STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0020	A. BUILDING _____ B. WING _____	07/10/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

(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 000	12 VAC 5- 412 Initial comments 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)	T 000		
T 020	12 VAC 5-412-140 C Organization and management 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.	T 020	7.25.14 T020 Policy on Administration of Drugs has been revised to reflect that only licensed personnel would handle medications. The governing body will require that narcotics be prepared & administered by licensed staff. Administrator is responsible for ensuring that job duties be carried out only by appropriate staff	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Administrator — (X6) DATE: 8-8-14

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)
Approved:	

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

Revised: Date & Initial:										
Reviewed: Date & Initial										

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T 065	Continued From Page 1	T 065		
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 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.	T 065	T065 8-20-14 Personnel files have been reviewed by our compliance officer. Particular staff member (#3) referred to here is no longer employed by us. Compliance officer will ensure that new hires have complete personnel files. Additionally, personnel files will be reviewed at least quarterly. Administrator is responsible for ensuring that personnel files are complete.	
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.	T 090		

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T 090	Continued From Page 2	T 090		

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 + meet with staff to ensure training is complete + documentation is complete. 5.20.14

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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T 130	Continued From Page 3	T 130		
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 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.	T 130	9-2-14 T 130 Policy for performing abortions on minors has been reviewed. Plan is to have more staff become notaries so that we can ensure that all minors have proper documentation of consent including notary signature & notary seal. Administrator will ensure that current notary always has seal with her. Further, charts will be reviewed before procedures to ensure that minors have parental consent on file. Administrator is responsible for ensuring parental consent	

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T 145	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 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 document review and interview the facility failed to include in the policy notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. The findings included: The facility's policy and procedure manual was reviewed on July 9, 2014 at approximately 5:00 pm. The facility has a complaint policy. The policy did not include notifying the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. Staff #1 and Staff #4 were interviewed on July 10, 2014 at approximately 10:45 am. Staff #1 reported he/she will add the complainant will be notified within 30 days from the date of receipt of the complaint to the facility's current policy.	T 145	T 145 Policy has been updated to include requirement that complaint be resolved within 30 days. Administrator is responsible for ensuring that complaints are handled appropriately	7-10-14
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	T 170		

Department: Organization and Management	**Policy Description:** Patients' Rights: Grievance and Complaint Management
Page: 1 of 4	**Replaces Policy Dated**:
Effective Date: 01/12	**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 expediently 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-compliants@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***

Revised: Date & Initial:	3/13									
Reviewed: Date & Initial	7/13/13 JA lgr									

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

Revised: Date & Initial:	3/13									
Reviewed: Date & Initial	7/13/13 JA lgr									

	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

Revised: Date & Initial:	3/13									
Reviewed: Date & Initial	7/13/13 JA lgr									

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T 170	Continued From Page 5	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-bourne 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.

T 170 7.10.14

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 + opened-on date. Additionally, compliance officer conducts quarterly inspections.

Administrator is responsible for ensuring opened solutions show the date they were opened

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T 200	12 VAC 5-412-240 B Medical testing, patient counseling and labor 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. This RULE: is not met as evidenced by: Based on document review and interview the facility failed to provide counseling for one of seventeen patients (Patient #3). The findings included: Seventeen patient records were reveiwed on July 9, 2014 (Patient #1-#17). Patient Record #3 had no documentation the patient received counseling prior to the procedure. Staff #1 was shown Patient #3's chart on July 9, 2014 at approximately 4:00 pm.	T 200	T 200 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. Administrator is responsible for ensuring proper documentation	7-16-14
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). This RULE: is not met as evidenced by: Based on observation, staff interview, and a	T 265		

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T 265	Continued From Page 7 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 benzodiazapine) 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 is has been for twenty (20) years. Staff #4 was asked if he/she was a licensed medical	T 265	T 265 7-16-14 Unlicensed staff has ceased drawing up medications. They must be drawn up ~~for~~ by RN, CRNA, or physician. The administrator must ensure proper staff perform these duties. Policy has been updated to outline proper staff perform these duties. Admin. Strator is responsible for staffing + duties	

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	AF-0020	A. BUILDING _____ B. WING _____	07/10/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTESVILLE MEDICAL CENTER FOR WOMEN	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

(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 265	Continued From Page 8 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 265		
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 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 anesthetic) 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.	T 275	7.16.14 T 275 Expiration dates are checked regularly. Unfortunately, these vials were missed. Policies are in place for ~~checking~~ checking expiration dates. Pt are not in procedure room unaccompanied. Administrator is responsible for ensuring that all medications & supplies are not expired.	

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T 275	Continued From Page 9 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 275	T 275 cont'd. and that they are properly stored	
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 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, #9, #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.	T 285	8-6-14 T 285 Documentation must be improved upon by all staff. Re-training has been done to ensure that documentation reflects care given. Log sheets have been changed to better reflect handling & dispensing of medications Administrator is responsible for ensuring that inventory is kept.	

