life
W.K.G. & J, Incorporated
118 North Boulevard
Richmond, Virginia  23220

The Governing Authority for Richmond Medical Center for Women, Charlottesville Medical Center for Women, Peninsula Medical Center for Women, and Roanoke Medical Center for Women

September 23, 2014

Response to CO report on QA for Peninsula 1-27-14

Concur with Action plan to continue monitoring infections and other complications.
Continue with patient satisfaction surveys. Complaints seem to be related to mis-communication of expectations with patients. Staff must listen to patients to ensure that staff and patients understand each other. Have concerns that staff gives information but doesn’t do enough listening.
Conduct chart audits to detect problem areas in documentation.
Consider sending letters to pt’s PMD with their permission. May increase goodwill with PMDs as well as increase awareness of complications.
Peninsula Medical Center for Women
10758A Jefferson Avenue  Newport News, Virginia  23601
(757) 599-6389 – phone (757) 599-0347– fax

Peninsula Medical Center for Women’s team of staff and physicians is dedicated to providing quality, personalized healthcare to the members of our community. Our plan of care encompasses all aspects of your surgical experience. Your pre-operative, intra-operative and optimal recovery needs will be met to the best of our best ability while you visit our center.

At the Peninsula Medical Center for Women your rights include the following:

❖ Safe considerate and respectful care
❖ Privacy, personal and informational
   ❖ Be kept well-informed and participate in your healthcare decisions
   ❖ Know the names and roles of Care-givers
   ❖ Be fully informed of risks, benefits, expected outcomes and alternative treatments for scheduled procedures
   ❖ Consent to or refuse treatment without being subjected to discrimination or reprisal
   ❖ An advance directive, such as a living will, health care proxy, or surrogate decision maker
   ❖ Confidentiality of your medical record
   ❖ Review your medical record
   ❖ Awareness of the potential ownership interest in the facility by your physician
   ❖ Consultation with a specialist
   ❖ Participate in your pain management treatment to enhance your recovery
   ❖ Consent to or decline to take part in research affecting your care
   ❖ Know about center rules that will affect you, your treatment and your payments
   ❖ Access protective services
   ❖ Access to an interpreter
   ❖ Accommodation of special needs for handicapped or sensory impaired persons
   ❖ Explanation of the need for your transfer to another facility

Americans United for Life
To voice concerns or grievances regarding care received please contact:
Administrator @ (757) 599-6389 or
Virginia Department of Health (804) 367-2104 or Toll-Free at 1 (800) 955-1819
9960 Mayland Drive, Suite 401
Henrico, Virginia 23223

You have the responsibility to:

❖ Provide information about your present and past health history and medications
❖ Ask questions when you do not understand information or instructions
❖ Keep your health care providers informed of your level of discomfort in a timely manner to maximize the effectiveness of your pain management treatment plan
❖ Be considerate of the rights of other patients, center staff and center rules and regulations
❖ Inform us if you have an advance directive and provide a copy to the center
❖ Comply with the treatment plan and instructions for follow-up care
❖ Assure financial obligations for healthcare services received are promptly met
❖ Inform center personnel if any special needs or accommodations are required
W.K.G. & J, Incorporated
118 North Boulevard
Richmond, Virginia  23220

The Governing Authority for Richmond Medical Center for Women, Charlottesville Medical Center for Women, Peninsula Medical Center for Women, and Roanoke Medical Center for Women

September 23, 2014

To:   Monica Hunter, RN, MSN, Administrator
       Lin Rasmussen, BSN RNC-OB, Compliance Officer

From:  Jill Abbey, President

Re:   Assessment of areas needing improvement

I have reviewed reports made by the CO and the report made by the inspectors with the Office of Licensure and Certification. In addition, I was present for the exit interview on the day of the inspection. (August 28, 2014)

Areas needing improvement

1. Cleanliness
   I have had conversations with the administrator to emphasize the need for routine cleaning and terminal cleaning. She has increased the floor cleaning provided by outside contractor. We have discussed having time set aside when the staff may concentrate their efforts on cleaning. I have discussed with her that cleanliness is a matter of infection control.

2. Documentation
   Documentation has been an issue at all of our sites. As the CO has pointed out, Peninsula has had the best performance but still needs improvement. The administrator will pay attention to missing pieces of documentation as we are seeing patients but also will conduct regular chart audits for completion.

3. Complaint Management
   Policies have been revised to indicate that all complaints must be addressed within 70 days of the complaint. The CO will monitor complaint reports as part of the quarterly inspections that she conducts to ensure that reports are complete and timely.
The diligence of the CO has been appreciated in detecting problem areas. The administrator must complete the next step in carrying out the correction of problems. The inspector graciously called deficiencies “opportunities for improvement”; we can all benefit from that attitude.

1. The CO will continue with her quarterly inspections.
2. She will submit her findings to the administrator and the Governing Authority.
3. The administrator will respond to the CO’s report within 15 days.
4. The Governing Authority will review the reports and provide a plan for improvement.
5. Staff will do terminal cleaning after each procedure day. Then they will use Friday mornings for an overall cleaning of the building.
6. Chart audits will be completed and the results provided to the CO
7. The CO will monitor any complaints and evaluate the handling of the complete to ensure that there is a documented outcome for each one.
An unannounced First Trimester Abortion Facility Biennial Licensure Inspection was conducted July 12, 2018 and July 13, 2018 by two (2) Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health.

The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Amended 3/22/2017).

12 VAC5-412-310 Record Storage

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.).

This RULE: is not met as evidenced by:
Based on observations and staff interview, facility staff failed to ensure that medical records were stored in a secure area.

Findings include:

Three (3) patient records containing personal information were observed lying on top of a shelf just inside the door where medications were also being stored. The records had prescriptions for oral contraceptives (OCP's) and Tylenol #3 lying on top of them, and were accessible to anyone who opened the door, which was not locked.

An interview was conducted with Staff Member (SM)#1 on 7/13/18 at 11:30 a.m. and a discussion was held related to the controlled substances not being stored under double lock, and medical...
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER: PLANNED PARENTHOOD SOUTH ATLANTIC-CHARLOTTESVILLE
STREET ADDRESS, CITY, STATE, ZIP CODE: 2964 HYDRAULIC ROAD CHARLOTTESVILLE, VA 22901

<table>
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<tr>
<th>ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<tr>
<td>T 360</td>
<td>Continued From Page 1 records with unsigned prescriptions lying on the records. SM #1 stated &quot;You are right, that door should be kept locked, I'm sure they got busy and didn't think about locking the door behind them. That is an easy fix&quot;. The concern was reviewed again with SM #1 at the exit conference on 7/13/18 at 12:30 p.m.</td>
<td>T 360</td>
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<td>T 000</td>
<td>12 VAC 5-412 Initial comments</td>
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<td>An unannounced Licensure Biennial survey was conducted 10/30/2014 through 10/31/2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC 412 Regulations for the Licensure of Abortion Clinics. (Effective 08/20/2013).</td>
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<tr>
<th>T 130</th>
<th>12 VAC 5-412-200 Minors</th>
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<td>No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian or other authorized person. If the emancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to 18.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.</td>
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This RULE: is not met as evidenced by: Based on interview and record review it was determined that the agency failed to provide evidence that a written consent was obtained from an authorized adult for a minor (Patient #5) in one (1) out of three (3) minors in a survey sample of three. (Patients #5)

The findings included:

- Review of electronic patient records on 10/30/2014, revealed that a 17 year old patient (#5) was admitted on 4/28/2014; and underwent an abortion on 5/2/2014. Review of the informed consent revealed that there was no signature of the parent or legal guardian.

Actions to correct the deficiency: Patients are our top priority. PPMW insists on the highest professional standards of care, and we follow all laws. During the state inspection, we became aware of one instance where our high standard was not met regarding our routine procedure of charting a minor's consent form. We have taken swift corrective action, including conducting an internal review to ensure that we are complying with all laws, retaining all staff, and instituting additional safeguards in our administrative and quality assurance systems.

Actions to prevent a recurrence of the deficiency: To ensure the highest quality care, PPMW Falls Church immediately implemented an expanded policy and additional procedures related to minor consent charting. The actions require extra checkpoints throughout a minor's visit to verify age and needed consent, a paperwork color coding system for minor patients, and expanded signing protocols for parents.

Specifically, the expanded policy and procedures require the following:
1. the age of each patient will be reviewed at multiple steps of the visit to determine if the patient is a minor, (2) when the patient is determined by the front desk staff to be a minor, a red folder will be used for that patient's records to indicate that the patient is a minor, and (3) the physician will document in the electronic health records that before beginning the procedure, he/she reviewed the age of the patient and determined that the necessary consents had been obtained. The initial retraining occurred in mid-November and all additional safeguards will be in place fully by January 7, 2015.

Actions to maintain compliance: All staff will be required to review the final policy and procedures and sign the retraining on record by January 7, 2015.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:
AF-0010

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
10/31/2014

NAME OF PROVIDER OR SUPPLIER
PL PARENTHOOD METRO WASHINGTON-FALLS C

STREET ADDRESS, CITY, STATE, ZIP CODE
303 S. MAPLE AVE, SUITE 300
FALLS CHURCH, VA 22046

(X4) ID PREFIX TAG

(SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL
REGULATORY OR LEGAL IDENTIFYING INFORMATION)

ID PREFIX TAG

PROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE
CROSS-REFERENCED TO THE APPROPRIATE
DEFICIENCY)

(X5) COMPLETE DATE

T 130 Continued From Page 1

An interview was conducted on 10/31/2014 at 10:15 AM with Staff #9. Staff #9 reviewed the electronic record for Patient #5 and acknowledged there was no signature of a parent or legal guardian on the informed consent. Staff #9 stated the agency had experienced "a problem with the system capturing electronic signatures."

T 135 12 VAC 5-412-210 A Patients' rights

A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.

This RULE: is not met as evidenced by:
Based on document review and interviews the agency failed to provide documentation that patients received a copy of their rights and responsibilities upon admission for six (5) of six (6) patients included in the survey sample (Patient #1-#6).

The findings included:
Review of six (5) patient records (#1-#5) on 10/30/2014, at approximately 1:00 p.m., showed no evidence of patient signatures acknowledging receipt of a copy of their rights and responsibilities.

A review of the facility's policy and procedure manual on 10/30/2014 revealed a policy containing a list of patient rights and

T 130 PPMW-Falls Church's Quality Risk Management program will review the charts of all minors every 3 months to ensure that the required documentation is complete. The review will also include a check of the physician's documentation that prior to beginning the procedure, the patient's age and the consent documents were reviewed. This audit will be recorded on the PPMW Schedule of FY 2015 CQRM Audits beginning on January 7, 2015.

T 135 PPMW-Falls Church's practice at the time of the inspection mandated that staff has a patient sign, in the electronic health record, to acknowledge that the patient has reviewed the laminated copy of the Patient's Bill of Rights & Responsibilities that is provided upon admission. There are additional framed copies of the Patient's Bill of Rights & Responsibilities available in every procedure and examination room for further review. When a patient is asked for a copy to take home, they received one from the Reception Desk, where there were copies of this document for this purpose.

Actions to correct the deficiency and prevent a recurrence: PPMW-Falls Church implemented a new policy on provision of the Patient's Bill of Rights & Responsibilities wherein all patients will receive a paper copy to take home, in English and Spanish, of the Patient's Bill of Rights and Responsibilities along with the other forms provided at the Registration Desk. This will be reflected in the Front Desk Registration protocols. Further, all patients will sign a newly created form, the Forms Received Acknowledgment, confirming the patient's receipt of this copy.

Staff will be retrained to provide these copies and all of these measures will be in place by January 7, 2015.

Actions to maintain compliance: PPMW-Falls Church will annually, as part of the Quality Risk Management program, randomly audit a certain number of medical records to ensure that the Forms Received Acknowledgment form has been fully completed in all cases.

This inspection will be recorded on the PPMW Schedule of FY 2015 CQRM Audits.
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<td>T 135</td>
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On 10/30/2014 at approximately 4:00 p.m., Staff #2 and Staff #5 were shown a patient rights and responsibilities documentation in the patient electronic record and policy and procedure manual. Staff were questioned about the process of providing the patients with a copy of this form on admission. Staff #2 acknowledged staff discuss with the patients their rights and responsibilities at admission, but the facility is not providing patients with a copy.

During an interview on 10/31/2014 at approximately 1:30 p.m., Staff #2 acknowledged that the patient files did not have signatures on receiving a copy of patient rights and responsibilities on the admission dates. Staff #2 provided a copy of admission forms that are given to the patients on admission. This procedure could not be substantiated as the form did not designate an area for the patients signature to acknowledge receipt. Staff #2 acknowledged he/she did not know the facility needed to provide a copy until it was brought to his/her attention by the surveyor.

During the exit interview on 10/31/2014, Staff #1, Staff #2, Staff #5 and Staff #7 acknowledged the agency failed to provide documentation showing patients received their rights and responsibilities during admission in the manner required by this regulation and their own approved and established procedure.

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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<td>T 150</td>
<td></td>
<td>12 VAC 5-412-210 D Patients' rights</td>
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<tr>
<td></td>
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<td>D. The patient shall be given a copy of the complaint procedures, in a language or manner</td>
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Continued From Page 3

she understands, at the time of admission to service.

This RULE: is not met as evidenced by:
Based on document review and interviews the agency failed to provide documented evidence that patients received complaint procedure information during admission for six (6) of six (6) patients included in the survey sample (Patient #1-#6).

The findings included:

Review of six (6) patient records (#1-#6) on 10/30/2014, beginning at approximately 1:00 p.m., showed no evidence of patient signatures acknowledging receipt of the Office of Licensure and Complaint (OLC) complaint information and telephone number, dated on patient admission. The six records also did not have complaint process and OLC information documented as given.

A review of the facility's policy and procedure manual on 10/30/2014 revealed a policy containing a list of patient rights and responsibilities and the OLC Complaint Unit toll-free complaint hotline and mailing address.

On 10/30/2014 at approximately 4:00 p.m., Staff #2 and Staff #5 were shown a complaint form taken from the waiting area, in the patient electronic record and policy and procedure manual. Staff were questioned about the process of providing the patients with a copy of this form on admission. The form reviewed in the policy and procedure manual included the OLC complaint information including the telephone number; however the form from the waiting area and electronic record showed no evidence the complaint procedures were given to the patient at
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<th>COMPLETE DATE</th>
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<td>T150</td>
<td>Continued From Page 4</td>
<td>the time of admission. Staff #2 acknowledged patients are given information regarding how to file a complaint with the agency; however the OLC's information is not provided to the patients. During an interview on 10/31/2014 at approximately 1:30 p.m., Staff #2 acknowledged that the patient files did not have signatures on a complaint process dated on the admission dates. Staff #2 provided a copy of admission forms that are given to the patients on admission. This procedure could not be substantiated as the form did not designate an area for the patient's signature to acknowledge receipt. Staff #2 acknowledged that the complaint procedure provided to six (6) patients, on the day of the procedure, did not have the information for contacting the OLC. During the exit interview on 10/31/2014, Staff #1, Staff #2, Staff #5 and Staff #7 acknowledged the agency failed to provide documentation that patients received the complaint procedure during admission in the manner required by this regulation and their own approved and established procedure.</td>
<td>T155</td>
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<td>PPMW Falls Church's practice mandated the time of the inspection that any time a patient informs any staff member of a complaint, the patient received the Laminated Complaint Handling Procedures form with the OLC Complaint Unit contact information from the Reception Desk or the Health Center Manager. When patients asked for a copy, they received one to take home. In the waiting room, the patients had access to a prominent box, with a sign on it indicating, &quot;Complaints and Comments,&quot; where patients may fill out complaints to PPMW-Falls Church and deposit them in the box. In 2012, the complaint procedure was framed and mounted on the wall. After the walls were painted in May 2014, the complaint procedure was inexplicably not replaced along with the framed.</td>
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<td>T 155</td>
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<td>T 155</td>
<td>Patient Bills of Rights &amp; Responsibilities and the internal complaint box.</td>
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<td>This RULE: is not met as evidenced by:</td>
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<td>Actions to correct the deficiency and prevent a recurrence: PPMW-Falls Church will create a new framed</td>
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<td>Based on observation and document review it was determined that the facility failed to display, in a conspicuous place, information on how to lodge a complaint with the facility contact person and the Office of Licensure and Certification (OLC) Complaint Unit.</td>
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<td>copy of the Complaint Handling Procedures form, in English and Spanish, which includes the OLC hotline information. This form will be posted on the wall by January 7.</td>
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<td></td>
<td>The findings included:</td>
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<td>Actions to maintain compliance: PPMW-Falls Church will mandate that monthly, the health center manager will check to make sure that the mounted Complaint Handling Procedures form is still present and is fully readable, and this inspection will be recorded on the Family Planning and Surgical Services Monthly Operational/Facility Survey.</td>
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<td>On 10/30/2014 at approximately 8:00 a.m., a tour of the facility revealed a complaint box in the patient waiting area, but no postings in the facility with information for making a complaint to the OLC Complaint Unit, including the toll-free complaint hotline number or the facility contact person.</td>
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<td>A review of the facility's policy and procedure manual on 10/30/2014 revealed a policy containing a list of patients rights and responsibilities and the OLC Complaint Unit toll-free complaint hotline and mailing address.</td>
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<td>On 10/31/2014 at approximately 10:30 a.m., an interview was conducted with a patient in the recovery room. The patient revealed to the surveyor that the facility did discuss patient rights but a copy was not given to them on admission. The patient acknowledged if he/she had a complaint they would contact the agency directly; however the patient reported he/she did not know that a complaint could be made to the OLC or the OLC's contact information.</td>
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<td>During the exit interview on 10/31/2014, Staff #1, Staff #2, Staff #5 and Staff #7 acknowledged the agency failed to display information on how to make a complaint with the facility contact person and the OLC Complaint Unit in the manner</td>
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<td><strong>T 155</strong></td>
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<td>required by this regulation and their own approved and established procedure.</td>
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<td><strong>T 175</strong></td>
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<td>12 VAC 5-412-220 C Infection prevention</td>
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<td>C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:</td>
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<td>1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);</td>
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<td>2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;</td>
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<td>3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);</td>
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<td>4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;</td>
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<td>5. Procedures for handling/temporary storage/transport of soiled linens;</td>
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<td>6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;</td>
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<td>7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment; (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;</td>
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**Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care (CDC, 2014), Key Recommendations for Safe Injection Practices in Ambulatory Care Settings**, page 11, the first two indicators state: "1. Use aseptic technique when preparing and administering medications. 2. Cleanse the access diephragms of medication vials with 70% alcohol before inserting a device into the vial." 

At PPMW-Falls Church, HCAs (Health Care Assistants) do not provide injections. HCAs do assist the providers who are wearing sterile gloves to draw up the local anesthetic into a syringe by placing and holding the multi-dose vial for the provider to insert the needle. Prior to insertion of the needle into the vial, the HCA will use aseptic technique and cleanse the diephragm with 70% alcohol. 

**Actions to correct the deficiency and prevent a recurrence:** To ensure the CDC's recommendations for safe injection practices in ambulatory care settings are followed:

1. The Abortion Coordinator (Nurse Practitioner) will review the 9 recommendations with all staff involved in the provision of abortion and practice the techniques pertinent to their tasks.
2. Abortion procedure training for HCAs will include the step of cleansing all medication vials with 70% alcohol.

**Actions to maintain compliance:** 

PPMW's New Clinical Employee Orientation Checklist has been revised and under the "Infection Control" section a new indicator was added – Preparation of injection vials. In addition, annual observations will include aseptic technique which includes preparation of multi-dose vials.
8. Procedures for appropriate disposal of non-reusable equipment;
8. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: Is not met as evidenced by:
Based on observation, interview, and review of CDC recommendation for Infection Protection for Outpatient Settings, it was determined that the facility failed to ensure infection prevention procedures necessary to prevent/control transmission of an infectious agent were followed.
Note: This deficiency was previously cited in the Summary Statement of Deficiencies dated 8/28/2012, related to staff failure to clean the tops of vials prior to a second puncture.
The findings included:
Observation of a procedure performed on 10/31/2014, revealed Staff #10 did not clean the top of a multi-use vial prior to the physician withdrawing medication for injection.
According to the CDC Guide to Infection Prevention for Outpatient Settings dated September 2014: Key recommendations for safe injection practices in ambulatory care settings: 1) Use aseptic technique when preparing and administering medications; 2) Cleanse the access diaphragms of medication vials with 70% alcohol before inserting a device into the vial.
An interview with Staff #10 and Staff #11 was conducted on 10/31/2014 at approximately 1:15
PM. Staff #10 stated he/she only cleansed the site after the top is originally removed, but not afterwards or between procedures. Staff #11 stated, "The vials need to be cleaned prior to each procedure."

T 380

12 VAC 5-412-360 B Maintenance

B. When patient monitoring equipment is utilized, a written preventative maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer’s specifications at periodic intervals, no less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

This RULE: is not met as evidenced by:
Based on observations, document review and interviews the agency failed to ensure that all electrical equipment had been inspected as documented by proof of preventative maintenance per the manufacturer’s recommendations as required in Section as required in Section 12 VAC5-412-360.

Note: This is a re-cite from 2012 related to staff’s failure to ensure all electrical equipment had been inspected.

The findings included:
During the tour of the clinic conducted on 10/30/2014 at 9:25 a.m., the following was observed: Exam room #2 was designated as the...
Procedure Room. A Triplite back up generator failed to have an updated preventive maintenance sticker indication it had been inspected for any potential electrical failures. The policy and procedure manual stated all equipment would be inspected annually.

In an interview with Staff #3 during the tour of exam room #2, reported he/she was unable to answer the surveyor in regards to the expired maintenance sticker. Staff #3 stated the surveyor would need to verify with Staff #2, because he/she did not utilize exam room #2 because he/she did not perform abortion procedures.

On 10/30/2014 at approximately 10:00 a.m., an interview was conducted with Staff #2. Staff #2 verified the generator's preventive sticker expired 02/2014 and would gather additional information. Staff #2 was asked to provide a list of annual equipment inspections for the surveyor to review.

On 10/31/2014 at 9:00 a.m., Staff #2 presented the survey team the facility's medical equipment inspection reports. The review of the equipment inspection reports revealed a Triplite power supply on the report for 8/15/2013, but failed to be included on the inspection report dated 3/26/2014. Staff #2 confirmed the Triplite power supply was not inspected for 2014, but he/she was not able to provide evidence the reason it was left off the list.

During the exit interview on 10/31/2014, Staff #1, Staff #2, Staff #5 and Staff #7 acknowledged that the facility failed to maintain the system in the manner required by this Virginia regulation.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

<table>
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<tr>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
<th>(X2) MULTIPLE CONSTRUCTION A. BUILDING ____________</th>
<th>(X3) DATE SURVEY COMPLETED 07/25/2018</th>
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<td>AF-0009</td>
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NAME OF PROVIDER OR SUPPLIER

RICHMOND MEDICAL CENTER FOR WOMEN

STREET ADDRESS, CITY, STATE, ZIP CODE

118 NORTH BOULEVARD
RICHMOND, VA 23220

<table>
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<td>Initial Comments</td>
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Two (2) Medical Facilities Inspectors from the Virginia Department of Health's Office of Licensure and Certification conducted an unannounced First Trimester Abortion Facility (FTAF) biennial licensure inspection on July 24, 2018 and July 25, 2018. The surveyors conducted observations, interviews and document reviews during the investigation process to determine compliance.

The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 03/22/2017). The deficiencies cited follow in this report.

| T 170              | 12 VAC5-412-210 B Quality Management                                                                                                                             |

The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.
Continued From Page 1

This RULE: is not met as evidenced by:
Based on interview and document review it was determined the agency's quality committee failed to evaluate staff concerns regarding patient care for adequacy and appropriateness of services or identify unexpected/acceptable trends and occurrences.

The findings included:

Staff Member #1 and the surveyor reviewed the agency's quality program at 4:07 p.m. on July 24, 2018. Review of the quality meeting minutes revealed the committee held meetings on May 08, 2017, July 10, 2017, September 18, 2017, November 13, 2017 and January 8, 2018. Staff Member #1 reported the committee had one meeting for 2018, at the time of the inspection.

Review of the minutes from the meeting on May 08, 2017, July 10, 2017, September 18, 2017, November 13, 2017 and January 8, 2018 did not include data related to "Staff concerns regarding patient care." Staff Member #1 reported four of the agency's staff completed the questionnaire. Staff Member #1 verified when the agency's staff failed to complete or turn in the questionnaires, the quality committee did not implement an action plan.

Staff Member #1 reported the committee dropped the area for lack of feedback from staff. Staff Member #1 reported the committee did not evaluate the non-engagement of the staff as an issue to pursue through quality. Staff Member #1 reported the quality committee did not utilize the lack of response to implement actions to identify unacceptable or unexpected trends.

A review of the agency's policy titled "Quality Management, Quality Assurance Process"
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<td>Improvement, QAPI&quot; read in part &quot;B. To ensure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences the following shall be evaluated: ...7. Staff concerns regarding patient care ....&quot; Staff Member #1 verified the agency's quality committee failed the follow the established policy and procedure.</td>
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<tr>
<td>T 175</td>
<td>12 VAC5-412-210 C Quality Management</td>
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<td>A quality improvement committee responsible for oversight and supervision of the program shall be established and at a minimum shall consist of: 1. A physician; 2. A nonphysician health care practitioner; 3. A member of the administrative staff; and 4. An individual with demonstrated ability to represent the rights and concerns of the patient. The individual may be a member of the facility's staff. In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.</td>
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This RULE is not met as evidenced by: Based on interview and document review it was determined the agency's quality committee failed to ensure it consisted of the required members. The membership of the agency's quality committee failed to include a physician and an individual with demonstrated ability to represent the rights and concerns of patients.
The findings included:

Staff Member #1 and the surveyor reviewed the agency's quality program starting at 4:03 p.m. on July 24, 2018. Review of the quality meeting minutes revealed the committee held meetings on May 08, 2017, July 10, 2017, September 18, 2017, November 13, 2017 and January 8, 2018. Staff Member #1 reported the committee had one meeting for 2018, at the time of the inspection.

Review of the minutes from the meeting of May 08, 2017, July 10, 2017, September 18, 2017, November 13, 2017 and January 8, 2018 listed two (2) members Staff Member #1 and Staff Member #8. Staff Member #1 reported the quality committee did not have a physician or an individual to represent the right and concerns of the patients. Staff Member #1 verified awareness that the agency's quality committee should include a physician and an individual to represent patient's rights and concerns.

Review of the agency's policy titled Quality Improvement Committee read in part "The Quality Improvement Committee is responsible for oversight and supervision of the program shall consist of: Administrator, Medical Director, Nursing Supervisor, [and] Office Manager. Staff Member #1 verified the agency's quality committee failed the follow the established policy and procedure.

Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and
improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

This RULE: is not met as evidenced by: Based on interview and document review it was determined the agency’s quality committee failed to provide evidence of an annual report to the governing body.

The findings included:

Staff Member #1 and the surveyor reviewed the agency's quality program at 4:18 p.m. on July 24, 2018. Review of the quality meeting minutes revealed the committee held meetings on May 08, 2017, July 10, 2017, September 18, 2017, November 13, 2017 and January 8, 2018.

The surveyor requested evidence that the quality committee reported annual findings to the governing body, as well as proof the governing body reviewed and acted on the quality report. Staff Member #1 reported the proof of the annual report existed in an email. Staff Member #1 reported he/she could not access the information at the time of the interview and review.

Review of the agency’s policy titled Quality Improvement Committee" read in part, "This committee shall meet annually and shall submit its findings to the Governing Authority. The committee shall review any reports of concern or deficiencies identified during the year and shall make recommendations for corrections and
T 185 Continued From Page 5

improvements. All corrective actions shall be acted on by the Governing Authority and shall be documented. Any identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the Governing Authority by the quality improvement committee."

The agency provided no further information prior to exit on July 25, 2017.

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;

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;
T 195 Continued From Page 6

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 observation, interview and document review, it was determined the facility staff failed to ensure policies and procedures relating to infection control and prevention during one (1) of one (1) procedures observed and two (2) of two (2) procedure room cleanings observed.

The findings include:

An observation was conducted starting at 2:38 p.m. on July 24, 2018 as Staff Member #2 entered the Procedure Room to clean and disinfect between patients’ procedures.

The observation revealed Staff Member #2 obtained at least two (2) disposable disinfectant cloths from a container. Staff Member #2 used the cloths to wipe the top surface of the black pads on the procedure table, the seat of the rolling stool, one side of the gel pad in the stirrup attached to the procedure table and the surface of one arm rest attached to the procedure table. Staff Member #2 did not clean or disinfect the sides or base of the procedure table. Staff Member #2 did not clean and disinfect the cart at the end of the procedure table where clean supplies were prepared. Staff Member #2 did not clean and disinfect the suction machine and cart utilized during the previous procedure.

At 2:45 p.m., Staff Member #2 prepared to exit the...
Procedure Room; Staff Member #2 informed the surveyor he/she had finished and Staff Member #3 would complete the set-up for the next patient. Staff Member #3 entered the room with clean linens for the procedure table. The surveyor inquired regarding the "wet contact time" for the disposable disinfectant cloths. Staff Member #3 stated, "Three (4) to four (4) seconds." Staff Member #3 allowed the top surface of the black pad to air-dry, then proceed to place the linens on the procedure table. Staff Member #3 place a disposable blue pad on the cart at the end of the procedure table, which had not been disinfected and set-up clean supplies. Staff Member #3 did not remove the blue disposable pad from the left-side armrest. The surveyor inquired regarding how Staff Member #3 knew which areas of the Procedure Room had been disinfected. Staff Member #3 reported he/she "set up the room" and Staff Members #1 or #2 actually cleaned and ensured disinfection of the room.

At approximately 2:48 p.m., Staff Member #1 entered the Procedure Room. Staff Member #1 picked up the right-side leg stirrup from the floor. Staff Member #1 disinfected the gel pad on both sides and reattached the stirrup to the procedure table with gel pad in place. Staff Member #1 did not clean or disinfect the metal stirrup. Staff Member #1 escorted the next patient into the Procedure Room.

During the end of the day meeting on July 24, 2018 the surveyor inquired regarding what items/areas of the Procedure Room needed to be cleaned and disinfected between patients. Staff Member #1 reported the procedure table especially where the physician sat during the procedure related to high potential of blood and body fluid splatter. Staff Member #1 included the cart near the end of the procedure table, the
suction machine and its cart and any other areas with visible blood/body fluid splatter. The surveyor informed Staff Member #1 of the findings during the observation and requested the policy.

The surveyor reviewed of job descriptions for Staff Members #2 and #3. Staff Member #2's job description included "10. Disinfect work area as needed." Staff Member #2's job description did not specify or clarify "work area." Review of Staff Member #3's job description included responsibility for "10. Cleanliness of assigned area."

Review of the agency's policy titled "Processing of Reusable Medical Equipment" stated the policy "Purpose: To prevent the spread of infection via reusable medical equipment by detailing levels of cleaning and disinfecting each type of equipment." The policy presented did not differentiate between cleaning and disinfection post procedure versus terminal cleaning of the Procedure Room.

On July 24, 2018 at 1:49 p.m., surveyors observed a surgical abortion procedure. Staff Member #1, the administrator of the facility, acted as the surgical assistant for the physician, Staff Member #4. Staff Member #1 stood beside the physician during the procedure and performed tasks such as assisting with medication preparation, removing tubing from the suction machine (with blood and body fluids contained inside), disposing of the tubing, and handling of products of conception (POC) contained in a glass jar. While acting as the assistant during the surgical procedure, Staff Member #1 wore scrubs and gloves with no outer gown or eye protection to guard against contact or splashes of blood or body fluids.

On July 24, 2018 at 2:06 p.m., surveyors observed
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<td>T 195</td>
<td>Continued From Page 9 cleaning of the procedure room after the surgical abortion outlined above. One of the clinic counselors, Staff Member #7, performed the primary cleaning. Staff Member #7 wiped the surgical bed with a disinfecting wipe and then the top of the surgical rolling table used for the storage of medical tools. Staff Member #3, after less than thirty (30) seconds and while the surgical bed remained wet, placed a sheet on the bed without allowing for the necessary disinfecting solution dwell time. The staff members cleaned no other items in the room to include the stirrups used during the procedure, the surgical lamp manipulated by the physician, or the physician’s rolling chair used during the procedure. Staff Members exited the room at 2:11 p.m. with five (5) minutes used to clean the area and a new patient entered the room at 2:15 p.m. with a nine (9) minute turn-around time from surgical patient to surgical patient. On July 24, 2018 at 2:15 p.m., surveyors asked Staff Member #3 if counselors are usually responsible for cleaning the procedure room between surgical procedures. Staff Member #3 advised &quot;anyone&quot; can clean the room but sometimes staff members help each other out. On July 25, 2018 at 11:18 a.m. during a telephone interview with Staff Member #1 with Staff Member #4 listening-in, Staff Member #1 advised counselors and other recovery room staff are capable of cleaning the procedure room. Staff Member #1 acknowledged the proper dwell time for the disinfection solution is two (2) minutes. Staff Member #1 further advised the following items should be cleaned in-between surgical abortion procedures: surgical bed, surgical tray with suction machine, floor near the area where the procedure occurs, and stirrups. Staff Member #1 further advised he/she does not wear a gown</td>
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<td>as the surgical assistant because he/she does not believe they are in the &quot;splash zone.&quot;</td>
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<td>A review of the facility's policy titled, &quot;Personal Protective Equipment&quot; states in part:</td>
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<td>&quot;Wear a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated.&quot;</td>
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<td>&quot;Wear mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids.&quot;</td>
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<td>A review of the facility's policy titled, &quot;Environmental Surfaces Cleaning&quot; states in part:</td>
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<td>&quot;Cleaning of procedure room between procedures must be done with a facility-approved, EPA-registered disinfectant.&quot;</td>
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<td>Clean hands and put on gloves</td>
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<td>Collect and remove waste</td>
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<td>Collect and remove all soiled linen</td>
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<td>Remove gloves and clean hands</td>
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<td>Use a cloth dampened in disinfectant solution to clean and disinfect horizontal surfaces that have come in contact with a patient or body fluids, including blood pressure cuffs, tourniquets and leads</td>
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<td>Clean suction canisters</td>
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<td>Clean and disinfect bed</td>
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<td>When cleaning is complete, remove gloves and clean hands.&quot;</td>
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<td>An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or</td>
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T 355 Continued From Page 11

surgical service. If medically indicated, it shall include, but not be limited to the following:

1. Patient identification;

2. Admitting information, including patient history and physical examination;

3. Signed consent;

4. Confirmation of pregnancy;

5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist’s report of tissue, and radiologist’s report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses’ progress notes;
   h. Condition at time of discharge;
   i. Patient instructions (preoperative and postoperative);
   j. Names of referral physicians or agencies; and

6. Any other information required by law to be maintained in the health information record.

This RULE: is not met as evidenced by:
Based on interview and document review it was determined the facility staff failed to ensure:

1. Voluntary Termination of Pregnancy consents were complete for one (1) of thirteen (13) patients included in the survey sample. (Patient #8)

2. An accurate and complete medical record, namely proper physician orders, for four (4) out of thirteen (13) patients included in the survey sample (Patients # 1, 4, 8, 9).
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The findings included:

1. Review of Patient #8’s medical record indicated the physician terminated Patient #8’s pregnancy under monitored anesthesia care (MAC) on February 10, 2018. Patient #8 signed the back of the consent, but the front side of the form did not have the required initials by the patient. The form explained the patient's initials verify the facility’s counselor had reviewed and explained each point as well as giving the patient time to ask questions. The front page included a verification by the patient related to past medical history, last menstrual period, notice of deemed consent for HIV (Human Immunodeficiency Virus) testing, risk associated with anesthesia, the provision of “Pain Killers”, consent for collecting laboratory studies, and the complications associated with the termination of pregnancy.

During an interview on July 24, 2018 at 1:18 p.m., Staff Member #1 verified the front of the form was blank. Staff Member #1 acknowledged Patient #8’s consent for voluntary termination of pregnancy failed to provide proof facility staff had reviewed the risks and other information with the patient.

2. Incomplete discharge orders:

a. Review of Patient #1’s medical record indicated the physician terminated Patient #1’s pregnancy under MAC on December 12, 2017. The physician failed to document the date and time of his/her signature on the discharge order.

During an interview on July 24, 2018 at 1:23 p.m., Staff Member #1 verified the physician had failed to date and time his/her signature.
Continued From Page 13

b. Review of Patient #8's medical record indicated the physician terminated Patient #8's pregnancy under MAC on February 10, 2018. The physician failed to sign Patient #8's discharge order. The discharging nurse failed to sign with data and time related to Patient #8's discharge.

During an interview on July 24, 2018 at 1:18 p.m., Staff Member #1 verified the physician had failed to sign Patient #8's discharge order and the discharging nurse failed to sign off on the discharge criteria, status and time of Patient #8's discharge.

c. Review of Patient #9's medical record indicated the physician terminated Patient #9's pregnancy under monitored anesthesia care on February 24, 2018. The physician signed the discharge order but failed to document the date and time his/her signature.

During an interview on July 24, 2018 at 1:03 p.m., Staff Member #1 verified the physician had failed to date and time his/her signature on the discharge order.

d. On July 24, 2018 at 12:03 p.m., surveyors conducted a review of the medical record for Patient #4. The review revealed a surgical abortion on March 10, 2018. Staff Member #4 performed the abortion but failed to issue a proper discharge order after the procedure as the discharge area in the medical record did not contain a signature or date.

12 VAC5-412-310 Record Storage

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable
federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.).

This RULE: is not met as evidenced by:
Based on observation, interview and document review, it was determined the facility failed to make provisions for the safe storage of medical records.

The findings include:

On Jul 24, 2018 at 9:15 a.m., surveyors entered the facility to begin an inspection. Staff Member #6 provided a greeting. Staff Member #6 walked surveyors back to the medical file storage room. Along the way, no locked doors or other security measures were encountered to obstruct someone from entering the area where medical files are stored. Additionally, surveyors found the door to the medical file storage room open and the file cabinets that contained the medical files unlocked.

On the afternoon of July 24, 2018 surveyors realized there were times when this area had little, if any, staff in the area who could see if someone was in the file area.

On July 24, 2018 at 3:00 p.m., the medical records remained in unlocked file cabinets within the unsecured room.

