

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0007	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/21/2014
NAME OF PROVIDER OR SUPPLIER AMETHYST HEALTH CENTER FOR WOMEN, INC		STREET ADDRESS, CITY, STATE, ZIP CODE 9380-B FORESTWOOD LANE MANASSAS, VA 20110	

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(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	T 000		
	An unannounced Licensure Biennial survey was conducted 10/20/2014 through 10/21/2014. Three Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)		T-000 Initial Comments <ul style="list-style-type: none"> AHCW was caught unawares that revised Facility Regulations were in effect until the Administrator was notified by the inspectors. Their advice "to check the VDH/OLC website for updates" was an attempt to be helpful, however, it would appear, given the limited number of facilities covered by this regulation and given that e-mail or fax information is provided within the application for licensure, direct notification of regulation change would not be onerous to the State. It is of note that the Regulatory Identification provided, for some deficiencies, within the deficiency report utilized the numbering associated with the Regulations that were superseded on 20 June 2013. AHCW responses utilize the 6/20/2013 numbering. 	12/18/14
T 020	12 VAC 5-412-140 C Organization and management	T 020		
	C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs. This RULE: is not met as evidenced by: Based on document review and interview the facility's governing body: 1. Failed to ensure the appointment of a qualified person to perform the duties of the administrator, whenever the administrator was not available. 2. Failed to ensure qualified licensed personnel prepared injectable medications during procedures. 3. Failed to ensure the policies and procedures were reviewed annually and documented in the policy/procedure manual and failed to ensure the facility's policies reflected the updated State licensing regulation requirements for personnel. 4. Failed to ensure the facility had an on-going comprehensive, integrated, self-assessment program. 5. Failed to ensure the quality committee			12/18/14

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Maria Elisabeth Bewerslew TITLE: adm. owner. (X6) DATE: 12-11-2014

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T 020	Continued From Page 1 gathered and analyzed data to identify unforeseen and unexpected trends for the seven requires areas for licensure; implemented documented corrective action for problems, and prepared at least an annual report for the governing body. The findings included: 1. An interview was conducted on October 20, 2014 at 12:01 p.m., Staff #1 and Staff #3. Staff #1 explained to the survey team upon entrance the administrator was not available. The surveyor requested to perform the entrance conference with the alternate administrator. Staff #1 reported he/she was not aware of anyone being an alternate for the administrator. Staff #1 stated, "I will call [name of the administrator] and let you talk to [him/her]." A telephone interview was conducted on October 20, 2014 at approximately 12:11 p.m. with Staff #2. During the telephone interview Staff #2 reported that he/she would not be able to return to the facility until 3:00 p.m. The surveyor requested to perform the entrance conference with the appointed alternate administrator. Staff #2 stated, "I don't have an alternate administrator." 2. An interview was conducted on October 21, 2014 at 9:50 a.m. with Staff #4. The surveyor requested to observe the preparation of injectable medications utilized during the procedure. Staff #4 stated, "I don't prepare the Lidocaine injections. [Name of Staff #1] prepares the Lidocaine injections in the room just prior to the procedure." A second surveyor conducted observations during a procedure on October 21, 2014 at approximately 10:36 a.m. The observation confirmed Staff #1, a non-licensed healthcare personnel, prepared the injectable Lidocaine utilized by the physician during the abortion procedure.	T 020	T-020 12 VAC 5-412-140 C Management and Administration • The Governing body will undertake a review of the revised Regulations (12 VAC 5-412 effective 6/20/2013) immediately and take all required actions necessary to mitigate all deficiencies noted within this report. The Governing Body will meet with the Administrator and fully review the updated Policy and Procedure Manual (including 12 VAC 5-412) prior to the completion date for correcting Deficiencies noted in this report (18 December 2014). • Appointment of an acting administrator is responded to in T-055 • Injectable Medication preparation id responded to in T-285 • Annual Review of the AHCW Policy & Procedure Manual is responded to in T-035 • Facility Ongoing assessment program is responded to in T-315 • Quality Committee procedures and annual report for Governing Body and Licensee is responded to in T-335	12/18/14 2/18/14

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T 020 Continued From Page 2

T 020

3. Review of the facility's policies and procedures on October 20, 2014 at 5:35 p.m. did not contain evidence the policy and procedure manual had been reviewed and updated since 2012.

