

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: FTAF-0018	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/12/2012
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NAME OF PROVIDER OR SUPPLIER CHARLOTTESVILLE MEDICAL CENTER FOR WOM	STREET ADDRESS, CITY, STATE, ZIP CODE 2321 COMMONWEALTH DR CHARLOTTESVILLE, VA 22901
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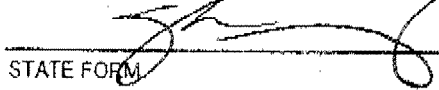
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
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T 000	<p>12 VAC 5- 412 Initial comments</p> <p>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.</p> <p>The following regulations were not cleared from the initial survey and were re-cited:</p> <p>12 VAC5-412-170 (B) (C) (E) (F) (G) - Personnel (with new findings included)</p> <p>12 VAC5-412-220 (C) and (E) - Infection Prevention</p> <p>12 VAC5-412-240 (A) - Medical Testing, patient counseling and laboratory services (new finding included)</p> <p>12 VAC5-412-250 (C) (H) - Anesthesia Services</p> <p>12 VAC5-412-300 (A) (B) (D) - Quality Assurance (new findings included)</p> <p>New findings were cited in the following areas:</p> <p>12 VAC5-412-140 (A)- Governing Body</p> <p>12 VAC5-412-150 - Policy and Procedure Manual</p> <p>12 VAC5-412-180 (C) - Clinical Staff</p> <p>12 VAC5-412-310 - Medical Records</p> <p>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.</p>	T 000		
T 010	<p>12 VAC 5-412-140 A Organization and management</p> <p>A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility.</p>	T 010		

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

TITLE

(X5) DATE



Administrator

2-25-13

State of Virginia

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T 010	<p>Continued From Page 1</p> <p>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.</p> <p>The findings included:</p> <p>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.</p> <p>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</p> <p>New findings were cited in the following areas:</p> <p>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</p> <p>On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee # 4.</p>	T 010	<p>T010</p> <p>Governing Body has been informed of these findings. Governing Body will require reports from the administrator. Administrator is responsible for implementing plan of correction + for reporting such to Governing Body.</p> <p>Completion date Dec. 15, 2012</p> <p>T010 Addendum Governing Body to require reports from Administrator re: progress.</p>

State of Virginia

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T 035	Continued From Page 2	T 035	
T 035	<p>12 VAC 5-412-150 Policy and procedure manual.</p> <p>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:</p> <ol style="list-style-type: none"> 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. 	T 035	T 035

State of Virginia

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T 035. Continued From Page 3

T 035

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

T 035
Governing Body has been informed. Administrator is responsible for implementing policies & procedures. Administrator is delegating tasks to other staff to ensure completion of personnel files. Chart forms have been revised to reflect admission & discharge criteria. Training & education of staff has been brought up to date with new staff. Annual training is ongoing. Quality/Risk Management is ongoing.
Jan 10, 2013

State of Virginia

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T 035	Continued From Page 4 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 035	<i>T 035 Addendum Governing body to require reports from Administrator</i>
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 10:28 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 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	T 065	<i>T 065 Applications have been completed for those staff who did not have them in their files. Training records have been brought up to date. Completion date January 10, 2013 Administrator is responsible for ensuring personnel files + training are complete + ongoing training is conducted + documented.</i>

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T 065	<p>Continued From Page 5</p> <p>qualifications for their position through verification of training.</p> <p>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 ..."</p> <p>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.</p>	T 065	<p><u>T 065 Addendum -</u></p> <p>Administrator will review personnel files at least ^{2x} annually to ensure completeness. Further, she will delegate to support staff tasks as appropriate.</p>
T 080	<p>12 VAC 5-412-170 E Personnel</p> <p>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.</p> <p>This RULE: is not met as evidenced by: Based on record review and interview the facility failed to implement their policies related to</p>	T 080	T 080

State of Virginia

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T 080 Continued From Page 6

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

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 &
oriented. Administrator
is responsible for
maintaining personnel
files.

T 080 Addendum
Administrator will review
personnel files at least
2 times annually to ensure
completeness

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T 085	Continued From Page 7	T 085	
T 085	<p>12 VAC 5-4-12-170 F Personnel</p> <p>F. Job descriptions.</p> <ol style="list-style-type: none"> 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. <p>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)</p> <p>The findings included:</p> <p>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.</p> <p>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</p>	T 085	<p>T 085</p> <p>job descriptions are in place for each staff member.</p> <p>Completion date Jan. 10, 2013.</p> <p>Administrator is responsible for ensuring each staff member receives a job description.</p> <p>Governing body had approved policy manual which included naming of administrator & adm. in her absence.</p> <p>Governing body has issued statement clarifying appointments.</p> <p>Jan. 10, 2013.</p>

State of Virginia

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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 085	<i>T 085 Addendum personnel files will be reviewed at least 2 times annually to ensure completeness.</i>	
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.	T 090		