On July 24, 2018 at 3:47 p.m. as surveyors reviewed paperwork inside the medical records room, they were startled by someone not associated with the facility, entering the staff lounge adjacent to the medical file room. A staff member did not escort this person and he/she stated staff allow him/her to enter the staff lounge (adjacent to the unsecured medical file storage...
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<td>room) during the day to enjoy a soft drink.</td>
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<td>On July 25, 2018 at 11:18 a.m. during a telephone interview with Staff Member #1 while Staff Member #4 listened-in, Staff Member #1 acknowledged there are times when a staff member is not present at the front desk area. Staff Member #1 further advised the person who entered the staff lounge was familiar to the staff and they encourage him/her to come in to get a drink. Staff Member #1 further stated regarding the unlocked medical file storage room, &quot;[the] door does lock, maybe they should use it [the lock] after hours or during.&quot;</td>
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<td>A review of the facility's policy titled &quot;Health Information Records&quot; states in part:</td>
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<td>&quot;Medical records will be maintained consistently in accordance with state and federal guidelines.&quot;</td>
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<td>T 395</td>
<td>12 VAC5-412-330 Abortion Facility Security and Safety</td>
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<td>The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the abortion facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not be limited to safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services.</td>
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<td>This RULE: is not met as evidenced by: Based on observation, interview and document review it was determined the facility failed to implement policies and procedures to ensure safety within the abortion facility and on its grounds.</td>
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The findings include:

On July 24, 2018 at 9:15 a.m., surveyors arrived at the abortion facility to begin a biennial survey. As the inspection began, the surveyors observed a lack of security of the facility.

On July 24, 2018 at 9:48 a.m., surveyors conducted a tour of the facility with Staff Member #2. Upon approaching the facility entrance, surveyors inquired about building security. Staff Member #2 advised the surveyors of the current process. During the tour, surveyors learned that patients and staff are sometimes in different parts of the facility, requiring them to be in/move through unsecured areas.

On the afternoon of July 24, 2018 surveyors

On July 25, 2018 at 11:18 a.m. during a telephone interview with Staff Member #1 while Staff Member #4 listened-in, Staff Member #1 advised of some of the security plan. Staff Member #1 acknowledged there are times when a staff member is not present at the front desk area.

A review of the facility's policy titled "Abortion facility security and safety" states in part:

"Staff will..."
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NAME OF PROVIDER OR SUPPLIER: RICHMOND MEDICAL CENTER FOR WOMEN

STREET ADDRESS, CITY, STATE, ZIP CODE: 118 NORTH BOULEVARD, RICHMOND, VA 23220

STATE FORM 03199 YUJV11

STATE OF VIRGINIA

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0009

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED: 07/25/2018

Printed: 08/24/2018
FORM APPROVED

Americans United for Life
<table>
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<tr>
<th>ID</th>
<th>T000</th>
<th>12 VAC 5-412 Initial comments</th>
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<td>An unannounced biennial licensure survey was conducted November 3 - 4, 2014 by three Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics (Effective 06/20/2013). Deficiencies were cited.</td>
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<td>E. The facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training. This RULE: is not met as evidenced by: Based on personnel file review and staff interview it was determined the agency failed to show evidence documenting ongoing education and annual participation in fire safety and infection prevention in-service training for one (1) of twelve (12) employees in the survey sample (Employee #8). The findings include: A review of twelve (12) personnel files was conducted on November 3, 2014, between the hours of 3:00 PM and 3:30 PM. The personnel file for Employee #8 failed to show documentation of ongoing education including</td>
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Continued From Page 1

annual participation in fire safety and infection prevention in-service training.

An interview was conducted with Staff Member #2 on November 4, 2014 between the hours of 3:15 and 4:00 PM, acknowledging that this facility failed to ensure ongoing education including annual participation in fire safety and infection prevention in-service training for Employee #8.

12 VAC 5-412-170 H Personnel

H. Personnel policies and procedures shall include, but not be limited to:
1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;
2. Process for verifying current professional licensing or certification and training of employees or independent contractors;
3. Process for annually evaluating employee performance and competency;
4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and
5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.

This RULE: is not met as evidenced by:
Based on personnel file review and staff interview it was determined the facility failed to have documented evidence for verifying current professional licensing and/or certification and training of employees or independent contractors for two (2) of twelve (12) employees in the survey sample (Employee #2 and 4).
A review of twelve (12) personnel files was conducted on November 3, 2014, between the hours of 3:00 PM and 3:30 PM. The files for Employees #2 and #4 failed to contain all the required components for licensure as stated in the regulations governing the licensure of Nurse Practitioners.

The personnel file for Employee #2 contained a current license for Registered Nurse (RN) and a current license for Nurse Practitioner with the specialty - Anesthesia, but failed to contain evidence of his/her Professional certification consistent with his/her specialty area, Certified Registered Nurse Anesthetist (CRNA).

The personnel file for Employee #4 contained a current license for Registered Nurse and an expired license for Nurse Practitioner with the specialty of Anesthesia. The file also contained an expired Professional certification for Certified Registered Nurse Anesthetist (CRNA).

An interview was conducted with Staff #2 on November 4, 2014 between the hours of 3:15 and 4:00 PM. Staff #2 acknowledged that this facility failed to obtain the current license for Nurse Practitioner specialty - Anesthesia and professional certification - Certified Registered Nurse Anesthetist (CRNA).

12 VAC 5-412-210 A Patients' rights

A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory
Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.

This RULE: is not met as evidenced by:
Based on observations, select document review and interviews it was determined that this facility failed to implement their policies and procedures related to patient's rights and responsibilities for one (1) of seventeen (17) patients (Patient #16). Specifically the facility failed to provide safe considerate and respectful care;
Know the names and roles of Care-givers;
Be fully informed of risks, benefits, expected outcomes and alternatives treatments for scheduled procedures and,
Confidentiality of your medical record

The findings include:

1. On 11/4/14 from 12:50 PM to 2:10 PM: Patient #16 was selected as a tracer patient and was observed from admission to discharge. The following observations were made during that time:

Patient #16 was directed to the changing room by Staff Member #1. The Surveyor met Staff Member #1 outside the changing room. Staff Member #1 stated that she instructed Patient #16 to remove all her clothing from the waist down and put on the hospital gown provided. Patient #16 opened the changing room door when she was ready. Patient #16 was then escorted to the procedure room by the Surveyor and Employee #1, 2 and 6. Patient #16 attempted to hold the back of the gown closed with her hand, as we
**T 135** Continued From Page 4

walked down the hall but at one point, Patient #16's buttock and tattoo were revealed.

Once inside the Procedure Room, Staff Members #1 and 5 assisted Patient #16 onto the exam table. Staff Member #2 did not stay for the procedure. Staff Member #3 arrived and appeared to prepare for the procedure, but did not acknowledge Patient #16. The surveyor introduced herself/himself to Staff Member #5, and asked for their name and title. Staff Member #3 asked that we not talk about who we are at that time.

Staff Member #5 was at Patient #16's left side, Staff Member #3, walked up to the patient's right side, did not introduce them self, did not call Patient #16 by name, did not explain what was about to occur, remained silent, took the patient's right arm, and placed an intravenous catheter (IV) into the patient's vein with the assistance of Staff Member #1. Staff Member #3 remained silent while administering medications through the IV. Staff Member #3 then went to the foot of the exam table, spread the patient's legs, and hung them over the stir-ups. Neither foot was placed in the foot rest. No drape was used to cover the patient leaving her completely exposed from the waist down. Staff Member #1 then introduced Staff Member #3 to the patient and provided a brief medical history to Staff #3. Patient #16 appeared to be falling asleep during these introductions.

The procedure was complete at 1:20 PM. the patient had been exposed from the waist down for 30 minutes. Staff Member #3 left the room. Staff Members #1 and 5 prepared the patient for transfer to the recovery room by removing the patient's legs from the stir-ups and placing them on the foot of the exam table and pulling her gown down from over her waist. A stretcher was
Continued From Page 5

wheeled into the procedure room but the wheels were not locked. Staff Members #1 and 5 woke the patient up and asked her to move from the exam table to the stretcher. Once the patient was on the stretcher, Staff Member #5 took the sheet that was under the patient on the exam table and used it to cover her on the stretcher, and then wheeled her into the recovery room.

Staff Member #1 was asked if the wheels on the stretcher are able to lock. Staff Member #1 stated, "Yes, but I never lock them. I use my body. I would never let them fall."

Best Practices: Evidence-based Nursing Procedures Lippincott, Williams & Wilkins 2007 states, "Place the stretcher parallel to the bed, and lock the wheels of both."

On 11/4/14 at 1:45 PM Staff Member #6 was observed in the recovery room assisting Patient #16 in transfer from the stretcher to a chair without locking the wheels of the stretcher. At 1:50 PM Staff Member #6 offered Patient #16 cookies, snacks, and drinks. Patient #16 declined and reminded staff that she has allergies to animal protein. The patient's medical record did reveal a notation of the patient's allergies. The patient was observed explaining her allergies to the staff present. The patient did wear a personalized bracelet on her right wrist that cautioned others of her allergies.

On 11/4/14 at 1:55 PM Staff Member #4 was observed in the recovery room discussing with Patient #16, her personal and confidential information related to her procedure, health history, birth control plans, and follow-up care all in the presence of another patient.

2. On 11/4/14 at 3:00 PM a review of this facility's
Patient's Rights and Responsibilities was conducted which revealed that patients have the right to the following:

"Safe considerate and respectful care; Privacy, personal and informational; Be kept well-informed and participate in your healthcare decisions; Know the names and roles of Care-givers; Be fully informed of risks, benefits, expected outcomes and alternatives treatments for scheduled procedures; Confidentiality of your medical record; Review your medical record; Consult with a specialist; Participate in your pain management, treatment to enhance your recovery; Accommodation of special needs for handicapped or sensory impaired persons."

3. On 11/4/14 at 4:15 PM an interview was attempted with Staff Member #3, who declined to participate.

4. On 11/4/14 beginning at 4:14 PM an exit interview was conducted with Staff Members #1 and 2. Staff Member #1 acknowledged having to assist patients, by holding the back of their gowns in the hall, so the patient is not exposed. Staff Member #1 also acknowledged that Patient #16 was exposed from the waist down during the 30 minute procedure and acknowledged that drapes were not used to cover patients during procedures.

Staff Member #1 was interviewed regarding the process for the doctor identifying himself to the patient. Staff Member #1 acknowledged that the doctor did not introduce himself to the patient.

B. The following shall be evaluated to assure
### T 320

Continued From Page 7

adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

This RULE: is not met as evidenced by:

Based on select document review and interview it was determined that the facility failed to ensure staff concerns regarding patient care were included in the annual evaluation of the program.

The findings include:

On 11/04/14 Staff Member #2 was interviewed regarding the Quality Program. She stated, "We do not have any documentation related to staff concerns regarding patient care."

### T 325

12 VAC 5-412-300 C Quality assurance

C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:

1. A physician
2. A non-physician health care practitioner;
3. A member of the administrative staff; and
4. An individual with demonstrated ability to represent the rights and concerns of patients.

The individual may be a member of the facility's staff. In selecting members of this committee, consideration shall be given to the candidate's
T 325 Continued From Page 8

abilities and sensitivity to issues relating to quality of care and services provided to patients.

This RULE: is not met as evidenced by:
Based on document review and interview it was determined the facility failed to have a quality improvement committee that included a physician, a health care provider and an individual with the demonstrated ability to represent the rights and concerns of the patients.

The findings include:

On 11/04/14 Staff Member #2 was interviewed regarding the quality improvement committee. She stated, "I think I may have misunderstood how this was suppose to be working. There is only me and I report to the governing board what is going on related to quality. We do not have any meetings about quality."

T 340 12 VAC 5-412-310 Medical records

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:
1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
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<th>ID</th>
<th>Prefix Tag</th>
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<th>Description</th>
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<td>T 340</td>
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<td>e. Surgical medication and medical treatments;</td>
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<td>f. Recovery room notes;</td>
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<td>g. Physician and nurses' progress notes,</td>
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<td>h. Condition at time of discharge,</td>
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<td>i. Patient instructions, preoperative and postoperative; and</td>
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<td>j. Names of referral physicians or agencies.</td>
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This RULE: is not met as evidenced by: Based on document review and interview, it was determined that the facility failed to maintain accurate and complete medical records. The records contained insufficient information to satisfy the need for medical or surgical services for eleven (11) of seventeen (17) patient's medical records (Patient #1 - 5, 9, 11, 12 and 15 - 17).

The findings include:

1. On November 4, 2014 seventeen (17) patients' medical records were reviewed. Eleven (11) of seventeen (17) patients' medical records failed to be complete and accurate.

   a. Patient #3's medical record failed to contain a discharge date and time with a nurse and physician's signature.

   b. Patient #4's medical record failed to contain a discharge date and time with a nurse's signature

   c. Patient #11's medical record failed to contain the documented Estimated Date of Conception (EDC) or Gestational age of the fetus and, the documented date and time of pre op teaching, counseling and family planning.

2. The following medical records were reviewed on 11/04/14 and the findings were shared with
Staff Member #2 who audits the medical records for accuracy and completeness.

a. Patient #1's medical record did not contain a date and time of discharge noted by the physician.

b. Patient #9's counseling note found in the medical record was incomplete. The record did not contain information related to the birth control method discussed, no after care was described and there was no signature or date as to who performed the counseling. In Patient #9's Pre Op Anesthesia record the following information was noted: Tylenol #3 appeared as though 13 tabs were given and also there were no initials, Versed 2 mg was intubated with no time or amount given and Fentanyl 100 mcg IV was checked with no initials, no amount and no time given was noted.

c. Patient #10's medical record for Pre Op Anesthesia contained documentation that Versed 2 mg and Fentanyl 100 mcg were given at 4:05 but there was no record of who gave the medication or the results of the medication. Also, the patient's medical record did not contain a condition at the time of discharge.

d. Patient #12's operative report noted the following, "The cervix was dilated to a size _____ (left blank) Pratt dilator. The uterus was evacuated with a size ___ (left blank) cannula."

Patient #12's medical record did not contain any information related to recovery or any documentation on the progress notes by the nurse or physician.

e. Patient #15's operative report noted, "The cervix was dilated to a size ____ (left blank) Pratt dilator." Patient #15's medical record indicated the received Xanax (a medicine for anxiety), but no amount was documented or who gave the
medication.

f. Patient #17's medical record indicated that the patient was given Versed 2 mg and Fentanyl 100 mcg but the record did not contain documentation of who gave the medication or the results of the medication. Patient #17's operative report had the following missing information, "The cervix was dilated to a size ____ (left blank) Pratt dilator." The recovery room note did not indicate if Patient #17 was experiencing any bleeding, the type, amount or if the patient was experiencing the passing any clots.

g. On 11/04/14 the medical record of Patient #2 was reviewed and revealed the following: The form titled, "24 Hour Informed Consent," was signed by a staff member on 7/25/14 at 3:33 P.M. but the form did not contain the patient's signature indicating that she had received all necessary information at least 24 hours in advance of the procedure.

h. On 11/04/14 the medical record of Patient #5 was reviewed and revealed the following: The form titled, "24 Hour Informed Consent," was signed and dated by Patient #5 and a staff member on 6/26/14, except in the top left corner under the heading for, "Today's Date" where it is dated 6/25/14.

On 11/4/14, an interview and a review of Patient #5's medical record was conducted with Staff Member #2, who acknowledged Patient #5's medical record indicated an initial visit and procedure was done on 6/26/14. Staff Member #2 stated, "It does look confusing. She may have come in and registered on 6/25/14."

i. On 11/04/14 the medical record of Patient #16 was reviewed. The form titled, "24 Hour Informed
Consent," in the record was dated for 9/10/14, crossed out, and replaced with 11/4 next to the patient's signature. The staff signature and date remained unchanged. The top of the form, where credit card information and ultrasound information is provided was documented in pencil.

The form titled, "Ultrasound Certification Form For Patients who Live Less Than 100 Miles From The Facility Where The Abortion Is To Be Performed," found in Patient #16's record has three questions requiring an accept/decline answer. Question #2 states, "I was offered an opportunity to receive a printed copy of the image produced by my ultrasound examination, and I accept/decline." The box for accept and the box for decline were checked, and the form was signed and dated by the patient. There was no documented evidence to support the answer to question #2 was reviewed or clarified with the patient.

The form titled, "Post operative anesthesia instructions," had the date 9/10/14 crossed out and replaced with 10/9/14 written above it. Then 10/9/14 was crossed out and 11/4/14 was written. There were no initials or notations explaining the changes in the dates.

The form titled Consent To Voluntary Abortion was dated for 10/9/14, crossed out and re-dated for 11/4/14. There were no initials or notations explaining the changes in the dates.

The Pre-Op note dated for 11/4/14 contained the following documentation:
Under the heading for the "Time" of the procedure, the time is crossed out two (2) times and is illegible.
Under the heading for Pre-Op Anesthesia, the documentation for Versed and Fentanyl Initial and Time are crossed out and illegible.
Under the heading of Operative Procedure, a
Continued From Page 13

space is provided to document the area an IV was started, a notation was made in that area, but is illegible.
In the space provided for notes, there are two (2) markings that are illegible.
Under the heading: Other Medication/Lab Work, next to Pitocin: IM is crossed out there is a scribble and a notation that is illegible.

On 11/4/14 at 4:15 PM, an interview was conducted with Staff Members #1 and 3. Staff Member #1 acknowledged that the patient's record failed to be accurate and complete. Staff Member #3 looked at the form titled, "24 Hour Informed Consent" with the top portion filled out in pencil, turned to Staff Member #1, and said, "She's got a point with that." Staff Member #3 declined to continue with the rest of the interview and left the room.

12 VAC 5-412-360 A Maintenance

A. The facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be all be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

This RULE: is not met as evidenced by:
Based on observations and interview it was determined the facility failed to have a means for a patient to call for help from the recovery room bathroom.

The findings include:
An interview and tour was conducted simultaneously with Staff Member #1 on 11/3/14 beginning at 3:00 PM. Staff Member #1 acknowledged that there was no emergency system in place for patients to use to call for help when using the Recovery Room bathroom.
Twelve Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted an unannounced Licensure Revisit survey to the initial survey performed May 15, 2012 through May 16, 2012. The Revisit survey was conducted March 26, 2013. The following are citations from the initial survey, which were not corrected and therefore repeat citations:

12 VAC 5-412-220 (C) [Infection prevention]
12 VAC 5-412-260 (C) [Administration, storage and dispensing of drugs]
12 VAC 5-412-380 [Local and State Codes and standards].

The following citation is a new finding:
12 VAC 5-412-170 (H) [Personnel].

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 12/29/2011)

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**Laboratory Director's or Provider/Supplier's Representative's Signature**

**Title**

**Date**
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<tr>
<th>ID</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID</th>
<th>PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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<td>T095</td>
<td>Continued From Page 1</td>
<td>Health Professions. This RULE: is not met as evidenced by: Based on employee record review and staff interview, the center staff failed to ensure job descriptions for employees were reviewed at least annually for one (#4) of thirteen (#1-#13) employee records reviewed as required in Section 12 VAC 5-412-170. H.3. The findings included: 1. On March 26, 2013, at 11:00 a.m., employee records were reviewed, in the facility's office. Of the thirteen records reviewed, one employee (#4) failed to have evidence that an annual job performance was conducted. Employee #4 was hired on July 12, 2013. Review of the Policy and Procedure manual stated that job evaluations would be performed annually. 2. On March 26, 2013, at 12:05 p.m., Staff #1 acknowledged during interview, that the annual evaluations were not completed for Staff #4.</td>
<td>T095</td>
<td>Continued</td>
<td>Incomplete areas. Completion date April 13, 2013.</td>
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<td>T175</td>
<td>12 VAC 5-412-220 C Infection prevention</td>
<td>C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following: 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers); 2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies; 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures); 4. Procedures for handling, storing and</td>
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transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
(i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
(ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
(iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer’s recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: is not met as evidenced by: Based on observations and interview it was determined the facility failed to ensure the implementation of infection prevention practices as required in Section 12 VAC 5 412-220 C., as evidenced by:
### T 175 Continued From Page 3

1. Dried blood was observed on the outside metal cover of the exam light in the procedure room.
2. Gel pads used in the leg rests for the procedure table had multiple tears. The non-intact areas prevented proper disinfection of the gel pads.
3. One of the metal leg and foot support's to the procedure table had a dried yellowish brown stain on the footrest portion.
4. Snacks provided for patients were multiple unwrapped items in a large Tupperware like container which increased cross-contamination of the food products.

The findings were:

A tour of the facility was conducted on March 26, 2013 with the Administrator beginning at 10:10 A.M.

While in the procedure room this inspector noted a yellowish brown dried substance on the footrest portion of a leg and footrest support for the procedure table. This inspector pointed to the dried substance on the footrest and asked the Administrator what she thought it was. The Administrator responded, "Oh, that's Betadine," and then got a disinfectant wipe and gloves to clean it off. Betadine is a brown liquid that is used to clean surgical areas before a procedure is started. The facility uses large gel pads to cover and cushion the leg supports for the table. Both gel pads had multiple small tears in them preventing the proper disinfection of their surface.

When examining the gel pads more closely the Administrator commented, "We can order more." The exam light next to the procedure table also had a dried reddish brown stain on the metal lamp shade and again this inspector pointed to it and asked, what do you think this is? The

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**Summary Statement of Deficiencies**

- (Each deficiency must be preceded by full regulatory or LSC identifying information)

**Provider's Plan of Correction**

- (Each corrective action should be cross-referenced to the appropriate deficiency)
T 175  Continued From Page 4

Administrator looked at the light and responded, "That's blood," and proceeded to clean it off.

A tour of the Recovery room followed the procedure room tour. Sitting on top of the nourishment refrigerator was a large Tupperware type container that appeared to have unwrapped cookies and crackers inside. The Administrator stated, "That is food for the patient's, we used to put them in individual baggies but I guess we got away from that and we shouldn't have."

T 275  12 VAC 5-412-260 C Administration, storage and dispensing of dru

C. 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. 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 observations and staff interviews it was determined that the facility's staff failed to discard expired medications and medications that had not been dated when opened as required in Section 12 VAC 5-412-220 C..

The findings included:

An observation and interview was conducted on March 26, 2013 from 10:10 a.m. to 11:30 a.m. with Staff #1 during the initial tour of the procedure room and Recovery Room. The observation by both Staff #1 and this inspector revealed the following medications were expired and available for administration:

50% Dextrose 25 grams expired 7/1/12,
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<th>ID</th>
<th>PREMISE</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID</th>
<th>PREMISE</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tr>
<td>T 275</td>
<td>Continued From Page 5</td>
<td></td>
<td>1 vial Vasopressin 30 Units/ml (milliliter) expired June 2012,</td>
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<td>T 275</td>
<td>Crash cart drugs which had expired were discarded.</td>
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<td>1 vial Lidocaine 2% 20 mg/ml 100 mg (milligrams) expired January 2013,</td>
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<td>list of drugs were reviewed for necessity</td>
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<td>10% Calcium Chloride 100 mg/ml expired June 2012,</td>
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<td>before placing order for replacement.</td>
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<td>1 glass Abboject of Epinephrine 1:10,000 expired February 1, 2013,</td>
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<td>Lists of drugs have been updated.</td>
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<td>2 ampoules of Atropine 1 mg expired December 2012,</td>
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<td>Nurses have been instructed to check the crash cart weekly for expired drugs.</td>
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<td>2 ampoules of Isuprel 1:5000 expired January 1, 2013,</td>
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<td>2 ampoules of Epinephrine 1:1000 expired October 1, 2012,</td>
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<td>4 vials of Adenosine 3 mg/ml expired January 2012,</td>
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<td>3 ampoules of Methylene 20 mg expired January 2013</td>
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<td>The following medications were not dated when opened:</td>
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<td>One tube of KY jelly.</td>
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<td>12 VAC 5-412-380 Local and state codes and standards</td>
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<td>Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001. Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced</td>
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Americans United for Life
Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.

Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements.

This RULE: is not met as evidenced by:

Based on interview and facility tour it was determined the facility failed to have an architect’s attestation and failed to meet FGI (AIA) Guidelines for Chapters 3.1 and 3.7 as required in Section 12 VAC 5-412-380.

The findings include:

1. On March 26, 2013 a facility tour was conducted with the Administrator between 10:10 a.m. and 11:30 a.m.

The facility failed to have an attestation from a licensed Architecture stating that the facility met the required FGI (AIA) guidelines. There was no over head shelter for Buildings #1 and #2 to protect patients from inclement weather. The refrigerator that housed nourishments for the clients and a small compact refrigerator both in the Recovery Room; failed to have documentation of a temperature logs for the refrigerator. No temperature control or separate ventilation was noted in the Clean Storage Room. The facility’s Public Corridors failed to meet the minimum 5 feet width.

The Administrator was unable to provide documentation that the insulation provided conservation of energy, protected personnel,
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<th>(X5) COMPLETE DATE</th>
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<td>T 400</td>
<td>Prevented vapor condensation and reduced noise. Insulation must have a flame-spread rating of 25 or less and a smoke-developed rating of 50 or less in accordance with NFPA 255. The facility was unable to provide any information for HVAC ductwork and no manual for the fire system was available as required.</td>
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<td>It is ultimately the administrator who is responsible for ensuring adherence to regulations. Temperature logs are to be reviewed by the administrator to ensure that temps are in proper range.</td>
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2. On March 26, 2013 at 12:10 p.m., an interview was conducted with the Administrator in the agency's office. The Administrator acknowledged that the facility was unable to provide evidence that the facility met the state and local codes and building ordinances.
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<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>COMPLETE DATE</th>
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<tr>
<td>T 000</td>
<td>12VAC5-412 Initial Comments</td>
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<td>An unannounced First Trimester Abortion Facility (FTAF) biennial licensure inspection was conducted on August 08, 2016. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the inspection. The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)</td>
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<tr>
<td>T 355</td>
<td>12VAC5-412-300 Health Information Records</td>
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<td>An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses' progress notes, h. Condition at time of discharge, i. Patient instructions, preoperative and postoperative; and</td>
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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**AF-0004**

**NAME OF PROVIDER OR SUPPLIER**
A TIDEWATER WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**
891 NORFOLK SQUARE
NORFOLK, VA 23502

**STATE FORM**

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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<td>T 355</td>
<td>Continued From Page 1</td>
<td>T 355</td>
<td>So there is a designated line for the Recovery Room Attendant to initial, date &amp; time. We are conducting an audit of charts one day a week for 4 weeks to ensure the physician's signature is present &amp; to ensure the Recovery Room Attendant's initials are present. We will also add these to the Medical Records Evaluation Tool which is a part of quarterly Quality Assurance to monitor to make sure physician is signing medical history &amp; Recovery Room Attendant is initialing the Surgical &amp; Recovery &amp; Discharge Record. The admin director is in charge of Quality Assurance.</td>
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</table>

j. Names of referral physicians or agencies.

6. Any other information required by law to be maintained in the health information record.

This RULE: is not met as evidenced by:
Based on document review and interview, it was determined the facility failed to ensure the health information for four (4) of twenty (20) patients (Patients #5, 10, 12 and 13) were accurate and complete; one record did not have the H&P (history and physical) signed by the physician and did not have the initials of the employee who completed the recovery room assessment and three additional records did not have the initials of the employee who completed the recovery room assessment documented.

The findings include:

On August 08, 2016 the medical records of twenty (20) patients were reviewed and the following information was noted to not be present:

Patient #5's medical record did not have a physician's signature on the H&P noting it had been reviewed by the physician and there were no initials next to the date and time for the recovery room attendant.

Patient #10's medical record did not have initials next to the date and time for the recovery room attendant.

Patient #12's medical record did not have initials next to the date and time for the recovery room attendant.

Patient #13's medical record did not have initials next to the date and time for the recovery room attendant.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**Provider/Supplier/Clinic Identification Number:** AF-004

**Multiple Construction**
- Building: ______________________
- Wing: ______________________

**State of Virginia**

**NAME OF PROVIDER OR SUPPLIER**
A TIDEWATER WOMEN'S HEALTH CLINIC

**Street Address, City, State, ZIP Code**
891 NORFOLK SQUARE
NORFOLK, VA 23502

**SUMMARY STATEMENT OF DEFICIENCIES**
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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**ID | Prefix | Tag | Provider's Plan of Correction**
(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

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*The countertops in the two procedure rooms have been removed and replaced. The countertop in central sterile has been repaired. The nurses' desk in the Recovery Room has been replaced. The doctor's desk has been repaired. The ultrasound room floor has been repaired and resealed at the seam. The wheelchair arms have been replaced. We have added each item to the OHC Deficiency Checklist.*

**The findings include:**

- On Monday, August 08, 2016 during facility tour the following was observed:
  - The countertops in the two (2) procedure rooms and central sterile had exposed wood. The nurse's desk in the recovery room and the doctor's desk, used for medication preparation, had exposed wood. The floor in the ultrasound room had cracks.

**STATE FORM**

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**Amberly United for Life**

**VDH/OLC**
in the tile. The wheelchair used to transport patients had one cracked arm on the right and the arm on left was broken with a piece missing from the arm. These areas will not allow for sanitization.

The findings were discussed during interview with Staff Members #1 and #5 on Monday, August 8, 2016 at 4:00 p.m. This checklist is performed during quarterly Quality Assurance. This will ensure surfaces are being maintained in good repair. The admin director is in charge of Quality Assurance.
Initial Comments

An unannounced Licensure Biennial survey was conducted August 28 and 29, 2018 by two Medical Facilities Inspectors with the Virginia Department of Health's Office of Licensure and Certification.

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective March 22, 2017.)

12 VAC5-412-220 C Infection Prevention

Written policies and procedures for the management of the abortion facility, equipment and supplies shall address the following:

1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);

2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;

3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);

4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;

5. Procedures for handling/temporary storage/transport of soiled linens;

6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;

The table in Ultrasound Procedure Room #2 are being recovered. All table will have rusted areas sanded and repainted. Procedure Room #1 walls will have new formula like trim reapplied. Procedure Room #1 will be patched where necessary and repainted. The 4 reclining chairs will have the finish restored on all arm rests and levers. Blood pressure cuff barriers were used as used with each patient to minimize the transmitting infection risk.
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
(i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
(ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
(iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved.

The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;

8. Procedures for appropriate disposal of non-reusable equipment;

9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;

10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;

11. An effective pest control program, managed in accordance with local health and environmental regulations; and

12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observation and interview, the facility...
T 200 Continued From Page 2

failed to ensure reusable medical equipment was cleaned/disinfected between patient use and failed to ensure patient care equipment were able to be cleaned and disinfected between use in four (4) areas observed.

The findings include:

On 8/28/18, during the initial tour of the facility, two (2) Procedure Rooms, one (1) Ultrasound room and a recovery room were observed and the following noted:

The table in the Ultrasound Room had a torn cover and rusted areas.

The table in Procedure Room #2 had multiple tears in the cover. There was a package of open sterile 2 X 2's left in the drawer of the cabinet.

The table in Procedure Room #1 had missing Formica-like trim from around the drawer(s) directly below where the patient would sit for a procedure.

The Procedure Room #1 wall, directly behind the area where the physician would sit while performing a procedure, had chips in the wall leaving exposed dry wall.

The recovery room had four (4) reclining chair with wooden arm rests and wooden levers for reclining. Two (2) of the chairs arms and levers had the finish worn off leaving exposed porous wood.

On 8/29/18 at approximately 10:00 A.M. while observing care in the recovery room, Staff Member #4 was observed obtaining the blood pressure of Patient #17. Staff Member #4 removed the blood pressure cuff and placed it on the next patient without cleaning the cuff.
The above findings were discussed with Staff Member #1 and #3. Staff Member #1 stated: "We will get the walls, tables and chairs repaired. I will place another blood pressure cuff in the recovery room so each patient, while here, has their own cuff."

When moderate sedation or conscious sedation is administered, the licensed health care practitioner who administers the anesthesia shall routinely monitor the patient according to procedures consistent with such administration. The administration of sedation and monitoring of the patient shall be documented in the patient's medical record.

This RULE: is not met as evidenced by:

Based on document review and interview, the facility staff failed to document the condition of three (3) patients (Patients #1, #2, and #10) at discharge after receiving conscious sedation, who left AMA (Against Medical Advice), and who they left the facility with.

The findings include:

On 8/28/18, the medical records of three (3) patients, Patient #1, #2 and #10, who received "Twilight" anesthesia (fentanyl and Versed), were reviewed. All three (3) patients left AMA and there was no documentation of their condition at discharge or who they left the facility with.

Patient #1 received fentanyl and Versed on 6/27/18 at 9:25 A.M. and left AMA at 9:50 A.M.
Patient #10 received fentanyl and Versed on 6/25/18 at 5:35 P.M. and left AMA at 6:08 P.M.
Patient #2 had no time documented as to when they left the facility.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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<td>2. Recovery + Discharge Record will be checked periodically for one month to ensure all surgical AEs that sign an AMA have all discharge criteria that was monitored checked off as well as discharge time + driver's name on the sheet. The sheet has been updated.</td>
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<td>3. A monthly check will be completed + if there are any deficiencies noted, we will add it to our monthly check-list + retrain staff.</td>
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**NAME OF PROVIDER OR SUPPLIER**

A TIDEWATER WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**

891 NORFOLK SQUARE

NORFOLK, VA 23502

**STATE OF VIRGINIA**

**DATE SURVEY COMPLETED**

08/29/2018

**STATE FORM**

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relaxed during the endoscopic procedure and to experience little to no pain. Deep sedation, in most cases, allows patients to sleep through the procedure without remembering any medical activity upon waking up. The disadvantages relate to the aftereffects, which include drowsiness and impaired cognitive function for 4 to 24 hours afterwards. Therefore, patients are unable to work or operate a motor vehicle, and require an accompanying person to drive them home after the endoscopy...

How Midazolam Affects Your Body: By Buddy T | Reviewed by a board-certified physician; Updated July 02, 2017 VeryWellMinded.com

Versed (midazolam) is a drug usually used for pre-anesthesia sedation and for procedural sedation for children. For adults, it is often used for uncomfortable procedures such as colonoscopies because it produces memory loss. It is a benzodiazepine and a central nervous system depressant. Knowing how long it stays in your system and has effects can also help you avoid dangerous drug interactions and potential overdoses.

There are several ways Versed can be administered, but it must always be done where there is immediate access to monitoring for breathing and heart function due to the risks. It is done by medical professionals in a hospital, day surgery clinic, or doctor’s office.

It can be given as an injection, by tablet, or in a syrup. This will determine how fast it takes effect. An injection or IV takes effect in 5 to 15 minutes with maximum effect in 15 to 60 minutes and has effects lasting for about 2 hours but with a range of 1 to 6 hours. The amnesia effect lasts for 20
An unannounced Licensure Biennial survey was conducted March 16, 2015 by two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following:
1. Patient identification;
2. Admitting information, including a patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy; and
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist’s report of tissue, and radiologist’s report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses’ progress notes,
   h. Condition at time of discharge, i. Patient instructions, preoperative and postoperative; and
   j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by:

1. 12 VAC 5- 412 Initial comments
2. 12 VAC 5-412-310 Medical records

T340
- Our surgical AB Recovery & Discharge Record form has been updated to include specific discharge criteria as well as a specific area for physician to discharge PT, including signature, date & time.
- Employees will be retrained on updated Surgical AB Recovery & Discharge Record form.

LABORATORY DIRECTOR’S OR PROVIDER/SUPPLIER REPRESENTATIVE’S SIGNATURE
Admin Director

STATE FORM
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TUL912
4/16/15
Based on document review and interview the agency staff failed to ensure the condition of 5 of 10 patients (Patient #1, 2, 4, 5 and 9) was documented in the medical record at the time of discharge and failed to have a dated and timed order for discharge from the physician for 10 of 10 patients (Patients #1, 2, 3, 4, 5, 6, 7, 8, 9 and 10).

The findings include:

On 3/16/15 the medical records of Patient #1, 2, 4, 5 and 9 were reviewed. The records had an area to document the Patients’ conditions at the time of discharge; none of the medical record had any documentation.

Staff Member #2 stated, “I must have been rushed and forgot to fill that in.”

During the review of Patients #1, 2, 3, 4, 5, 6, 7, 8, 9 and 10’s medical records on 3/16/15 an order for discharge could not be found.
STATEMENT OF DEFIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER: VIRGINIA HEALTH GROUP
STREET ADDRESS, CITY, STATE, ZIP CODE: 8316 ARLINGTON BLVD, SUITE 220, FAIRFAX, VA 22031

DEFICIENT PRACTICES CITED IN THE FOLLOWING AREAS:
- 12VAC5-412-140D, tag # 0004, Management and Administration
- 12VAC5-412-150A, tag # 0010, Governing Body
- 12VAC5-412-150E, tag # 0030, Governing Body
- 12VAC5-412-160A, tag # 0035, Policies and Procedures
- 12VAC5-412-170B, tag # 0050, Administration
- 12VAC5-412-170C, tag # 0055, Administration
- 12VAC5-412-180A, tag # 0060, Personnel
- 12VAC5-412-180B, tag # 0065, Personnel
- 12VAC5-412-180D, tag # 0080, Personnel
- 12VAC5-412-180F, tag # 0090, Personnel
- 12VAC5-412-180G, tag # 0095, Personnel
- 12VAC5-412-180H, tag # 0100, Personnel
- 12VAC5-412-220A, tag # 0190, Infection Prevention
- 12VAC5-412-220B, tag # 0195, Infection

An unannounced Complaint Licensure inspection which led to the initiation of an unannounced Biennial Licensure inspection was conducted April 4, 2016 through April 5, 2016 by two Medical Facilities Inspectors (Surveyors) from the Office of Licensure and Certification, Virginia Department of Health. The facility was not in compliance with the Rules and Regulations for the Licensure of Abortion Facilities 12VAC5-412. In addition, the surveyors exited the facility prior to completing the licensure inspection because they were to be closed for the next three (3) weekdays and then scheduled to see patients on Saturday (a day we did not plan to work), such that the license was suspended prior to completion of the Licensure inspections. Therefore, there may be additional deficiencies present that we did not inspect, observe or cite.