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

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

5. An interview and review of the facility's quality program documents was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 and the surveyor reviewed the facility's quality program documentation. The facility's documentation did not include the required seven elements of: staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; and staff concerns regarding patient care. Staff #2 reported the quality committee had not collected or evaluated dated for the seven required areas.

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T 020 Continued From Page 3

T 020

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

T 055 12 VAC 5-412-160 C Administrator

T 055

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

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

The findings included:

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

T-055 12 VAC 5-412-170 Administrator
Complete Date: 11/14/14

An acting Administrator was appointed immediately. This Letter of Appointment has been executed by the Administrator. The Acting Administrator has read, understood, signed and dated a copy of the Administrator Job Description and copies of the Letter of Appointment and the Administrator Job Description have been placed within the personnel file of the appointed individual. The AHCW Policy and Procedure regarding the Administrator will be updated to reflect the appointment of an Acting Administrator during periods of absence by the Administrator and completed as indicated in T-035.

11/14/14

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T 055 Continued From Page 4 T 055

be able to return to the facility until 3:00 p.m. The surveyor requested to perform the entrance conference with the appointed alternate administrator. Staff #2 stated, "I don't have an alternate administrator." Staff #2 verbally authorized Staff #1 to assist the surveyors and conduct the entrance conference.

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

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

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

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T 065 Continued From Page 5 - **FO55??** T 065

T 065 12 VAC 5-412-170 B Personnel T 065

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

This RULE: is not met as evidenced by:
Based on document review and staff interviews it was determined the facility failed to implement a mechanism to verify professional credentials for five (5) of seven (7) staff members. (Employee files #2, #4, #5, #6 and #7)

The findings included:

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

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

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

T-065 12 VAC 5-412-180 B Personnel
Complete Date: 11/15/14

- The AHCW Policy and Procedure for the Verification and Documentation of employee professional credentials will be updated to reflect an Annual review of credentials through the Virginia Department of Health Professionals and copies of the credential will be placed into the employee personnel files each year.
- Following the inspection AHCW validated the professional credentials for all credentialed employees and copies were placed in their personnel records.

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T 065	Continued From Page 6 regulation.	T 065		
T 070	12 VAC 5-412-170 C Personnel C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility. This RULE: is not met as evidenced by: Based on document review and staff interview it was determined the facility failed to obtain a criminal history record check as specified in section §32.1-126.02 of the Code of Virginia for two (2) of seven (7) employees in the survey sample (Employee files #4 and #5) not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility. The findings included: At the entrance conference on 10/20/2014 at 12:15 p.m., Staff #1 and Staff #3 were asked to provide a list of current staff including contract staff and to include date of hire and title for the surveyor to review. Staff #2 arrived at 2:15 p.m. and was asked again about providing the list of current staff and include whose job duties provide access to controlled substances. The review of personnel records found two (2) of seven (7) employees (Staff #4 and #5) have access to controlled substances and did not have a criminal history record check. The findings related to the criminal history record checks were discussed with Staff #2 on 10/21/2014 at 3:15 p.m. Staff #2 acknowledged	T 070	T-070 12 VAC 5-412-180 C Personnel Complete Date: 11/14/14 • Regarding Staff 4, a criminal background check from the City of Manassas was within the employee file. Subsequent to the inspection a State Criminal Background check was received. • Regarding Employee 5, a credentialed contracted consultant, licensed by the Virginia Board of Medicine and the DEA. VDH/OLC was contacted on 11 February 2013 for clarification and was advised that NO CRIMINAL BACKGROUND CHECK was required. This was documented in responses to VDH/OLC Survey conducted 12/11/2012 Reference T 170. AHCW has started background cks on its credentialed physicians and VA state criminal check forms which have already been mailed are in our submittal. AHCW has only just been notified in the last week that our 2012 policy would not cover the physicians -	11/14/14

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T 070 Continued From Page 7

T 070

the agency has a process to obtain a criminal record report on applicants from the Virginia Department of State Police; however it was not until it was brought to his/her attention by the surveyor that the criminal history record checks were not being obtained as stated in the agency's policy and procedures and Virginia regulations.