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T 090	<p>Continued From Page 9</p> <p>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 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.</p> <p>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 ..."</p>	T 090	<p>7090 Applications have been completed & are in the personnel files. Doc. of orientation is in file - verification of qualifications complete. Training documentation updated. Job descriptions in place. Hire dates complete. Administrator is responsible for following personnel policies & ensuring complete personnel files are maintained. Completion date Jan. 10, 2013</p>

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T 090	Continued From Page 10 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."	T 090	<i>T 090 Addendum Personnel files will be reviewed at least 2 X annually to ensure completeness</i>	
T 115	12 VAC 5-412-180 C Clinical staff 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		

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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 115	<i>Recovery room form has been re-written to better reflect the care given and appropriate discharge made by physician. Completion date Jan 9, 2013</i>	
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	T 175	<i>T 115 Addendum Chart completion audits are to be conducted at least quarterly to ensure proper documentation in the JH files.</i>	

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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)
T 175	<p>Continued From Page 12</p> <p>and transporting regulated medical waste in accordance with applicable regulations;</p> <p>7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:</p> <ul style="list-style-type: none"> (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; <p>8. Procedures for appropriate disposal of non-reusable equipment;</p> <p>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;</p> <p>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;</p> <p>11. An effective pest control program, managed in accordance with local health and environmental regulations; and</p> <p>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.</p> <p>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.</p> <p>The findings included:</p> <p>Review of the facility's policy regarding performance of spore testing of the autoclave</p>	T 175	

State of Virginia

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NAME OF PROVIDER OR SUPPLIER CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN		STREET ADDRESS, CITY, STATE, ZIP CODE 2321 COMMONWEALTH DR CHARLOTTESVILLE, VA 22901	
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T 175	<p>Continued From Page 13</p> <p>indicated the testing would occur weekly.</p> <p>A review conducted on December 11, 2012 at 9:08 a.m. of the facility's log for spore testing revealed:</p> <p>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.</p> <p>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.]</p> <p>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."</p>	T 175	<p>T 175</p> <p>Spore testing is done weekly. The log has been brought up to date & the administrator will ensure that it remains up to date. The spore testing policy has been revised to reflect corrective action in case of invalid or failed testing. Completion date Jan. 10, 2013</p> <p>T 175 <u>Addendum</u></p> <p>Spore test report form has been amended to include space for corrective action.</p>

Spore Test Report

Date of Test: _____

Location: _____

Result(s): Autoclave _____

Autoclave _____

Control _____

Technician: _____

Corrective Action: NA As below

State of Virginia

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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

T 175

T 185

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: FTAF-0018	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/12/2012
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T 185	<p>Continued From Page 15</p> <p>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."</p> <p>At 12:30 p.m. on 12/11/12, the surveyor discussed the findings with Employee #1.</p> <p>On 12/12/12 at 7:30 p.m., the survey team reviewed the survey findings with Employee #1 and Employee # 4.</p>	T 185	<p>T 185</p> <p>Infection log is up-to-date Administrator is responsible for maintaining log. Completion date Jan 10, 2013</p> <p><u>T-185 Addendum</u></p> <p>Infection log is to be reviewed monthly.</p>
T 195	<p>12 VAC 5-412-240 A Medical testing, patient counseling and labor</p> <p>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.</p> <p>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.</p> <p>2. Medical testing shall include a recognized pregnancy test and determination on Rh factor.</p> <p>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.</p> <p>4. A written report of each laboratory test and examination shall be a part of the patient's record.</p>	T 195	

State of Virginia

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T 195	Continued From Page 16 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.	T 195	T 195. procedure forms have been revised to make clear that the physician has reviewed pt history. Physician is responsible for reviewing the history. Administrator is responsible for ensuring that documentation reflects that it has been reviewed. Completion date January 10, 2013.
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 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 though	T 230	T 195 <u>Addendum</u> Chart completion is to be audited at least quarterly.

State of Virginia

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NAME OF PROVIDER OR SUPPLIER CHARLOTTESVILLE MEDICAL CENTER FOR WOM	STREET ADDRESS, CITY, STATE, ZIP CODE 2321 COMMONWEALTH DR CHARLOTTESVILLE, VA 22901
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T 230	<p>Continued From Page 17</p> <p>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.)</p> <p>The findings included:</p> <p>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 during, 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.)</p> <p>Employee #1 was interviewed regarding this on 12/11/12 at 12:15 p.m., and stated, "There is some documentation here but, no, there is do documentation of the condition on discharge."</p> <p>On 12/12/12 at 7:30 p.m., the survey team reviewed the survey findings with Employee #1 and Employee # 4.</p>	T 230	<p>7 230.</p> <p>forms have been revised and staff trained to improve documentation of medications given.</p> <p>Additionally, forms now better reflect that the criteria for discharge have been met</p> <p>Completion date January 10, 2013</p> <p>Staff is responsible for proper documentation. Administrator is responsible for training and continually evaluating evaluating proper care & documentation.</p>	
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State of Virginia

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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 in 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 pre/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 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