Deficient practices were cited in the following areas:
- 12VAC5-412-140D, tag # 0004, Management and Administration
- 12VAC5-412-150A, tag # 0010, Governing Body
- 12VAC5-412-150E, tag # 0030, Governing Body
- 12VAC5-412-160A, tag # 0035, Policies and Procedures
- 12VAC5-412-170B, tag # 0050, Administration
- 12VAC5-412-170C, tag # 0055, Administration
- 12VAC5-412-180A, tag # 0060, Personnel
- 12VAC5-412-180B, tag # 0065, Personnel
- 12VAC5-412-180D, tag # 0080, Personnel
- 12VAC5-412-180F, tag # 0090, Personnel
- 12VAC5-412-180G, tag # 0095, Personnel
- 12VAC5-412-180H, tag # 0100, Personnel
- 12VAC5-412-220A, tag # 0190, Infection Prevention
- 12VAC5-412-220B, tag # 0195, Infection
### Virginia HEALTH GROUP

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**STATE OF VIRGINIA**

**NAME OF PROVIDER OR SUPPLIER:** Virginia Health Group

**STREET ADDRESS, CITY, STATE, ZIP CODE:**

8316 Arlington Blvd, Suite 220
Fairfax, VA 22031

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<td>Prevention 12VAC5-412-220C, tag # 0200, Infection Prevention 12VAC5-412-220E, tag # 0210, Infection Prevention 12VAC5-412-230E, tag # 0235, Patient Services 12VAC5-412-240B, tag # 0250, Medical Testing and Laboratory Services 12VAC5-412-240C, tag # 0255, Medical Testing and Laboratory Services 12VAC5-412-260C, tag # 0315, Administration, Storage and Dispensing of Drugs 12VAC5-412-260D, tag # 0320, Administration, Storage and Dispensing of Drugs 12VAC5-412-270, tag # 0330, Equipment and Supplies 12VAC5-412-300, tag # 0355, Health Information Records 12VAC5-412-310, tag # 0360, Records Storage 12VAC5-412-340A, tag # 0400, Disaster Preparedness 12VAC5-412-350A, tag # 0410, Maintenance</td>
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<th>12VAC5-412-140 D Management and Administration</th>
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<td>An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes:</td>
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<td>1. Change of location.</td>
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<td>2. Change of ownership.</td>
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<td>3. Change of name.</td>
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<td>4. Voluntary closure.</td>
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<td>5. Change of administrator.</td>
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<td>Notices shall be sent to the attention of the</td>
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**State of Virginia**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**

**VIRGINIA HEALTH GROUP**

**STREET ADDRESS, CITY, STATE, ZIP CODE**

8316 ARLINGTON BLVD, SUITE 220
FAIRFAX, VA  22031

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<th>COMPLETE DATE</th>
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<tr>
<td>T 004</td>
<td>Continued From Page 2 This RULE: is not met as evidenced by: Based on staff interview, the facility staff failed to give written notification 30 calendar days in advance of the change in Administrator. The findings included: On 4/4/16 at 2:00 p.m. the survey team entered the facility and requested to speak to the Administrator. Staff #1 introduced him/herself and the surveyor asked if he/she was the Administrator. Staff #1 stated, &quot;No&quot;. The surveyor inquired as to who the administrator was. Staff #1 stated, &quot;Well, we don't have one.&quot; The surveyor asked Staff #1 who was in charge. Staff #1 stated, &quot;Well I guess that would have to be our Director of Operations.&quot; The surveyor asked Staff #1 where he/she could find the Director of Operations (DOO). Staff #1 stated, &quot;He/she is in New Jersey.&quot; The surveyor asked the name of the DOO and Staff #1 stated, &quot;It's (first name) but I don't know what his/her last name is.&quot; Staff #1 stated, &quot;I used to be the Administrator but I have stepped down as of March 22. I am not the administrator any longer.&quot; The surveyor inquired as to who was the Alternate Administrator. Staff #1 stated, &quot;We don't have one.&quot; The surveyor inquired as to who was in charge at the moment. Staff #1 stated, &quot;Well I guess I am.&quot;</td>
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<td>T 010</td>
<td>12VAC5-412-150 A Governing Body Each abortion facility shall have a governing body responsible for the management and</td>
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**STREET ADDRESS, CITY, STATE, ZIP CODE**

8316 ARLINGTON BLVD, SUITE 220
FAIRFAX, VA  22031

**STATE FORM**

021199

PK3411
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

STATE OF VIRGINIA
VIRGINIA HEALTH GROUP
8316 ARLINGTON BLVD, SUITE 220
FAIRFAX, VA 22031

NAME OF PROVIDER OR SUPPLIER

NAME OF PROVIDER OR SUPPLIER

STATE FORM PRINTED: 04/18/2016

FORM APPROVED

T 010 Continued From Page 3

control of the operation of the abortion facility.

This RULE: is not met as evidenced by:
Based on observations, staff interviews, facility document reviews, clinical record reviews and results of the survey, the facility Governing Body failed to ensure appropriate and adequate management and control of the operation of the abortion facility.

Multiple areas of deficient practice were identified during the survey conducted April 4, 2016 through April 5, 2016. The facility presented a document for the meeting of the Quality/Governing Body which occurred "via phone" on 4/4/16 which did not address the areas of concern identified by the survey team. No previous meeting minutes were presented by the facility.

When Staff #1 was asked about the Governing Body meetings and Quality/policy reviews, he/she stated, "I don't know. I have only been at one meeting and that was the one we had by phone today."

T 030 12VAC5-412-150 E Governing Body

The bylaws shall include at a minimum the following:
1. A statement of purpose;
2. Description of the functions and duties of the governing body, or other legal authority;
3. A statement of authority and responsibility delegated to the administrator and to the clinical
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<td></td>
<td>staff;</td>
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<td></td>
<td>4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and</td>
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<td>5. Provision of guidelines for relationships among the governing body, the Administrator and the clinical staff.</td>
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<td>T 035</td>
<td>This RULE: is not met as evidenced by:</td>
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<td>Based on facility document review and staff interview, the facility staff failed to ensure a current organizational chart was available in order to identify lines of authority within the facility.</td>
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<td>The findings included:</td>
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<td>On 4/4/16 at 2:25 p.m. the survey team requested an organizational chart from Staff #1 in order to be able to identify the lines of authority within the facility. Staff #1 stated, &quot;I will see if I can find it.&quot;</td>
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<td>On 4/5/16 at 3:10 p.m. the surveyors made a second request for this document and were given a copy of a chart which did not identify names associated with positions. The surveyors requested that Staff #1 provide the names of the current lines of authority on the organizational chart.</td>
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<td>By the end of the survey, 4/5/16 at 9:10 p.m., this document was not presented to the survey team.</td>
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<td>12VAC5-412-160 A Policies and Procedures</td>
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<td>Each abortion facility shall develop, implement</td>
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and maintain documented policy and procedures, which shall be readily available on the premises and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but not limited to the following:

1. Personnel;

2. Types of elective services performed in the abortion facility;

3. Types of anesthesia that may be used;

4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;

5. Obtaining informed written consent of the patient pursuant to § 18.2-76 of the Code of Virginia prior to the initiation of any procedures;

6. When to use sonography to assess patient risk;

7. Infection prevention;

8. Quality an risk management;

9. Management and effective response to medical and/or surgical emergency;

10. Management and effective response to fire;

11. Ensuring compliance with all applicable federal, state, and local laws;

12. Abortion facility security;

13. Disaster preparedness;

14. Patient rights;
15. Functional safety and abortion facility maintenance; and

16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable.

This RULE: is not met as evidenced by: Based on document review and staff interview, the facility staff failed to ensure Policies and Procedures were reviewed /updated annually.

The findings included:

On 4/4/16 at 5:00 p.m., the surveyor reviewed the policy and procedure manual which was presented by Staff #1. The Policy and Procedure Manual contained a document signed by (Governing Body) which evidenced the manual had not been updated/reviewed since November 12, 2013. When Staff #1 was asked about the Governing Body meetings and Quality/policy reviews, he/she stated, "I don't know. I have only been at one meeting and that was the one we had by phone today."

This RULE: is not met as evidenced by: Based on staff interview, the facility staff failed to...
The findings included:

On 4/4/16 at 2:00 p.m. the survey team entered the facility and requested to speak to the Administrator. Staff #1 introduced him/herself and the surveyor asked if he/she was the Administrator. Staff #1 stated, "No". The surveyor inquired as to who the administrator was. Staff #1 stated, "Well, we don't have one." The surveyor asked Staff #1 who was in charge. Staff #1 stated, "Well I guess that would have to be our Director of Operations." The surveyor asked Staff #1 where he/she could find the Director of Operations (DOO). Staff #1 stated, "He/she is in New Jersey." The surveyor asked the name of the DOO and Staff #1 stated, "It's (first name) but I don't know what his/her last name is." Staff #1 stated, "I used to be the Administrator but I have stepped down as of March 22. I am not the administrator any longer."

The surveyor inquired as to who was the Alternate Administrator. Staff #1 stated, "We don't have one." The surveyor inquired as to who was in charge at the moment. Staff #1 stated, "Well I guess I am."

T 055 12VAC5-412-170 C Administrator

A qualified individual shall be appointed in writing to act in the absence of the administrator.

This RULE: is not met as evidenced by:

Based on staff interview, the facility staff failed to ensure a qualified individual was appointed in writing to act in the absence of the administrator.
The findings included:

On 4/4/16 at 2:00 p.m. the survey team entered the facility and requested to speak to the Administrator. Staff #1 introduced him/herself and the surveyor asked if he/she was the Administrator. Staff #1 stated, "No". The surveyor inquired as to who the administrator was. Staff #1 stated, "Well, we don't have one." The surveyor asked Staff #1 who was in charge. Staff #1 stated, "Well I guess that would have to be our Director of Operations." The surveyor asked Staff #1 where he/she could find the Director of Operations (DOO). Staff #1 stated, "He/she is in New Jersey." The surveyor asked the name of the DOO and Staff #1 stated, "It's (first name) but I don't know what his/her last name is." Staff #1 stated, "I used to be the Administrator but I have stepped down as of March 22. I am not the administrator any longer."

The surveyor inquired as to who was the Alternate Administrator. Staff #1 stated, "We don't have one." The surveyor inquired as to who was in charge at the moment. Staff #1 stated, "Well I guess I am."

On 4/5/16 at 2:30 p.m. Staff #1 stated, "I am the acting administrator. I put in my four weeks notice on February 22nd and as of March 22nd I stepped down, but now I am the acting administrator." The surveyor verified with Staff #1 that yesterday 4/4/16 he/she had informed the survey team that he/she was not the administrator and that there "was not one". Staff #1 stated, "Yes, I said that."

Each abortion facility shall have a staff that is...
### PROVIDER'S PLAN OF CORRECTION

**T 060**

Continued From Page 9

- Adequately trained and capable of providing appropriate service and supervision to patients.
- The abortion facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided.

This RULE: is not met as evidenced by:

- Based on staff interview and facility document review, the facility staff failed to ensure each staff member received necessary training to provide appropriate service to patients.

The findings included:

- Upon review of the personnel records for staff, there was no documentation that the staff had received documented education or training on the examination and verification that tissues removed from the resulting abortion procedure contained villi or fetal parts. Staff #2 stated, on 4/5/16 at 5:43 p.m., "Well (name of Staff #7) came and showed me how a couple of times and then the rest I learned from other staff members. I catch on quick...."
- Staff #1 stated on 4/5/16 at 6:30 p.m. that "All staff rotate through each assignment..."

**T 065**

12VAC5-412-180 B Personnel

The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable.
This RULE: is not met as evidenced by:
Based on staff interview and facility document review, the facility staff failed to ensure all staff members had a written application for employment for all staff.

The findings included:
When reviewing the list of staff employed by the facility and personnel records, Staff #7 (Director of Operations) did not have a personnel file maintained at the facility.

The surveyor requested the personnel file and credentials for Staff #7 in order to verify the education/training and qualifications as Staff #7 was documenting he/she was providing multiple areas of training for staff.

Staff #1 stated on 4/5/16 at 1:50 p.m., that he/she did not have that (credentials) for Staff #7. On 4/5/16 at 2:05 p.m., Staff #1 stated that Staff #7 was on the phone and requested to speak to the surveyor. The surveyor spoke to Staff #7 who questioned: "Why do you need my information? The information you get is available to the public and I am not going to send you my personal information to be broadcast to the public." The surveyor informed Staff #7 that his/her personal information was not something that was available to the public, but that the surveyor needed to examine his/her credentials in order to verify his/her qualifications for the training of staff. Staff #7 stated, "I am a doctor so I am qualified." The surveyor questioned Staff #7 as to whether he/she had a license to practice in the State of Virginia and Staff #7 stated, "I have passed all my tests but I do not have a license..."

At 2:45 p.m. on 4/5/16 Staff #1 brought the survey
Continued From Page 11

Team a faxed resume for Staff #7. No verification of education other than the resume was presented. The survey team reviewed documentation under the Department of Health Professionals website (www.dhp.virginia.gov) and no professional license was listed for Staff #7.

12VAC5-412-180 D Personnel

The abortion facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.

This RULE: is not met as evidenced by: Based on employee record review and staff interview, the facility staff failed to ensure on-going training and education for staff that was directly related to their duties was provided/documented and failed to ensure staff participated in annual fire safety and inservice training.

The findings included:

1. Upon review of the personnel records for staff, there was no documentation that the staff had received documented education or training on the examination and verification that tissues removed from the resulting abortion procedure contained villi or fetal parts. Staff #2 stated, on 4/5/16 at 5:43 p.m., "Well (name of Staff #7) came and showed me how a couple of times and then the rest I learned from other staff members. I catch on quick...." When interviewed as to what he/she...
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**

**VIRGINIA HEALTH GROUP**

**STREET ADDRESS, CITY, STATE, ZIP CODE**

8316 ARLINGTON BLVD, SUITE 220

FAIRFAX, VA  22031

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<td>T 080</td>
<td>Continued From Page 12</td>
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<td>would do if he/she were unable to identify the POC (products of conception) Staff #2 stated, &quot;I have not had a problem, but I guess I would let the doctor or someone else look at it...&quot;</td>
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<td>Staff #1 stated on 4/5/16 at 6:30 p.m. that &quot;All staff rotate through each assignment...&quot;</td>
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<td>2. The surveyor asked Staff #1 for documentation of the facility's fire drill and emergency preparedness inservice/training. Staff #1 submitted a notebook for review which documented the last fire drill practice as done in 2014, and stated &quot;I haven't done one since I have worked here.&quot;</td>
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| T 090 | 12VAC5-412-180 F Personnel | T 090 | A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable. |

This RULE: is not met as evidenced by:

Based on staff interview and facility document review, the facility staff failed to ensure all staff members had a personnel record which was contained within the employee file.

The findings included:

1. When reviewing the list of staff employed by the facility and personnel records, Staff #7
The surveyor requested the personnel file and credentials for Staff #7 in order to verify the education/training and qualifications as Staff #7 was documenting he/she was providing multiple areas of training for staff.

Staff #1 stated on 4/5/16 at 1:50 p.m., that he/she did not have that (credentials) for Staff #7. On 4/5/16 at 2:05 p.m., Staff #1 stated that Staff #7 was on the phone and requested to speak to the surveyor. The surveyor spoke to Staff #7 who questioned: "Why do you need my information? The information you get is available to the public and I am not going to send you my personal information to be broadcast to the public." The surveyor informed Staff #7 that his/her personal information was not something that was available to the public, but that the surveyor needed to examine his/her credentials in order to verify his/her qualifications for the training of staff. Staff #7 stated, "I am a doctor so I am qualified." The surveyor questioned Staff #7 as to whether he/she had a license to practice in the State of Virginia. and Staff #7 stated, "I have passed all my tests but I do not have a license..."

At 2:45 p.m. on 4/5/16 Staff #1 brought the survey team a faxed resume for Staff #7. No verification of education other than the resume was presented. The survey team reviewed documentation under the Department of Health Professionals website (www.dhp.virginia.gov) and no professional license was listed for Staff #7.

2. Review of the employee files for Staff # 1, 2, 3, 4, 5, and 6 revealed no current job description contained within the employee files.
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<td>12VAC5-412-180 G Personnel</td>
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Personnel policies and procedures shall include, but not be limited to:
1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;
2. Process for verifying current professional licensing or certification and training of employees or independent contractors;
3. Process for annually evaluating employee performance and competency;
4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and
5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.

This RULE: is not met as evidenced by:
Based on staff interview and facility document review, the facility staff failed to ensure each employee had a written job description contained in the personnel file.

The findings included:
Review of the personnel files for Staff 1 who stated he/she was previously the administrator, then the "acting administrator" revealed no job description for either job title. Staff #2, 4, and 5 who were identified as "Health Care Team Members" did not have a job description. Staff #
A. BUILDING ____________________________

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0015

(X2) MULTIPLE CONSTRUCTION

A. BUILDING ____________________________

B. WING ____________________________

(X3) DATE SURVEY COMPLETED: 04/05/2016

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

State of Virginia

NAME OF PROVIDER OR SUPPLIER: VIRGINIA HEALTH GROUP

STREET ADDRESS, CITY, STATE, ZIP CODE: 8316 ARLINGTON BLVD, SUITE 220, FAIRFAX, VA 22031

PRINTED: 04/18/2016

FMAFIRAX, VA  22031
8316 ARLINGTON BLVD, SUITE 220
VIRGINIA HEALTH GROUP

T 095 Continued From Page 15

4. identified as the Licensed Practical Nurse, did not have a job description in the personnel file which evidenced the staff were aware of their duties and responsibilities.

T 100 12VACS-412-180 H Personnel

A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health related information shall be maintained separately within the employee’s personnel file.

This RULE: is not met as evidenced by:

Based on staff interview and facility document review, the facility staff failed to maintain a personnel record for each employee.

The findings included:

When reviewing the list of staff employed by the facility and personnel records, Staff #7 (Director of Operations) did not have a personnel file maintained at the facility.

The surveyor requested the personnel file and credentials for Staff #7 in order to verify the education/training and qualifications as Staff #7 was documenting he/she was providing multiple areas of training for staff.

Staff #1 stated on 4/5/16 at 1:50 p.m., that he/she did not have that (credentials) for Staff #7. On 4/5/16 at 2:05 p.m., Staff #1 stated that Staff #7 was on the phone and requested to speak to the
Continued From Page 16

surveyor. The surveyor spoke to Staff #7 who questioned: "Why do you need my information? The information you get is available to the public and I am not going to send you my personal information to be broadcast to the public." The surveyor informed Staff #7 that his/her personal information was not something that was available to the public, but that the surveyor needed to examine his/her credentials in order to verify his/her qualifications for the training of staff. Staff #7 stated, "I am a doctor so I am qualified." The surveyor questioned Staff #7 as to whether he/she had a license to practice in the State of Virginia. Staff #7 stated, "I have passed all my tests but I do not have a license..."

At 2:45 p.m. on 4/5/16 Staff #1 brought the survey team a faxed resume for Staff #7. No verification of education other than the resume was presented. The survey team reviewed documentation under the Department of Health Professionals website (www.dhp.virginia.gov) and no professional license was listed for Staff #7.

The abortion facility shall have an infection prevention plan that encompasses the entire abortion facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards.
### Statement of Deficiencies and Plan of Correction

**State of Virginia**

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<th>(X2) Multiple Construction</th>
<th>(X1) Provider/Supplier/CLIA Identification Number</th>
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<td>AF-0015</td>
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<td>B. Wing:</td>
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</table>

**Name of Provider or Supplier**: Virginia Health Group

**Street Address, City, State, Zip Code**:

8316 Arlington Blvd, Suite 220
Fairfax, VA 22031

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<th>ID Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID Prefix Tag</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
<th>(X5) Complete Date</th>
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<td>T 190</td>
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1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.

2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.

3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

This RULE: is not met as evidenced by:

Based on facility document review and staff interview, the facility staff failed to ensure the infection control/prevention policies and procedures were reviewed at least annually by the facility administrator and appropriate members of the clinical staff.

The findings included:

On 4/4/16 at 5:00 p.m., the surveyor reviewed the policy and procedure manual containing the Infection Control/Prevention policy/plan which was presented by Staff #1. The Policy and Procedure Manual contained a document signed by (Governing Body) which evidenced the manual had not been updated/reviewed since November 12, 2013. When Staff #1 was asked about the Governing Body meetings and Quality and policy reviews, he/she stated, "I don't know. I have only been at one meeting and that was the one we had by phone today."
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<tr>
<td>T 195</td>
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<td>12VAC5-412-220 B Infection Prevention  Adamantly, written infection prevention policies and procedures shall include, but not be limited to:</td>
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<tr>
<td>1.</td>
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<td>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;</td>
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<td>2.</td>
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<td>Training of all personnel in proper infection prevention techniques;</td>
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<td>3.</td>
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<td>Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;</td>
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<td>4.</td>
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<td>Use of standard precautions;</td>
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<td>5.</td>
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<td>Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety &amp; Health Administration;</td>
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<td>6.</td>
<td></td>
<td>Use of personal protective equipment;</td>
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<td>7.</td>
<td></td>
<td>Use of safe injection practices;</td>
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<td>8.</td>
<td></td>
<td>Plans for annual retraining of all personnel in infection prevention methods;</td>
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<td>9.</td>
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<td>Procedures for monitoring staff adherence to recommended infection prevention practices; and</td>
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<td>10.</td>
<td></td>
<td>Procedures for documenting annual retraining of all staff in recommended infection prevention practices.</td>
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This RULE: is not met as evidenced by:
Based on observations, staff interview and facility document review, the facility staff failed to ensure proper infection control practices were followed and adhered to in relation to: Cleanliness of patient areas and equipment, proper use of personal protective equipment and sanitary use of patient supplies and failed to ensure that procedures to prevent transmission of community-acquired infection within the facility were followed.

The findings included:

1. Upon entrance to the facility on 4/4/16 at 2:00 p.m., the survey team observed the patient waiting area to be unclean. The carpet was dirty and had large dark stains in multiple areas. There was debris on the floor and black smudges on multiple areas on the walls. There were fifteen (15) chairs which were made of a black strap type cloth/elastic type material that could not be adequately cleaned or disinfected. Nine (9) metal folding chairs were available with cloth seats and back rest, several of which were stained and dirty and could not be adequately cleaned nor disinfected.

Further observations made during a tour of the facility patient care areas revealed the following:
In Exam Room one (1), also the procedure room (where the surgical procedures were performed), the cabinet doors were taped together with a micropore tape which was adhered to the cabinet doors. When the surveyor attempted to open the cabinet to view the contents, the door fell off. In the bottom of this cabinet was a blue chux (pad) which had debris and dried brown material (betadine) that had leaked all over the pad. There was a box of exam gloves and two boxes of...
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<th>T 195</th>
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- Tissues which had brown splatters dried on the packaging.

The ultrasound machine in this room was dusty and contained areas of debris which was yellowish and brown in color. The bottom of the machine which was on casters, was dirty and had dried liquid which had collected dust and debris. The area where the ultrasound probe was kept had a wadded paper towel which appeared to have dried material on it. The keyboard was also dusty and contained debris and dried splatters of some foreign material.

In the room designated as the "sterilization room" (where instruments were taken for sterilization and packaging), the monthly cleaning log for the autoclave machine (the machine used to sterilize instruments used during the surgical procedure) had the last cleaning date recorded as "January 19, 2016". There were surgical instruments inside the autoclave that had not been cleaned and the door was ajar. Staff #1 stated "I did not have any distilled water."

In a room identified as the "physician’s office" the surveyors observed blue surgical scrubs rolled up lying on a cabinet. At 6:15 p.m., the physician arrived and "dressed" and the rolled up scrubs were gone, and the physician was observed wearing blue scrubs. There was yellow liquid on the wall which appeared to be in a splatter pattern behind the desk near a plastic cart where various medications were kept. On 4/5/16 at approximately 2:00 p.m., this "yellow" material was identified by Staff #1 as "Methotrexate" (a medication used to induce abortion for the medical procedure) which had "accidentally been sprayed onto the wall when it was drawn up." On 4/5/16 at 5:00 p.m., the survey team observed the blue scrubs lying on the side cabinet in the physicians...
Continued From Page 21

office. When the physician arrived and "dressed" for procedures, the scrubs were gone. Surgical procedures were performed on both days and the physician did not wear any other covering during all procedures performed other than the blue scrubs. During the tour and subsequent observations on 4/4/16 the survey team did not observe any other scrubs stored at the facility and upon arrival to the facility on 4/4/16, the physician was not observed carrying in any scrubs.

On 4/5/16 the surveyor accompanied Staff #2 in the "pathology room" in order to observe the process of receipt and examination of the products of conception (POC) and handling/cleaning of surgical instruments. Staff #2 donned a yellow PPE (personal protective equipment) gown, goggles and gloves. After completing the examination, weighing and packaging of the POC, Staff #2 removed the gloves, goggles and gown. Present on the gown was blood stains. Staff #2 held up the gown and looked at it and proceeded to hang it on the back of the door for future use stating "Oh it's not that bad", referring to the amount of blood on the gown.

The policy and procedure regarding the cleaning of the autoclave documented, "Cleaning of Autoclave: "...this task shall be performed monthly."

The facility had no specific policies or procedures regarding cleaning. Staff #1 stated, "We (staff) clean the (patient care) equipment and the building housekeeping cleans the floors and bathrooms..."

2. On 4/4/2016 at 3:45 PM the surveyors observed a plastic basket of instruments sitting on a wire rack in the sterilization room. Staff #1 was
A. BUILDING ____________________________  PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1)  PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  (X2) MULTIPLE CONSTRUCTION A. BUILDING ____________________________

AF-0015  B. WING ____________________________  (X3) DATE SURVEY COMPLETED  04/05/2016

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

VIRGINIA HEALTH GROUP  8316 ARLINGTON BLVD, SUITE 220

FAIRFAX, VA  22031

STATE FORM  PK3411

If continuation sheet  23 of 52

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<th>(X5) COMPLETE DATE</th>
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<td>T 195</td>
<td>Continued From Page 22  asked whether the instruments were clean, he/she stated &quot;They are disinfected but not sterilized, they need to be repackaged. We usually sterilize them at the end of every day, but we didn't sterilize those on Saturday because there was no distilled water for the autoclave.&quot; When asked where the distilled water was at that time, he/she stated &quot;it's in my car.&quot;  On 4/4/2016 at 3:50 PM, the surveyors observed a tray on the counter in the sterilization room which contained sterilization integrators for use in the autoclave. Steam integrators detect critical sterilization parameter failures for exposure time, temperature and steam quality. Fourteen of the sterilization integrators available for use Expired 10/20/2015.  At 5:45 PM on 4/4/2016 the surveyors observed paper towels and ultrasound gel stored under the sink of exam room 2.  At 6:00 PM on 4/5/2016 the surveyor, after talking with Patient #6 and obtaining permission, entered exam room 1 to observe a surgical procedure. Staff #1 poured 2 Misoprostol tablets into the cap of the bottle and placed cervical swabs into a bottle of Monsel's solution in preparation for the procedure, while Staff #6 spoke with the patient. Staff #6 told Patient #6 that because of a slightly lower than normal hematocrit (the proportion of total blood volume that is composed of red blood cells), she was at increased risk of death and or complications related to the procedure. Patient #6 stated &quot;I want to call my husband,&quot; and picked up her cell phone. Staff #6 asked if the patient's husband was in the waiting room, and she said, &quot;No, he is in the car.&quot; Staff #6 told Staff #1 and Patient #6 he would &quot;talk to (patient's name) and husband in his/her office.&quot;  While preparing for the procedure, Staff #1 poured 2 Misoprostol tablets into the cap of the bottle, and placed 2 cervical swabs into a multi-dose bottle of Monsel's...</td>
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solution. Staff #1 then poured the 2 Misoprostol tablets back into the bottle but left the swabs sitting in the Monsel's solution. The facility staff exited the exam room, leaving the inspector with the patient.

At 6:10 PM on 4/5/2016 while standing outside the patient bathroom the surveyor heard Staff #1 and 2 having a discussion about the toilet in the patient bathroom being stopped up. Staff #1 stated "that happens all the time in that bathroom." The surveyor observed Staff #2 don gloves, retrieve a plunger from the staff bathroom, go into the patient bathroom and use the plunger to unstop the toilet. Staff #2 then walked back down the hallway to the staff bathroom carrying the plunger with gloves on, he/she put down the plunger, removed the gloves, and cleaned his/her hands with hand sanitizer. Staff #2 was then approached by Staff #6 and asked if he/she wanted to go into the next procedure to translate for a Spanish speaking client, or whether he/she wanted to assist and translate. Staff #2 stated "It will be easier to translate and let (Staff #1's name) assist." Staff #2 then went into exam room 1 where he/she stood beside Patient #7 during the surgical procedure to translate and also held the patient's hand during the procedure. Staff #2 did not change scrubs or don PPE prior to entering the exam room where the procedure took place. On 4/5/2016 at 6:25 PM the surveyor observed the surgical procedure for Patient #7. The surveyor observed Staff #1 setting up while Staff #6 was talking with Patient #7. He/she poured 2 Misoprostol tablets into the cap of a multi dose bottle leaving the bottle open and sitting on the counter during the procedure until pouring the tablets from the cap into the gloved hand of Staff #6. Staff #6, while wearing gloves visibly soiled with blood, removed cervical swabs which had been sitting in the multi-dose bottle of Monsel's solution since 6:00 PM where they were placed.
preparation for a procedure which was canceled. On 4/5/2016 at approximately 6:30 PM, the surveyor observed that exam room 1, where a surgical procedure was being performed, did not have a sink available for handwashing. While performing the surgical procedure, Staff #1’s gloves were observed to be visibly soiled with blood. After the procedure, Staff #1 removed his/her gloves and used hand sanitizer. The surveyor did not observe Staff #1 wash his/her hands with soap and water after exiting the procedure room.

On 4/5/2016 at approximately 6:35 PM the surveyor observed Staff #1 clean exam room 1 after Patient #7’s surgical procedure. The surveyor noted that the rolling exam light which was touched by Staff #6 while wearing contaminated gloves during the procedure was not cleaned, the ultrasound machine sitting in the room beside the patient was not cleaned, neither the can of Hurricane numbing spray nor the bottle of Monist’s solution were wiped off after having been used, and only the top of the vacuum suction machine was cleaned.

12VAC5-412-220 C Infection Prevention

Written policies and procedures for the management of the abortion facility, equipment and supplies shall address the following:

1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);

2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;

3. Appropriate storage for cleaning agents (e.g.,...
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locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);

4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;

5. Procedures for handling/temporary storage/transport of soiled linens;

6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;

7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection /sterilization to be used for each type of equipment, (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved.

The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;

8. Procedures for appropriate disposal of non-reusable equipment;

9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;

10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
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11. An effective pest control program, managed in accordance with local health and environmental regulations; and

12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observation, the facility staff failed to ensure the availability of sinks for proper handwashing, proper cleaning of environmental surfaces, proper disinfection of equipment, ability to verify the recommended level of sterilization was achieved and periodic and ongoing maintenance of equipment.

The findings included:

1. The surveyors observed multiple pieces of equipment being used for patient care which included the following:
   - Exam light (2)
   - Exam Table (2)
   - Suction Machine -gomco recovery room
   - Pulse oximeter
   - AED/Defibrillator (used in the event of a cardiac arrest)
   - Datascop-e-vital signs monitor
   - Heating pad (2)
   - Autoclave
   - Centrifuge
   - Gel warmer
   - Vacuum Suction machine in procedure room used during the surgical procedures
   - All of the equipment listed above with the
### Exception of the Suction Machine

The vacuum suction machine used for the surgical procedures contained a sticker which documented no preventative maintenance check since 2012.

2. The survey team requested information for the facility pest control and prevention plan. Staff #1 stated, "We do not have one. The building has one, but it is for the whole building, not just this area.

3. At 2:30 PM on 4/4/2016 the surveyors observed that the ultrasound machine in exam room one (1) was stained, and the keyboard had dried particles of debris between the keys.

On 4/4/2016 at 3:45 PM the surveyors observed a plastic basket of instruments sitting on a wire rack in the sterilization room. Staff #1 was asked whether the instruments were clean, he/she stated "They are disinfected but not sterilized, they need to be repackaged. We usually sterilize them at the end of every day, but we didn't sterilize those on Saturday because there was no distilled water for the autoclave." When asked where the distilled water was at that time, he/she stated "It's in my car."

On 4/4/2016 at 3:50 PM, the surveyors observed a tray on the counter in the sterilization room which contained sterilization integrators for use in the autoclave. Steam integrators detect critical sterilization parameter failures for exposure time, temperature and steam quality. Fourteen of the sterilization integrators available for use Expired 10/20/2015.
At 6:00 PM on 4/5/2016 the surveyor, after talking with Patient #6 and obtaining permission, entered exam room one (1) to observe a surgical procedure. Staff #1 poured 2 Misoprostol tablets into the cap of the bottle and placed cervical swabs into a bottle of Monsel’s solution in preparation for the procedure, while Staff #6 spoke with the patient. Staff #6 told Patient #6 that because of a slightly lower than normal hematocrit (the proportion of total blood volume that is composed of red blood cells), she was at increased risk of death and or complications related to the procedure. Patient #6 stated, "I want to call my husband," and picked up her cell phone. Staff #6 asked if the patient's husband was in the waiting room, and she said "No, he is in the car." Staff #6 told Staff #1 and Patient #6 he would "talk to (patient's name) and husband in his/her office." While preparing for the procedure, Staff #1 poured 2 Misoprostol tablets into the cap of the bottle, and placed 2 cervical swabs into a multi-dose bottle of Monsel's solution. Staff #1 then poured the 2 Misoprostol tablets back into the bottle but left the swabs sitting in the Monsel's solution. The facility staff exited the exam room, leaving the inspector with the patient.

On 4/5/2016 at approximately 6:30 PM, the surveyor observed that exam room 1, where a surgical procedure was being performed, did not have a sink available for handwashing. While performing the surgical procedure, Staff #1’s gloves were observed to be visibly soiled with blood. After the procedure, Staff #1 removed his/her gloves and used hand sanitizer. The surveyor did not observe Staff #1 wash his/her hands with soap and water after exiting the procedure room.

On 4/5/2016 at approximately 6:35 PM the inspector observed Staff #1 clean exam room 1 after Patient #7’s surgical procedure. The inspector noted that the rolling exam light which
### Statement of Deficiencies and Plan of Correction

**State of Virginia**

**Name of Provider or Supplier:** Virginia Health Group

**STATE ADDRESS, CITY, STATE, ZIP CODE:** 8316 Arlington Blvd, Suite 220, Fairfax, VA 22031

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<td>was touched by Staff #6 while wearing contaminated gloves during the procedure was not cleaned, the ultrasound machine sitting in the room beside the patient was not cleaned, and only the top of the vacuum suction machine was wiped down.</td>
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<td>T 210</td>
<td>12VAC5-412-220 E Infection Prevention</td>
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<td>The abortion facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities: 1. A procedure for surveillance, documentation and tracking of reported infections; and 2. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease.</td>
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This RULE: is not met as evidenced by: Based on record review, and staff and patient interview, the facility staff failed to ensure that the facility implemented policies and procedures for surveillance of reportable infections.

Findings include:

1. A review of the medical record for Patient #1 included documentation on the patient information form that he/she had a history of chlamydia. The CDC (Centers for Disease Control and Prevention) screening recommendations for STI's (sexually transmitted infections), including chlamydia states "sexually active women aged 25 years and older is recommended if a patient is at increased risk". ACOG (The American College of Obstetricians and Gynecologists) recommends annual testing for chlamydia in women of all ages.

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**State FORM:** 021199 **PK3411**

**Printed:** 04/18/2016 **Form Approved:**
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<td>Obstetricians and Gynecologists) FAQ-009 (frequently asked questions)-gynecologic problems- lists previous infection with an STI as an increased risk factor for acquiring an STI. During an interview with Staff #2 about what STI testing the facility offered on 4/4/2016 at 3:50 PM, he/she stated &quot;We don't offer STI testing. We refer them out for that. The doctor would decide if they need that, if they are high risk, they might send them to be tested/treated before the procedure.&quot; During an interview on 4/5/2016 at 5:45 PM with Patient #6 regarding whether she was offered STI testing by facility staff, she stated &quot;No, they just told me my blood was ok. I signed a lot of papers, they didn't ask me about testing.&quot; The facility's STI Screening Consent Form states that for patients who choose to undergo STI testing lab fees could cost between $50.00 and $150.00 per test in addition to $45.00 per test for (name of facility's) professional fee, plus the cost of supplies, for performing the tests, receiving the results, and counseling.&quot; There was no documentation that patients received information about STI testing through low cost or free clinics.</td>
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<td>12VAC5-412-230 E Patient Services; Patient Counseling</td>
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<td>The abortion facility shall offer each patient seeking an abortion, in a language or manner she understand, appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients.</td>
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<td>This RULE: is not met as evidenced by: Based on a patient interview, the facility staff failed</td>
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<td>to ensure that a patient seeking an abortion procedure was counseled in a language or manner she understood.</td>
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Findings include:

1. At 6:00 PM on 4/5/2016 the surveyor, after talking with Patient #6 and obtaining permission, entered exam room one (1) to observe a surgical procedure. Staff #6 asked the patient if she consented to the procedure, and told her that because of a slightly lower than normal hematocrit (proportion of total blood volume that is composed of red blood cells), she was at increased risk of death and or complications. Patient #6 stated "I want to call my husband," and picked up her cell phone. Staff #6 asked if the patient's husband was in the waiting room, and she said "No, he is in the car." Staff #6 told Staff #1 and Patient #6 he would "talk to (patient's name) and husband in his/her office." The facility staff exited the exam room, leaving the inspector with the patient. Patient #6 looked at the surveyor and stated, "Can you tell me what he was talking about?" The surveyor explained that he/she was not an employee of the facility and could not explain the procedure/complications, but that Staff #6 would talk with both she and her husband when he arrived.

The surveyor interviewed Patient #6 and asked if she received counseling about the procedure and what to expect during and after the procedure, and she stated, "No, they just told me my blood was ok and I signed a lot of papers."

2. Staff #6 spoke with Patient #6 and her husband about possible complications related to a low hematocrit and counseled them that she had time to think about what she wanted to do and could reschedule the procedure if she chose to do so. While speaking to Patient #6, her husband...
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<td>transcribed in their native language so that Patient #6 understood what Staff #6 was saying.</td>
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<td>T 250</td>
<td>12VAC5-412-240 B Medical Testing and Laboratory Services</td>
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<td>Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) (42 CFR Part 493).</td>
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The findings included:

During the survey conducted 4/4 through 4/5/16 the survey team examined the CLIA (Clinical Laboratory Improvement Amendments) document for Laboratory Services. The document listed (Name identified as Staff # 8 for identification purposes) as the laboratory director with a title of MD (physician). Upon review of the facility personnel records and staff list, Staff #8 was not employed at the facility. Staff #1 was interviewed previously (4/4/16 at 2:15 p.m.) as to who the medical director was for the facility and he/she first stated (name of Staff #8) but then said it was Staff #6. The surveyors accessed the Department of Health Professionals for the State of Virginia and were unable to locate a license for Staff #8.