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

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

T 095 12 VAC 5-412-170 H Personnel

T 095

T-095 12 VAC 5-412-180 H Personnel

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

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

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

11/02/14

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

The Policy and Procedure Manual will be updated to reflect Annual Performance Reviews to be conducted in January.

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T 095	Continued From Page 8 performance for seven (7) of seven (7) employees in the survey sample (Employee files #1, #2, #3, #4, #5, #6 and #7). The findings included: The review of personnel records on 10/21/2014 failed to contain evidence that verify professional credentials of licensed staff members for five (5) of seven (7) staff members (Employee files #2, 4, 5, 6 and 7); and six (6) of seven (7) staff (Staff #1, 2, 3, 4, 6 and 7) had no evidence of an annual performance evaluation or evidence policies were being implemented. The six (6) staff members had been employed over one (1) year. The findings related to implementing the policy for verifying current professional licensing or certification and evaluating employees were discussed with Staff #2 on 10/21/2014 at 3:15 p.m. Staff #2 acknowledged that although the agency has a process to complete employee annual performance evaluations, he/she knew the personnel files should have contained these documents but failed to do so. Staff #2 reported he/she was not aware staff license needed to be validated until it was brought to his/her attention by the surveyor. During the exit interview on 10/21/2014, Staff #2 acknowledged that the facility failed to maintain the facility's system in the manner required by this regulation and their own approved and established procedure.	T 095	
T 100	12 VAC 5-412-170 I Personnel I. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and	T 100	T-100 12 VAC 5-412-180 I Personnel Complete Date: 12/18/14 • Prior inspections required AHCW to maintain employee health information separately from Personnel records in a controlled container. In accordance with the regulations, employee health records have been placed in an envelope within the employee record. • The AHCW P&P Manual will be updated to reflect this changed direction by regulation.
			10/26/14 12/18/14

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T 100 Continued From Page 9

T 100

unauthorized use. Employee health-related information shall be maintained separately within the employee's personnel file.

This RULE: is not met as evidenced by:
Based on document review and staff interview the facility failed to maintain employee health-related information be maintained separately within the employees' personnel files for seven (7) of seven (7) employees (Employee Files #1, #2, #3, #4, #5, #6 and #7).

The findings included:

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

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

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

T 105 12 VAC 5-412-180 A Clinical staff

T 105

A. Physicians and non-physician health care practitioners shall constitute the clinical staff. Clinical privileges of physicians and non-physician health care practitioners shall be clearly defined.

T-105 12 VAC 5-412-190 A Clinical Staff
Complete Date: 12/18/14

- AHCW will create a new P&P to clearly designate Privileges for the clinical staff ~~for~~ to include; a Letter of Qualifications signed by the Medical Director and using the existing Physician Consulting Contract as well as designation of Clinical Privileges by the Governing Body ~~for the~~ physicians.

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T 105 Continued From Page 10

T 105

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to define and document the delineation of privileges for two of three physicians. (Credentialing Files #1 and #2)

The findings included:

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

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

T 110 12 VAC 5-412-180 B Clinical staff

T 110

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

T-110 12 VAC 5-412-190 B Clinical Staff
Complete Date: 11/15/14

11/15/14

• Documentation of physicians Education and Training qualifying to conduct abortions. Following the inspection, the Physician's Education and Training have been added to their credentialing files which show they have the necessary expertise and experience to perform abortion services.