T 255

*T 230 Addendum
chart completion to
be audited at least
quarterly. Appropriateness
of patient records forms
to be evaluated at
least annually.*

State of Virginia

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T 255	<p>Continued From Page 19</p> <p>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.</p> <p>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 patients record which reflected the above criteria was met.</p> <p>On 12/11/12 at 12:15 p.m., the survey team discussed the findings with Employee #1.</p> <p>On 12/12/12 at 7:30 p.m., the survey team reviewed the survey findings with Employee #1 and Employee # 4.</p>	T 255	<p>T 255 forms have been revised to better reflect care + adherence to discharge policy.</p> <p>Completion date January 10, 2013.</p> <p>T 255 <u>Addendum</u> Chart completion to be audited at least quarterly.</p>
T 315	<p>12 VAC 5-412-300 A Quality assurance</p> <p>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.</p> <p>This RULE is not met as evidenced by: Based on facility document review, staff interview,</p>	T 315	

State of Virginia

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T 315	<p>Continued From Page 20</p> <p>and survey revisit findings, the facility staff failed to ensure an ongoing, comprehensive, integrated, self-assessment Quality Assurance program was implemented.</p> <p>The findings included:</p> <p>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.</p> <p>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.</p> <p>On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee # 4.</p>	T 315	<p>T 315</p> <ul style="list-style-type: none"> - Personnel files brought into completion. - forms revised to reflect proper care - - Spore testing logs completed - infection log created & data generated - Admission & discharge criteria reflected in forms. <p>Administrator is responsible for maintain QA.</p>	
T 320	<p>12 VAC 5-412-300 B Quality assurance</p> <p>B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:</p> <ol style="list-style-type: none"> 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	<p>T 315 <u>Addendum</u></p> <p>Administrator is to report QA to governing Authority</p>	

State of Virginia

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T 320	<p>Continued From Page 21</p> <p>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.</p> <p>The findings included:</p> <p>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:</p> <ol style="list-style-type: none"> 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. <p>On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee #4.</p>	T 320	<p><i>T 320 Addendum</i> <i>QA Reports to be made to Governing Authority quarterly at this time. may go to annually once QA program firmly established</i></p> <p><i>T 320</i> <i>QA minutes ^{review} is continuously being implemented. Staff + surveys done. Audits will continue to be done. Complaint log to be maintained. Infection log to be maintained. Administrator is responsible but may assign tasks to other staff as appropriate.</i> <i>Completed on date January 10, 2013 - but also ongoing.</i></p>
T 330	12 VAC 5-412-300 D Quality assurance D. Measures shall be implemented to resolve	T 330	

State of Virginia

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T 330	<p>Continued From Page 22</p> <p>problems or concerns that have been identified.</p> <p>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.</p> <p>The findings included:</p> <p>During the revisit survey the following regulations were not cleared and were re-cited by the survey team:</p> <p>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</p> <p>New findings were cited in the following areas:</p> <p>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</p> <p>On 12/12/12 at 7:30 p.m., the survey team reviewed the findings with Employee #1 and Employee # 4.</p>	T 330	<p>T 330 - See T 320</p>

State of Virginia

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA
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 WOM

STREET ADDRESS, CITY, STATE, ZIP CODE

2321 COMMONWEALTH DR
CHARLOTTESVILLE, VA 22901

(X4) ID
PREFIX
TAG

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL
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PROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE
CROSS-REFERENCED TO THE APPROPRIATE
DEFICIENCY)

(X5)
COMPLETE
DATE

T 340 Continued From Page 23

T 340

T 340 12 VAC 5-412.310 Medical records

T 340

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
Medical records forms have been revised
staff trained in their use.
Administrator is responsible for ensuring that the medical record is complete

Completion date
Jan. 10, 2013

T 340 Addendum
chart completion audits to be performed at least quarterly

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: FTAF-0018	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/12/2012
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NAME OF PROVIDER OR SUPPLIER CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN	STREET ADDRESS, CITY, STATE, ZIP CODE 2321 COMMONWEALTH DR CHARLOTTESVILLE, VA 22901
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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 340 Continued From Page 24

T 340

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 a

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T 340	<p>Continued From Page 25</p> <p>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.</p> <p>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.</p> <p>Eight of eight clinical records failed to indicate the patients had received discharge instructions.</p> <p>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.</p> <p>According to Drugs.com Midazolam hydrochloride (midaz'lam), [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.</p> <p>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</p>	T 340	<p>T 340 forms have been revised. Process for ensuring 24 hr Informed Consent being performed has been changed.</p>	

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T 340	Continued From Page 26 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." 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, "I see your point." Staff #1 verified the eight clinical records did not have the required information.	T 340	<p>T 340 cont'd</p> <p>Administrator is responsible for ensuring that medical record properly reflects care given to patient administrator is responsible for ensuring that laws are adhered to.</p> <p>Completion date: January 10, 2013</p> <p>T 340 <u>Addendum</u> Chart completion audits to be performed at least quarterly QA to report to governing authority.</p>

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