According to the regulations at 493.1405 for CLIA regarding the qualifications for laboratory director, the following was evidenced:

The laboratory director must be(b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications
that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; and 493.1407:

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. If the director cannot practically provide personal, on-site supervision it must be demonstrated that the director:

· Provides direction and consultation by telephone or electronic means (e.g. email, text message or fax), as necessary; or
· Delegates to qualified personnel specific responsibilities as provided in the regulations.

The survey team was unable to validate the credentials of the laboratory Director (Staff #8) as the personnel file was not accessible/on site and there was no evidence that any person had been delegated to fulfill the responsibilities.

All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.

This RULE: is not met as evidenced by:
Based on staff interview and facility document review, the facility staff failed to ensure each staff member received necessary training to provide appropriate service to patients.

The findings included:

Upon review of the personnel records for staff, there was no documentation that the staff had received documented education or training on the examination and verification that tissues removed from the resulting abortion procedure contained villi or fetal parts. Staff #2 stated, on 4/5/16 at 5:43 p.m., "Well (name of Staff #7) came and showed me how a couple of times and then the rest I learned from other staff members. I catch on quick...." When interviewed as to what he/she would do if he/she were unable to identify the POC (products of conception) Staff #2 stated, "I have not had a problem, but I guess I would let the doctor or someone else look at it...

Staff #1 stated on 4/5/16 at 6:30 p.m. that "All staff rotate through each assignment..."

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<th>ID</th>
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<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
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<td>T 255</td>
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Based on observation and staff interview, the facility staff failed to ensure 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, the facility staff failed to ensure drugs maintained
the facility were not expired and properly stored with access limited to authorized personnel only.

The findings included:

1. On 4/4/16 at 2:45 p.m. the surveyors observed in the "Recovery Room" a cabinet which was unlocked and contained the following:

Diphenhydramine 50mg (milligram) vial three (3) vials which had the following expiration dates: 2 vials 12/2013, 1 vial 10/2014.
Naloxone 0.4mg/ml (milligrams per milliliter) 1 ml vial (4) with the expiration date 1 March 2015.
Digoxin 500mcg,2ml (micrograms per milliliter) 2 ml ampoule (0.5mg/2ml) expired 12/2014.
Clonidine 0.1mg tablet (2) expiration 1/2014
Furosemide 20mg vial 10mg/ml expired 1 August 2014
Sodium Bicarb 8.4% (2) expired 1 May 2014
Diazepam 10mg/2ml injection expired 1 May 2014
Atropine Sulfate 1mg syringe expired 1 May 2015
ProAir HFA Albuterol Inhaler 90mcg (micrograms) per activation expired September 2014

Also contained in the unlocked cabinet were:
Acetaminophen 500mg bottle (opened and not dated as to when opened)
Metronidazole tablets 500mg 50 tablet bottle opened 8/18/15
Ibuprofen 800mg tablets 500 tablet bottle opened 2/6/16
Doxycycline 100mg tablets 500 tablet bottle opened 1/19/16

On 4/5/16 at 3:15 p.m., the surveyors observed the cabinet had been locked, however the doors still opened with enough space to allow a hand to be inserted into the cabinet where any medications stored could be easily accessed.
### Statement of Deficiencies and Plan of Correction

**State of Virginia**

**Name of Provider or Supplier:**

**VIRGINIA HEALTH GROUP**

**Street Address, City, State, Zip Code:**

**8316 ARLINGTON BLVD, SUITE 220**

**FAIRFAX, VA 22031**

**ID Prefix Tag:**

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<tr>
<th>T 315</th>
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</table>

Diphenhydramine (Bendaryl) - an antihistamine used for the treatment of allergic reactions.

Naloxone is used to treat a narcotic overdose in an emergency situation.

Digoxin helps make the heart beat stronger and with a more regular rhythm.

Clonidine is used to treat hypertension (high blood pressure).

Furosemide (Lasix) treats fluid retention (edema) and is also used to treat high blood pressure (hypertension).

Sodium Bicarb buffers excess hydrogen ion concentration, raises blood pH and reverses the clinical manifestations of acidosis. Used to reverse acidosis in an emergency situation.

Diazepam- is used to treat anxiety disorders, alcohol withdrawal symptoms, or muscle spasms.

Diazepam is sometimes used with other medications to treat seizures. It is a schedule IV (four) controlled substance.

Atropine Sulfate is used to treat bradyasystolic cardiac arrest.

ProAir HFA is indicated for the treatment or prevention of bronchospasm.

Acetaminophen (Tylenol) an analgesic for mild to moderate pain relief.

Ibuprofen- a non-steroidal antiinflammatory medication used to treat mild to moderate pain.

Doxycycline- an antibiotic.

Metrodinazole (Flagyl) an antibiotic.

Medication list per www.drugs.com accessed 4/8/16 at 11:41 a.m.

In the "physician's office" the surveyors observed Lidocaine for injection (multiple vials), Pitocin and Methotrexate on a plastic cart.

The door to the office could not be locked as there was tape over the latch preventing the door from locking. Staff #2 stated, "That door doesn't lock. It's broken."
2. At 2:15 PM on 4/4/2016, the surveyors observed vials of Lidocaine and Pitocin sitting on top of a plastic rolling cabinet behind a desk in the physician's office. The latch on the door to the office was broken and the door could not be locked.

3. At 2:30 PM on 4/4/2016, the surveyor observed a key hanging in a door between the reception area and the nursing station where a printer and blank paperwork sat on a counter. The surveyor entered the door with Staff #1 and observed office supplies and multiple bottles of Misoprostol 100 mg (milligram) tablets with "prescription only" written on the label. The key remained in the door throughout the inspection.

4. During the course of the physical plant tour on 4/4/2016 at 2:50 PM, the following observations were made by the surveyors in the laboratory area:
   - Methergine (4 vials) stored in the refrigerator with blood samples and lab testing controls.
   - 6 prefilled syringes of Hepatitis B vaccine which expired 2/2016
   - Tubersol PPD derivative with an open date of 12/5/2015 written on the box, and a manufacturer's expiration date of 12/17/2015.
   - An unlocked drawer of the desk in the laboratory room contained an open container of Methotrexate which was not labeled with an open date.

5. In a cabinet of exam room 1 where procedures were performed the following expired items were observed by the surveyors to be available for use on 4/5/2016 at 3:30 PM:
   - 2 bottles of Ferric Subsulfate solution expired 10/2015 and 3/12/16.
### Statement of Deficiencies and Plan of Correction

**State of Virginia**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
<th>MULTIPLE CONSTRUCTION</th>
<th>DATE SURVEY COMPLETED</th>
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<tbody>
<tr>
<td>AF-0015</td>
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<td>04/05/2016</td>
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</table>

**NAME OF PROVIDER OR SUPPLIER**

**VIRGINIA HEALTH GROUP**

**STREET ADDRESS, CITY, STATE, ZIP CODE**

**8316 ARLINGTON BLVD, SUITE 220**

**FAIRFAX, VA 22031**

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<th>COMPLETE DATE</th>
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<td>T 315</td>
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<tr>
<td></td>
<td>- A bottle of Misoprostol 200 mg with &quot;expires 2/26/16&quot; written on the label was in the cabinet of exam room 1 where procedures were performed.</td>
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<td></td>
<td>- (1) 22 gauge angiocath expired 9/2014.</td>
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<tr>
<td></td>
<td>6. The surveyors observed (2) ammonia inhalants expired 9/2014 were lying on top of the counter in exam room 1 at 3:30 PM on 4/5/2016.</td>
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<tr>
<td></td>
<td>Misoprostol is a medication used to cause an abortion.</td>
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<tr>
<td></td>
<td>Methergine is a medication used to control bleeding after an abortion procedure.</td>
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<td></td>
<td>Methotrexate is a chemotherapy drug used in this case to induce abortion.</td>
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<tr>
<td></td>
<td>Lidocaine is a medication used to numb tissue.</td>
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<tr>
<td></td>
<td>Ferric Subsulfate is a liquid used to stop bleeding of tissues.</td>
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<tr>
<td></td>
<td>Tubersol PPD is a medication used to test for tuberculosis (TB).</td>
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<tr>
<td></td>
<td>Pitocin is a medication used to induce contraction of the uterus, in this case to induce abortion.</td>
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<td>(<a href="http://www.drugs.com">www.drugs.com</a> accessed 4/12/16 at 12:24 p.m.)</td>
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<td>T 320</td>
<td>12VAC5-412-260 D Administration, Storage, Dispensing of Drugs</td>
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<td>The mixing, diluting or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18 VAC 85-20-400 et seq.).</td>
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This RULE: is not met as evidenced by:
Based on observation, the facility staff failed to ensure medications were prepared for administration in a sanitary environment.
The findings included:

1. On 4/4/16 at 2:00 p.m. the survey team entered the facility and were put into the "Physician’s office" in order to have a space in which to work. The desk in the office was not clean. It contained debris, smudges of foreign dried material and the surface was not intact (worn off shellac/lacquered finish). The surveyors used hand sanitizer in order to clean the desk in order to work. When the provider arrived at approximately 6:00 p.m., the survey team was asked to move to another space in which to work as the provider "needed the office to work and see patients and change". When the surveyor returned to the office to finish collecting items, the provider was sitting at the desk, with no barrier on the desk, drawing up multiple syringes of medications and placing them together, aside, on the surface of the desk. It was also observed that none of the syringes had been labeled as to their contents and they remained on the desk surface.

   Staff #1 stated on 4/6/16 at 6:50 p.m. when asked if there were medications kept anywhere else in the facility, "No, the physician keeps his medications in his office and draws them up there."

2. The surveyor observed dried yellow splatter on the wall near a sharps container in the laboratory area. An interview was held with Staff #1 at 4:10 PM on 4/5/2016 regarding the yellow splatter, and he/she stated, "That's the Methotrexate. When the doctor tops it off he/she puts the cover over the end of the needle but is messy sometimes and it shoots out of the syringe and gets on stuff." Staff #1 was asked what his/her knowledge of Methotrexate and how it works, he/she stated "It stops cell growth."
3. The MSDS (material safety data sheet) for Methotrexate gives the following guidance for general handling: "Avoid breathing vapor or mist. Avoid contact with eyes, skin, clothing. When handling use appropriate PPE (personal protective equipment) (see section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal methods to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems, or other equivalent controls".

T 330
12VAC5-412-270 Equipment and Supplies

An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:
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

This RULE: is not met as evidenced by:

Based on clinical record review and facility document review, the facility staff failed to maintain adequate medical equipment for the treatment of patients. Sterile suturing equipment and supplies were not available when a patient experienced prolonged bleeding after a procedure and the patient had to be transported to the local emergency department for care.

The findings included:

In February 2016, Patient #2 had a surgical abortion performed at the facility. Documentation in the clinical record revealed the patient experienced prolonged bleeding and had to be transported to the local emergency department for treatment. Further review of the record revealed a discussion with the facility provider and the "on call" emergency room provider which documented, "(time) laceration on internal cervix os (os is the part of the cervix that can be seen from inside the vagina during a gynecologic examination is known as the ectocervix. An opening in the center of the ectocervix, known as the external os, opens to allow passage between the uterus and vagina) sutured and patient sent home..." Review of the facility adverse occurrence log revealed "no sutures were available..." on that date but that the facility had obtained the supplies.
### Virginia Health Group

**Address:**
8316 Arlington Blvd, Suite 220, Fairfax, VA 22031

**Provider Identification Number:**
AF-0015

**Date Survey Completed:**
04/05/2016

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<th>ID</th>
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<th>Summary Statement of Deficiencies</th>
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<tr>
<td>T 335</td>
<td>12VAC5-412-280 Emergency Equipment and Supplies</td>
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An abortion facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope and intensity of services provided. Such medical equipment, supplies and drugs shall be determined by the physician and shall be consistent with the current edition of American Heart Association’s Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Drugs shall include, at a minimum, those to treat the following conditions:

1. Cardiopulmonary arrest;
2. Seizure;
3. Respiratory distress;
4. Allergic reaction;
5. Narcotic toxicity;
6. Hypovolemic shock; and
7. Vasovagal shock.

This RULE: is not met as evidenced by:

Based on an audit of the facility’s emergency drugs and equipment and staff interview, the facility staff failed to ensure that appropriate emergency medical equipment, supplies, and drugs were maintained adequately to manage potential emergencies.

Findings include:

1. The facility’s emergency box was audited on
4/5/2016 at 3:00 PM and it was noted that the following medications and supplies were expired:
- Diphenhydramine 50 mg/ml (milligrams per milliliter) injectable 4 vials expired 7/2015
- Procainamide HCl 1gm/2ml (grams per milliliter) 1 vial expired 9/1/2015
- Sodium Bicarb 2 syringes
- (2) 20 gauge angiocaths expired 11/2015
- (1) 22 gauge angiocath expired 9/2015
- Sodium Bicarb 8.4% 50 meq (millequivalents) expired 12/1/2015

2. The surveyor audited the facility’s emergency cart located in the recovery room on 4/5/2016 at 3:00 PM and noted the following:
   - It was noted that the last PM (preventative maintenance) sticker on the AED (automated external defibrillator) was dated 1/12/2015.
   - The adult monophasic or biphasic pacing defibrillator electrodes available for use had an expiration date of 12/2013.
   - 3 packs of EKG (electrocardiogram) electrodes available for use expired 1/2016.
   - The PM on the pulse oximeter was last done on 1/12/2015.
   - The PM on the EKG machine was last done on 1/12/2015.
   - The PM on the data scope monitor was last done on 1/12/2015.


3. The surveyor interviewed Staff #1 and Staff #3 and asked how often staff checked the emergency supplies and medications, and whether there was a log for documentation of the checks on 4/5/2016 at 5:30 PM. Staff #1 stated "There is no log for checking the emergency equipment." Staff #3 stated, "I haven't checked the emergency
### Continued From Page 45

The surveyor asked Staff #3 to demonstrate how to check the AED to assure it was working properly. Staff #3 turned the AED on, and it said "Place electrodes, replace battery."

### T 335

**12VAC5-412-300 Health Information Records**

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:

1. Patient identification;
2. Admitting information, including patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy;
5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses' progress notes,
   h. Condition at time of discharge,
   i. Patient instructions, preoperative and postoperative; and
   j. Names of referral physicians or agencies.
6. Any other information required by law to be maintained in the health information record.
This RULE: is not met as evidenced by:

Based on review of 6 (six) clinical records, the facility staff failed to ensure an accurate and complete clinical record was maintained for Patient # 1, 2, and #3.

The findings included:

1. For Patient #2, the clinical record did not contain any documentation of the "pathology report" documenting the examination of the Products of Conception (POC) that were removed during the procedure. There was no documentation of the medication "hurricane topical" which is a numbing spray which Staff #6 stated was "used on all patients". The patient had to be sent to the emergency room due to prolonged bleeding. There was no documentation of when the ambulance was called, or when the patient left the facility, condition at discharge or discharge vital signs. There was no "nursing notes" documentation of the events. Corrections in the chart were made by "scribbling" through the information or marking over it with a darker correction.

2. For Patient #3 there were no pre-op vital signs documented. Corrections in the chart were made by "scribbling" through the information or marking over it with a darker correction. There was no documentation of the medication "hurricane topical" which is a numbing spray which Staff #6 stated was "used on all patients".

3. A review of Patient #1’s medical record included documentation that he/she was allergic to Aspirin. The abortion procedure records dated 11/14/2015 included medication orders for administration of Ibuprofen 800 mg or Acetaminophen 1,000 mg by mouth as needed for pain in recovery. Documentation on the recovery
### SUMMARY STATEMENT OF DEFICIENCIES

**ID**

**PREFIX**

**TAG**

**ROOM RECORD**

<table>
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Room record was that Patient #1 was administered Ibuprofen 800 mg (milligrams) at 8:51 PM. FDA (food and drug administration) postmarket drug safety information for patients and providers for Ibuprofen includes the following:

"Warnings: Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, and blister".

An interview with Staff #6 on 4/5/2016 at approximately 7:00 PM regarding whether patients who have Aspirin allergies are specifically questioned about allergies to Ibuprofen of other NSAID's (non-steroidal anti-inflammatory drugs), he/she stated, "Yes, but how often does that reaction happen due to Aspirin allergy? No, we don't usually ask if they have taken Ibuprofen if they have an Aspirin allergy."

The abortion procedure record dated 11/14/2015 for Patient #1 documented that the procedure time started at 9:34 PM and the procedure time ended at 9:44 PM. Documentation of care on Patient #1’s RR (recovery room) record started at 8:45 PM, ended at 9:25 PM, and the patient's discharge time was documented as 9:49 PM. The time entries on the RR record had been written over and were difficult to read. Staff #1 and #6 were interviewed on 4/5/2016 at approximately 7:00 PM about the inconsistent time documentation, and Staff #6 stated, "I noted my signature as 8:45 at the end of the abortion procedure note, and that lines up with what is on the recovery room notes corrected time. The clock must not have been right-when does the time change?" Staff #1 stated, "The procedure start and end time was just documented wrong, the time on the recovery room record is right."

At approximately 7:30 PM on 4/5/2016 Staff #1,
when questioned about the use of Hurricane numbing spray for surgical procedures, stated "We use Hurricane on everybody." Operative reports for Patient 4 and Patient 1 lacked documentation of the application of Hurricane numbing spray.

**12VAC5-412-310 Records Storage**

Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.).

This RULE: is not met as evidenced by: Based on observations and staff interview, the facility staff failed to ensure that medical records were stored according to applicable federal and state laws.

Findings include:

1. At 2:40 PM on 4/4/2016 the surveyor opened a door in the patient bathroom and observed boxes of patient medical records being stored in boxes. One of the boxes had the top off, was lying on its side, and records were spilling out of the side of the box. The record storage area was accessible to anyone who entered the patient bathroom.

2. At 3:00 PM on 4/4/2016 the surveyor opened an unlocked door at the end of the hall between exam room 2 and the office where patient counseling was conducted and observed boxes of patient records.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

**NAME OF PROVIDER OR SUPPLIER:** VIRGINIA HEALTH GROUP  
**STREET ADDRESS, CITY, STATE, ZIP CODE:** 8316 ARLINGTON BLVD, SUITE 220, FAIRFAX, VA 22031

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<td>T 400</td>
<td>12VAC5-412-340 A Disaster Preparedness</td>
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3. At 7:00 PM on 4/4/2016 while speaking with Staff #1 about patient record reviews and information which the surveyors would need to access, he/she was asked about the boxes of records that had been observed in the unlocked closets in the patient bathroom and in the hallway. Staff #1 stated, "That's where we keep the records. They are in boxes by date and by patient's names alphabetically."

12VAC5-412-340 A Disaster Preparedness

Each abortion facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.

This RULE: is not met as evidenced by:

Based on staff interview and review of the facility’s documentation of emergency practices, the facility staff failed to ensure that employees received training in the evacuation of all occupants in order to protect them from hazards in the event of a fire or other disaster.

Findings include:

1. The surveyor asked Staff #1 for documentation of the facility’s fire drill and emergency preparedness in-service/training. Staff #1 submitted a notebook for review which documented the last fire drill practice as done in 2014, and stated, "I haven't done one since I have worked here."
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

- **STATE OF VIRGINIA**
- PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0015
- MULTIPLE CONSTRUCTION
  - A. BUILDING ________________
  - B. WING ________________
- COMPLETED DATE: 04/05/2016

#### NAME OF PROVIDER OR SUPPLIER
- VIRGINIA HEALTH GROUP

#### STREET ADDRESS, CITY, STATE, ZIP CODE
- 8316 ARLINGTON BLVD, SUITE 220
- FAIRFAX, VA 22031

#### SUMMARY STATEMENT OF DEFICIENCIES

**T 410** Continued From Page 50

**T 410** 12VAC5-412-350 A Maintenance

The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

This RULE: is not met as evidenced by:

Based on observation, the facility staff failed to maintain patient areas in good repair.

The findings included:

Upon entrance to the facility on 4/4/16 at 2:00 p.m., the survey team observed the patient waiting room to have chipped and peeling paint on the walls and panel boards hanging loose around an air conditioning unit. There was a piece of the countertop missing from a small ledge which exposed sharp edges. The area was unclean. There was graffiti scratched into the wall on the left side of the room and black smudges on the paint in multiple places on the walls of the entire room. There was a plastic type vase containing some artificial flowers and decorative pebbles on the receptionist window ledge which was cracked allowing some of the pebbles to fall onto the floor.

In Exam Room 1 (one), also the procedure room (where the surgical procedures were performed), the cabinet doors were taped together with a micropore tape which was adhered to the cabinet doors. When the surveyor attempted to open the...
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

<table>
<thead>
<tr>
<th>A. BUILDING</th>
<th>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0015</th>
<th>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0015</th>
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<td>B. WING</td>
<td>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</td>
<td>(X3) DATE SURVEY COMPLETED 04/05/2016</td>
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**STATE OF VIRGINIA**

**NAME OF PROVIDER OR SUPPLIER**

**VIRGINIA HEALTH GROUP**

**STREET ADDRESS, CITY, STATE, ZIP CODE**

8316 ARLINGTON BLVD, SUITE 220
FAIRFAX, VA 22031

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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<td>T 410</td>
<td>Continued From Page 51</td>
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<td>cabinet to view the contents, the door fell off. Please refer to 12VAC5-412-220 (0195) for additional information.</td>
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<td>The surveyors also observed multiple pieces of equipment being used for patient care which included the following:</td>
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<td>Exam light (2)</td>
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<td>Exam Table (2)</td>
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<td></td>
<td>Suction Machine -gomco recovery room</td>
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<td></td>
<td>Pulse oximeter</td>
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<td>AED/Defibrillator (used in the event of a cardiac arrest)</td>
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<td>Datascope-vital signs monitor</td>
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<td></td>
<td>Heating pad (2)</td>
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<td></td>
<td>Autoclave</td>
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<td>Centrifuge</td>
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<td>Gel warmer</td>
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<td></td>
<td>Vacuum Suction machine in procedure room used during the surgical procedures</td>
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<td></td>
<td>All of the equipment listed above with the exception of the Suction machine used in the procedure room for surgical procedures had not had an annual preventative maintenance check since January 2015 as per a document presented to the survey team by Staff #1 on 4/5/16 at 4:10 p.m..</td>
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<td>The vacuum suction machine used for the surgical procedures contained a sticker which documented no preventative maintenance check since 2012.</td>
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<td>The survey team also observed that there was no call system located in the patient bathroom which could be used in the event a patient required assistance.</td>
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</table>
An unannounced Licensure Biennial survey for a First Trimester Abortion Facility was conducted 10/15/2014 through 10/16/2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey.

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

A physician shall not perform an abortion without first obtaining the informed written consent of the patient pursuant of 18.2-76 of the Code of Virginia.

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to obtain a signed written consent for an abortion for one (1) of twenty (20) patients included in the sample. (Patient #3)

The findings included:

Review of Patient #3's medical record revealed the patient was admitted to the facility on 11/15/2013 for a medical abortion. Review of Patient #3's medical record indicated the patient elected to have an in-center suction abortion. Patient #3's medical record contained an informed consent form titled "In-Center Suction Abortion", which had not been signed by the patient or staff. Patient #3 had an in-center suction abortion on 12/04/2013.

An interview was conducted on 10/15/2014 at approximately 4:45 p.m. with Staff #1 and Staff #7. Staff #1 reviewed Patient #3's medical record.

VLPP abortion patients generally sign at least four consent documents as part of their service:
- 24 Hour Informed Consent Record
- Client Information for Informed Consent (specific to abortion type: surgical or medication)
- Request for Surgery or Special Procedure (specific to abortion type: surgical or medication)
- Request for Medical Services (general consent to receive services at the facility)

The first document includes all of the information required by Virginia state law for purposes of informed consent and was completed and signed by the patient. Therefore, the facility did not perform a surgical/suction abortion without a signed written informed consent. The second document was inadvertently missed in the process of the patient changing her mind about the type of abortion she would select. All other documents were properly signed and witnessed.
Staff #1 stated, "The consent is not signed, it was missed." Staff #1 acknowledged the facility performed a surgical/suction abortion without Patient #3 signing the informed consent.

12 VAC 5-412-220 B Infection prevention

B. 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;
   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 observation, interview and document review the facility staff failed to perform hand hygiene after removing gloves and prior to donning new gloves for three of three observations.

To prevent any such omissions in the future, VLPP has implemented a QA review step to confirm all signature lines are completed prior to scanning documents into the electronic health record. In addition, a staff review will be conducted on or before 12/12/14 to reinforce the importance of thorough completion of all consent documents.

VLPP management is working with our infection control consultant to review and revise our infection control policies specific to glove use and hand hygiene. With her guidance/assistance we will identify and contract with an infection control specialist to complete a hands-on training with abortion staff members by 12/12/14.

In addition, periodic targeted observational audits will be incorporated into the 2015 QA work plan to ensure consistent implementation of these policies and procedures.
The findings included:

Observations conducted on 10/15/2014 at 9:30 a.m., with Staff #3 during quality check for equipment. Staff #3 obtained a vial of blood, removed the top from the vial and used a pipette to place blood on a slide for Rh factor testing. Staff #3 removed his/her contaminated gloves potentially contaminating his/her hands. Staff #3 without performing hand hygiene retrieved a new set of gloves from the box of gloves potentially contaminating the other gloves in the box and the new gloves. Staff #3 handled other equipment in the laboratory area with the potentially contaminated gloves.

Observations were conducted on 10/16/2014 at approximately 12:09 p.m. in Procedure Room #1 as Staff #2 and Staff #4 cleaned the room post a procedure. Staff #2 handled the contaminated equipment from the previous procedure. Staff #2 changed gloves six times without performing hand hygiene between glove changes during the process of removing dirty items and setting up clean areas. Staff #2 failed to utilize the hand sanitizer located next to the box of gloves.

Review of the facility’s policy titled “VIII. Hand Hygiene Instructions: ... A. When to Wash Hands: 1. After touching blood, body fluids, secretions, excretions or items that touch these substances. 2. After removing gloves. 3. Before donning gloves. 4. Between each patient even if gloves are used. B. Where to Wash Hands: 1. ... exam room ...lab ... D. When to Use Alcohol-Based Waterless Hand cleaner ... 2. Soap and water are not immediately available...”

An interview was conducted on 10/16/2014 at 2:15 p.m., with Staff #8 related to the findings and the
review of the facility's policy. Staff #8 reviewed the facility's policy and stated, "I think that it is just your interpretation of the policy." The surveyor informed Staff #8 regarding the potential cross-contamination of not having cleaned hands prior to reaching into the box of gloves and then spreading infectious agents.

"CDC (Center for Disease Control and Prevention) Protocol for hand hygiene and glove use" in part read: "Glove use: 1. In general, gloves should be worn prior to contact with patients at the treatment station and potentially contaminated surfaces (e.g. environmental surfaces) ... Gloves should always be changed between patients and between clean and contaminated sites on the same patient. Holding a glove in one's hand instead of wearing it is not considered acceptable. Glove use does not preclude the need for hand hygiene after removing gloves. 2. Examples of situations when gloves should be changed: 1. After contact with blood or body fluids ... 2. After contacting a potentially contaminated site before moving to a clean site"

T 175 12 VAC 5-412-220 C Infection prevention

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
   1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);  
   2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;  
   3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);

T 175

The tape residue was immediately removed from the exam table. Nursing staff will no longer apply tape to the exam table.

Staff #4 was misquoted. The recliners are in fact disinfected between patients; they are thoroughly wiped down with germicidal disposable wipes, air dried and re-covered with disposable cloth liners. The food particles (from patient snacking) that were discovered in the lower crevices of the
4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
   (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
   (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer’s recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observations and document review the facility failed to ensure:

1. Environmental surfaces were disinfected

recliners were removed with a small vacuum. The recovery room nurse now applies additional liners to the recliner seat to prevent crumbs from falling between the cushion and sides. In addition, the janitorial service has been notified to incorporate this additional cleaning step into the daily routine.

A review of room cleaning/disinfecting procedures, with opportunities for hands-on practice, will be incorporated into the planned training with the infection control specialist (see T170).
between patients;
2. Staff maintained procedures which prevented cross-contamination and the transmission of infectious agents.

The findings included:

1. An observation and interview was conducted in "Procedure Room #1" on 10/15/2014 at 10:45 a.m., with Staff #1 and Staff #4. The facility staff verified the procedure room was ready for use. The observation revealed a sticky residue on the left side of the exam table. The finding was verified by Staff #4. Staff #4 reported the nurse applied tape to the table during the process of anchoring the patient's intravenous (IV) site. Staff #1 agreed the "tape residue" provided a surface for the potential spread of infectious agents and prevented the exam table from being disinfected between patients.

An observation and interview was conducted in "Procedure Room #2" on 10/15/2014 at 10:56 a.m., with Staff #1 and Staff #4. The facility staff verified the procedure room was ready for use. The observation revealed a sticky residue on the exam table. The finding was verified by Staff #4. Staff #1 acknowledged the "stick residue" should have been removed during the cleaning process. Staff #1 agreed the substance prevented the exam table from being disinfected between patients.

Observations were conducted in the "Recovery area" on 10/15/2014 at 11:05 a.m., with Staff #1, Staff #3, and Staff #4. The facility staff verified the "Recovery area" was ready to receive patients. The observation revealed four (4) of the seven (7) recliners had food particles between the seat cushion and the bilateral sides. Staff #3 reported the recliners were cleaned between each patient.
Staff #3 reported the patients were given cracker-like snacks during the recovery process. Staff #3 and Staff #4 verified the four recliners had food particles between the seat cushion and the bilateral sides. Staff #4 verified the recliners had not been disinfected between patients.

2. Observations were conducted on 10/16/2014 at approximately 12:09 p.m. in Procedure Room #1 as Staff #2 and Staff #4 cleaned the room after a procedure. Staff #2 picked up a container of disinfecting cloths from a cart containing supplies located in the procedure room. Staff #2 removed several disinfectant cloths from the container and sat the container on the top of the biohazard (red) box. Staff #2 determined the exam table had air dried and informed Staff #4 to prepare the exam table. Staff #2 picked up the container of disinfecting cloths from the bio-hazard box and placed the container on the exam table. Staff #4 began to set up the exam table. The surveyor stopped the process and asked Staff #2 if he/she had picked up the container of disinfecting cloths from the bio-hazard box? Staff #2 replied “Yes.” Staff #2 was able to determine he/she had moved an item from a "dirty/contaminated area" to a "clean area." Staff #2 obtained several disinfectant cloths and wiped the exam table again. Staff #2 explained while the exam table was air drying, he/she would set-up the physician's equipment for the next procedure. The observation revealed a cart with a disposable absorbent padding covering the top shelf. Staff #2 reported the absorbent padding was not changed between cases. The top shelf of the cart had six emesis basins stacked inside of each other, a pump bottle of hand sanitizer, a partially used box of gloves, and a container of antiseptic skin cleanser. Staff #2 obtained four large cotton tip applicator and gauzes and placed them on the absorbent pad, which had been used during the
previous case. Staff #2 picked up the container of disinfecting cloths from the bio-hazard box and placed it on the cart along with the clean supplies on the absorbent pad. The surveyor attempted to stop Staff #2 prior to his/her reaching into a drawer, retrieving a sterile pack, and placing it next to the clean supplies with the contaminated container of disinfecting cloths. The surveyor asked Staff #2 to process the potential contamination by moving the container of disinfecting cloths from the bio-hazard box to an area with “clean supplies.” Staff #2 was able to process that he/she had contaminated the field and introduced potential infectious agents to the clean supplies.

An interview was conducted on 10/16/2014 at approximately 2:15 p.m., with Staff #1 and Staff #8. The surveyor informed Staff #1 and Staff #8 regarding the above findings. Staff #1 acknowledged the staff involved in the cleaning process had failed to perform the task in the proper manner.
**Summary Statement of Deficiencies**

An unannounced First Trimester Abortion Facility (FTAF) Biennial Licensure inspection was conducted June 4, 2018, June 5, 2018 and June 7, 2018. Two (2) Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the inspection. The inspectors conducted observations, interviews and document reviews to determine compliance.

The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Rev. 03/22/2017). The deficiencies cited follow in this report.

**12 VAC5-412-170 A Administrator**

The governing body shall select an administrator who shall be responsible for the managerial, operational, financial, and reporting components of the abortion facility including but not limited to:

1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;

2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation;

3. Ensuring the accuracy of public information materials and activities;

4. Ensuring an effective budgeting and accounting system is implemented; and

5. Maintaining compliance with applicable laws and regulations and implementing corrective action.
This RULE: is not met as evidenced by:

Based on interview and document review it was determined the administrator failed to ensure nursing staff administered medication in compliance with physician orders for three (3) of four (4) patients that received oral sedation.

(Patients #1, #10, and #11)

The findings included:

During an interview on June 4, 2018 at approximately 11:30 a.m., Staff Member #4 reported the facility's Administrator was away and would not return until June 7, 2018. Staff Member #4 reported he/she was the alternate Administrator. Staff Member #4 reported the facility utilized standing physician orders.

Review of the facility's "Standing Orders for Surgical Abortions" included under "Sedation Options" "If a patient request oral sedation she may receive the following 0.5 mg (milligram) Diazepam (Valium) Or 0.5 mg Alprazolam (Xanax) ...

Review of Patient #1's medical record documented the patient was admitted and terminated her pregnancy on April 10, 2018. Patient #1's medical record documented the nurse administered "Xanax 1 mg."

Review of Patient #10's medical record documented the patient was admitted on April 6, 2018 and terminated her pregnancy on April 10, 2018. Patient #10's medical record documented the nurse administered "Xanax 1 mg."

Review of Patient #11's medical record
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<td>T 045</td>
<td>Continued From Page 2</td>
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<td>documented the patient was admitted on March 15, 2018 and terminated her pregnancy on March 22, 2018. Patient #11's medical record documented the nurse administered &quot;Xanax 1 mg.&quot;</td>
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<td>T 195</td>
<td>12 VAC5-412-220 B Infection Prevention</td>
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<td>Written infection prevention policies and procedures shall include, but not be limited to:</td>
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<td>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;</td>
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<td>2. Training of all personnel in proper infection prevention techniques;</td>
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<td>3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;</td>
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<td>4. Use of standard precautions;</td>
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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 observation, interview and document review the facility failed to develop safe injection practices policies and procedures to protect patients and medical staff.

The findings included:

On June 07, 2018 at 11:30 a.m., surveyors observed Staff Member #7 during the preparation of intravenous medication for two patients. Staff Member #7 removed the top cover from a single dose vial of Fentanyl packaged as 100 mcg in 2 ml. Staff Member #7 did not wipe the septum with an alcohol wipe prior to piercing with a sterile needle attached to a syringe. Staff Member #7 then pulled the entire 2 ml solution into the syringe and removed the needle from the septum. Staff Member #7 then took a second sterile syringe that did not have a needle attached and placed the needle of the first syringe into the opening of the
Second syringe so medication could be transferred between the two syringes. Staff Member #7 then injected 1 ml of solution into the second syringe so that both syringes would contain 1 ml of Fentanyl or a dose of 50 mcg for each patient, namely turning the single dose vial into a multi-dose vial. Staff Member #7 then prepared a 2 mg dose of Midazolam for each patient by using a single dose vial for each. Staff Member #7 failed to wipe the rubber septum of both vials of Midazolam with an alcohol wipe prior to piercing with a sterile needle. Staff Member #7 recapped the needles used during the preparation of the drugs and placed all used items in a sharps container before leaving the station.

On June 07, 2018 at 12:21 surveyors discussed the medication preparation observation with Staff Member #5 and reviewed the clinic's policy and procedure. Although Staff Member #5 could identify a list of sources used as a basis for the clinic's policy and procedures as a whole, he/she could not specifically identify the nationally recognized standard used as a source for the policy and procedure relating to the preparation of IV medication. Staff Member #5 further advised "my silence is agreement."

Staff Member #7 provided a copy of two policies and procedures relating to the preparation of IV medication. Both policies specifically describe the preparation of medication from a multi-dose vial but neither policy and procedure outlined the preparation of medication from a single dose vial.

The policies titled "Procedure for Handling Controlled Medications" and "Medication Therapy Practices" state in part:

"If using the multi-dose vials, staff will clean the stopper of the MDV before each needle puncture."
Neither policy addresses the puncture of the stopper on a single dose vial.

The policy titled "Medication Therapy Practices" states in part:

"5. Staff will use a clean syringe and needle for each medication. For example, if the physician has ordered the staff to prepare IV sedation medications for 5 patients, the staff will...

d. Draw up 10 cc of Midazolam (10 mg/ 10 ml) into a syringe.
e. From that syringe, inject 2 cc (2 mg) each into 5 syringes...

Staff Member #7 generally followed the policy and procedure as outlined by the clinic when preparing Fentanyl for two patients although it should be noted that neither policy or procedure specifically discussed single does vials.

According to the Safe Injection Practice Coalition (SIPC) in conjunction with the Centers for Disease Control and Prevention (CDC) regarding safe injection practices. "... IV.H. Safe Injection Practices
The following recommendations apply to the use of needles, cannulas that replace needles, and, where applicable, intravenous delivery systems: ... IV.H.5. Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use ... CDC guidelines call for medications labeled as "single-dose" or "single-use" to be used for only one patient. ... Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile
12 VAC5-412-220 C Infection Prevention

Written policies and procedures for the management of the abortion facility, equipment and supplies shall address the following:

1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air driers);

2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;

3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);

4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;

5. Procedures for handling/temporary storage/transport of soiled linens;

6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;

7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER
WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE

STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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SUMMARY STATEMENT OF DEFICIENCIES

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PROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

COMPLETE DATE

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to be used for each type of equipment, (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved.

The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;

8. Procedures for appropriate disposal of non-reusable equipment;

9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;

10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;

11. An effective pest control program, managed in accordance with local health and environmental regulations; and

12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the abortion facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observation, interviews, and document review it was determined the facility staff failed to ensure surfaces were disinfected between patients for one (1) of one (1) observation of cleaning post procedure. (Exam Room #2)
The findings included:

An observation was conducted on June 7, 2018 at 11:31 a.m., with Staff Member #6 during the cleaning/disinfection of Exam Room #2. Staff Member #6 removed the disposable paper from the exam table utilized during the termination of a pregnancy. Staff Member #6 used two (2) disinfectant wipes to clean and disinfect the surface of the exam table. Staff Member #6 cleaned in stages moving from the foot of the table to the head. On reaching the head of the exam table, Staff Member #6 picked up the pillow housed in a cloth pillow case. While holding the pillow in one hand, Staff Member #6 cleaned/disinfected the head portion of the exam table. After wetting the exam table with the disinfectant wipes, Staff Member #6 replaced the pillow on the exam table without changing the pillowcase.