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0007	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/21/2014
NAME OF PROVIDER OR SUPPLIER AMETHYST HEALTH CENTER FOR WOMEN, INC		STREET ADDRESS, CITY, STATE, ZIP CODE 9380-B FORESTWOOD LANE MANASSAS, VA 20110	

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T 110	Continued From Page 11 This RULE: is not met as evidenced by: Based on document review and interview the facility failed to obtain documentation of physicians' education and training for qualification to perform abortions for two of three physicians. (Credentialing Files #1 and #2) The findings included: Review of the physician files for credentialing was conducted on October 21, 2014. Review of Credentialing File #1 did not have documentation of the physician's education or training which qualified him/her to perform abortions. Credentialing File #2 did not have documentation of the physician's education or training which qualified him/her to perform abortions. An interview was conducted on October 21, 2014 at approximately 2:00 p.m., with Staff #2. Staff #2 stated, "[Name of Credentialing File #1] has been performing abortions for more than 40 years. [He/she] is definitely qualified and so is [Name of Credentialing File #2]." Staff #2 verified Credentialing Files #1 and #2 did not have documentation related to their training or education. Staff # 2 stated, "I guess I needed to get their CVs (curriculum vitae) and put it in their files." [According to On-linefreedictionary.com: "A Curriculum Vitae [Sic] is a form of resume, which documents a person's background, skills, experience and education ..."]	T 110	T-115 12 VAC 5-412-190 C Clinical Staff Complete Date: 12/18/14 • Physicians did not adhere to the facility policy regarding discharge. The Policy and Procedure Manual will be updated to specifically state that physicians MUST sign the discharge order in order for the physician to depart the facility. • Physicians did not adhere to the facility policy that an adequately trained health care practitioner must remain with the patient until discharged from the facility. The Policy and Procedure Manual will be updated to place responsibility on the physician to ensure that adequately trained health care personnel remain with the patient until discharge. • The Medical Director will provide counseling to all physicians regarding discharge procedures and Staff 5 will receive a Letter of Admonishment to be placed into the personnel file regarding this violation of facility policy.	12/18/14 12/18/14
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.	T 115		

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T 115	Continued From Page 12	T 115	CORRECTED COPY

Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The facility shall develop, implement and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the facility.

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

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T 115 Continued From Page 13

T 115

is an licensed practical nurse (LPN), who must work under the supervision of a physician or registered nurse.

An interview was conducted with Staff #2 on 10/20/14 at approximately 4:00 p.m.. Staff #2 acknowledged that seven patient records did not have a discharge order signed by the physician.

T 130 12 VAC 5-412-200 Minors

T 130

No person may perform an abortion upon an unemancipated minor unless informed written consent is obtained from the minor and the minor's parent, guardian or other authorized person. If the emancipated minor elects not to seek the informed written consent of an authorized person, a copy of the court order authorizing the abortion entered pursuant to 16.1-241 of the Code of Virginia shall be obtained prior to the performance of the abortion.

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

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

The findings included:

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

T-130 12 VAC 5-412-230 B Patient Services; Patient Counseling Complete Date: 12/18/14

- The AHCW consent form for informed minors consent will be created and include specific warnings that special circumstances exists. Specifically a block for notarization will be added and warning text box will articulate the specific statute.

Additionally, Patient Records of Minors will be color coded to reflect the need for specific informed consent.

- The AHCW Policy and Procedure will be updated to reflect the updated form.

- All employees handling informed consent will be counseled by the Administrator regarding this regulation.

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T 130 Continued From Page 14

T 130

incomplete. The formed lacked the date for the procedure and the date the parent or legal guardian signed the form.

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

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

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

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

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

[The Code of Virginia at subsection 16.1-241 read

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T 130 Continued From Page 15

