

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0004	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/25/2014
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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
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
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T 000 12 VAC 5- 412 Initial comments

T 000

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.

T 035

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;

T035
Prior to inspection by the Virginia Department of Health ATWHC 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.

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE Lab Director	(X6) DATE 9/29/14
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T 035 Continued From Page 1

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

T095 9/15/14

- A policy has been created to ensure compliance pertaining to reporting licensed & certified health care practitioners for violations of their licensing or certification standards.
- The administrative & clinical directors will review the Virginia Department of Health website every six months to make sure regulations have not been updated.
- A policy has been implemented to ensure compliance with reporting licensed & certified health care practitioners. The directors will review the VDH website every six months to ensure compliance with all regulations.

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

T130 9/8/14

- We have created a check list label that will be affixed to the front on each minor's chart to ensure that each mandatory component

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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

T 035

T 095

is accounted for. Each label will be checked off accordingly and employee will authenticate with date, time & initials. If all components of minors chart is not accounted for, patient will need to produce missing component before continuing with abortion. All staff has been retrained on this policy.

- The directors will periodically monitor the minors charts to ensure labels are being used accordingly, i.e. all components are intact & employees are documenting day, time & initials for completion.
- We will keep a minors log & will continuously monitor for 1. Valid photo ID for patient
2. Valid photo ID for parent or legal guardian
3. birth certificate
4. notarized parental

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T 095. Continued From Page 3
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.

Staff #1 was interviewed at approximately 6:00 pm. Staff #1 confirmed he/she was unable to locate the policy.

T 095
Consent 5. Judicial bypass. If any chart is found incomplete, employees will be retrained & monitored by directors to ensure compliance

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 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

T 130
T 175
#1
9/8/14
• Employees have been retrained how to properly disinfect & clean per job descriptions.
• The employees use a cleaning checklist by job description on a daily basis.
• The directors will do a periodic check behind employees to ensure proper cleaning & disinfecting has been completed. To this periodic check finds improper cleaning & disinfecting techniques are being utilized or not done at all, retraining with daily monitoring will be done in order to remain compliant.

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T 130 Continued From Page 4

means "the minor has delivered to the physician a notarized, written statement signed by an authorized person that the authorized person knows of the minor's intent to have an abortion and consents to such abortion being performed on the minor."

Staff #1 was informed the surveyor was unable to locate the notarized consent in Patient #3's medical record. Staff #1 was given the opportunity to locate the notarized consent and was unable to find the consent. Staff #1 confirmed during the exit conference at approximately 7:00 pm he/she could not locate the notarized consent.

T 130

#2 (T175)

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.

8/25/14

#3 (T175)

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 tables for rust & how to thoroughly clean.

9/10/14

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;

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T 175 Continued From Page 5

T 175

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.

• 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 & not overlooked.

#4 (T175) 9/8/14

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

• The administrative & clinical directors will periodically monitor employees to ensure barrier protection & sanitation 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.

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:

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T 175 Continued From Page 6

T 175

T230

9/23/14

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.

- Discharge criteria have been established & approved by physician. All applicable staff has been retrained to new criteria.
- Directors will randomly observe to ensure the discharge criteria is being followed and all personnel trained accordingly.
- The directors will review the Virginia Department of Health website every six months to make sure regulations have not been updated.

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.

T265

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 were retrained on how to properly label, document & dispose of all liquid i.e. including but not limited to vinegar solution, medication mixed and/or drawn up by the physician & all cleaning products.
- The directors will continuously monitor that all substances have proper labeling, rooms are checked at the end of each day to ensure no leftover products are

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.

T 230 12 VAC 5-412-250 C Anesthesia service

T 230

C. The facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care.

State of Virginia

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T 230 Continued From Page 7

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.

T 230

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 retrained & monitored by directors to ensure compliance.

T340 9/23/14

- Upon further review of the policy & 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.

T 265 12 VAC 5-412-260 A Administration, storage and dispensing of dru

A. Controlled substances, as defined in 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18 VAC 110-30).

T 265

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T 265 Continued From Page 8

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, unlabeled, 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 265

- ~~The directors will terror~~ Physician 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 the 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.

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;

T 340

T345
#1

- We are in the process of researching products that are best suited for our office that will raise the medical records from floor level.
- Directors will monitor that all medical records are stored appropriately to ensure compliance.

10/20/14

State of Virginia

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- 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 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

All medical records will be kept in designated area & stored above floor level.

#2 (T345)

8/28/14

• The doors to the records storage area is kept locked to ensure compliance. Staff retrained 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.

T365

8/26/14

• signs have been placed on recovery room doors so patients know they can be used as emergency exits, we have since added signs

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information about the patient is documented.

T 340

To the hallway that point ~~to~~^{error} the patients to the exit clearly with no confusion of which door to exit.

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.

T 345

- The directors will periodically check on signage to make sure they are in place & visible.
- We will continue to monitor all signs for visibility as well as continue with training of employees on the preparedness plan.

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 375

9/1/14

- We have purchased a wireless remote call button and have placed it in the recovery restroom. The receiver is kept in the recovery room so the recovery nurse can be alerted should patient need assistance.

T 365 12 VAC 5-412-350 A Disaster preparedness
A. Each abortion facility shall develop, implement and maintain policies and procedures

T 365

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State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA 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 NORFOLK 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) COMPLETE DATE
T 365	<p>Continued From Page 11</p> <p>to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The polices and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.</p> <p>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.</p> <p>The findings included:</p> <p>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.</p> <p>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."</p> <p>Staff #1 and Staff #2 were present during the initial tour and confirmed the findings pertaining to the unmarked exits.</p>	T 365	<p>The directors will monitor the wireless remote to ensure it is properly functioning.</p> <p>A log will be maintained daily to ensure proper function of device.</p>	

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T 375	Continued From Page 12	T 375	
T 375	12 VAC 5-412-360 A Maintenance	T 375	
	<p>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.</p> <p>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.</p> <p>The findings included:</p> <p>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.</p> <p>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.</p>		

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