Staff Member #6 verbalized the exam table cleaning and disinfection was completed and started to pull up the disposable paper to cover the pillow and the rest of the exam table. The surveyor asked when the pillowcase would be changed. Staff Member #6 stated, "I change the pillow's case at the end of the day." Staff Member #6 verbalized understanding related to the need to change the cloth pillowcase between each patient's use of a pillow.

At approximately 11:55 a.m. on June 7, 2018, the surveyor informed Staff Member #5 of the finding. Staff Member #5 verbalized the cloth pillowcases should be changed after each patient and placed in the dirty linen container.
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<th>ID PREFIX</th>
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<td>T 260</td>
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<td>12 VAC5-412-240 D Medical Testing and Laboratory Services</td>
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</table>

All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120).

This RULE: is not met as evidenced by:
Based on interview and document review it was determined facility staff failed to ensure the disposal of regulated medical waste, namely products of conception (POC), occurred within the required 14 days, for 6 out of eight surgical procedures reviewed during the medical records assessment.

The findings included:

On June 5, 2018 at 9:32 a.m. during a tour of the room where POC is packaged and stored, Staff Member #6 advised the facility policy states medical waste can be stored in the medical waste refrigerator for up to two weeks. He/she further advised some items may have remained in the refrigerator for a month specifically the month before due to a significant rainstorm.

On June 5, 2018, during a medical records review, surveyors found 8 surgical procedure dates that resulted in POC storage. On that same date, surveyors examined the medical waste pick-up log and cross-referenced the log finding the following POC storage where the medical waste remained at the facility for more than 14 days.

a. On April 10, 2018, Patient #1 underwent a surgical procedure that resulted in POC. That
medical waste remained at the facility for 20 days until picked-up on April 30, 2018.

b. On April 10, 2018, Patient #4 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 20 days until picked-up on April 30, 2018.

c. On April 10, 2018, Patient #10 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 20 days until picked-up on April 30, 2018.

d. On April 12, 2018, Patient #8 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 18 days until picked-up on April 30, 2018.

e. On May 1, 2018, Patient #5 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 34 days until picked-up on June 4, 2018.

f. On May 3, 2018, Patient #2 underwent a surgical procedure that resulted in POC. That medical waste remained at the facility for 32 days until picked-up on June 4, 2018.

On June 05, 2018 at 4:11 p.m. surveyors reviewed the medical records and medical waste pick-up logs with Staff Member #4 and Staff Member #5 in relation to the disposal of medical waste. Staff Member #4 advised the policy for the clinic is to have medical waste removed from the facility within 14 days. Staff Member #4 further reviewed the Virginia regulation and advised the regulation provided for a 15 day storage period before removal. Staff Member #4 advised he/she does acknowledge the facility violated its policy.

A review of the clinic's policy titled "Regulated Medical Waste Disposal Policy" states in part: "Storage of Biomedical/Biohazardous Waste shall not be greater than 14 days."

According to 9VAC20-120-150 products of
conception is considered regulated waste. "List of controlled regulated wastes ... 3. Tissues and other anatomical wastes. All human anatomical wastes and all wastes that are human tissues, organs, or body parts are regulated medical waste ..."

According to 9VAC20-120-360. "Temperature Control and Storage Period. Any regulated medical waste stored for more than seven days must be refrigerated, stored in an ambient temperature between 35° and 45°F (2° and 7°C). If the material is stored away from the site of generation and the time in storage is unknown, the regulated medical waste must be refrigerated. No regulated medical waste shall be stored for more than 15 days at the site of generation. Procedures shall be provided to ensure that the above storage timeframes are met. The date that the waste is first placed in storage will be provided on any outer packaging while the waste is in storage."

An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies and pharmacological agents, as required by 18 VAC 85-20-360 B:

1. Appropriate equipment to manage airways;
2. Drugs and equipment to treat shock and anaphylactic reactions;
3. Precordial stethoscope;
4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen...
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER: WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE

STREET ADDRESS, CITY, STATE, ZIP CODE: 2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

ID PREFIX TAG: T 280

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

T 280

Continued From Page 12

saturation;

5. Continuous electrocardiograph;

6. Devices for measuring blood pressure, heart rate and respiratory rate;

7. Defibrillator; and

8. Accepted method of identifying and preventing the interchangeability of gases.

This RULE: is not met as evidenced by:

Based on observation, interview and document review it was determined the facility failed to maintain equipment as required by 18VAC85-20-360 B for a facility administering moderate sedation/conscious sedation, namely a device for continuous electrocardiograph monitoring.

The findings included:

On June 4, 2018, at 4:15 p.m. with Staff Member #5 and Staff Member #7, surveyors examined clinic equipment, supplies and pharmacological agents to determine if they were present and in good working order to satisfy the regulation for facilities administering moderate sedation/conscious sedation. During that examination, surveyors could not locate equipment capable of continuous electrocardiograph monitoring. Staff Member #5 and Staff Member #7 confirmed the clinic did not have the equipment onsite to satisfy that requirement.

On June 5, 2018, a surveyor review of privileging documents for Staff Member #2 and Staff Member

STATE FORM O4EN11
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Americans United for Life
On June 07, 2018 at 10:10 a.m. during an interview with Staff Member #5, he/she revealed the clinic performed 37 procedures utilizing conscious sedation since March 01, 2018. Additionally, at 1:12 p.m., Staff Member #4 advised two (2) conscious sedation procedures were scheduled on this date and a device for continuous electrocardiograph monitoring was not in place after the realization of the deficient practice three days prior.

A review of the clinic's policy and procedures titled "Anesthesia Services states in part:

"THE CLINIC offers Office Based conscious sedation, and local anesthesia services, directed and under the supervision of a Virginia licensed physician who is certified in ACLS..."

The following supplies and equipment are readily available on site ...
5. Continuous electrocardiograph ..."

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 observations, interviews and document reviews it was determined the clinical staff failed to ensure:

1. Controlled medication withdrawn from its vial was stored with a label that identified the amount, strength, and date, with the initials of the clinician that placed the medication in the syringe or discarded.

2. Expired medications were not available for administration.

The findings included:

1. Observations during the initial tour of the facility on June 4, 2018 at 1:00 p.m., with Staff Members #4 and #5 revealed a syringe of clear liquid within the controlled medication lock box. The syringe on inspection had a partially attached blue label with the printed word "Fentanyl." The label did not identify the amount, strength, date or who removed the medication from its vial. The label also did not include a patient's name.

An interview was conducted on June 4, 2018 at approximately 1:09 p.m., with Staff Members #4 and #5. Staff Member #5 verified the syringe was not stored according to the facility's policy. Staff Member #5 reported if the medication was been drawn to administer to a patient and the patient declined, the medication should have been wasted by two (2) licensed staff. The surveyor requested the facility's policy.

Review of the facility's policy titled "Medication Therapy Practices" and the policy titled "Procedure for Handling Controlled Medications"
Continued From Page 15

The policies read in part "Drawing up IV [Intravenous] Sedation ... 6. Each syringe drawn up will be labeled with the patient’s name, medication quantities and strength, date and staff initials ..."

Review of the facility's policy titled "Medication Therapy Practices" directed "Wasting Medications ... 2. Controlled medications: once a dose has been drawn and prepared for patient use, if the medication is not administered, a staff member will dispose of the syringe into a sharps container while another staff witnesses. You can drain the medication into the sharps container before throwing the syringe as well. Or you can simply throw the syringe into the container without draining it ..."

An interview was conducted on June 5, 2018 at approximately 4:33 p.m., with Staff Members #4 and #5. Staff Members #4 and #5 verified two (2) licensed staff should have wasted the syringe/medication found in the controlled medication lock box.

2. An observation was conducted on June 4, 2018 at 1:37 p.m., in the facility's "Aftercare Area” with Staff Members #4 and #5. The observation revealed a medication refrigerator in the "Aftercare Area.” Observation of the medications housed in the refrigerator included an opened vial of Tuberculin Purified 5 TU (tuberculin units)/0.1 mL (milliliter) 1 mL vial dated as opened on "11/14/17." Staff Member #4 verified the vial was approximately "half full."

The surveyor inquired regarding the facility's policy for discarding multidose medication vials after opening. Staff Member #5 reported the medication was discarded twenty-eight (28) days after being opened. The surveyor requested Staff
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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<tr>
<th>ID</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<th>PROVIDER’S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<td>T 315</td>
<td>Continued From Page 16</td>
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<td>Member #4 to verify the date recorded on the Tuberculin Purified 5 TU/0.1 mL vial and the box. Staff Member #4 verbalized the date as &quot;11/14/17.&quot;. Staff Member #4 reported the licensed staff was responsible for ensuring all expired medications were properly discarded. Staff Member #5 stated, &quot;It's over the limit. Don't place it back in the refrigerator. We need to discard it.&quot; The surveyor requested the facility's policy regarding when opened medication needed to be discarded. The surveyor requested the manufacturer's directions included within the Tuberculin Purified 5 TU/0.1 mL box. Review of the manufacturer's directions &quot;...Vials in use for more than 30 days should be discarded.&quot; Review of the facility's policy titled &quot;Medication Therapy Practices,&quot; which read in part &quot;Wasting Medications 1. All expired non-controlled medications should remain in the original bottle, and disposed into the Medical RX disposal container. This container will be removed from the facility by a specialized contracted company for proper disposal ...&quot; During an interview on June 5, 2018 at approximately 4:35 p.m., Staff Members #4 and #5 verified the findings of the surveyor regarding the medications.</td>
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<td>T 355</td>
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<td>12 VAC5-412-300 Health Information Records An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. If medically indicated, it shall include, but not be limited to the following:</td>
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

AF-0020

06/07/2018

NAME OF PROVIDER OR SUPPLIER
WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE

STREET ADDRESS, CITY, STATE, ZIP CODE
2321 COMMONWEALTH DRIVE
CHARLOTTESVILLE, VA 22901

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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1. Patient identification;

2. Admitting information, including patient history and physical examination;

3. Signed consent;

4. Confirmation of pregnancy;

5. Procedure report to include:
   a. Physician orders;
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses' progress notes,
   h. Condition at time of discharge,
   i. Patient instructions (preoperative and postoperative);
   j. Names of referral physicians or agencies; and

6. Any other information required by law to be maintained in the health information record.

This RULE: is not met as evidenced by:

Based on interviews and document review it was determined:

1. The licensed nursing staff failed to document patient progress notes for three (3) of nine (9) surgical abortion patients included in the inspection sample. (Patients #11, #1 and #10)

2. The discharging nurse failed to document the correct level of consciousness (LOC) in accord with the facility's scale, for five (5) of nine (9) surgical abortion patients included in the inspection sample (Patients #1, #2, #6, #8, #10 and #11)
The findings include:

1. The facility’s nurse providing after procedure care failed to document a patient progress note, leaving that section of the patient's medical form blank for Patient #11 on March 22, 2018, and for Patient #1 and Patient #10 on April 10, 2018.

2. The facility's "Standing Orders for Surgical Abortion:" includes the discharge criteria for surgical patients. The facility's standing orders indicates the patient could be discharged when their "LOC (level of consciousness) is 10." On April 10, 2018, the discharging nurse indicated Patient #1's LOC was "2" at discharge. On May 3, 2018, the discharging nurse indicated Patient #2's LOC was "2" at discharge. On April 28, 2018, the discharging nurse indicated Patient #6's LOC was "2" at discharge. On April 12, 2018, the discharging nurse indicated Patient #8's LOC was "2" at discharge. On April 10, 2018, the discharging nurse indicated Patient #10's LOC was "2" at discharge. On March 22, 2018, the discharging nurse indicated Patient #11's LOC was "2" at discharge.

Interviews and patient chart reviews were conducted on June 5, 2018 from 3:36 p.m. through 4:03 p.m., with Staff Members #4 and #5. Staff Member #5 reviewed each patient medical record with the surveyors. Staff Member #5 verified each finding. Staff Member #5 stated, "[Name of Staff] works at a hospital, their scale must be different than the one we use" regarding the level of consciousness at the time of discharge. Staff Member #5 reported per the facility's scale for LOC at a level two (2) "the patient would not be able to walk." Staff Member #5 reported the surveyors' findings indicated the facility's medical records were inaccurate.
###审查

“政策和计划的纠正”

#### A. 建筑

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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<tr>
<th>ID</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
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- **Review of the facility's policy titled "Policy for Medical Records/Clinical Records" read in part "The Clinic will maintain clinical records in their original state. Each entry will be accurate, dated with the date of entry, and signed by the individual making the entry ..." With regard to medical record content the facility's policy titled "Policy for Medical Records/Clinical Records" specified the inclusion of progress notes.**

#### B. 翼

**STATE FORM**

- **STATE FORM**

**ADDRESS, CITY, STATE, ZIP CODE**

- **2321 COMMONWEALTH DRIVE**
- **CHARLOTTESVILLE, VA 22901**

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**Americans United for Life**

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**STATE FORM**

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**STATE FORM**
July 30, 2012

Certified Mail Delivery

Lilly Kane, Administrator
Women’s Health Clinic
101 South Whiting Street, Suite 215
Alexandria, Virginia 22304

RE: Woman’s Health Clinic, Alexandria, Virginia
Abortion Facility Initial Licensure Survey

Dear Ms. Kane:

An announced Initial Abortion Facility Licensure survey of the above agency was completed on July 19, 2012 by a Medical Facilities Inspector team from the Virginia Department of Health’s Office of Licensure and Certification (OLC).

Enclosed is the Licensure Inspection Report. This document contains a listing of deficiencies found at the time of this inspection.

You are required to file a plan for correcting these deficiencies. Your statements shall reflect the specific detailed actions you will take to correct deficiencies, prevent a recurrence of the deficiencies, and measures implemented to maintain compliance. You must also give the expected completion date of each deficiency.

Completion of corrective actions shall not exceed 30 working days from the last day of the inspection (due August 30, 2012) except for those corrective actions for deficiencies cited under 12VAC5-412-280 of the Regulations for the Licensure of Abortion Facilities, for which corrective action must be completed within two years of the issuance of the license.

After signing and dating your Plan of Correction, retain one copy of the report for your files and return the original to OLC within 15 working days of receipt of this inspection report. Please provide written documentation of the corrective actions taken by your agency for each of the deficiencies cited on the enclosed Licensure Inspection Report.
A copy of the completed form “Licensure Inspection Report” will be kept on file in this office and will be available for public review. OLC is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

Should you have any questions, please feel free to call Kathaleen Creegan-Tedeschi, Supervisor, Acute Care Licensing, Office of Licensure and Certification, at (804) 367-2156.

Sincerely,

[Signature]

Karen Remley, M.D., M.B.A., F.A.A.P.
State Health Commissioner

c: Erik Bodin, Director
   Office of Licensure and Certification

Enclosure
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**: ALEXANDRIA WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**: 101 S. WHITING ST. SUITE #215 ALEXANDRIA, VA 22304

**DATE**: 07/19/2012

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<td>T 000</td>
<td>12 VAC 5-412 Initial comments</td>
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</table>

An announced Initial Licensure Abortion Facility inspection was conducted at the above referenced facility July 18 and 19, 2012 by two (2) Medical Facility Inspectors from the Virginia Department of Health's, Office of Licensure and Certification.

The facility was found to not be in compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies were identified and cited, and will follow in this report.

<table>
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<th>ID TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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**Plan of Correction**

**T 030**

The Bylaws of the Governing Authority will be amended to specify that the governing body appoints the administrator and delegates to the administrator the authority and responsibilities as defined in the job description of the administrator.

The Governing Body minutes will be amended to appoint the (name of person) as the administrator.

The governing body minutes will be amended to contain guidelines on how clinical staff are granted privileges.

**LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER/REPRESENTATIVE'S SIGNATURE**

**STATE FORM**

**TITLE**

**PRESIDENT / ADMINISTRATOR**

**RECEIVED**

**AUG 27 2012**

**VDH/OLC**
# STATE WORKLOAD REPORT

Provider/Supplier Number: [ ]
Provider/Supplier Name: ALEXANDRIA WOMENS HEALTH CLINIC

**Type of Survey (Select all that apply)**
- A. Complaint Investigation
- B. Dumping Investigation
- C. Federal Monitoring
- D. Follow-up Visit
- E. Initial Certification
- F. Inspection of Care
- G. Validation
- I. Recertification
- J. Sanctions/Hearing
- K. State License
- L. CHOW
- M. Other

**Extent of Survey (select all that apply)**
- A. Routine/Standard Survey (all providers/suppliers)
- B. Extended Survey (HHA or Long Term Care Facility)
- C. Partial Extended Survey (HHA)
- D. Other Survey

---

## SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor/Use the surveyor's identification number

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<th>Last Date Departed</th>
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<th>On-Site Hours 8am-6pm</th>
<th>On-Site Hours 6pm-12am</th>
<th>Travel Hours</th>
<th>Off-Site Report Preparation Hours</th>
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<td>Total RO Clerical/Data Entry Hours</td>
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**Was Statement of Deficiencies given to the provider on-site at completion of the survey?** No
<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LEGAL IDENTIFYING INFORMATION)</th>
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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<td>T030</td>
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<td>On 7/18/12 the facility policy and procedure manuals were reviewed. The administrator was asked to provide the governing body minutes on 7/18/12, they were not available until 7/19/12. The governing body minutes did not have evidence of appointing (name of person) as the administrator. The governing body minutes also did not contain guidelines on how clinical staff were granted privileges.</td>
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<tr>
<td>T035</td>
<td>12 VAC 5-412-150 Policy and procedure manual.</td>
<td>T035</td>
<td>There will be a reorganization of the existing policies and procedures in individual binders to make a policy and procedures manual readily available for review by the Office of Licensure and Certification inspectors. The policy and procedure manual shall include:</td>
</tr>
</tbody>
</table>
|               | Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics: |               | 1. type of elective procedures  
2. types of anesthesia  
3. admission and discharge criteria  
4. obtaining the patient’s written consent prior to the procedure  
5. management and effective response to fire,  
6. disaster preparedness  
7. patient rights |
|               | 1. Personnel;  
2. Types of elective and emergency procedures that may be performed in the facility;  
3. Types of anesthesia that may be used;  
4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;  
5. Obtaining written informed consent of the patient prior to the initiation of any procedures;  
6. When to use ultrasound to determine gestational age and when indicated to assess patient risk;  
7. Infection prevention;  
8. Risk and quality management;  
9. Management and effective response to medical and/or surgical emergencies;  
10. Management and effective response to fire;  
11. Ensuring compliance with all applicable federal, state and local laws;  
12. Facility security;  
13. Disaster preparedness; |               |                                                                                                          |
<table>
<thead>
<tr>
<th>(X4) ID TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>T 035</td>
<td>Continued From Page 2 14. Patient rights; 15. Functional safety and facility maintenance; and 16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable. These policies and procedures shall be based on recognized standards and guidelines.</td>
<td></td>
<td></td>
<td>8-30-12</td>
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</table>

This RULE: is not met as evidenced by: Based on document review and staff interview the facility staff failed to ensure policies and or procedures were documented for the following topics: Types of elective procedures, types of anesthesia, admission and discharge criteria, obtaining the patient's written consent prior to the procedures, management and effective response.
<table>
<thead>
<tr>
<th>ID</th>
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<tbody>
<tr>
<td>T035</td>
<td>Continued From Page 3</td>
<td>8-30-12</td>
</tr>
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</table>

T 035

continued from page 3

to fire, disaster preparedness and patient rights.

The findings include:

On 7/18/12 a review of the facility policies and procedures was performed with the facility administrator present. There were no policies related to types of elective procedures and whether or not emergency procedures were performed, types of anesthesia used, admission and discharge criteria, obtaining the patients' written consent prior to the procedures, management and effective response to fire, disaster preparedness and patient rights.

The administrator stated, "No we don't have policies specific to those things (topics listed above)."

T 045

A written statement will be adopted by the governing body that the governing body will appoint the administrator and define the administrator's authority, qualifications and duties.

T 046

12 VAC 5-412-160 A Administrator

A. The governing body shall select an administrator whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body.

This RULE is not met as evidenced by:
Based on document review and staff interview the facility failed to ensure the governing body appointed the administrator.

The findings include:

On 7/19/19 the facility administrator was interviewed regarding her appointment and approval by the governing body as the administrator. She stated, "My husband and I are the governing body. I did not know I needed to appointment myself as the administrator."
### Statement of Deficiencies and Plan of Correction

<table>
<thead>
<tr>
<th>Provider/Supplier/CLIA Identification Number:</th>
<th>Building</th>
<th>Wing</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTAF-0016</td>
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</table>

<table>
<thead>
<tr>
<th>Name of Provider or Supplier:</th>
<th>Street Address, City, State, ZIP Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALEXANDRIA WOMEN'S HEALTH CLINIC</td>
<td>101 S. WHITING ST, SUITE #215 ALEXANDRIA, VA 22304</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID Prefix Tag</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>T 055</td>
<td><strong>12 VAC 5-412-160 C Administrator</strong>&lt;br&gt;C. A qualified individual shall be appointed in writing to act in the absence of the administrator.**&lt;br&gt;This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure the governing body appointed, in writing, a person to act in the absence of the administrator. The findings include: On 7/1/19 the facility administrator was interviewed regarding who would be responsible for the day to day management of the facility should she be absent. She stated, &quot;Oh that would be (name of person). I don't have that in writing anywhere.&quot;</td>
<td>T 055</td>
<td><strong>The governing body will appoint in writing, an assistant administrator, an individual to act in the absence of the administrator.</strong>&lt;br&gt;$30-12$</td>
<td></td>
</tr>
<tr>
<td>T 065</td>
<td><strong>12 VAC 5-412-170 B Personnel</strong>&lt;br&gt;B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member. **&lt;br&gt;This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure they verified the licenses of the nursing and medical staff who perform duties in the facility. The findings include: A review of the administrators' (who is a registered nurse), the CRNA (Certified Registered Nurse Anesthetist) and the physicians' credentials</td>
<td>T 065</td>
<td><strong>The facility will verify the licenses of the nursing and medical staff through the respective Va. Board of Medicine and Va. Board of Nursing (license look-up)</strong>&lt;br&gt;$30-17$</td>
<td></td>
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<tr>
<td>ID</td>
<td>TAG</td>
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<tr>
<td>T065</td>
<td></td>
<td>Continued From Page 5 revealed no verification of their respective licenses. The administrator stated, &quot;I have a copy of their licenses but I guess I need more.&quot;</td>
<td>T065</td>
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<tr>
<td>T070</td>
<td></td>
<td>12 VAC 5-412-170 C Personnel</td>
<td>T070</td>
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<tr>
<td>T080</td>
<td></td>
<td>12 VAC 5-412-170 E Personnel</td>
<td>T080</td>
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</tr>
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</table>
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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<tbody>
<tr>
<td>T 080</td>
<td>Continued From Page 6. This RULE: is not met as evidenced by: Based on document review and staff interviews the facility staff failed to ensure policies and procedures were implemented and maintained regarding initial and ongoing training and education related to their duties. The findings include: The policy and procedure manuals were reviewed on 7/18/12 with the administrator present. There were no policies related to staff training and education at hire or on an ongoing basis. The administrator stated, &quot;I guess I have to have policies about their training even though they are trained.&quot;</td>
<td>T 080</td>
<td>T 080 The policy regarding staff training at hire and the policy regarding on-going training and education related to their duties will be included in the policy and procedure manual. On-going in-service training will be documented to include the following: 1. date of in-service 2. names of attendees 3. topic of in-service 4. name of trainer 5. signed approval of Administrator/Administrator</td>
<td>7-30-12</td>
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<tr>
<td>T 095</td>
<td>12 VAC 5-412-170 H Personnel H. Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors; 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.</td>
<td>T 095</td>
<td></td>
<td>8-30-12</td>
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</table>
This RULE: is not met as evidenced by:
Based on document review and staff interview the facility failed to ensure they verified the licenses of the nursing and medical staff who perform duties in the facility. The facility also failed to have a policy in place that addressed how they would report a licensed and or certified health care provider to the appropriate board within the Department of Health Professions.

The findings include:

On 7/18/12 a review of the administrator's, who is a registered nurse, the CRNA (Certified Registered Nurse Anesthetist) and the physicians' credentials revealed no verification of their respective licenses. The administrator stated, "I have a copy of their licenses but I guess I need more."

Also on 7/18/12 a review of the facility policies and procedures with the administrator present was performed. A policy on how they would report a licensed and or certified health care provider to the appropriate board within the Department of Health Professions could not be located. The administrator stated, "No, I don't have one (a policy)."

B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the facility are only performed by physicians who are qualified by training and experience.

3. The process for evaluating employees' performance and competency shall include: a) an annual self evaluation and review of the evaluation utilizing a checklist and verified by the immediate supervisor/surgical coordinator and the Administrator. b) an evaluation of performance and competency after assignment/training of any new job duties.

4. There will be a process for verifying that contractors and their employees meet the personnel qualifications.

5. A policy and procedure will be formulated to include the process for reporting licensed and certified health care practitioners for any violations of their licensing or certification standards to the appropriate board within the Dept. of Health Professions. (Ref: Commonwealth of Virginia enforcement division.)
T 110 Continued From Page 8

This RULE: Is not met as evidenced by:
Based on a review of facility personnel files and an interview it was determined the facility failed to ensure physicians were licensed to practice medicine in Virginia and had the necessary training and experience to perform abortions.

The findings were:

A review of the personnel files for the physicians and certified registered nurse anesthetist (CRNA) revealed the facility staff failed to run a NPDR (National Data Bank Request) on practitioners as required by the regulations. The facility failed to verify through the NPDR the practitioners met the training and experience required to perform the job requirements.

An interview was conducted with the administrator on 7/18/2012 at approximately 3pm and the he/she stated the facility does not require the physicians to be board certified in Obstetrics and Gynecology.

T 135 12 VAC 5-412-210 A Patients' rights

A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.

This RULE: Is not met as evidenced by:
Based on interviews and document review the

T 110

The administrator will run a NPDR (National Data Bank Request) on all physicians to verify through the NPDR that the physicians meet the training and experience required to perform first trimester abortions and fulfill their job requirements.
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<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<th>(X5) COMPLETE DATE</th>
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</table>
| T 095             | Continued From Page 7
This RULE: is not met as evidenced by:
Based on document review and staff interview the facility failed to ensure they verified the licenses of the nursing and medical staff who perform duties in the facility. The facility also failed to have a policy in place that addressed how they would report a licensed and/or certified health care provider to the appropriate board within the Department of Health Professions.
The findings include:
On 7/18/12 a review of the administrator's, who is a registered nurse, the CRNA (Certified Registered Nurse Anesthetist) and the physicians' credentials revealed no verification of their respective licenses. The administrator stated, "I have a copy of their licenses but I guess I need more."
Also on 7/18/12 a review of the facility policies and procedures with the administrator present was performed. A policy on how they would report a licensed and/or certified health care provider to the appropriate board within the Department of Health Professions could not be located. The administrator stated, "No, I don't have one (a policy)."
| T 110             | 12 VAC 5-412-180 B Clinical staff
B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the facility are only performed by physicians who are qualified by training and experience. | T 110        |                                                                                                  |                  |
<table>
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<tr>
<th>T 135</th>
<th>Continued From Page 9</th>
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<tr>
<td></td>
<td>facility staff failed to ensure each patient was given a copy of their rights and responsibilities upon admission.</td>
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<td>The findings include:</td>
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<td>On 7/18/12 the administrator was interviewed regarding what information is given to the patient on admission. When asked if the patients are given a copy of their rights she stated, &quot;No, we show it to them and if they want a copy we give them one.&quot;</td>
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<tr>
<th>T 145</th>
<th>12 VAC 5-412-210 C Patients' rights</th>
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<tr>
<td></td>
<td>C. The facility shall designate staff responsible for complaint resolution, including:</td>
</tr>
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<td>1. Complaint Intake, including acknowledgement of complaints;</td>
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<td>2. Investigation of the complaint;</td>
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<td>3. Review of the investigation findings and resolution for the complaint; and</td>
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<td>4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.</td>
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<td>This RULE: is not met as evidenced by:</td>
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<td>Based on interviews and document review the facility staff failed to ensure a person was designated as the person responsible for handling complaints which includes intake, investigation, review of findings and notification to the complainant of the resolution with 30 days.</td>
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<td>The findings include:</td>
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<td>The administrator was interviewed on 7/18/12 regarding how the facility handles complaints. She stated, &quot;I handle complaints but we have not had any in all the years I have been here&quot;.</td>
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<thead>
<tr>
<th>T 135</th>
<th>All patients will be given a copy of their rights and responsibilities upon admission.</th>
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<td>T 145</td>
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<tr>
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<td>The patient rights and responsibilities protocol will show that the administrator or her designee is responsible for complaint resolution which will include: complaint intake, acknowledgment of complaint, review of findings, resolution, and notifying the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.</td>
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**STATE FORM**

**RECEIVED**

**AUG 27 2012**

**VDH/OLC**
T 155 12 VAC 5-412-210 E Patients' rights

   E. The facility shall provide each patient or her
designee with the name, mailing address, and
telephone number of the:
   1. Facility contact person; and
   2. The OLC Complaint Unit, including the
toll-free complaint hotline number. Patients may
   submit complaints anonymously to the OLC.
The facility shall display a copy of this
   information in a conspicuous place.

This RULE: is not met as evidenced by:
Based on interviews and document review the
facility staff failed to ensure each patient was
given a copy of their rights and responsibilities
upon admission.

The findings include:

On 7/18/12 the administrator was interviewed
regarding what information is given to the patient
on admission. When asked if the patients are
given a copy of their rights she stated, "No, we
show it to them and if they want a copy we give
them one." The information shown to the patients
failed to include the complaint information for the
Office of Licensure and Certification.

During the tour of the facility on 7/18/12 with the
administrator the rights and responsibilities of
patients was not posted anywhere in the facility.

T 170 12 VAC 5-412-220 B Infection prevention

   B. 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
<table>
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<tr>
<th>ID</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LCS IDENTIFYING INFORMATION)</th>
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<td>T 170</td>
<td>Continued From Page 11</td>
<td>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; 4. Use of standard precautions; 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety &amp; 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 observations, document review and staff interviews the facility failed to ensure all staff followed an infection prevention program. The findings include: On 7/19/12 the following observations were made: the attending physician was sitting at a desk reading the newspaper. He put the paper away when the patient arrived. The physician interviewed the patient. The staff escorted the patient to the exam room. The physician went into the room (followed immediately by the surveyor who stood by the sink and continued the observation). The physician put on gloves and proceeded to perform a vaginal ultrasound of the patient.</td>
<td>T 170</td>
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<td>8-30-12</td>
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</table>
Once the procedure had been completed the physician told the patient to get dressed and he would see her outside the exam room. The surveyor followed the physician out of the exam room. The physician picked up the patients medical record and began to make notations. He removed a prescription pad from a drawer. At no time was the physician observed washing his hands or performing hand hygiene.

The observations were pointed out to the physician who stated, "I was not doing a procedure only an ultra sound. If I had been doing a procedure I certainly would have washed my hands."

The above information was discussed with the administrator who stated, "He never washes his hands, he always uses gloves." When it was pointed out that sometimes the gloves may have holes in them the administrator stated, "Oh! That is gross!"

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);
4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
   (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
   (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: is not met as evidenced by: Based on observations and staff interviews the facility staff failed to ensure a policy and procedure was in place to address how scrub attire and blankets for patient use were to be

The facility will implement a policy and procedure for the use of blankets for patient use. The facility will employ a hospital linen service to provide blankets for patient use.

All staff will wear impermeable, disposable surgical scrub gowns, disposable head covers and disposable foot covers with each surgical procedure and with any procedure involving contact with and/or exposure to blood and blood products.

Patients will be given disposable patient gowns.

Individual surgical attire will be laundered at home if the staff member will not be in contact with contamination. Staff may opt to wear hospital linen service scrubs.
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<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tbody>
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<td>T175</td>
<td>Continued From Page 14</td>
<td>laundered in a manner to prevent the spread of infections.</td>
<td>T175</td>
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The findings include:

During the tour of the facility on 7/18/12 with the administrator scrub attire was observed hanging in an office area and blankets used by patients were in and on cabinets in the recovery area. The administrator stated, "The scrubs and blankets were laundered in the building laundromat." The administrator explained the first 3 floors of the building are zoned for commercial use and the remaining 12 or 13 floors are private apartments. She stated, "The laundromat is in the basement."

The 2010 Perioperative Standards and Recommended Practices: Aseptic Practice of AORN (Association of Perioperative Registered Nurses) recommended the following. Home laundering of surgical attire is not recommended. Without clear evidence about the safety for patients, health care workers, and their family members, AORN does not support the practice of home laundering of surgical attire. Reusable surgical attire, including cover jackets and cloth hats, should be laundered by a designated facility-approved and monitored commercial laundry after daily use. Commercial laundries are required to follow strict guidelines that incorporate:

- proper and controlled water temperatures;
- use of detergents;
- use of oxidizing agents (e.g., chlorine bleach) in specified and monitored concentrations;
- repeated changes of water; and
- dryer or iron and press drying temperatures that typically are not found in home laundry equipment.

Home laundering of surgical attire that is not visibly soiled is controversial, and there is no concrete evidence to either support or refute the practice.
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| T 175        | Continued From Page 15  
   practice. Surgical attire becomes soiled or contaminated with microorganisms during wear. Taking worn, soiled, or contaminated surgical attire into the home can result in the spread of contamination to the home environment. AORN is aware that some provider facilities require personnel to launder scrub attire at home. Although AORN does not support this practice, steps should be taken to minimize contaminants to the home environment. | T 175        | T 230  
The facility will implement a policy and procedure providing the necessary criteria for the discharge from anesthesia care. Such criteria shall include documentation of: stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting. | 8-30-12       |
| T 230        | 12 VAC 5-412-250 C Anesthesia service  
   C. The facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting.  
   This RULE: is not met as evidenced by: Based on interviews and document review the facility failed to have in place policies and procedures related to the criteria for discharge from anesthesia care.  
   The findings include:  
   On 7/18/12 the administrator was asked to provide a copy of the policies outlining their criteria for discharge. The administrator provided a copy of a blank medical record indicating where vital sign were to be entered. The administrator stated, “I don’t have a policy related to discharge.” | T 230        |  
| T 285        | 12 VAC 5-412-280 E Administration, storage and dispensing of dru  
   E. Records of all drugs in Schedules I-V | T 285        |  

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<tr>
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| T 285        | Continued From Page 16 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. This RULE: is not met as evidenced by: Based on observations, interviews and document review the facility failed to maintain records regarding Scheduled I-V drugs in such a manner as to be able to regularly perform a narcotic count to ensure accuracy. The finding include: On 7/18/12 and 7/19/12 during the tour of the facility with the administrator the procedure room was inspected. The inspection revealed a locked metal box to which no one had a key to open. The administrator stated, "That box is (name of CRNA (Certified Registered Nurse Anesthetist)) and only he has a key to the box. He keeps his drugs, needles and syringes in there and I don't know what else." The administrator stated, "I will try to contact him and ask him to come and open the box." The administrator located the CRNA who told her where a hidden key was kept. The box was opened on 7/19/12 and needles, syringes, propofol, tourniquets and a sign out sheet for medications were in the box. The medication sign out sheet was for versed and fentanyl. On a shelf was a notebook with a medication sign out sheet for versed and fentanyl. The administrator was asked why there are 2 separate sign out sheets and she stated, "One is for (name of CRNA) and the other is for (name of another CRNA). When asked how she as the registered nurse on duty does a count of the narcotics she stated, "I don't, the CRNAs do the...
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<th>ID</th>
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<tr>
<td>T 285</td>
<td>Continued From Page 17</td>
<td>count.&quot;</td>
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<tr>
<td>T 280</td>
<td>12 VAC 5-412-270 Equipment and supplies</td>
<td>An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include: 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. This RULE: is not met as evidenced by: Based on observations and interviews the facility staff failed to ensure equipment was maintained to ensure proper infection control and failed to ensure expired supplies were not available for use. The findings include: On 7/18/12 during the tour of the facility with the administrator and assistant administrator, the following items were noted to have tears which would prevent the items from being cleaned properly after each patient use: The table in the ultrasound room had large tears in the vinyl covering and paper towels were found under the sink in the ultrasound room.</td>
<td>T 290</td>
<td>The exam table in the ultrasound room has been replaced with another table without any tears in the vinyl covering. All items under the sink have been removed. The wait area for medical abortions will be replaced with chairs free of any tears. The pre-procedure room wait area will have viny-covered chairs. The gurneys used for recovery from IV sedation will be re-upholstered with vinyl covering. There will be no supplies stored under the gurney. There will be a monthly check for expiration date of all curettes. All curettes will be placed in individual plastic bags indicating: size and type of curette and expiration date.</td>
</tr>
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</table>
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER:** ALEXANDRIA WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE:** 101 S. WHITING ST, SUITE #215 ALEXANDRIA, VA 22304

**ID PREFIX TAG:** T 290

**SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION):**

**ID PREFIX TAG:** T 290

- Continued From Page 18

  The areas described as the wait area for medication abortions and ultrasounds had 4 chairs with tears in the vinyl.

  The area described as the pre-procedure room had 4 cloth chairs that could not be wiped clean after use by patients.

  The recovery area had 3 of 4 chairs with tears in them.

  The stretcher used for recovery from IV sedation was torn and items for multi patient use was stored under the stretcher.

  The administrator stated, "We will get the chairs and tables replaced and will move the supplies."

  On 7/18/12 during a tour of the procedure room with the administrator and assistant administrator the following expired items were observed:

  - 19 - 12 mm (milliliter) disposable rigid curettes
  - 7 - 12 mm flexible curettes
  - 14 - 10 mm flexible curettes
  - 2 - 9 mm flexible curettes
  - 4 - 11 mm flexible curettes
  - 23 - 5 mm flexible curettes
  - 2 - 7 mm flexible curettes
  - 6 - 4 mm flexible curettes

  The facility administrator stated, "We will get rid of those right now."

**ID PREFIX TAG:** T 315

**SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION):**

**ID PREFIX TAG:** T 315

- 12 VAC 5-412-300 A Quality assurance

  A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise...
### T 315

**Policies and Practices, as Necessary.**

This RULE: is not met as evidenced by:

Based on interviews and document reviews the facility staff failed to implement an ongoing comprehensive integrated self assessment program of the quality and appropriateness of care or service provided.

The finding include:

On 7/18/12 the administrator was asked to provide documentation related to the services that provide related to quality improvement. She stated, "I don't collect data." When asked if the facility collects data on patient satisfaction she stated, "We used to but we stopped because we were not getting anything back from the patient after they left." The administrator was asked how she and the staff knew what areas to improve or where improvement was needed she stated, "We just know when we do something that needs to be fixed."