T 130

in part "A physician shall not knowingly perform an abortion upon an unemancipated minor unless consent has been obtained or the minor delivers to the physician a court order entered pursuant to this section and the physician or his agent provides such notice as such order may require. However, neither consent nor judicial authorization nor notice shall be required if the minor declares that she is abused or neglected and the attending physician has reason to suspect that the minor may be an abused or neglected child as defined in §63.2-100 and reports the suspected abuse or neglect in accordance with §63.2-1509 or if there is a medical emergency, in which case the attending physician shall certify the facts justifying the exception in the minor's medical record. For purposes of this subsection: "Authorization" means the minor has delivered to the physician a notarized, written statement signed by an authorized person that the authorized person knows of the minor's intent to have an abortion and consents to such abortion being performed on the minor. "Authorized person" means (i) a parent or duly appointed legal guardian or custodian of the minor or (ii) a person standing in loco parentis, including, but not limited to, a grandparent or adult sibling with whom the minor regularly and customarily resides and who has care and control of the minor. Any person who knows he is not an authorized person and who knowingly and willfully signs an authorization statement consenting to an abortion for a minor is guilty of a Class 3 misdemeanor.]

T-150 12 VAC 5-412-200 D Patient's Rights Complete Date: 12/18/14
 • The P&P Manual will be updated to reflect that the patient will receive a copy and sign/date a second copy of the complaint procedures before the procedure which will be inserted into the Patient Record.

12/18/14

This is entered in the submittal.

• The inspectors interviewed Staff 1 and 3, who by their position have nothing to do with preadmission procedures. Consequently, it is highly likely they were unfamiliar with this form.
 • AHCW is unable to reconcile inspector statement in their findings: 1. Para 3 states "The form had OLC complaint information" with 2. Para 2 "complaint procedure..., did not have information for contacting OLC". The form provided the inspectors was "AHCW Patient Rights and Responsibilities dated 11 February 2012". Findings 1 and 2 are referring to the same form.

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

T 150

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

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T 150 Continued From Page 16

T 150

service.

This RULE: is not met as evidenced by:
Based on interview and record review, the agency failed to provide documentation that patients received the complaint procedure and information during admission for ten (10) of ten (10) patients included in the survey sample. (Patient #1 - #10)

The findings included:

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

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

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

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

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T 150 Continued From Page 17

T 150

documented as given.

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

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

E. The facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:

1. Facility contact person; and
2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC.

The facility shall display a copy of this information in a conspicuous place.

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

The findings included:

On 10/20/14, at approximately 3:00 PM, a tour of the facility revealed there were no postings in the

T 155 T 150 and T 155 are referring to the same form. AHCW refers to it by the name of Patients Rights and Responsibilities. On the back of this sheet patients are encouraged to voice concern to the Adm- with address- etc. and then the OLC - with the name, address, toll-free hotline number, etc. AHCW has this framed in the Waiting Room - and gives every patient this information in waiting and the patient signs that she has received it to take home.
A copy is in this submittal.

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T 155 Continued From Page 18

recovery room with information for making a complaint to the OLC Complaint Unit, including the toll-free complaint hotline number.

T 155

T 165 12 VAC 5-412-220 A Infection prevention

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

1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented.
2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing.
3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review.

T 165

T-165 12 VAC 5-412-220 A.3 Infection Prevention
Complete Date: 12/18/14

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

12/18/14

This RULE: is not met as evidenced by:
Based on document review and staff interviews the facility failed to designate an individual with training and expertise in infection prevention, participating in the development of infection prevention policies and procedures and involved

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T 165

in the annual review.

The findings included:

A review of seven (7) personnel records (Employee files #1-7) failed to contain evidence that verified any person with training and expertise in infection prevention had assumed the responsibilities/role of the infection preventionist. The facility failed to implement its policy and procedures and the administrator failed to appointment a designated qualified individual as required in the Virginia licensure regulations.

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

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

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

T 170

B. Written infection prevention policies and procedures shall include, but not be limited to:

1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community acquired infection within the facility;
2. Training of all personnel in proper infection prevention techniques;
3. Correct hand-washing technique, including

T-170 12 VAC 5-412-220 B Infection Prevention
Complete Date: 12/18/14

- Staff 5 violated facility infection control procedures and will be counseled by the Medical Director and Administrator regarding these violations. Staff 1 made statements to the inspectors that were false regarding not being trained in infection prevention regarding PPE.
- AHCW will update the P&P and provide a means of verifying Infection Prevention Training for credentialed employees.
- Infection Training will be reviewed by the Quality Committee/ Governing Body annually

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

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T 170

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

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

It was observed on 10/21/14 that Staff #4 wore the same PPE gown during two (2) procedures performed between 10:30 AM and 11:15 AM.