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	AF-0020	A. BUILDING _____ B. WING _____	07/10/2014

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T 285	Continued From Page 10	T 285		

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 6:50 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

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T 285	Continued From Page 11	T 285		

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 then 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,

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T 285	Continued From Page 12 patient's name, medication, amount, and the initials on the ledger sheet." Staff #4 was unable to provide documentation of a ledger at the above named facility. The policy further states controlled substances will be stored in a double locked cabinet. The drugs were brought into the facility by Staff #4 and Staff #5 and kept in a red tackle type box. The policy includes those who have access to the controlled substances which included Registered Nurses, Anesthesia Personnel, and the Administrator. The administrator is unlicensed. Nowhere in the policy does it state unlicensed personnel shall be "drawing up" narcotics or have access to controlled substances. During a review of Staff #5's credentials file on July 9, 2014 and July 10, 2014 it was noted the documentation indicated Staff #5's DEA (drug enforcement agency) number expired 09/30/2012. A review of Staff #4's employee file was conducted on July 9, 2014 at approximately 3:30 pm. Staff #4's exact date of hire unknown. Staff #4 has no professional license which would allow him/her to handle controlled substances. Staff #4 has no evidence of training in medications in his/her employee file. Staff #4 has job descriptions for administrator and laboratory supervisor. Staff #4 reported he/she has been "drawing up" medications for about twenty (20) years. http://www.deadiversion.usdoj.gov/pubs/manuals/pract/	T 285	T 285 cont'd 8-6-14 Ledger of medications will be kept to reflect inventory and usage of medications Only licensed staff will prepare or administer medications Administrator is responsible for ensuring that licensed staff perform duties & un-licensed staff do not.	
T 290	12 VAC 5-412-270 Equipment and supplies An abortion facility shall maintain medical equipment and supplies appropriate and	T 290		

Date	Patient Name	Prep by	Admin by	Versed	Fentanyl	Xanax	Tylenol 3	Dilaudid

	Versed	Fentanyl	Brevital	Dilaudid	T 3	Xanax	Signature and Date
Count in							
Dispensed							
Received							
Count out							
Diff							
Count in							
Dispensed							
Received							
Count out							
Diff							
Count in							
Dispensed							
Received							
Count out							
Diff							
Count in							
Dispensed							
Received							
Count out							
Diff							
Count in							
Dispensed							
Received							
Count out							
Diff							

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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	T 290	T 290 8-6 14 T 290 Suture material is kept in box that is brought to center on procedure days & could have been shown to inspectors on day 1 of survey. Suture has been brought to center to remain there as well so that it would be present on non-procedure day as well. Administrator is responsible for stocking the center.	

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T 290	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.	T 290		
T 305	12 VAC 5-412-290 B Emergency services B. An abortion facility that performs abortions using intravenous sedation shall provide equipment and services to render emergency resuscitative and life-support procedures pending transfer of the patient to a hospital. Such medical equipment and services shall be consistent with the current edition of American Heart Association's Guidelines for Advanced Cardiovascular Life Support. 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 (ACLS) while using intravenous sedation. 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.	T 305	T 305 A staff member (licensed) will become ACLS certified Administrator is responsible for ensuring that there is an ACLS certified staff if IV medications ~~are~~ are given.	9-1-14

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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 inform ation 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:	T 340		

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T 340	Continued From Page 16	T 340		

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

T340 8-6-14

1. Documentation of IV medication given must be documented by physician. Phys has been re-trained on need for documentation

2. There is a section on both procedure record & recovery room record for additional notes. An additional sheet for progress notes by physician & by nurse have been added to charts.

3. Time must be documented. Phys has been made aware & trained to document time

4. Vital signs must be taken prior to procedure. Procedure asst will

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T 340	Continued From Page 17 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 no be 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	T 340	T 340 cont'd. review charts prior to procedure to ensure vitals are documented. 5. Physician reviews history prior to procedure. Documentation reviewed w/ physician 6. Documentation of discharge to recovery room is done by phys. Phys. retrained on documentation 7. Counseling is always done prior to a proc. Documentation of counseling was been reviewed w/ counselors. (this particular staff member no longer on staff).	
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	T 345		

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T 345	Continued From Page 18	T 345		

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 340 cont'd

8. Hgb & Rh must be documented on procedure form as well as on lab slip. Procedure rm. asst will review chart to ensure proper documentation. Administrator will ensure all staff are aware of proper documentation. Chart completion audits will be conducted on 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

Counseling Notes _____

24 hr consent _____

Ultrasound form _____

Pre-op Vital Signs _____

Parental Consent if minor _____

Local meds given _____

Physician

- Admission time _____
- History review _____
- IV site _____
- Time for IV med _____
- O2 and Pulse _____
- Progress note _____
- Discharge time to Recovery _____

Recovery

- Time admitted _____
- Vitals _____
- Progress note _____
- Pt understanding Of information _____
- Discharge criteria Met _____
- Physician sig _____