### T 320

12 VAC 5-412-300 B Quality assurance

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.
T 320  Continued From Page 20

This RULE: is not met as evidenced by:

Based on interviews and document reviews the facility staff failed to implement an ongoing comprehensive integrated, self assessment program of the quality and appropriateness of care or service provided.

The findings include:

On 7/18/12 the administrator was asked to provide documentation related to the services that provide related to quality improvement. She stated, "I don't collect data." When asked if the facility collects data on patient satisfaction she stated, "We used to but we stopped because we were not getting anything back from the patient after they left." The administrator was asked how she and the staff knew what areas to improve or where improvement was needed she stated, "We just know when we do something that needs to be fixed."

T 325

12 VAC 5-412-300 C Quality assurance

C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:

1. A physician
2. A non-physician health care practitioner;
3. A member of the administrative staff; and
4. An individual with demonstrated ability to represent the rights and concerns of patients.

The individual may be a member of the facility's staff. In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.

This RULE: is not met as evidenced by:

T 320 will not be signed or dated, unless the patient would like a response. All surveys will be placed in a suggestion box which will be reviewed and any actions will be made to improve our services.

T 325

The quality improvement committee responsible for the oversight and supervision of the program shall be established and shall consist of a physician, a non-physician health care practitioner; a member of the administrative staff and a staff member/patient representative.
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<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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<tbody>
<tr>
<td>T 325</td>
<td>Continued From Page 21</td>
<td>T 325</td>
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<td></td>
<td>Based on interviews and document reviews the facility staff failed to have a quality improvement committee and to identify who should be on the committee.</td>
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<td>The finding include:</td>
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<td>On 7/18/12 the administrator was asked to provide documentation related to the services/program provided related to quality improvement. She stated, &quot;We don't have a program.&quot;</td>
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<tr>
<td>T 335</td>
<td>2 VAC 5-412-300 E Quality assurance</td>
<td>T 335</td>
<td>T 335</td>
<td>8-30-12</td>
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<td></td>
<td>E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.</td>
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<td>T 335</td>
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<td></td>
<td>This RULE: is not met as evidenced by: Based on interviews and document reviews the facility staff failed to have a quality improvement committee and to identify who should be on the committee.</td>
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<td>On 7/18/12 the administrator was asked to provide documentation related to the services that provide related to quality improvement. She stated, &quot;I don't collect data.&quot; When asked if the facility collects data on patient satisfaction she stated,</td>
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</table>
"We used to but we stopped because we were not getting anything back from the patient after they left." The administrator was asked how she and the staff knew what areas to improve or where improvement was needed. She stated, "We just know when we do something that needs to be fixed."

T 365 12 VAC 5-412-350 A Disaster preparedness

A. Each abortion facility shall develop, implement, and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.

The facility shall maintain a policy and procedure with specific steps to be taken to ensure all staff and patients are protected from the hazards of fire and other disasters.

The fire and disaster preparedness plans shall be implemented and fire drills shall be documented. There shall be mock fire drills and documentation of same.
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<th>T 370</th>
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<tr>
<td>This RULE: is not met as evidenced by: Based on document review and staff interviews the facility failed to implement and maintain policies and procedures to ensure reasonable precautions were taken to protect staff and patients in the event of a fire or disaster and their community disaster plan. The findings include: On 7/18/12 the administrator was asked to provide the policies and procedures related to fire drills and disaster drills. She stated, &quot;We don't have policies about fire and disaster drills. We just move all patients and staff to the hall way. We have never had a community disaster plan.&quot;</td>
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| T 370-B | The facility does not participate in a community disaster plan as the facility does not have the capability to provide emergency care. |

<table>
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<tr>
<th>T 385</th>
<th>12 VAC 5-412-370 A Fire-fighting equipment and systems</th>
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</thead>
<tbody>
<tr>
<td>A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program. This RULE: is not met as evidenced by: Based on document review and staff interviews the facility failed to implement and maintain policies and procedures to ensure reasonable precautions were taken to protect staff and patients in the event of a fire or disaster and to designate who would be in charge of ensure the program was maintained. The findings include: On 7/18/12 the administrator was asked to provide the policies and procedures related to fire drills and disaster drills. She stated, &quot;We don't have</td>
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<th>T 385</th>
<th>Fire-fighting equipment and systems</th>
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<td>There shall be a monitoring program and implementation of fire and disaster drills. The administrator and assistant administrator shall be responsible for the enforcement of the monitoring program. The Fire Marshall's office from the City of Alexandria shall be called upon to conduct an annual fire safety plan and in-service training for the staff.</td>
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| T 385 | Continued From Page 24  

policies about fire and disaster drills. I guess I would be the person in charge of making sure we did fire and disaster drills. I don't think that is in my job description though." | T 385 | | |
| T 390 | 12 VAC 5-412-370 B Fire-fighting equipment and systems  

B. All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested in accordance with current edition of the Virginia Statewide Fire Prevention Code (27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.  

This RULE: is not met as evidenced by: Based on observations, document review and staff interviews the facility failed to ensure firefighting equipment (fire extinguishers) were inspected and safely secured.  

The findings include:  

On 7/18/12 during a tour of the facility with the administrator fire extinguishers without inspection stickers or tags were observed sitting on the floor on both the exam side of the suite and the procedure side of the suite. The administrator stated, "I guess we need to get those mounted to the wall or something." | T 390 | | 8-31-12 |
| T 400 | 12 VAC 5-412-380 Local and state codes and standards  

Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section | T 400 | | |
**T 400**

3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001. Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.

Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements.

This RULE: is not met as evidenced by:

Based on observations, interviews and a facility tour it was determined that the facility failed to ensure full compliance with state/local codes, building ordinances as well as the Uniform Statewide Building Code. Additionally, the facility failed to comply with having the following: an architect attestation that the facility meets all FGI standards, proper ventilation, humidity, temperature controls, waste management program/services, HVAC duct system and inspection reports, proper ventilation of the treatment rooms, proper air exchange for all treatment rooms, the heating/cooling and plumbing system to meet all codes, electrical system meets the National Electrical Code ordinance and all hand washing stations meet the necessary width, length, depth & splash prevention.

The findings include:

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</table>
| T 400 | Continued From Page 25 | T 400 | The following findings of the OLC inspectors and the responses are:

1. The ultrasound room shall maintain full privacy by ensuring the sliding plastic window remains closed.

2. A waiver is needed for the laboratory cannot accommodate a reclining chair nor a ventilation hood.

3. The patient bathroom door is deliberately left unlocked and patients are informed that staff personnel will be standing outside the door should the patient require any help or assistance.

4. The staff bathroom shall be kept locked at all times and a key will...
On July 18, 2012 a facility tour was conducted with the Administrator and Assistant Administrator. During the facility tour the following findings were noted to include but not limited to:

1. The ultrasound room had a sliding plastic window that was partially open to the room on the other side preventing full privacy for the patient receiving an ultrasound.
2. The laboratory failed to have a hood for ventilation and a reclining chair for patients who become unsteady.
3. The administrator stated the door did not lock on the patient bathroom. The door was found to have a functioning lock however, no key was available for the lock and no emergency alarm is available in the bathroom.
4. The staff bathroom is kept locked at all times and the staff have no key to open the door. Staff use their fingernail to open the door.
5. The procedure and recovery area of the facility has no toilet facilities available to patient's.
6. The soiled utility room has no floor drain.
7. None of the sinks in the facility meet regulation codes.
8. The procedure room failed to have a sink readily available for use and the staff use the sink located in the soiled utility room.
9. The facility failed to have a janitor closet.
10. The facility failed to have hygiene services for uniforms and blankets.
11. The facility failed to have any indication of an air ventilation system within the facility. All air vents were blowing air out with the exception of one vent that was located in the hallway separate from the actual facility and it was found to be dirty, also unclear if it was functional.

On day two of the survey, the administrator...

be used and kept in the staff lounge.

5. The procedure and recovery area will be moved to Suite 215, expanding the workroom to be the procedure and recovery area. A waiver will be needed to allow time and resources with the property management's input and approval to complete the renovations.

6. A waiver will be needed. It is impossible to place a floor drain in the utility room as the flooring is made of concrete, and we are on the second floor.

7. All the faucets in sinks in the facility will be...
T 400

Presented a report from an Architect that surveyed the facility. The report is a summary and there is no indication of when the survey was done. In addition the report failed to contain the name of the architect completing the report. The report list the necessary items needed to get the facility in compliance with the regulations and contained the following to include but not limited to:

1. Signage required to identify restricted, semi-restricted, and unrestricted areas of the center and proper attire for each area.
2. Ultrasound room does not meet requirements for acoustical and visual privacy and a hand washing sink.
3. 6' wide corridor required from surgery to public corridor for emergency ambulance transfer. Hand washing sinks brought into compliance.
4. No janitor closet or eyewash station.
5. No air exchange.
6. No 100 square ft. clean storage room.
7. Building elevators do not comply with required regulations or ADA requirements.
8. Wall surfaces not washable.
9. Pre and post op don't meet square footage requirements per ARC report.
10. No emergency communication system.
11. Pass through between soiled and clean workroom must have self closing door.
12. Overall building does not meet ADA standards as to exterior access, elevators and toilet facilities.
13. HVAC system likely will not meet current standards.
14. Fire and smoke alarm and control systems will not meet current standard.
15. Mechanical equipment rooms and exit corridors do not meet fire code requirements.
16. The 2 pipe perimeter HVAC system will likely not meet current standards but should be evaluated by and engineer or contractor.

T 400

Replaced to meet regulation codes.

8. A waiver is needed to allow time to move the procedure room to Suite 215 (see #5). Use of current Procedure room could be moved to the Ultrasound Room where there is a sink available for staff use.

9. A janitor’s closet can be maintained in the current storage area in Suite 217.

10. See T 175 regarding use of Hospital Linen service. Use of the building laundry room will cease immediately.

11. Air ventilation system is controlled by the building management.

All above are continued from pg 27.
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<tr>
<td></td>
<td>Survey report was done on May 12/12 by George Johannes.</td>
<td></td>
<td>T 400 re: Architect survey/report</td>
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<td></td>
<td>Our facility will not be able to comply with the 2010 Guidelines</td>
<td></td>
<td>Our facility occupies office space designated as a doctor’s office. The first 3 floors are coded for commercial use. Our facility is located on the 2nd floor, with doctors and dentists occupying other floors. If the current amendments to the emergency regulations are subsequently approved by the Governor, our facility will be able to continue to provide abortion services. Our facility has been in this location for the past 25+ years, and patient safety, patient care and</td>
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abortion services have not been adversely affected. We request a waiver for the 2010 Guidelines for design and construction to make changes to our facility that are allowable by the building management and if necessary to review the possibility of moving to another location.
February 22, 2019

Facility Administrator
Alexandria Women's Health Clinic
101 S. Whiting St. Suite 215
Alexandria, Virginia 22304

RE: Alexandria Women's Health Clinic
First Trimester Abortion Facility (FTAF) Biennial Licensure Inspection
Facility ID: AF-0014

Dear Facility Administrator,

An unannounced First Trimester Abortion Facility Biennial Licensure Inspection was conducted January 15, 2019 through January 16, 2019 and January 24, 2019 by two (2) Medical Facilities Inspectors from the Virginia Department of Health's Office of Licensure and Certification.

Enclosed is the licensure inspection report. The facility was not in compliance with 12VAC5-412 regulations for the Licensure of Abortion Facilities, amended November 2018. This document contains a listing of deficiencies found at the time of this inspection.

You are required to submit a plan for correcting the deficiencies cited. Your statements shall reflect the specific detailed actions you will take to correct deficiencies, prevent a recurrence of the deficiencies, and measures implemented to maintain compliance. You must also give the expected completion date of each deficiency.

Completion of corrective actions shall not exceed 45 working days from the last day of the inspection.

After signing and dating your Plan of Correction, retain one copy of the report for your file and return the original to OLC within 15 (fifteen) working days of receipt of the inspection report. The Administrator shall be notified if any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with the Code of Virginia §32.1-27 or in denial, revocation or suspension of a license in accordance with 12VAC5-412-130.
Facility Administrator
Alexandria Women's Health Clinic
February 22, 2019

Page 2

A copy of the completed form will be kept on file in this office and will be available for public review. The Virginia Department of Health – Office of Licensure and Certification is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

Thank you for the cooperation that was extended to our inspectors during this investigation. If you should have any question or concerns regarding this report or the report findings, please contact me at (804) 367-2164.

Sincerely,

[Signature]

Douglas Middlebrooks, PhD
Supervisor, Division of Acute Care Services

Enclosure
An announced First Trimester Abortion Facility (FTAF) biennial licensure inspection was conducted 1/15/19 through 1/19/19 and 1/24/19 by two (2) Medico Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health.

The facility was not in compliance with 12 VACS-412 Regulations for the Licensure of Abortion Clinics (Amended November 2018). Deficient practice is identified in this report.

Each abortion facility shall post notice of the existence of a human trafficking hotline to alert possible witnesses or victims of human trafficking to the availability of a means to gain assistance or report crimes. This notice shall be in a place readily visible and accessible to the public, such as the patient admitting area or public or patient restrooms. The notice shall meet the requirements of §40.1 - 11.3 C of the Code of Virginia.

This RULE: Is not met as evidenced by:
Based on observation and staff interview, the facility staff failed to ensure the posting of the existence of a human trafficking hotline was readily available and accessible to the public.

The findings included:
During the inspection beginning 1/15/19 at 1:45 p.m., the inspectors were unable to locate any posting relating to the existence of a human trafficking hotline within the facility. At 3:35 p.m.,

<table>
<thead>
<tr>
<th>T000</th>
<th>Initial Comments - 4</th>
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<tbody>
<tr>
<td>T000</td>
<td>Plan of Correction</td>
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<tr>
<td>T000</td>
<td>Corrective action taken by:</td>
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<td>The facility shall display human trafficking hotline information to alert possible witnesses or victims. The information will be posted in an area where the patient has privacy, such as: patient restrooms, Sonogram room, and counseling room.</td>
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**LAWRENCE**
President
22 Feb. 19
<table>
<thead>
<tr>
<th>T005</th>
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<tr>
<td></td>
<td>the inspectors talked with and updated the information as needed every month.</td>
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<td>The administrator will be responsible for checking and updating the information as needed every month.</td>
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<tr>
<td>T006</td>
<td>Corrective action taken by providing written application on staff records personal record related to education, training and experience. The administrator will verify that all physicians and/or staff obtain ACLS.</td>
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<thead>
<tr>
<th>QSO</th>
<th>Prefix</th>
<th>Description of Deficiency</th>
<th>Each Deficiency Must Be Preceded by Full Regulatory or Leg Identifying Information</th>
<th>ID Prefix</th>
<th>QSO</th>
<th>Provider's Plan of Correction</th>
<th>Each Correcting Action Should Be Cross-Referenced to the Appropriate Deficiency</th>
<th>ID Prefix</th>
<th>QSO</th>
<th>Complete Date</th>
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<tbody>
<tr>
<td>12 VAC5-412-180 E Personnel</td>
<td>T085</td>
<td>1. Written job descriptions that adequately describe the duties of every position shall be maintained.</td>
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<td>214019</td>
<td>1. The facility will implement an annual review and documentation for job descriptions for all Staff members.</td>
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<td>T085</td>
<td>2. Each job description shall include position title, authority, specific responsibilities and minimum qualifications.</td>
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<td>214019</td>
<td>2. A written job description for ultrasound technician will be added to Staff Member #2 Personnel record.</td>
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<td>T085</td>
<td>3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.</td>
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<td>214019</td>
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<tr>
<td>Title</td>
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<tr>
<td>Class</td>
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<td>Code</td>
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<tr>
<td>Date of Expiration</td>
<td>12/31/2015</td>
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</table>

1. **Surgical Tech** | **ST-001** |
| Date of Expiration | 12/31/2015 |


3. The job description for Surgical Tech will be updated on 12/31/15.

4. Staff #7 will complete her training related to her job.

5. The facility will update the employee's training documentation related to her job.

6. Staff #7 will complete her job description update on 12/31/15.

7. For surgical assistant updates, the job description will be reviewed annually.
### T 085

Continued From Page 4

diploma or GED (General Education Development test). A review of SM #7's personnel record revealed that he/she lacked a high school diploma or GED. The 2018 performance evaluation for SM #7 included the following documentation: "Needs to accomplish GED to continue to grow."

On 1/19/19 at 11:15 a.m., an interview related to annual review of job descriptions was conducted with Staff Member (SM) #1, the Assistant Administrator, who stated "Those are very old, I guess we should look at those every year."

Concerns related to the lack of annual review of job descriptions, missing job descriptions, and job requirements inconsistent with staff training and education, were discussed with SM #1, the Assistant Administrator, and SM #2, the Administrator, on 1/24/19 at approximately 4:00 p.m.

### T 270

12 VACS-412-280 B Anesthesia Services

The anesthesia service shall be directed by and under the supervision of a physician licensed in Virginia who is certified in advanced resuscitative techniques and has met the continuing education requirements.

This RULE: is not met as evidenced by:

Based on staff interview and review of facility documentation, facility staff failed to ensure that anesthesia services were performed under the supervision of a physician certified in advanced resuscitative techniques.

Findings included:

The facility's procedure log for the period between

<table>
<thead>
<tr>
<th>Corrective action taken by:</th>
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</thead>
<tbody>
<tr>
<td>ACLS has been scheduled for March 28, 2019 for all physician(s) responsible for performing abortions as well as the physician(s) responsible for providing anesthesia.</td>
</tr>
</tbody>
</table>
### STATEMENT OF DEFICIENCY AND PLAN OF CORRECTION

**STATE OF VIRGINIA**

**DATE:** 02/19/2019

<table>
<thead>
<tr>
<th>STATEMENT OF DEFICIENCY AND PLAN OF CORRECTION</th>
<th>ID</th>
<th>PROVIDER/SUPPLIER IDENTIFICATION NUMBER</th>
<th>MULTIPLE CONSTRUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STATE OF VIRGINIA</strong></td>
<td></td>
<td>ALEXANDRIA WOMEN'S HEALTH CLINIC</td>
<td></td>
</tr>
<tr>
<td>STREET ADDRESS, CITY, ZIP CODE</td>
<td></td>
<td>101 S. WATTERS ST, SUITE 2210</td>
<td>ALAXANDRIA, VA. 22304</td>
</tr>
</tbody>
</table>

#### SUMMARY STATEMENT OF DEFICIENCIES

Each deficiency must be preceded by full regulatory or legal identifying information.

<table>
<thead>
<tr>
<th>ID</th>
<th>Provider/Supplier ID</th>
<th>Summary of Deficiencies</th>
<th>Corrective Action</th>
<th>Date Corrective Action Completed</th>
</tr>
</thead>
</table>
| T270 | 3250-8270 | Continued From Page 5: 1/3/19 and 1/10/19 evidenced that SM #4, physician, and SM #9, anesthesiologist, performed procedures together on the following days: 1/3/19, 1/9/19, 1/10/19, 1/10/19, 1/10/19, 1/11/19, and 1/16/19. Personnel records reviewed for Staff Member (SM) #4, a physician, responsible for performing surgical abortions at the facility, and SM #9, a physician, responsible for providing anesthesiology services for surgical abortions at the facility, revealed that neither SM #4 nor SM #9 were certified in ACLS (Advanced Cardiac Life Support). Both SM #4 and SM #9 were certified in BLS (Basic Life Support) on the dates listed above. SM #1, the Assistant Administrator was interviewed on 1/10/19 at approximately 12:15 p.m., and stated "SM #4 and #9 have their CPR documentation in their email, they will get it to me."

On 1/24/19 at 3:00 p.m. SM #1 advised the surveyors that "ACLS had been scheduled for (SM #4 and SM #9's names) next month.

Concerns related to procedure days when SM #4 and SM #9 worked together, and the lack of ACLS certification for either provider, were discussed with SM #1, Assistant Administrator, and SM #2, Administrator, on 1/24/19 at approximately 4:00 p.m. |
| T270 | 3250-8270 | The administrator will review each physician(s) file annually, in order to be in full compliance |

<table>
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<tr>
<th>ID</th>
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<th>Summary of Deficiencies</th>
<th>Corrective Action</th>
<th>Date Corrective Action Completed</th>
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</thead>
<tbody>
<tr>
<td>T330</td>
<td>3250-8270</td>
<td>12 VACS-412-370 Equipment and Supplies</td>
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</table>

An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:

T330 The facility will provide sterile suturing kits. There will be a checklist for the
monitoring of all supplies for expiration dates to be performed monthly. The assistant administrator will be responsible for the monthly checks.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

**STATE OF VIRGINIA**

**NAME OF PROVIDER OR SUPPLIER:**
ALEXANDRIA WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE:**
101 S. WHITING ST, SUITE 2216
ALEXANDRIA, VA 22314

**DATE OF INSPECTION:**
01/24/2019

<table>
<thead>
<tr>
<th>ID #</th>
<th>PREVIEW</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>PLAN OF CORRECTION</th>
</tr>
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<tbody>
<tr>
<td>T 390</td>
<td>Continued From Page 7</td>
<td>On 1/24/19 at 3:10 p.m., the inspectors interviewed Staff Member #1 as to whether the supplies (including materials) had been received by the facility. Staff Member #1 stated, “No. It is not here. Next time I will postpone them until I have received the new supplies, so at least we will have something we could use if there were an emergency.”</td>
<td>Y 390</td>
</tr>
</tbody>
</table>

**IDENTIFICATION NUMBER:**
AP-5214

**A BUILDING:**

**PROMISSED DATE:**
01/25/2019

**E HANG:**

**PROMISSED CORRECTION DATE:**
01/25/2019

**HANG:**

**PROMISSED CORRECTION DATE:**
01/25/2019

**STATE FORM:**

**QF111**

**Evaluation sheet 5 of 8**

---

*From my iPhone*

---

Douglas Middlebrooks, Ph.D
Acute Care Supervisor
Office of Licensure and Certification

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**Americans United for Life**
April 9, 2013

Certified Mail Delivery

Administrator
Alexandria's Women's Health Clinic
101 S. Whiting St., Suite # 215
Alexandria, VA 22304

Dear Administrator:

An unaunounced Licensure Revisit survey was conducted March 27, 2012 to the Initial Licensure survey conducted July 18, 2012 through July 19, 2012, by two (2) Medical Facilities Inspectors for the Office of Licensure and Certification, Virginia Department of Health.

The following are citations from the initial survey of July 18, 2012 through July 19, 2012, which were not corrected and therefore repeat citations:

12 VAC 5-412-160 (A) (C) [Administrator]
12 VAC 5-412-170 (E) (H 2, 5) [Personnel]
12 VAC 5-412-180 (B) [Clinical staff]
12 VAC 5-412-210 (C) [Patient rights]
12 VAC 5-412-220 (B) (2, 3, 10), (C) (7) [Infection prevention]
12 VAC 5-412-260 (C) [Administration, storage and dispensing of drugs]
12 VAC 5-412-2-270 [Equipment and supplies]
12 VAC 5-412-300 (A) (B) (C) (D) (E) [Quality assurance]
12 VAC 5-412-350 (A) [Disaster preparedness]
12 VAC 5-412-370 (A) [Fire-fighting equipment].
The following citations are new findings:

12 VAC 5-412-140 (A) [Organization and management]
12 VAC 5-412-170 (E) (H) (3) [Personnel]
12 VAC 5-412-180 (A) [Clinical staff]
12 VAC 5-412-220 (B) (7) [Infection prevention]
12 VAC 5-412-2-350 (B) [Disaster preparedness]

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics (effective 12/29/2011). Deficiencies cited follow in this report.

I am enclosing a "provider copy" of the "Statement of Deficiencies and Plan of Correction" Report which states that deficiencies were cited at the time of the unannounced Licensure Revisit survey conducted March 27, 2013.

You are required to submit a plan for correcting the deficiencies cited. Your statements should reflect the specific detailed actions you will take to correct each deficiency and prevent its recurrence, and measures that will be implemented to maintain compliance.

You must also give the specific calendar date on which correction of each deficiency will be completed. (Completion dates should be within thirty (30) days from the date of the inspection.)

After signing and dating the Plan of Correction, retain a copy for your files and return the original to this office within 15 (fifteen) working days of receiving this certified letter. The Administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with the Virginia Code § 32.1-27 or in denial, revocation or suspension of a license in accordance with 12VAC5-412-130.

A copy of the completed form will be kept on file in this office and will be available for public view. This Division is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

I would like to thank you and your staff for the cooperation and assistance that was extended to the surveyors. Should you have any questions, please contact me at (804) 367-2156.

Sincerely,

Kathleen Creegan-Tedeschi, Supervisor
Acute Care Division
Office of Licensure and Certification

Enclosure
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**(X1) PROVIDER/Supplier/CLIA IDENTIFICATION NUMBER:**
FTAF-0016

**(X2) MULTIPLE CONSTRUCTION**
A. BUILDING

**(X3) DATE SURVEY COMPLETED**
03/27/2013

**NAME OF PROVIDER OR SUPPLIER**
ALEXANDRIA WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**
101 S. WHITING ST, SUITE #215 ALEXANDRIA, VA 22304

<table>
<thead>
<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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<tbody>
<tr>
<td>T 000</td>
<td>12 VAC 5-412 Initial comments</td>
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On March 27, 2013, two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted an unannounced Licensure Revisit survey to the survey performed July 18, 2012 through July 19, 2012.

The following are citations from the initial survey of July 18, 2012 through July 19, 2012, which were not corrected and therefore repeat citations:

- 12 VAC 5-412-160 (A) (C) [Administrator]
- 12 VAC 5-412-170 (E) (H 2, 5) [Personnel]
- 12 VAC 5-412-180 (B) [Clinical staff]
- 12 VAC 5-412-210 (C) [Patient rights]
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- 12 VAC 5-412-300 (A) (B) (C) (D) (E) [Quality assurance]
- 12 VAC 5-412-350 (A) [Disaster preparedness]
- 12 VAC 5-412-370 (A) [Fire-fighting equipment].

The following citations are new finding:

- 12 VAC 5-412-140 (A) [Organization and management]
- 12 VAC 5-412-170 (E) (H) (3) [Personnel]
- 12 VAC 5-412-180 (A) [Clinical staff]
- 12 VAC 5-412-220 (B) (7) [Infection prevention]
- 12 VAC 5-412-2-350 (B) [Disaster preparedness]

The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 12/29/2011)

| T 010              | 12 VAC 5-412-140 A Organization and management                                                                 |

A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility.
This RULE: is not met as evidenced by:
Based on observations, document review and interview the governing body failed to manage and ensure the facility operated in compliance with state regulations. The governing body failed to:

1. Document in writing the appointment of the Administrator and Alternate Administrator;
2. Ensure policies and procedures were implemented for personnel training, a process for verifying professional license, annual evaluation of employees and a process for reporting licensure or certification violations to the appropriate board.
3. Ensure the facility had established a complaint process and designated a staff responsible for complaint resolution.
4. Ensure staff were trained and had annual in proper infection prevention measures, correct hand washing technique, practiced safe injection practices by not having expired medications available for administration to patients, replace the facility's equipment (chairs, procedure tables), which had non-intact surfaces.
5. Maintain oversight of the quality assurance program.
6. Ensure the facility's staff was knowledgeable and trained in disaster preparedness, fire safety and designated a fire-safety staff member had been appointed.

The findings included:
1. The governing body failed to appoint in writing the Administrator and the Administrator's

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<th>DATE</th>
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<tr>
<td>T010</td>
<td>Continued From Page 1</td>
<td>The governing body will document in writing the appointment of the Administrator and the Assistant Administrator. There will be a policy and procedure for verifying professional licenses. There will be a policy and procedure for annual evaluation of employees There will be a policy and procedure for reporting licensure or certification violations to the appropriate boards of medicine and nursing.</td>
<td>T010</td>
<td></td>
<td>The Administrator has established a complaint policy and procedure and has designated the Assistant Administrator responsible for complaint resolution. There will be documentation and annual in-service training for staff in proper infection prevention measures, practice safe injection practices, checking medications monthly with a checklist to replace medications before their expiration dates. There will be replacement of the facility's equipment...chairs with washable surfaces to decontaminate any equipment and chairs between patients' use.</td>
<td>4:22:13 4:22:13 4:22:13 4:22:13</td>
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</table>
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

FTAF-0016

NAME OF PROVIDER OR SUPPLIER: ALEXANDRIA WOMEN'S HEALTH CLINIC
STREET ADDRESS, CITY, STATE, ZIP CODE: 101 S. WHITING ST, SUITE #215 ALEXANDRIA, VA 22304

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<th>COMPLETE DATE</th>
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<tr>
<td>T 010</td>
<td>Continued From Page 2 alternate. Review of documents provided to the surveyors on March 27, 2013 did not indicate in writing the appointment of the Administrator and Alternate Administrator. The governing body minutes did not reflect the appointment of the Administrator or the Administrator's alternate. An interview conducted on March 27, 2013 at 10:48 a.m., Staff #2 reported the governing body had not incorporated the appointment of the Administrator or the designated alternative in writing. 2. The governing body failed to ensure staff received training and evaluation of their skills. Review of personnel files on March 27, 2013 did not include documented personnel training related to job duties, infection control training, and annual evaluation of employees. An interview was conducted on March 27, 2013 at 12:40 p.m., with Staff #1 and Staff #2. Staff #2 reported the training had not occurred. The governing body failed to provide oversight and ensure the facility had the required policies and procedures. Review of the facility's policy and procedure manual did not include a process for reporting licensure or certification violations to the appropriate board. Staff #2 verified the governing body had not made the necessary changes to the policy and procedure manual. 3. The governing body failed to ensure the facility developed a complaint process and designate a staff to be responsible for complaint resolution. Review of the documents provided on March 27, 2013 did not include an established complaint process. The document provided did not designate a staff responsible for complaint resolution</td>
<td>T 010</td>
<td>The governing body has documented in writing in the corporate minutes that the Administrator has been appointed. The governing body has also documented the appointment of the Assistant Administrator. 2. There will be documentation of in-service training of staff members related to their job duties, infection control training, fire safety, and disaster preparedness training and annual self-evaluations. There will be a policy and procedure for reporting licensure or certification violations to the appropriate board. 3. The Administrator has established a complaint policy and procedure and has designated the Assistant Administrator responsible for complaint resolution</td>
<td>4/22/13</td>
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</table>
An interview was conducted on March 27, 2013 at approximately 11:30 a.m., with Staff #1. Staff #1 reported he/she was not aware the agency had to designate a person to handle the complaints. Staff #1 reported the facility did not have a procedure to handle complaints in accord with the licensure regulations.

4. Observations on March 27, 2013 from 9:45 to 11:52 a.m. revealed the governing body had failed to provide oversight of infection prevention practices. Observations conducted with Staff #2 on March 27, 2013 revealed expired medications available for administration to patients. The observations revealed the governing body had failed to replace chairs, a gurney and make changes to ensure reusable items were able to be disinfected between patients.

Observations conducted on March 27, 2013 at 9:45 a.m., with Staff #2 revealed the cloth chairs remained in patient care areas. The governing body had failed to replace the cloth chairs, with chairs that could be disinfected between patients. Staff #2 reported awareness of the inability to disinfect the cloth chairs between patients.

Observations conducted on March 27, 2013 at 10:40 a.m., with Staff #2 revealed the procedure table and a gurney in the "Immediate Recovery" area had rust and tape residue, which prevented disinfection between patients.

Review of employee files on March 27, 2013 did not provide documentation of staffs’ infection prevention training. The employee files did not contain documentation of annual infection prevention training and correct hand washing technique and the situations, which require hand

4. There will be documentation and annual in-service training and review of infection prevention practices.

All medications available for administration to patients will have monthly checks for expiration and will be replaced the month before any medication has expired.

There will be replacements of all cloth chairs by vinyl chairs in order to properly disinfect and decontaminate any chairs between patients’ use. Due to financial constraints, the time-line for the replacements of these chairs will be approximately two-four chairs every two weeks. Approximately dead-line for full replacement of all patient-contact chairs will be 2-3 months. (total of 16 chairs).

Reception (waiting rooms) and conference rooms will be the last rooms to replace the cloth chairs with vinyl chairs. There are approximately 12 chairs in the immediate waiting room, and 5 chairs in the second waiting room. In addition, there is the conference room with 3 chairs...used solely for individual counseling (patients with interpreters, or minor patients with parent/legal guardians). Finally, there is the conference room where pre-procedure counseling and first visit counseling is done that has four chairs and a round table. With 25 cloth chairs all-told from the waiting rooms and conference rooms, we may need to reduce this number by half in order to be in full compliance.
T 010  Continued From Page 4

hygiene.

An interview was conducted on March 27, 2013 at 12:40 p.m., with Staff #1 and Staff #2. Staff #2 reported the training had not occurred.

5. The governing body failed to ensure the development of an integrated on-going quality assurance program. A second request was made on March 27, 2012 at 12:43 p.m. for the facility’s quality assurance documents. Staff #2 stated, “I have not completed the quality policies. I’ve been busy and have not gotten to it yet.” Staff #2 reported no action had been taken on developing the required components of the facility’s quality assurance program.

6. Review of employee files on March 27, 2013 did not reveal staff training regarding fire safety and disaster preparedness. A request was made on March 27, 2013 for the facility’s documentation of staffs’ training related to disaster preparedness, fire safety training and documentation of the designated fire-safety staff member.

An interview was conducted on March 27, 2013 at 12:40 p.m., with Staff #1 and Staff #2. Staff #2 reported the training had not occurred. Staff #2 reported the governing body had not established a designated fire safety staff.

T 045  12 VAC 5-412-160 A Administrator

A. The governing body shall select an administrator whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body.

The procedure table and gurney in the immediate recovery area has been cleaned of the tape residue and the rust on the gurney has been removed and refinished to allow for proper disinfection.

The employee files will have updated documentation of annual infection prevention training. The training had been done but files did not have documentation of same.

The Administrator is in the process of completing the quality assurance program policies and procedures.

The Administrator did not document the staff training of fire safety or documentation of training related to disaster preparedness. Policy and procedure for fire safety and disaster preparedness training will be implemented and documented in each employee’s file. The surgical coordinator will be designated the fire safety and disaster preparedness trainer.
T 045  Continued From Page 5

This RULE: is not met as evidenced by:
Based on document review and interview the
governing body failed to document in writing the
appointment of the administrator.

The findings included

Review of documents provided to the surveyors
on March 27, 2013 did not indicate in writing the
appointment of the Administrator. The governing
body minutes did not reflect the appointment of
the Administrator.

An interview conducted on March 27, 2013 at
10:48 a.m., Staff #2 reported the governing body
had not incorporated the appointment of the
Administrator or the designated alternative in
writing. Staff #2 stated, "I had a piece of paper
somewhere that listed me as the administrator."
Staff #2 reported he/she was not able to locate the
paper that listed him/her as administrator.

12 VAC 5-412-160 C Administrator

C. A qualified individual shall be appointed in
writing to act in the absence of the administrator.

This RULE: is not met as evidenced by:
Based on document review and interview the
governing body failed to designate a staff member
to function as the alternate administrator in the
administrator’s absence.

The findings included:

On arrival, an interview was conducted on March
27, 2013 at 9:25 a.m., with Staff #5. Staff #5
reported the administrator had not arrived. A
request was made to speak to the alternate
administrator. Staff #5 did not initially answer the

T 055

The governing body has documented in writing in the corporate minutes the appointment of the Administrator, whose qualification, authority, and duties are listed in the job description.

The governing body has documented in writing in the corporate minutes the appointment of the Assistant Administrator to act in the absence of the Administrator.
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<th>T 055</th>
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<td></td>
<td>request. Staff #5 reported the surveyors could speak to one of the nurses, while he/she contacted the administrator. At 9:26 a.m., Staff #1 assisted the surveyors to an area to set up for the survey. Staff #1 introduced himself/herself as the assistant to the administrator.</td>
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<thead>
<tr>
<th>T 080</th>
<th>12 VAC 5-412-170 E Personnel</th>
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<td></td>
<td>E. The facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.</td>
</tr>
<tr>
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<td>This RULE: is not met as evidenced by: Based on staff interview and staff record review, the agency staff failed to implement policies and procedures for staff training and participation in fire safety and infection control.</td>
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<thead>
<tr>
<th>T 055</th>
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<td>EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY</td>
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| T 080 | The facility has developed policies and procedures for the training in fire safety and infection prevention practices. Although there was initial training there was no documentation in each employee file of such training and/or retraining on an annual basis. Record-keeping and updating each employee file shall be done. Monthly in-service training shall be recorded and signed off by each employee of said in-service and placed in each employee's file. Meetings and reviews of infection prevention practices shall also be documented. |

| 5.6-13 | |
On 3/27/13 at 12:40 p.m., the survey team requested evidence of training and participation for staff for fire and safety, including fire drills, and infection control. Staff #2 stated, "I did some training on handwashing and infection control, but I didn't write it down...we have not had any fire drills and I did not do any fire safety training for our staff..." Staff #1 stated, "I called for training but they never came..."

During review of staff records on 3/27/13 at 11:00 a.m., there was no evidence of current infection control training related to handwashing/infection control practices, or fire/safety/disaster preparedness training included in 5 (five) of 5 (five) employee records reviewed.

No further information was provided by the end of the survey.

The process for verifying current professional licensing or certification and training of employees or independent contractors is through the license look-up from the respective board of medicine or board of nursing. These licenses and certifications need to be updated and reviewed to ensure the current licensure and that none of the licenses have expired.
This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to verify the licensure for one of three nursing staff (Staff #4), failed to have policies and procedures for verification of licensure, and reporting licensure /certification violations to the appropriate board. The facility failed to ensure employees had annual evaluations for seven (7) of seven (7) employees. (Employee records #1 - #7)

The findings included:

Review of the registered nurses' employee files revealed Staff #4's file did not have current licenses and certifications. The licenses in Staff #4's file expired on "02/28/2013." Staff #4's certification related to his/her provision of anesthesia had also expired as of "10/01/12."

An interview was conducted on March 27, 2013 at 11:58 a.m., with Staff #2. Staff #2 was informed of the findings and reviewed Staff #4's employee file and offered the photocopy of Staff #4's licenses and certification. Staff #2 was encouraged to notice the expiration date and stated, "I'm sure [Staff #4's name] has a current license and certification. We just don't have them in [his/her] file." Staff #2 acknowledged the facility had not verified Staff #4's license with the Department of Health Professionals. Staff #2 reported the facility had not created policies and procedures for verification of professional license and certifications. Staff #2 reported the facility had failed to correct previous deficient practice related to the development of a policy and procedure for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board.
T 005  Continued From Page 9

An interview was conducted on March 27, 2013 at approximately 12:05 p.m. with Staff #4. Staff #4 stated, "I turned in a copy of my current licenses. I don't know why they are not in my file."

2. A review of seven employee files was conducted on March 27, 2013. The employee files did not include annual evaluation of the staff's performance or skills.

An interview was conducted on March 27, 2013 at 12:01 p.m., with Staff #2. Staff #2 reported the annual evaluations had not been performed. Staff #2 reported the facility had not followed its policy and procedures for annual evaluations.

T 110  12 VAC 5-412-180 B Clinical staff

B. Abortion shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the facility are only performed by physicians who are qualified by training and experience.

This RULE: is not met as evidenced by: Based on document review and interview the facility failed to implement policies and procedures to ensure the verification of physicians' national data, the provision of appointment to clinical staff, and the physician's delineation of privileged for three of three physicians (Physicians #1 - #3)

The findings included:

During the entrance conference on March 27,
**State of Virginia**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(X1) PROVIDER/SUPPLIER/GIA</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
<th>(X3) DATE SURVEY COMPLETED</th>
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<tr>
<td>IDENTIFICATION NUMBER:</td>
<td>A. BUILDING</td>
<td>03/27/2013</td>
</tr>
<tr>
<td>FTAF-0016</td>
<td>B. WING</td>
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**NAME OF PROVIDER OR SUPPLIER**

ALEXANDRIA WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**

101 S. WHITING ST, SUITE #215
ALEXANDRIA, VA 22304

<table>
<thead>
<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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<tbody>
<tr>
<td>T 110</td>
<td>Continued From Page 10 2013 at approximately 10:28 a.m., with Staff #2 a request was made for the credentialing files for the facility's three physicians. Staff #3 provided the surveyor a file folder at 11:44 a.m. on March 27, 2013. Staff #3 stated, &quot;All I have is in this folder. I have not been able to make the corrections from the last survey.&quot; Review of the documents in the file folder did not reveal the facility had performed a national databank inquiry for the three physicians. The file folder did not contain documentation that the governing body had granted the three physicians appointment to the clinical staff. The file folder did not contain documentation of the physician's delineation of privileges. The file folder did not include the three physicians' board certification, medical education, or other qualifications related to their ability to perform of abortions. An interview was conducted on March 27, 2013 at approximately 11:59 a.m., with Staff #3. Staff #3 stated, &quot;I just didn't get to make the needed corrections or pull their data.&quot; Staff #3 verbalized understanding the national databank inquiry and delineation of privileges were essential components to ensure the physicians were qualified. Staff #3 verbalized understanding the governing body's appointment of the physicians to the clinical staff verified the type of procedures the physicians' were allowed to perform.</td>
<td>T 110</td>
<td>Staff #3 is not responsible for making any corrections to this or to the previous deficiency report. The governing body has appointed the administrator and the medical director to jointly grant physician hires and clinical staff privileges. The National Practitioner Data Bank does not provide the criteria that the physicians meet the training and experience necessary to perform first trimester abortions. Rather, the NPDB is charged with the collection and release of certain information relating to the professional competence and conduct of physicians, dentists and other health care practitioners.&quot; As an abortioncare facility, the administrator will request information from the Data Bank for Adverse Information on Physicians and other Health Care Practitioners. Each physician's agreement and job description lists the responsibilities of the physician in providing abortion care to our patients. Physicians are not required to be Board-Certified in Obstetrics and Gynecology.</td>
<td>6-13</td>
</tr>
<tr>
<td>T 145</td>
<td>12 VAC 5-412-210 C Patients' rights C. The facility shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgement of complaints; 2. Investigation of the complaint; 3. Review of the investigation findings and</td>
<td>T 145</td>
<td>The Governing Body shall designate the Assistant Administrator the responsibility of handling complaints and complaint resolution including: 1. Complaint intake, including acknowledgement of the complaint;</td>
<td>6-13</td>
</tr>
</tbody>
</table>
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/ SUPPLIER/CALIA IDENTIFICATION NUMBER:

FTAF-0016

(X2) MULTIPLE CONSTRUCTION

A. BUILDING

B. WING

(X3) DATE SURVEY COMPLETED

FTAF-0016

03/27/2013

NAME OF PROVIDER OR SUPPLIER

ALEXANDRIA WOMEN'S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE

101 S. WHITING ST, SUITE #215

ALEXANDRIA, VA 22304

(X4) ID PREFIX

T 145

T 145

T 170

T 170

T 145 Continued From Page 11

resolution for the complaint; and

4. Notification to the complainant of the
proposed resolution within 30 days from the date
of receipt of the complaint.

This RULE is not met as evidenced by:
Based on staff interview and agency document
review, the agency staff failed to designate a staff
member responsible for complaint resolution and
devise a procedure to acknowledge, investigate,
review complaints/grievances, and notify the
complainant of a resolution within 30 days.

The findings included:

On 3/26/13 at approximately 11:30 a.m., the
survey team requested the agency
complaint/grievance log and policy/procedure.
The survey team was presented a log but no
policy and procedure. Staff #1 stated he/she was
not aware the agency had to designate a person
to handle the complaints and there was no written
procedure for how it would be done.

On 3/26/13 at 4:00 p.m., the survey team again
discussed with agency staff #1 and #2 the need
for a procedure to handle complaints including the
designation of a person responsible for ensuring
the complaint procedure was followed.

12 VAC 5-412-220 B Infection prevention

B. 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

2. Investigation of the complaint;
3. Review of the investigation findings with the
Quality Assurance Committee and
4. Notify the complainant of a resolution within
30 days.

A policy and procedure will be written to address
complaints and resolutions.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

(X1) PROVIDER/SUPPLIER/CUA IDENTIFICATION NUMBER:
FTAF-0016

(X2) MULTIPLE CONSTRUCTION
A. BUILDING

B. WING

(X3) DATE SURVEY COMPLETED
03/27/2013

NAME OF PROVIDER OR SUPPLIER
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ALEXANDRIA, VA 22304

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</table>
| T 170         | Continued From Page 12 prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 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 observation, staff interview and agency document review, the agency staff failed to ensure all staff were trained in infection prevention techniques, including proper handwashing, safe injection practices, and annual retraining of staff with documentation of the training for seven (7) of seven employees (Employee records #1-#7). The findings included:

1. During the tour of the agency on 3/27/13 at 10:00 a.m., the survey team observed in the "Crash Cart" the following medications were expired: *Aminophylline 250 mg (milligram) 10 ml (milliliter) via 25 mg/ml (milligram per milliliter) expiration date September 1, 2012, Epinephrine injection 1:10,000 (one to ten-thousand solution) 1 mg (0.1 mg/ml) expiration date March 1, 2013, and in the medication refrigerator in the "procedure room" were 2 (two) vials of succinylcholine 200 mg (20 mg/ml) vials expiration 5/6/13 5/6/13| T 170 | 2. Infection prevention relating to training and observation of proper hand-washing technique; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 7. policy and procedure in the use of safe injection practices; 10. Procedures for and documentation of annual retraining of all staff in recommended infection prevention practices. | 5/6/13 |
T 170 Continued From Page 13

date December 1, 2012. Staff #1 stated the medications should have been removed when expired.

During an observation of a procedure on 3/27/13 at 11:20 a.m., Staff #1 was observed to don gloves without washing hands prior to the procedure. Staff #1 then completed the procedure for Patient # 6, removed the gloves, spoke to the patient, providing some education and information, and left the room without washing his/her hands.

On 3/27/13 at 12:40 p.m., the survey team requested the agency evidence of training and participation for infection control. Staff # 2 stated, "I did some training on handwashing and infection control, but I didn't write it down..."

During review of staff records on 3/27/13 at 11:00 a.m., there was no evidence of current infection control training related to handwashing/infection control practices, or fire/safety/disaster preparedness training included in 5 (five) of 5 (five) employee records reviewed. There was no evidence of annual re-training for staff on infection control. At 12:40 p.m. on 3/26/13, Staff #2 stated, "It has not been done..."

On 3/27/13 at 4:00 p.m. Staff #1 acknowledged that he/she had not washed his/her hands prior to or after the procedure observed by the surveyor.

*Aminophylline- a bronchodilator used to relax the muscles in the lungs to allow more ventilation. Epinephrine-used to treat anaphylactic reactions and cardiac arrest (adrenaline). Succinylcholine- a neuromuscular blocker, paralytic agent. Used for rapid sequence endotracheal intubation and relax skeletal muscles during surgery. Drug
T 170 Continued From Page 14

Information Handbook for Nursing 2011
Lexi-Comp Corporation pages 1048, 427, and 1149.
2. Observations conducted on March 27, 2013 at
10:10 a.m., with Staff #1 in the laboratory area
revealed three vials of blood used to verify Rh
factor. The vials had expired on "3/21/13",
"3/22/13", and "2/22/13."

A review of seven employee files was conducted
on March 27, 2013. The employee files did not
include infection control/prevention training or
annual re-training.

A interview was conducted on March 27, 2013 at
12:01 p.m., with Staff #2. Staff #2 reported the
infection control/prevention training had not been
documented. Staff #2 stated, "I know if its not
documented it hasn't been done." Staff #2 verified
the employee files did not have proof of annual
infection prevention re-training.

[According to Merriam Webster online Medical
dictionary- Rh Factor "a genetically determined
protein on the red blood cells of some people that
is one of the substances used to classify human
blood as to compatibility for transfusion and that
when present in a fetus but not in the mother
causes a serious immunogenic reaction in which
the mother produces antibodies that cross the
placenta and attack the red blood cells of the fetus
-- called also rhesus factor."]

T 275 12 VAC 5-412-260 C Administration, storage and
dispensing of dru

C. 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. Drugs shall be maintained at appropriate
Rh factor vials of blood are kept in the laboratory
refrigerator only until we receive the written Rh
positive and Rh negative results from Fairfax
Medical Laboratories. These reports are posted
in the laboratory to be used as references for
daily monitoring of patients' Rh factor. The reports
are only used for a 4 week period...the next group
of testing must be sent out to Fairfax Medical
Labs. There should have been monitoring of
any Rh vials kept in this refrigerator, and discarded
in the red sharps container as soon as the lab
reports are received, since these vials were only
kept as back-up in the event that Fairfax Medical
Lab. either lost or could not send us the first set
of reference reports.
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, the agency staff failed to ensure drugs maintained at the facility were not expired and that staff were educated on the medications that were available for use.

The findings included:

During the tour of the agency on 3/27/13 at 10:00 a.m., the survey team observed in the “Crash Cart” the following medications were expired:
* Aminophylline 250mg (milligram) 10 ml (milliliter) vial 25mg/ml (milligram per milliliter) expiration date September 1, 2012, Epinephrine injection 1:10,00 (one to ten-thousand solution) 1mg (0.1mg/ml) expiration date March 1, 2013. Staff #1 stated the medications should have been removed when expired.
* Aminophylline- a bronchodilator used to relax the muscles in the lungs and allow better ventilation. Epinephrine- used to treat anaphylactic reactions and cardiac arrest (adrenaline) Drug Information Handbook for Nursing 2011 Lexi-Comp Corporation pages 1048 and 427.

In the medication refrigerator in the “procedure room” the surveyor observed 2 (two) vials of the drug **succinyllcholine 200mg (20mg/ml) vials expiration date December 1, 2012. The surveyor interviewed Staff #2 as to the use of the medication. Staff #2 stated, “It is on our list of drugs for the cart and it is used for convulsions...” The surveyor inquired as to when the medication was last administered to a patient. Staff #2 stated, “I can’t remember ever using this.” When asked if the medication was going to be re-ordered, Staff #2 stated, “Absolutely, if the..."
Continued From Page 16

doctor wants it to be." The surveyor inquired as to whether Staff #2 was familiar with the side effects of the succinylcholine and the potential for malignant hyperthermia (MH). Staff #2 stated he/she was not familiar with MH. The surveyor then asked Staff #2 if the medication Dantrolene was available at the agency. Staff #2 stated "No I do not know what that is for..." The medication (succinylcholine) was immediately removed by Staff #2.

On 3/27/13 at 1:15 p.m., Staff #3 (physician) was interviewed regarding the succinylcholine. Staff #3 stated, "I do not know why that medication would even be here. We do not use that. We do not have ventilators and we do not intubate...we would never use that medication and it will not be reordered. I don't know why it is here in the first place. I think (Staff #2) thought it was needed for the cart, but it is not and will be removed from that list. That medication has never been used here..."

** Succinylcholine- a neuromuscular blocking agent used to facilitate rapid sequence intubation during surgery. Malignant Hyperthermia a life threatening condition associated with the use of Succinylcholine. [According to www.drugs.com "Possibly fatal Malignant Hyperthermia;Malignant manifested by a rapid, profound elevation in body temperature and sometimes extreme muscular rigidity. Risk increases with concomitant administration of inhalation anesthetics. If Malignant Hyperthermia occurs, discontinue all anesthetic agents and initiate IV dantrolene therapy in conjunction with supportive measures (e.g., administering oxygen, treating metabolic acidosis, instituting cooling procedures); maintain urinary output and monitor serum electrolytes."] [According to www.askhealth.com "DANTROLENE (DAN troe lean) helps to relieve spasms and stiffness of muscles in conditions
such as multiple sclerosis, cerebral palsy, stroke, or injury to the spine. This medicine can also help prevent and treat a condition called Malignant Hyperthermia, which may occur after surgery or anesthesia.

The findings were again discussed with Staff #1 and #2 on 3/27/13 at 4:00 p.m.

An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include:
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.

This RULE: is not met as evidenced by:
Based on observations and interviews the facility failed to ensure suitable equipment was available in patient care areas. The facility utilized cloth chairs in patient care areas, which could not be disinfected between patients. The facility's recovery area gurney and procedure table had non-intact surfaces, which could not be disinfected between patients. The facility failed to ensure that supplies utilized in patient care were not expired.

There will be replacements of all cloth chairs by vinyl chairs in order to properly disinfect and decontaminate any chairs between patients' use. Due to financial constraints, the time-line for replacement of these chairs will be approximately 2 to 4 chairs every two weeks. The approximate dead-line for full replacement of all patient-contact chairs will be 2-3 month (total of 16 chairs).

Reception (waiting rooms) and conference rooms will be the last rooms to replace the cloth chairs with vinyl chairs. There are approximately 12 chairs in the immediate reception room and 6 chairs in the second waiting room. These chairs are not patient-contact chairs. In addition, there is the conference room with 3 cloth chairs...used solely for individual counseling (patients with interpreters, or minor patients with parent/legal guardians). Finally there is the conference room where pre-procedure counseling and first-visit counseling is done that has four chairs and a round table. With 25 cloth chairs all-told from the 2 waiting rooms and conference, we may need to reduce this number by half in order to be in full compliance.
T 290 Continued From Page 18

The findings included:

Observations conducted on March 27, 2013 at 9:45 a.m., with Staff #2 revealed the cloth chairs remained in patient care areas. The facility had six (6) cloth chairs in its sonogram area, two (2) cloth chairs, for patients in the counseling areas, seven (7) chairs in their front waiting area, and four (4) cloth chairs in the waiting area on the procedure side of the facility.

An interview was conducted on March 27, 2013 at 10:20 a.m., with Staff #1. Staff #1 stated, "We have not changed the chairs since the last survey. We have just not replaced them. We just don't have the money to replace them." Staff #1 reported the facility had "hoped to replace them two at a time, but had not been able to do it." Staff #2 joined the interview and reported awareness that cloth chairs should not be available in patient care related to the inability to disinfect the chairs between patients. Staff #2 could not provide documentation of purchase orders or a planned/schedule by the facility related to the replacement of the cloth chairs with chairs that could be disinfected between patients.

Observations conducted on March 27, 2013 at 10:40 a.m., with Staff #2 revealed the procedure table and a gurney in the "Immediate Recovery" area had rust and tape residue, which prevented disinfection between patients. Staff #2 verified the findings. Staff #1 reported the facility had not addressed the rust or non-intact surfaces on the procedure table or the "Immediate Recovery" area's gurney. Staff #2 reported, "After we covered the table cushion, nothing else has been done, really."

An observation conducted on March 27, 2013 at

T 290

The procedure table and the gurney in the immediate recovery area has been cleaned of the tape residue to allow for proper disinfection. The rust on the gurney has been removed and refinushed to allow for proper disinfection between patients. An order has been placed for a replacement gurney.
<table>
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<tr>
<th>T 290</th>
<th>Continued From Page 19</th>
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</thead>
<tbody>
<tr>
<td>10:45 a.m., in the procedure room with Staff #2 revealed two (2) yankauer suction devices, which had expired &quot;2010-09.&quot; Staff #2 verified the yankauer suction devices were available for use in case of an emergency or if a patient needed to be suctioned.</td>
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[According to www.online free medical dictionary.com a "Yankauer suction device" is a "rigid hollow tube made of metal or disposable plastic with a curve at the distal end to facilitate the removal of thick pharyngeal secretions during oral pharyngeal suctioning.

2. On 3/27/13 at 10:40 a.m., the surveyor observed a gurney (stretcher) in the "immediate recovery area" which had chipped metal and rust visible along the metal frame and handrails. This was also observed by Staff #2. Staff #2 acknowledged the condition of the stretcher at that time. There were also 2 (two) "Uterine Explora Model II curettes with vacu loc syringe" which expired on 7/2012 and 1/2013. These were removed by staff #1. |

<table>
<thead>
<tr>
<th>T 315</th>
<th>12 VAC 5-412-300 A Quality assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.</td>
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This RULE: is not met as evidenced by:

Based on interview the facility failed to develop an ongoing, comprehensive, and integrated quality assurance program to include: staffing patterns and performance; supervision of staff according to their job functions and responsibilities; patient records; patient satisfaction; complaint resolution; recording and reporting of infections, complications and other adverse events; and staff concerns regarding patient care.

| T 315 | The facility will implement a quality assurance program to include: staffing patterns and performance; supervision of staff according to their job functions and responsibilities; patient records; patient satisfaction; complaint resolution; recording and reporting of infections, complications and other adverse events; and staff concerns regarding patient care. | 5/6/13 |

<table>
<thead>
<tr>
<th>T 290</th>
<th>There will be a checklist for the monitoring of all equipment and supplies...disposable and nondisposable...for expiration dates to be performed monthly.</th>
</tr>
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<tbody>
<tr>
<td>T 290</td>
<td>Yankauer suction devices which have expired dates will be replaced, with longer shelf-life equipment.</td>
</tr>
<tr>
<td>T 290</td>
<td>The 2 &quot;Uterine Explora&quot; curettes with vacu loc syringe had expiration dates of July 2012 and Jan. 2013 were removed from the procedure room. They will not be replaced as they are no longer used.</td>
</tr>
</tbody>
</table>
### Continued From Page 20

assurance/self-assessment program. The facility failed to implement a program to assure that identified problems were corrected.

The finding included:

During the entrance conference on March 27, 2013 at approximately 10:28 a.m., with Staff #2 a request was made for the facility's quality assurance data and any documentation relate to the implementation of correction for identified deficient practice.

A second request was made on March 27, 2012 at 12:43 p.m. for the facility's quality assurance documents. Staff #2 stated, "I have not completed the quality policies, I've been busy and have not gotten to it yet." Staff #2 reported no action had been taken on developing the required components of the facility's quality assurance program.

### 12 VAC 5-412-300 B Quality assurance

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

This RULE: is not met as evidenced by; Based on interview the facility failed to develop a
quality assurance program, which included the required elements.

The findings included:

During the entrance conference on March 27, 2013 at approximately 10:28 a.m., with Staff #2 a request was made for the facility's quality assurance plan.

A second request was made on March 27, 2012 at 12:43 p.m. for the facility's quality assurance documents. Staff #2 stated, "I have not completed the quality policies, I've been busy and have not gotten to it yet." Staff #2 reported no action had been taken on developing the required components of the facility's quality assurance program.

12 VAC 5-412-300 C Quality assurance

C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of:
1. A physician
2. A non-physician health care practitioner;
3. A member of the administrative staff; and
4. An individual with demonstrated ability to represent the rights and concerns of patients.

The individual may be a member of the facility's staff. In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.

This RULE: is not met as evidenced by.
Based on interview the facility failed to develop a quality assurance committee.
The findings included:

During the entrance conference on March 27, 2013 at approximately 10:28 a.m., with Staff #2 a request was made for the facility’s quality assurance plan and members of the quality assurance committee.

A second request was made on March 27, 2012 at 12:43 p.m. for the facility’s quality assurance documents. Staff #2 stated, "I have not completed the quality policies, I’ve been busy and have not gotten to it yet." Staff #2 reported no action had been taken towards developing the quality assurance committee membership.

T 330 12 VAC 5-412-300 D Quality assurance

D. Measures shall be implemented to resolve problems or concerns that have been identified.

This RULE is not met as evidenced by:
Based on interview the facility failed to identify and implement corrective action.

The findings included:

During the entrance conference on March 27, 2013 at approximately 10:28 a.m., with Staff #2 a request was made for the facility’s quality assurance data and actions implemented to correct identified deficient practices.

A second request was made on March 27, 2012 at 12:43 p.m. for the facility’s quality assurance documents. Staff #2 stated, "I have not completed the quality policies, I’ve been busy and have not gotten to it yet." Staff #2 reported no action had been taken towards developing the quality assurance committee membership.
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<tr>
<td>T 330</td>
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<td>quality assurance program. Staff #2 reported the facility had not implemented necessary actions to correct identified deficient practices.</td>
<td>T 330</td>
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<tr>
<td>T 335</td>
<td>2 VAC 5-412-300 E Quality assurance</td>
<td></td>
<td></td>
<td>300 E Quality Assurance</td>
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</table>

E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

This RULE is not met as evidenced by:
Based on interview the facility failed to identify and implement corrective action. The facility failed to submit annual data to the governing body.

The findings included:

During the entrance conference on March 27, 2013 at approximately 10:28 a.m., with Staff #2 a request was made for the facility's analysis of quality assurance data and the corrective actions forwarded to the governing body.

A second request was made on March 27, 2012 at 12:43 p.m. for the facility's quality assurance documents. Staff #2 stated, "I have not completed the quality policies, I've been busy and have not gotten to it yet." Staff #2 reported no action had been taken towards developing the quality assurance program. Staff #2 reported the facility had not implemented necessary actions to
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<tr>
<th>ID</th>
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<th>Summary Statement of Deficiencies</th>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Provider's Plan of Correction</th>
<th>Complete Date</th>
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<tr>
<td>T 335</td>
<td>Continued From Page 24</td>
<td>T 335</td>
<td>correct identified deficient practices or forwarded information to the governing body.</td>
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<tr>
<td>T 365</td>
<td>12 VAC 5-412-350 A Disaster preparedness</td>
<td>T 365</td>
<td>Policies and procedures have been developed and written to ensure reasonable precautions are taken to protect all patients and staff from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.</td>
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<td>The agency staff must implement and practice drills for fire and other disasters. These in-service trainings in fire safety and disaster preparedness must be documented.</td>
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<td>T 370</td>
<td>12 VAC 5-412-350 B Disaster preparedness</td>
<td>T 370</td>
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T 370  Continued From Page 25

Disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

This RULE: is not met as evidenced by:
Based on staff interview and agency document review, the agency failed to ensure participation in a community disaster plan.

The findings included:

On 3/27/13 at 12:40 p.m., the survey team requested evidence of training and participation for staff for fire and safety, including fire drills, disaster preparedness and infection control. Staff # 2 stated, "We have not had any fire drills and I did not do any fire safety training for our staff..." Staff #1 stated, "I called for training but they never came..." Staff #1 stated the agency did not plan to participate in community disasters.

T 385 12 VAC 5-412-370 A Fire-fighting equipment and systems

A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program.

This RULE: is not met as evidenced by:
Based on staff interview and agency document review, the agency staff failed to ensure a monitoring program for internal enforcement of all applicable fire and safety laws and regulations.

The findings included:

On 3/27/13 at 12:40 p.m., the survey team requested evidence of training and participation...
<table>
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<tr>
<th>T 385</th>
<th>Continued From Page 26</th>
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<tr>
<td>for staff for fire and safety, including fire drills, disaster preparedness and infection control. Staff #2 stated, “We have not had any fire drills and I did not do any fire safety training for our staff...” Staff #1 stated, “I called for training but they never came...” Staff #2 stated there was not a program for fire safety and no person was designated responsible at the time of the survey.</td>
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</table>

| T 385 | The current Surgical Coordinator will ensure there will be fire drills at least biannually, and documentation of such fire drills and disaster preparedness training will be included in each employee file. |

| 5.6.13 |  |
January 8, 2015

Administrator
Alexandria Women's Health Clinic
101 S. Whiting Street - Suite 215
Alexandria, Virginia 22304

RE: Alexandria Women's Health Clinic - Alexandria, VA Abortion Facility Biennial Licensure Inspection

Dear Administrator:

An unannounced, Abortion Facility biennial licensure inspection of the above facility was conducted December 8, 2014 through December 9, 2014 by two (2) Medical Facilities Inspectors from the Virginia Department of Health's Office of Licensure and Certification.

Enclosed is the Biennial Licensure Inspection. The facility was not in compliance with 12VAC5-412 regulations for the Licensure of Abortion Facilities, effective June 20, 2013. This document contains a listing of deficiencies found at the time of this inspection.

You are required to submit a plan for correcting the deficiencies cited. Your statements shall reflect the specific detailed actions you will take to correct deficiencies, prevent a recurrence of the deficiencies, and measures implemented to maintain compliance. You must also give the expected completion date of each deficiency.

Completion of corrective actions shall not exceed 45 working days from the last day of the inspection.

After signing and dating your Plan of Correction, retain one copy of the report for your files and return the original to OLC within 15 (fifteen) working days of receipt of the inspection report. The Administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with the Code of Virginia §32.1-27 or in denial, revocation or suspension of a license in accordance with 12VAC5-412-130.
An unannounced Licensure Biennial survey was conducted 12/08/2014 through 12/09/2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013).

B. Any change in the position of the administrator shall be reported immediately by the licensee to the department in writing.

This RULE: is not met as evidenced by:
Based on interview and document review, it was determined the agency failed to develop a policy related to reporting changes of the position of administrator.

The findings included:

Review of the agency policy and procedure manual on 12/08/2014, revealed there was no policy requiring the governing body to notify the Office of Licensure and Certification in writing of a change in the position of administrator.

During an interview conducted on 12/08/2014, at approximately 6:00 PM, Staff #2 acknowledged there was no policy related to notifying the OLC of changes in the position of administrator.
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA
IDENTIFICATION NUMBER:

AF-0014

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED

12/09/2014

NAME OF PROVIDER OR SUPPLIER

ALEXANDRIA WOMEN'S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE

101 S. WHITING ST, SUITE #215
ALEXANDRIA, VA 22304

(X4) ID PREFIX TAG

T 060 Continued From Page 1

The facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided.

This RULE: is not met as evidenced by:
Based on observation, interview and document review, it was determined the agency failed to ensure staff training was documented in employee files.

The findings included:

In the recovery room on 12/09/2014 at approximately 11:00 AM, Staff #6 was observed taking vital signs of clients.

During an interview with Staff #6 on 12/09/2014, at approximately 12:25 PM, Staff #6 stated that he/she was currently taking classes required to attend nursing school, and that he/she had been trained to perform vital signs by Staff #4. During an interview conducted on 12/09/2014 at approximately 12:40 PM, Staff #4 stated that he/she had trained Staff #6 how to perform vital signs. A review of the employee file of Staff #6 did not include supporting documentation of training for performing vital signs.

T 095 12 VAC 5-412-170 H Personnel

H. Personnel policies and procedures shall include, but not be limited to:
1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification;
2. Process for verifying current professional licensing or certification and training of employees or independent contractors;

T 095

T 060

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The facility will update employee files with updated documentation of training related to their duties and will be included in the policy and procedure manual. The administrator or assistant administrator will be responsible that the employee training is documented and filed.

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TO 95

3. A policy and procedure will be developed for annual evaluation of employees. There will be an annual self-evaluation documentation of employee performance in which...
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:
AF-0014

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
12/09/2014

NAME OF PROVIDER OR SUPPLIER
ALEXANDRIA WOMEN’S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE
101 S. WHITING ST, SUITE #215
ALEXANDRIA, VA 22304

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
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<th>PROVIDER’S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCES TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
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<tr>
<td>T095</td>
<td>Continued From Page 2</td>
<td>3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. This RULE: is not met as evidenced by: Based on document reviews and staff interviews it was determined the facility failed to perform an annual employee performance for one (1) of seven (7) employees in the survey sample (Staff #3). The findings included: At the entrance conference on 12/08/2014 at 1:00 p.m., the administrator was asked to provide a list of new employees hired since the last inspection and to include date of hire and title for the surveyor to review. The review of personnel records on 12/08/2014 at 3:15 p.m. failed to contain evidence that verify one (1) of seven (7) staff (Staff #3) had no evidence of an annual performance evaluation. The seven (7) staff members had been employed over one (1) year. An interview was conducted on 12/08/2014 at 4:15 p.m., with Staff #1 and Staff #2. The surveyor requested documentation showing the facility would have an annual evaluation for employee performances. Staff #2 reported he/she was unsure if the facility did have policies and procedures to reflect the State licensure requirements for ensuring an annual employee performance evaluation would be conducted; however he/she would like to continue</td>
<td>T095</td>
<td>12/30/14</td>
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VDH/OLC
investigating.

The agency's policy titled, "Credentialing" was reviewed on 12/08/2014. The policy read in part: "The facility staff shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member."

The review of the facility's policies and procedures on 12/08/2014 at 2:30 p.m. did not include policies for evaluating employee performances annually.

The findings related to implementing the policy for evaluating employees were discussed with Staff #1 and Staff #2 on 12/09/2014 at 1:30 p.m. Staff #2 acknowledged that although the agency has a process to complete employee annual performance evaluations, he/she knew the personnel file should have contained these documents but failed to do so. Staff #2 reported he/she was not aware Staff #3's annual evaluation was not in the personnel file until it was brought to his/her attention by the surveyor.

During the exit interview on 12/09/2014, Staff #2 acknowledged that the facility has a process to obtain an annual employee performance evaluation, but failed to maintain the facility's system in the manner required by this regulation.

12 VAC 5-412-220 B Infection prevention

B. 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;
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 observation, interview and document review, it was determined the agency failed to:

1. Ensure the use of standard precautions by clinicians, when wearing gloves to prevent transmission of microorganisms
2. Develop a hand hygiene policy for clinicians when donning gloves

The findings included:

It was observed in the recovery room on 12/9/2014, at approximately 11:00 AM, that Staff #2 did not perform hand hygiene between glove changes. At approximately 11:15 AM, Staff #6 did not perform hand hygiene prior to donning gloves, when moving a stretcher to the procedure room.

T170 continued.

The facility will require that standard precautions are followed by all employees and medical staff caring for patients to prevent transmission of infectious agents.

Effective hand hygiene reduces the incidence of healthcare-associated infections by preventing the transmission of microorganisms from patient to patient and from inanimate surfaces to patients.

Hand hygiene shall be practiced before and after each patient contact as well as after glove removal and before donning new gloves.

A healthcare professional (physician, RN, etc.) will be responsible for the ongoing education regarding infection prevention techniques.
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<th>T 170 Continued From Page 5</th>
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During an interview on 12/09/2014, at approximately 12:20 PM, Staff #2 acknowledged that hands should be cleaned between glove changes and stated, "I guess I forgot." During an interview on 12/09/14, at approximately 12:25 PM, Staff #6 acknowledged that hands are to be cleaned prior to donning gloves with soap or alcohol rub.

It was observed in the tissue exam and equipment cleaning room on 12/09/2014, at approximately 11:00 AM, that Staff #3 did not perform hand hygiene between glove changes following two (2) procedures.

During an interview on 12/09/2014, at approximately 11:20 AM, Staff #3 stated "I wash hands before I come into the room and when I leave the room, after all procedures are done." Staff #3 acknowledged he/she would not leave the tissue room until all procedures were done for the day.

According to the Center for Disease Control (CDC), Guide To Infection Prevention For Outpatient Settings, hand hygiene should be performed:
1. Before touching a patient, even if gloves will be worn
2. Before exiting the patient's care area after touching the patient or the patient's immediate environment
3. After glove removal

Review of the agency policies and procedures manual on 12/09/2014, revealed there was no policy related to hand hygiene when wearing gloves.

During an interview on 12/09/2014, at approximately 2:00 PM, Staff #2 acknowledged
Continued From Page 6

there was no policy related to performing hand hygiene before donning gloves and after glove removal.

T 175 12 VAC 5-412-220 C Infection prevention

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);
4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
5. Procedures for handling/temporary storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
   (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
   (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
   (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines.

The vinyl padding in the procedure table will be replaced in order to properly disinfect and decontaminate between patient use.

The administrator or designee (assistant administrator, surgical coordinator, etc.) will be responsible for the replacement of any equipment in order to be in full compliance.
### T 175 Continued From Page 7

control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observation, interview, and document review, it was determined the agency failed to enforce its policy on environmental cleaning related to a tear in padding, located in the procedure room.

The findings included:

It was observed during a tour of the facility on 12/08/2014, at approximately 2:00 PM, that there was a tear in vinyl padding of a structure adjoining the procedure table, above the head of the mattress padding.

During an interview conducted on 12/08/2014, at approximately 2:00 PM, Staff #1 stated that this portion of the table was used by a clinician to make notes during the procedure. Staff #1 stated, "We can get rid of this."

A tear in vinyl inhibits the ability to disinfect the surface of microorganisms. Agency policy and procedures state "Stretcher mattresses, gurneys, wheelchairs and chairs will be examined first..."
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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<td>thing in the morning and between patients for tears. If there is any damage to any mattress, gurney or chair it will be removed from use and reported to the Director of Nursing.</td>
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<tr>
<th>T 180</th>
<th>12 VAC 5-412-220 D Infection prevention</th>
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<tr>
<td>D. The facility shall have an employee health program that includes:</td>
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<tr>
<td>1. Access to recommended vaccines;</td>
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<td>2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;</td>
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<tr>
<td>3. An exposure control plan for blood-borne pathogens;</td>
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<td>4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine;</td>
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<td>5. Compliance with requirements of the U.S. Occupational Safety &amp; Health Administration for reporting of workplace-associated injuries or exposure to infection.</td>
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This RULE is not met as evidenced by:

Based on document review and staff interviews the facility failed to have an employee health program that documented screenings and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities for seven (7) of seven (7) employees and five (5) of five (5) physicians.

The findings included:

A review of seven (7) personnel records
(Employee files #1-#7) and five (5) credentialing personnel records (Credentialing Employees #1-#5) failed to contain evidence verifying employees were offered/received screening for tuberculosis annually. One (1) of seven (7) personnel records (Employee #4) and four (4) of five (5) credentialing personnel records (Credentialing Employees #1, 2, 3 and 5) failed to contain evidence verifying employees had access to Hepatitis B vaccine.

The agency's policy titled, "Hepatitis B Vaccine" was reviewed on 12/08/2014. The policy read in part: "Each staff member whose position has identified them as being at risk of contracting, or there is reasonable anticipation that they may be exposed to Hepatitis B Virus (HBV) will be offered the HBV vaccination series free of charge. The vaccine will be available within 10 days of employment or assignment of a new position within the risk category. This vaccination does not have to be given if the employee has previously received the complete HBV vaccination series, antibody testing has revealed the employee is immune, the vaccine is contraindicated for medical reasons, or the employee refused the vaccine and signs the Informed Refusal Form."

The review of the facility's policies and procedures on 12/08/2014 at 2:30 p.m. did not include policies for screening for tuberculosis.

The findings related to having screening and immunizations offered/received by employees were discussed with Staff #2 on 12/08/2014 at 4:15 p.m. Staff #2 acknowledged the facility does have a process for offering employees screening and immunizations, including Hepatitis B and the influenza vaccine. Staff #2 reported many employees refuse this offered service. The surveyor inquired if Staff #2 had documented the
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0014

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED: 12/09/2014

NAME OF PROVIDER OR SUPPLIER
ALEXANDRIA WOMEN'S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE
101 S. WHITING ST, SUITE #215
ALEXANDRIA, VA. 22304

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<th>ID</th>
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<td>employee's refusal. Staff #2 reported the facility had developed a decline or refusal of immunizations form, but failed to have documentation of the employees/physicians declining the screenings and immunizations. Staff #2 stated, &quot;We don't have anything about tuberculosis screening and we don't require it because we didn't know we needed to.&quot;</td>
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<td>T 275</td>
<td>12 VAC 5-412-260 C Administration, storage and dispensing of dru</td>
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<td>C. 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. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10</td>
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<td>This RULE: is not met as evidenced by: Based on observations, interviews and document review the facility failed to maintain drugs in the facility for daily use which are unexpired. The findings included: A tour of the facility was conducted on 12/08/2014 at approximately 1:30 p.m. with Staff #1. The observation in the facility's double locked medication cabinet revealed three (3) boxes of single use Fentanyl vials with an expired date documented as &quot;1 Dec 2014.&quot; Two (2) boxes of Fentanyl were unopened and one (1) box of Fentanyl had approximately five (5) vials removed and documented by the physician in the medication log. The three (3) boxes of expired Fentanyl were removed by Staff #1 (Administrator).</td>
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**Americans United for Life**

**RECEIVED**

**FEB 02 2015**

**VDH/OLC**
Review of the facility's policy titled "Pharmaceuticals" read in part: "The Director of Nursing, under the supervision of the Medical Director is responsible for the ordering, storing, stocking, controlling, distributing and disposing of controlled substances and all other medications. In accordance with all applicable laws, records are kept on all ordering, purchasing and dispensing of drugs."

An interview was conducted on 12/08/2014 at 1:45 p.m. with Staff #1. Staff #1 verified the date on the three (3) boxes of single use Fentanyl. Staff #1 stated, "There is something wrong because we just received this shipment from the distributor approximately one month ago and it shouldn't be expired already. I am going to contact them about this, but these boxes should be discarded immediately from this locked medication cabinet."

[According to www.drugs.com: Fentanyl is an opioid medication. An opioid is sometimes called a narcotic. Fentanyl is used as part of anesthesia to help prevent pain after surgery or other medical procedure.]

T 285 12 VAC 5-412-260 E Administration, storage and dispensing of drug

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.

This RULE is not met as evidenced by: Based on document review, observation and interviews the facility failed to keep records of all...
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CALIA
IDENTIFICATION NUMBER:

AF-0014

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
12/09/2014

NAME OF PROVIDER OR SUPPLIER

ALEXANDRIA WOMEN'S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE

101 S. WHITING ST, SUITE #215
ALEXANDRIA, VA 22304

(X4) ID
PREFIX
TAG

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL
REGULATORY OR LSC IDENTIFYING INFORMATION)

T 285 Continued From Page 12

 drugs in Schedules I-V received in accordance
with federal and state laws.

Note: This is a re-cite from 2012.

The findings included:

A tour of the facility was conducted on 12/08/2014,
at approximately 1:30 p.m. with Staff #1
(Administrator). Staff #1 reported all narcotics are
stored in the double locked medication cabinet.
Staff #1 confirmed only patients who receive
sedation have an IV (intravenous line which is
inserted into the vein to receive fluids or
medications) started prior to the procedure. Staff
#1 confirmed he/she is not licensed as a health
professional. Staff #1 confirmed the narcotics are
received by him/her from the vendor; however
medications are removed from the locked cabinet
by the physicians and CRNA (certified nurse
anesthetist) and documented in the medication
logs. Staff #1 acknowledged all narcotics are
accounted for by documentation in each patient's
record and by the medication logs signed by the
physicians and/or CRNA, which is overseen by the
Medical Director. Staff #1 verified the narcotics
are counted at the above named facility by the
physicians prior to each use and documented on
the medication log. Staff #1 and Staff #2 count
the narcotics monthly and document the count on
a separate ledger from the physicians but
compare counts. Staff #1 again confirmed he/she
and Staff #2 are not licensed as health
professionals.

A review of the medication logs and ledgers were
conducted on 12/08/2014 with Staff #1.
Medication logs showed evidence the physicians
and CRNA signed each entry for narcotics
dispensed. A review of the monthly ledger showed evidence Staff #1 and Staff #2

T 285 continued

and other medications as stated
in the facility's policy and
procedure manual.

Monthly narcotic count will be
done by a healthcare licensed
professional and verified by
the director of nursing and/or
medical director.
the monthly narcotics count co-signed by the Medical Director. Staff #1 confirmed he/she and Staff #2 are not licensed as health professionals.

An interview was conducted with Staff #5 on 12/09/2014 at approximately 9:10 a.m. Staff #5 verified a narcotics count is done at the beginning of each clinic and documented on the medication log. Staff #5 acknowledged there have been no problems; however if any problems were encountered with the count, he/she would notify the Administrator and the Medical Director immediately and his/her obligation is to report it the proper authorities.

A review was done of the Code of Virginia 54.1-3408 Professional use (of controlled substances) by Practitioners. There was no allowance for non-licensed persons to handle narcotic medications, even if under the supervision of a physician.

A review of the facility's policy titled "Pharmaceuticals" read in part: "The Director of Nursing, under the supervision of the Medical Director is responsible for the ordering, storing, stocking, controlling, distributing and disposing of controlled substances and all other medications. In accordance with all applicable laws, records are kept on all ordering, purchasing and dispensing of drugs. The Medical Director and/or the Director of Nursing is responsible for the correct, safe storage of medications, IV solutions and chemicals. Access to drug storage is limited to licensed Medical and Nursing personnel. Adequate space, cabinetry and refrigeration shall be made available in the pharmacy area to house all pharmacy medications and related supplies." Nowhere in the policy does it state unlicensed personnel shall have access to controlled substances.
During a review of Staff #5's credentials file on 12/06/2014 it was noted the documentation indicated Staff #5's DEA (drug enforcement agency) number expires on 10/31/2016.

A review of Staff #1 and Staff #2’s employee file were conducted on 12/08/2014. Staff #1’s date of hire was 07/01/2000. Staff #1 has no professional license which would allow him/her to handle controlled substances. Staff #1 has no evidence of training in medications in his/her employee file. Staff #1 has a job description for administrator. Staff #2’s date of hire was 09/04/2004. Staff #2 has no professional license which would allow him/her to handle controlled substances. Staff #2 has evidence of attending nursing school and training in medications in his/her employee file. Staff #2 has job descriptions for alternate administrator and surgical and laboratory technician.

An interview with Staff #1 and Staff #2 was conducted on 12/09/2014 in regards to the findings. Staff #1 acknowledged approximately two (2) years prior to the survey a staff Registered Nurse was responsible for the task of handling all medications. After the Registered Nurse left the facility, the medication task became the responsibility of the Administrator because the physicians were not in the office everyday. Staff #1 didn’t want to add more responsibilities to the physicians so he/she took the duty of ordering, storing and stocking the controlled substances and all other medications. Staff #1 stated, "I didn’t realize I couldn't receive, store and count the narcotics until it was brought to my attention by the surveyor."
T 315 Continued From Page 15

T 315 12 VAC 5-412-300 A Quality assurance

A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary.

This RULE: is not met as evidenced by:

Based on document review and interview the quality committee failed to ensure the facility maintained an ongoing, comprehensive, integrated, self-assessment program.

Note: This is a re-cite from 2012.

The findings included:

An interview and review of the facility's quality program was conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 initially stated he/she did not understand the State licensure requirement of implementing "an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement."

The review revealed documents titled "Quality Meeting," which listed items discussed as part of the facility's quality program meeting. The surveyor asked Staff #2 how the quality committee determined, which items to discuss and if the committee had formulated the items from data collected. Staff #2 denied that data had been collected as the basis for what was discussed.
T 315 Continued From Page 16

during the quality committee's meetings.

An interview was conducted on 12/09/2014 at 1:50 p.m., the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 denied awareness of the updated State licensure regulations. Staff #2 stated, "We have not collected data or performed a program assessment."

T 320

12 VAC 5-412-300 B Quality assurance
B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:
1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

This RULE: is not met as evidenced by:
Based on document review and interview the quality committee failed to ensure an evaluation of the adequacy and appropriateness of services as required by the State licensure regulations.

Note: This is a re-cite from 2012 related to staff's failure to ensure all subjects of the quality improvement committee would be addressed.

The findings included:
An interview and review of the facility's quality

T 315 Continued
4. Patient satisfaction (surveys, suggestion box).

5. Complaint resolution

6. Recording and reporting of infections, complications and other adverse events (monthly compilation).

7. Staff concerns regarding patient care (staff suggestion box, meetings).

This program will allow the facility to correct and make improvements to patient care and in our respective duties to better serve the care of our patients.

T 320

The adequacy and appropriateness of services will be evaluated by the Quality Assurance Committee. This evaluation will identify the unexpected or unacceptable trends or occurrences. This will address the following:
1. Staffing patterns and performance;
2. Supervision appropriate to the level of service.
program documents were conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 and the surveyor reviewed the facility’s quality program documentation. The facility’s documentation did not include the required seven (7) elements of: staffing patterns and performance, supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; and staff concerns regarding patient care. Staff #2 reported the quality committee had collected data but had not evaluated data for the seven required areas or identified unacceptable or unexpected trends or occurrences.

During an interview conducted on 12/09/2014 at 1:30 p.m. the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 denied awareness of the updated State licensure regulations. Staff #2 reported the quality committee had collected data, but had not analyzed or trended data for the required areas to identify unacceptable or unexpected outcomes.

**T 330** 12 VAC 5-412-300 D Quality assurance

3. Patient records.
4. Patient satisfaction (surveys, suggestion box).
5. Complaint resolution
6. Recording and reporting of infections, complications and other adverse events (monthly compilation).
7. Staff concern regarding patient care (staff suggestion box, meetings).

All data collected will be evaluated to correct and/or make improvements regarding patient care.

**T 330**

The Quality Assurance Committee will provide proper documentation of all data collected and will be evaluated to correct and/or make improvements regarding patient care.
The findings included:

An interview and review of the facility's quality program was conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 initially acknowledged the quality improvement committee did discuss concerns/problems that had been identified by services provided, appropriateness of care including reports from staff, patients, performance patterns, or any other sources of data collected.

The review revealed documents titled "Quality Meeting," which listed items discussed as part of the facility's quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were implemented.

An interview was conducted on 12/09/2014 at approximately 1:50 p.m., with Staff #2. The findings were reviewed. Staff #2 reported the facility's quality program needed to address the issues found by the survey team. Staff #2 acknowledged the quality program's failure to implement measures to resolve problems or concerns that have been identified.

All results from the Quality improvement program will be reported at least annually. These results will be reported to the Governing Body and License and
corrective actions shall be documented.
Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

This RULE: is not met as evidenced by:
Based on document review and interview the quality committee failed to compile results of deficient practices or corrective action implemented to the governing body.

Note: This is a re-cite from 2012 related to staff’s failure to ensure results of the quality improvement program would be reported to the licensee at least annually and deficiencies identified, recommendations and improvements were being acted upon by the governing body and the facility.

The findings included:

An interview and review of the facility’s quality program was conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 initially acknowledged the quality improvement committee did discuss concerns/problems that had been identified by services provided, appropriateness of care including reports from staff, patients, performance patterns, or any other sources of data collected.

The review revealed documents titled “Quality Meeting,” which listed items discussed as part of the facility’s quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were

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T 335  Continued From Page 20

implemented. Staff #2 reported the quality committee did not compile a report for the governing body to review at least annually.

An interview was conducted on 12/09/2014 at approximately 1:50 p.m., with Staff #2. The findings were reviewed. Staff #2 reported the facility's quality program needed to address the issues found by the survey team. Staff #2 acknowledged the quality program’s failure to report the deficiencies identified and recommendations for corrections and improvements.

T 360  12 VAC 5-412-340 Policies and procedures

The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not limited to:
1. Facility security;
2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and
3. Provisions for disseminating safety-related information to employees and users of the facility.

This RULE: is not met as evidenced by:
Based on interview and document review, it was determined the agency failed to develop policies related to safety within the facility and on the grounds.

The findings included:
Review of the agency policy and procedure manual on 12/08/2014, revealed there was no

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policy detailing how the agency provided security for employees and patients within the facility.

During an interview on 12/08/2014, at approximately 6:00 PM, Staff #2 stated that the facility had installed bullet proof glass, a video camera, and a process of locking all doors to ensure safety of staff and clients. The exterior door to the building was locked at 7:00 PM by the owners, as a safety measure. Staff #2 acknowledged there was no policy related to the security measures that had been put in place.

1. Facility security (security camera installed, bullet proof glass at reception desk, passcode on all doors).

2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services (in-service, drills, periodic review).

3. Provisions for disseminating safety-related information to employees and users of the facility (in-service, drills, literature, periodic review).
COMMONWEALTH of VIRGINIA

Department of Health
P.O. BOX 2448
RICHMOND, VA 23218

April 17, 2015

Certified Mail Delivery

Administrator
Alexandria Women's Health Clinic
101 S. Whiting Street, Suite 215
Alexandria, Virginia 22304

Dear Administrator:

An unannounced Licensure Revisit inspection was conducted March 17, 2015 to the Biennial Licensure inspection conducted December 8, 2014 through December 9, 2014, by two (2) Medical Facilities Inspectors for the Office of Licensure and Certification, Virginia Department of Health.

The following regulations were not cleared from the biennial inspection and were re-cited:
12 VAC 5-412-220 (B)(1)(D) - Infection Prevention

The facility was not in compliance with 12 VAC 412 Regulations for the Licensure of Abortion Clinics (effective 12/29/2011). Deficiencies cited follow in this report.

I am enclosing a "provider copy" of the "Statement of Deficiencies and Plan of Correction" Report which states that deficiencies were cited at the time of the unannounced Licensure Revisit inspection conducted March 17, 2015 to the Biennial Licensure inspection conducted December 8, 2014 through December 9, 2014.

You are required to submit a plan for correcting the deficiencies cited. Your statements should reflect the specific detailed actions you will take to correct each deficiency and prevent its recurrence, and measures that will be implemented to maintain compliance.

You must also give the specific calendar date on which correction of each deficiency will be completed. (Completion dates should be within thirty (30) days from the date of the inspection.)
An unannounced Revisit Licensure Abortion Facility inspection, following the facility's December 2014 Biennial Licensure inspection, was conducted on 03/17/2015. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey.

The agency remained out of compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013). Deficiencies were cited.

B. 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;
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

Plan of Correction

Immediate Corrective Action:
A meeting was conducted on March 19, 2015 by the Medical Director/Director of Nursing about Infection Prevention regarding correct hand-washing techniques (all staff attended). Staff #4 has been re-educated on March 20, 2015 (one-on-one) to wash hands prior to donning gloves, before touching a patient, before exiting the patient's care area and after touching the patient or the patient's immediate environment.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER
AF-0014

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED
03/17/2015

NAME OF PROVIDER OR SUPPLIER
ALEXANDRIA WOMEN'S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE
101 S. WHITING ST. SUITE #215
ALEXANDRIA, VA 22304

(X4) ID PREFIX TAG

(X5) COMPLETE DATE

(T 170) Continued From Page 1

retraining of all staff in recommended infection prevention practices

This RULE: is not met as evidenced by:
Based on observation and interview, it was determined the agency failed to ensure the use of standard precautions by clinicians, when wearing gloves to prevent transmission of microorganisms

The findings included:

It was observed on 3/17/2015, at approximately 11:00 AM, that Staff #4 did not use standard precautions. Staff #4, who was assisting a post-procedural patient, proceeded to the recovery room and touched another patient, without changing gloves or performing hand hygiene per agency policy.

During an interview at 11:10 AM, Staff #4 acknowledged she had received training in hand hygiene

At approximately 11:45 AM, Staff #4 performed hand hygiene prior to donning gloves to assist a post-procedural patient. Staff #4 picked up a crate with the belongings of a pre-procedure patient and placed the crate in the procedure room. Staff #4 proceeded to touch the post-procedural patient without first performing hand hygiene and changing gloves.

According to the Center for Disease Control (CDC), Guide To Infection Prevention For Outpatient Settings, hand hygiene should be performed:

1. Before touching a patient, even if gloves will be worn
2. Before exiting the patient's care area after touching the patient or the patient's immediate

Random monitoring for proper infection control procedures (hand washing) will be done every two to three months for the next year and results will be reported to the Quality Assurance Committee.

Reporting shall continue if any compliance issues are found.

Measures to Maintain Compliance:
Staff retrained on March 19 and March 20, 2015. Training, in-services, and random monitoring will continue to ensure compliance.

Date of Completion:
March 20, 2015.
(T 170) Continued From Page 2

environment
3. After glove removal

During an interview on 3/17/2015 at approximately 12:00 PM, Staff #1 stated that staff members were trained in standard precautions and hand hygiene and thought they were doing a good job of hand hygiene. Staff #1 and #2 acknowledged that although the staff had been trained, ongoing training and monitoring was needed and that this process would be implemented.

(T 180) 12 VAC 5-412-220 D Infection prevention

D. The facility shall have an employee health program that includes:
1. Access to recommended vaccines;
2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;
3. An exposure control plan for blood-borne pathogens;
4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine;
5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.

This RULE is not met as evidenced by:
Based on staff interviews, chart reviews and document review the facility failed to have an employee health program that documented screenings offered/received by employees in

Immediate Corrective Action: 4/18/15

A review of all personnel records was done on March 19, 2015 to ensure records are complete, accurate, easily accessible and organized.

All staff personnel records contain evidence verifying an annual tuberculosis screenings and/or tuberculin test or Purified Protein Derivative test (PPD).

This corrective action includes all staff:
Personnel # 1, 2, 3, 4 and 5
accordance with statute, regulation or recommendations of public health authorities for five (5) of six (6) employees and three (3) of three (3) physicians.

The findings included:

A review of five (5) personnel records (Personnel #1, 2, 3, 4 and 9) and four (4) credentialing personnel records (Credentialing Personnel #5-#8) failed to contain evidence verifying employees were offered/received annual tuberculosis screenings. Personnel record #2 contained evidence a chest x-ray was performed on 03/07/2000, but no further evidence shown for an annual screening. Personnel record #3 contained no evidence of tuberculosis screenings or test being performed. Personnel record #4 contained evidence a chest x-ray was performed on 06/04/2012, but no further evidence of an annual screening. Personnel record #5 contained evidence of a negative tuberculosis test performed on 06/11/2012, but no further evidence of an annual screening. Credentialing Personnel record #7 contained evidence a chest x-ray was performed in 2011, but no further evidence of an annual screening. Credentialing Personnel record #8 and #9 contained no evidence of tuberculosis screenings or test being performed.

The agency's policy titled, "Employee Health" was reviewed on 03/17/2015. The policy acknowledged new staff members are required to have the tuberculosis skin test also known as the tuberculin test or Purified Protein Derivative (PPD) test upon hire or within five (5) days of employment. All staff will receive annually the PPD or chest x-ray if contraindicated.

An interview was conducted with Staff #1 on 03/17/2015 at approximately 11:00 a.m. The PPD given on 3/20/15 and was read on 3/23/15.

Three out of five personnel had a positive result and were referred for chest x-rays (CXR). CXR results were negative on March 24, 2015.

Credentialing Personnel #5, #6, #7, #8 and #9.

PPD given on 3/20/15 and was read on 3/23/15.

There were no positive PPD results/no adverse effect on credentialing personnel.

TB Screening was done from March 20 - April 3, 2015 on all personnel.

Measures to maintain Compliance:
All personnel were administered PPD and read on day 3. The administration of annual PPD test/screening was completed on April 3, 2015. The governing body
findings related to having screening and immunizations offered/received by employees were discussed. Staff #1 acknowledged the facility does have a process for offering employees screening and immunizations, including Hepatitis B and the influenza vaccine. Staff #1 reported many employees refuse this offered service but are required to sign an "Informed Refusal Form" found in the employee personnel record. Staff #1 reported he/she was only aware that once a x-ray or PPD test was performed, that was it and no further screening was necessary. Staff #1 stated, "PPD test is only contraindicated in people who have had a severe reaction to a previous tuberculin skin test; if contraindicated a chest x-ray is ordered for that employee." The surveyor inquired if Staff #1 had documented the employee's refusal of a screening. Staff #1 stated, "We don't have anything about tuberculosis screening and we don't require it because we didn't know we needed to after an employee received an x-ray or a skin test."

An exit interview was conducted with Staff #1 and Staff #2 on 03/17/2015 at 12:15 p.m. Staff #1 stated, "Everyone here goes some where else to have their PPD test or x-ray done. We decided a day will be picked within the next month and everyone will bring in the documents needed to show each employee's skin test or x-ray has been done and placed in their personnel record."
December 7, 2016

Administrator
Alexandria Women's Health Clinic
101 S. Whiting Street, Suite 215
Alexandria, Virginia 22304

RE: Alexandria Women's Health Clinic - Alexandria
Abortion Facility Biennial Licensure Inspection

Certified Mail Delivery

Dear Administrator:

An unannounced First Trimester Abortion Facility (FTAF) biennial licensure inspection of the above facility was conducted November 29, 2016 by two (2) Medical Facilities Inspectors with the Virginia Department of Health’s Office of Licensure and Certification.

Enclosed is the Biennial Licensure Inspection. The facility was not in compliance with 12VAC5-412 regulations for the Licensure of Abortion Facilities, effective June 20, 2013. This document contains a listing of deficiencies found at the time of this inspection.

You are required to submit a plan for correcting the deficiencies cited. Your statements shall reflect the specific detailed actions you will take to correct deficiencies, prevent a recurrence of the deficiencies, and measures implemented to maintain compliance. You must also give the expected completion date of each deficiency.

Completion of corrective actions shall not exceed 45 working days from the last day of the inspection.

After signing and dating your Plan of Correction, retain one copy of the report for your files and return the original to OLC within 15 working days of receipt of the inspection report. The Administrator shall be notified whenever any item in the plan of correction is determined to be unacceptable. Failure to submit an acceptable plan of correction may result in a penalty in accordance with the Code of Virginia §32.1-27 or in denial, revocation or suspension of a license in accordance with 12VAC5-412-130.
A copy of the completed form will be kept on file in this office and will be available for public review. The Virginia Department of Health – Office of Licensure and Certification is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

Thank you for the cooperation that was extended to our inspectors during this investigation. If you should have any question or concerns regarding this report or the report findings, please contact me at (804) 367-2112.

Sincerely,

Frederick W. Kyle
Director
Division of Acute Care Services

Enclosure
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER: ALEXANDRIA WOMEN'S HEALTH CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE: 101 S. WHITING ST. SUITE #215
ALEXANDRIA, VA 22304

11/29/2016

T000 12VAC5-412 Initial Comments

An unannounced licensure biennial survey was conducted November 29, 2016 by two medical facilities inspectors with the Office of Licensure and Certification, Virginia Department of Health. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 03/7/2015)

T135 12VAC5-412-200 A Patients' Rights

Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.

This RULE is not met as evidenced by:

Based on observations and interviews the facility failed to ensure they had a protocol relating to the right of the patient to have privacy and be treated in a dignified manner for 2 of 2 patients, patients #1 and #12 were observed during recovery.

The findings include:

During the initial tour of the facility on 11/19/16 revealed a recovery area with 4 reclining chairs in one section that had a curtain separating 2 additional reclining chairs. There was no separation curtain between each individual chair. Patients #1 and #12 were observed in the section with the 2 reclining chairs. Patient #2a/2 was observed in a hospital gown. Once recovered.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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<td>T 135</td>
<td>Continued From Page 1 Patient #12 was directed to get dressed. Patient #1 was sitting next to patient #12. Patient #12 had to remove her gown and get dressed in front of Patient #1. Staff Member #3 stated, &quot;We are looking into getting curtains put between each chair.&quot; The Joint Commission International Standard for Ambulatory Care 3rd Edition Page 9 Patient and Family Rights documents, &quot;The patients' rights to privacy and confidentiality of care and information are respected.&quot;</td>
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<td>T 150</td>
<td>12VAC5-412-200 D Patients' Rights Any patient seeking an abortion shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service. This RULE: is not met as evidenced by: Based on document review and interview the facility staff failed to ensure there was documentation indicating each patient received a copy of the complaint procedures. A total of 20 medical records were reviewed and there was no indication in any of the medical records the patients received a copy of the complaint procedures. The findings include: The medical records of Patients #1 through #20 were reviewed on 11/20/16. The records did not indicate a copy of the complaint procedure had been given to the patients Staff Member #3 stated, &quot;We give them this</td>
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T135 Continued will continue in order to be in full compliance. Training to all staff related to patient privacy will be offered quarterly to ensure competency.

T150 Corrective action taken by documenting that a copy of "The patient's rights and responsibilities" was provided to each patient. This documentation will include that the patient acknowledges that a copy was given by signing the form upon admission. *The Quality Assurance Committee will implement a policy and procedure that
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"(shown a copy of rights and responsibilities) but we have no way of showing we gave it to them."

Random current patients were asked if they received a copy of the complaint procedure and could not recall if they had or not.

The abortion facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:

1. Facility contact person; and

2. OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The abortion facility shall display a copy of this information in a conspicuous place.

This RULE: is not met as evidenced by:

Based on document review and interview the facility staff failed to ensure there was documentation indicating each patient received a copy of the facility contact person's name, mailing address and telephone number and the information to contact the Office of Licensure and Certification's (OLC) Complaint Unit. A total of 20 medical records were reviewed and there was no indication in any of the medical records the patients received a copy of the required contact information for the facility or the OLC.

The findings include:

The medical records of Patients #1 through #20

Also continued includes daily audits to review patients' charts and proper documentation. This audit will continue monthly and any deficiency will be reported to the QA committee and immediately reviewed by the governing body.

Each patient chart will show documentation that the patient received a copy of the facility contact person's name, mailing address and telephone number.

This information will be added to "the patient's right and responsibility form as well as the OLC complaint unit's address and telephone number. This information will be given upon admission."
**T155 Continued**

The Quality Assurance Committee will implement a Policy and Procedure that includes daily audits to review patients' charts and proper documentation. This audit will continue monthly and any deficiency will be reported to the Quality Assurance Committee and immediately reviewed by the Governing Body.

**T190**

Corrective action taken by having an in-service on policies related to "safe infection prevention practices" for all staff members.

This shall include the necessary criteria and documentation for the correct way to dispose of medication.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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<tr>
<td>ALEXANDRIA WOMEN'S HEALTH CLINIC</td>
<td>101 S. WHITING ST, SUITE #215</td>
</tr>
<tr>
<td></td>
<td>ALEXANDRIA, VA 22304</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(X4) ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
<th>(X6) COMPLETE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Each deficiency must be preceded by full regulatory or LSC certifying information)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>(Each corrective action should be cross-referenced to the appropriate deficiency)</th>
</tr>
</thead>
</table>

| T 190          | Continued From Page 4          | T 190                                                             |

- Recommendations for changes/updates shall be documented in writing.

- A designated person in the facility shall have received training in infection prevention, and shall also be involved in the annual review.

This RULE is not met as evidenced by:
Based on observations and interview the facility failed to ensure their infection control plan included facility surveillance and correct information related to opening a new vial of medication. The infection preventionist (IP) did not have audits of the facility, documenting areas in need of repair in order to ensure the areas could be properly cleaned (floor tiles, tape on procedure table, corrosion on stirrup bar, the use of betadine which was poured into a cylinder container and used on multiple patients, opened items with dates of expiration once opened were not dated and a sterile endotracheal tube was open and in the crash cart available for use. In addition, the facility failed to follow acceptable infection control practice when administering IV (intravenous) medications for 2 of 3 observations. Following the manufacturer's directions for cleaning when using disinfecting wipes to clean chairs and equipment after use.

The findings include:
On 11/29/16 the initial tour of the facility was conducted with Staff Member #1 and later discussed and reviewed with Staff Member #3.

The facility had 3 areas where the floor tile was broken and the floor could not be properly cleaned in the event of a blood spill. The lab floor directly under the chair leg where blood is drawn from a patient, the door way between the main corridor and the ER/ICU.

TIAO continued.

The facility shall also implement a policy and procedure for a quarterly audit of the facility to ensure safety and infection prevention.

This audit shall include monitoring and documentation of all areas of the facility such as electrical equipment, power supply, environment surfaces maintained in good condition (ex. floor tiles, cleaning tiles, etc.), storage areas are maintained so as to prevent hazards etc.

All outdated, expired, improperly opened supplies were removed and restocked as needed on 11/30/16.

### Americans United for Life

[ americansunitedforlife.org ]
T 190 Continued

Broken tiles replaced on 12/14/16 to ensure that the floor could be properly cleaned. Surgical tape has also been removed from the procedure room table and the procedure room table stirrups will be replaced for new ones.

Bethadine will not be poured from a large container into a metal cylinder covered with paper towel. Each tray will have an individual iodine cup to pour Bethadine for each patient and then disposed after the procedure. The facility will also purchase individually wrapped Bethadine solution swabs as provided from Moore Medical Supplies.

On 11/30/16, a container of HemoCue was observed in the lab opened and accessed with no date as to when it was opened. Staff Member #3 stated, "Once the HemoCue is opened the manufacturer says it must be discarded after 90 days. It should have been dated when it expires." During the inspection of the crash cart an opened and available for use were six endotracheal tubes. Staff Member #3 stated, "That should have been thrown away."

On 11/29/16 during the observation of a procedure Staff Member #8 opened 3 vials of medication. Staff Member #8 proceeded to withdraw the medication and administer the medication from 2 of the vials without first clearing the top of the vial or the injection port.

On 11/29/16 at approximately 11:55 a.m. Staff Member #1 was observed cleaning and disinfecting a chair vacated by a patient. Staff Member #1 proceed to wipe the chair with the disinfecting wipes and allowed the chair to air dry. The disinfecting process lasted for approximately 1 minute. The container of disinfecting wipes
T 190  Continued From Page 6

documents the surface must remain wet for 10 minutes for the product to be effective. Staff Member #3 stated, “She should have used the spray it stays wet until you wipe it off and it only takes 30 seconds.”

T 245

12VAC5-412-240 A Medical Testing and Laboratory Services

Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all requirements of informed written consent pursuant to § 18.2-76 of the Code of Virginia, shall be completed for each patient.

1. Use of any additional medical testing shall be based on assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented.

2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.

3. The abortion facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test.

4. A written report of each laboratory test and examination shall be a part of the patient’s record.

T 190

HAO continued 
Hemovue microcuvettes will be dated when is opened and when it expires. All disinfecting wipes have been removed and replaced with Medacide FD solution. This germicidal solutions wet period is 30 seconds. An in-service of this product was done on 11/30/16. Corrective actions will be monitored to ensure the alleged deficient practice does not reoccur.

T 245

An audit of all patient medical charts will be done every day for the next month to make sure that the Rh factor, Hgb, etc. are documented. Monthly inventory audits will continue to be done properly documented.
This RULE: is not met as evidenced by:
Based on record review and interview the facility failed to ensure the Rh factor was documented in the medical record for 2 of 20 patient's records reviewed. Patients #5 and #18.

The medical records of Patients #5 and 18 were reviewed on 11/29/16. The records did not indicate the results of the Rh factor. Staff Member #3 stated, "Oh I can get those." During the inspection no Rh factor documentation was provided for patients #5 and #18.

According to the American Pregnancy Association each person's blood is one of four major types: A, B, AB, or O. Blood types are determined by the types of antigens on the blood cells. Antibodies are proteins on the surface of blood cells that can cause a response from the immune system. The Rh factor is a type of protein on the surface of red blood cells. Most people who have the Rh factor are Rh-positive. Those who do not have the Rh factor are Rh-negative.

As part of prenatal care, patients have blood test to determine their blood type. If their blood lacks the Rh antigen, it is called Rh-negative. If it has the antigen, it is called Rh-positive. When the mother is Rh-negative and the father is Rh-positive, the fetus can inherit the Rh factor from the father. This makes the fetus Rh-positive too. Problems can arise when the fetus' blood has the Rh factor and the mother's blood does not. Patients who are Rh-negative, may develop antibodies to an Rh-positive baby. If a small amount of the baby's blood mixes with the mother's blood, which often happens, the mother's body may respond as if it were allergic to the baby. The mother's body may make antibodies to the Rh antigens in the baby's blood. This means the mother have become sensitized and her antibodies can cross the placenta and attack the
### Summary Statement of Deficiencies

<table>
<thead>
<tr>
<th>ID Prefix Tag</th>
<th>PROVIDER/PLAIN OR CLIA IDENTIFICATION NUMBER:</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>T 245</td>
<td>Continued From Page 8</td>
<td>baby's blood. They break down the fetus' red blood cells and produce anemia (a condition that happens when the blood has a low number of red blood cells). This condition is called hemolytic disease or hemolytic anemia. It can become severe enough to cause serious illness, brain damage, or even death to the fetus or newborn. Sensitization can occur any time the fetus's blood mixes with the mother's blood. It can occur if an Rh-negative woman has had a miscarriage, induced abortion, ectopic pregnancy, chorionic villus sampling or a blood transfusion.</td>
<td>T 245</td>
</tr>
<tr>
<td>T 255</td>
<td>12VAC5-412-240 C Medical Testing and Laboratory Services</td>
<td>All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present, if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately.</td>
<td>T 255</td>
</tr>
<tr>
<td>T 255</td>
<td>The physician will have a new form where he/she can document the examination of the product to verify that villi and fetal parts were present. This form shall also include additional space for notes.</td>
<td>The Medical Director will review all new forms to verify that the person is able to document properly. He will also be responsible for</td>
<td></td>
</tr>
</tbody>
</table>

The findings include:

Medical record review on November 28, 2016 between 11:30 a.m. and 3:45 p.m. revealed...
documentation under procedure as "pregnancy tissue: complete (x)" for Patients #1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 15, 16, 17, 18, 19 and 20). There is no evidence of villi or fetal parts identified.

Medical record review of Patient #4 revealed the patient had a procedure on October 29 and November 8, 2016. On November 8, 2016 documentation stated: "repeat for POC (products of conception)."

On November 29, 2016 at 12:00 p.m. Staff Member #5 was observed cleaning instruments from procedure. No staff member was observed examining tissue removed before disposed. Staff Member #5 stated that the doctor examines the tissue.

An interview with Staff Member #7 on November 29, 2016 at 2:30 p.m. revealed that "complete means everything." Staff Member #7 stated that the form needs updating.

**T 355**

12VAC5-412-300 Health Information Records

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:

1. Patient identification;
2. Admitting information, including patient history and physical examination;
3. Signed consent;
4. Confirmation of pregnancy;
5. Procedure report to include.

**T 355**

The facility shall implement a policy and procedure on how to file a complaint. Each patients chart will show documentation that the patient received a copy of the facility's contact person, name, mailing address and telephone number.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

NAME OF PROVIDER OR SUPPLIER: ALEXANDRIA WOMEN'S HEALTH CLINIC
STREET ADDRESS: 101 S. WHITING ST, SUITE #215
CITY: ALEXANDRIA
STATE: VA
ZIP CODE: 22304

T 355 Continued From: Page 10

a. Physician orders:
   b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
   c. Anesthesia record;
   d. Operative record;
   e. Surgical medication and medical treatments;
   f. Recovery room notes;
   g. Physician and nurses' progress notes,
   h. Condition at time of discharge,
   i. Patient instructions, preoperative and postoperative; and
   j. Names of referral physicians or agencies.

6. Any other information required by law to be maintained in the health information record.

This RULE: is not met as evidenced by:

    Based on medical record review and interview it was determined that the facility failed to maintain an accurate and completed medical record on each patient for twenty (20) of twenty (20) patients (Patients #1-20).

The findings include:

1. Medical record review on November 28, 2016 between 11:30 a.m. and 3:45 p.m. revealed the following.

   Medical record review for twenty (20) of twenty (20) patients (Patients #1-20) revealed the "Patients Rights and Responsibilities" form failed to document a copy was received by the patient and failed disclose procedure to file a complaint to include the Office of Licensure and Certification address and phone number.

   Medical record review for sixteen (16) of sixteen (16) surgical abortion patients Patients #1, 2, 3, 4, 5, 6, 7, 9, 12, 13, 15, 16, 17, 18, 19 and 20 revealed:

   T 355 continued

This information will be added to the "the patient's rights and responsibilities" form as well as the OLC Complaint Unit's address and phone number. This will include documentation that the patient acknowledges that a copy was given by signing the form upon admission.

Pre-op and Post-op medication section will be rewritten to add the route of administration, additional space for initials and/or signature will also be included.

The route of administration will also be added to the medical and nursing notes where hydrocodone APAP and oxycodone APAP are found.
### Statement of Deficiencies and Plan of Correction

<table>
<thead>
<tr>
<th>NAME OF PROVIDER OR SUPPLIER</th>
<th>STREET ADDRESS, CITY, STATE, ZIP CODE</th>
</tr>
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<tr>
<td>ALEXANDRIA WOMEN'S HEALTH CLINIC</td>
<td>101 S. WHITING ST, SUITE #215 ALEXANDRIA, VA 22304</td>
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<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<tr>
<td>T 355</td>
<td>Pre-op Medication section lists medication that can be administered but fails to identify route of administration. Ibuprofen 800 mg, Xanax 0.5 mg, Xylocaine 1,2,2, Toradol 10 mg.</td>
<td>T 355</td>
<td>Recovery room notes will be rewritten to include space for notes and signature from the recovery room nurse. Nothing will be written prior to the procedure/recovery. A meeting with the recovery room nurses was held on 11/30/10 to address the missing information on the patients chart, such as the amount of bleeding and cramping. This meeting will also include the information that is not completed in the &quot;Patients Ultrasound Consent and Certification of Waiting Period&quot; form by a qualified ultrasound professional. The fact that the patient was offered to view, receive and hear fetal heart tones.</td>
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</table>

**Patient's Ultrasound Consent and Certification of Waiting Period form failed to be completed and signed by staff to show that a qualified ultrasound professional was provided and the patient was verbally offered the opportunity to view, receive copy and hear fetal heart tones.**

**Medical record review for four (4) of four (4) medical abortion patients (Patients # 8, 10, 11 and 14) revealed on the nursing notes medication Hydrocodone/APAP and Oxydolone/APAP failed to identify route of administration.**

**All physician orders must include patient name, date, medication, dosage, route of administration and physician signature. To correct or change information in a medical document strike a single line through the incorrect information and write above or below with initials; according to Lippincott Nursing.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**
ALEXANDRIA WOMEN'S HEALTH CLINIC

**STREET ADDRESS, CITY, STATE, ZIP CODE**
101 S. WHITING ST., SUITE #215
ALEXANDRIA, VA 22304

**STATE OF VIRGINIA**

| (X1) PROVIDER/SUPPLIER IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION A BUILDING | (X3) DATE SURVEY COMPLETED |
| AF-0014 | B WING | 11/29/2016 |

| ID | PREFIX | TAG | SUMMARY STATEMENT OF DEFICIENCIES | ID | PREFIX | TAG | PROVIDER'S PLAN OF CORRECTION | (X5) COMPLETE DATE |
|---|---|---|---|---|---|---|---|---|---|
| T 355 | | | Continued From Page 12 | | | | | | |

The findings were discussed with Staff Member #3 on November 29, 2016 at 4:00 p.m.

**RECEIVED**
JAN 03 2017
VDH/OLC

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**Fallon Medical Group**

**Fallon United for Life**

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**T 355**

*Monthly ongoing audits of patients charts will be done to ensure proper documentation.*

*A strike or single line will be used when there is incorrect information that needs change and initials/signature will be added whenever a correction or change is made in a medical document.*

*The Quality Assurance Committee will implement a policy and procedure that includes daily audits to review patients charts and proper documentation.*

*The Medical Director is responsible to review all new forms to make sure that the route of administration and extra space for notes are added.*

*Training to all staff will be implemented on entry to proper documentation to improve compliance. The Medical Director will be responsible for staff education.*
March 23, 2017

Administrator
Alexandria Women's Health Clinic
101 S. Whiting Street, Suite 215
Alexandria, Virginia 22304

RE: Licensure Inspection Revisit
License Number # AF-0014
Survey Date: March 21, 2017

Dear Administrator:

Based on the Revisit Survey conducted March 21, 2017, by two (2) Medical Facilities Inspectors from the Virginia Department of Health's Office of Licensure and Certification it has been concluded that the facility meets the requirements of 12 VAC - 412 Regulations for the Licensure of Abortion Clinics.

A copy of the completed report will be kept in this office and will be available for public review. The Office of Licensure and Certification is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

Thank you for your cooperation during the inspection process and I look forward to working with you on a continuing basis in the administration of the Licensure program.

Sincerely yours,

[Signature]
Ruthanne Risser, Supervisor
Division of Acute Care Services

Enclosure
<table>
<thead>
<tr>
<th>T 000</th>
<th>Initial Comments</th>
</tr>
</thead>
</table>

An unannounced Licensure Revisit inspection was conducted on March 21, 2017 by two (2) Medical Facilities Inspectors from the Virginia Department of Health, Office of Licensure and Certification. This was a follow up to the Biennial Licensure inspection conducted on November 29, 2016.

The facility was in compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facilities. All previous citations were found to have been corrected. No new concerns were identified.