On 10/21/14 at approximately 5:00 PM, Staff #4 acknowledged that she had worn the same gown throughout the day and stated that she did not know to put on a clean PPE gown prior to a procedure or to remove the PPE gown after a procedure.

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

The findings related to having the required training were discussed with Staff #2 on 10/21/2014 at 4:30 p.m. A request was made for any information related to employees' training in proper infection prevention techniques. Staff #2 reported he/she was not aware the required training failed to be

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T 170 Continued From Page 22

T 170

documented in the three (3) credentialing personnel files. Staff #2 reported the facility trains staff to comply with infection prevention practices as documented in seven (7) of seven (7) employee personnel files (Employee files #1-7); however he/she reported the facility failed to show evidence the three (3) credentialing employees were trained in infection prevention practices.

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

T 175

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:

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

T-175 12 VAC 5-412-220 C.10
Infection Prevention
Complete Date: 11/10/14

11/10/14

- Immediately following the inspection the 2 damaged recliners were taken out of service and not replaced. The remaining 4 were cleaned and disinfected. The recovery room personnel were counseled regarding the procedure for cleaning the recovery room.

11/10/14

- Immediately following the inspection the administrator and procedure room employees inspected the procedure table and were not able to find the remnant of tape described in the inspectors' findings. The staff did find on the drawers of the procedure table labels (autoclave tape) on the drawers. These labels were removed and the procedure table was cleaned and disinfected.

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T 175 Continued From Page 23

T 175

(iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;

8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.

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

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

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T 175	Continued From Page 24 and can harbor bacteria. During a tour of the facility on 10/20/14, at approximately 2:30 PM, it was revealed that procedure table had a remnant of tape on the metal plate under the padding. The rough surface of the tape restricts the ability to disinfect and could harbor pathogens. According to the CDC Guide to Infection Prevention for Outpatient Settings: 1)Responsibility for routine cleaning and disinfection of environmental surfaces should be assigned to appropriately trained (staff); 2) Cleaning procedures can be periodically monitored or assessed to ensure that they are consistently and correctly performed. Staff #1 was present during recovery room inspection and facility tour. Staff #1 stated that some of the soil on the chair was from the floors being waxed that morning, but acknowledged the chairs had not been properly cleaned and disinfected. Staff #1 was made aware of the tape on the procedure table.	T 175		
T 180	12 VAC 5-412-220 D Infection prevention D. The facility shall have an employee health program that includes: 1. Access to recommended vaccines; 2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients; 3. An exposure control plan for blood-bourne pathogens; 4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine;	T 180	T-180 12 VAC 5-412-220 D Infection Prevention Date: 12/18/14 • Documentation of employee refusal regarding screening and immunizations had previously been noted by the administrator in the employee health file. AHCW will update the P&P manual to incorporate a form which will be signed by the employee indicating their decline/refusal of screening and immunizations.	12/18/14

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T 180 Continued From Page 25

T 180

5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.

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

The findings included:

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

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

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T 185	Continued From Page 26	T 185		
T 185	12 VAC 5-412-220 E Infection prevention	T 185	T-185 12 VAC 5-412-220 E Infection Prevention Complete Date: 12/18/14	12/18/14
	<p>E. The facility shall develop, implement and maintain policies and procedures for the following patient education, follow-up, and reporting activities:</p> <ol style="list-style-type: none"> 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. <p>This RULE: is not met as evidenced by: Based on record review and interview the facility failed to document the patient's condition, or that instructions for infections were provided prior to discharge for seven (7) out of ten (10) patients included in the survey sample. (Patients #2, #3, #5, #7-#10)</p> <p>2. The facility failed to develop a procedure for tracking infections and reporting the findings to the local health department. The findings included: Review of ten (10) patient records on 10/20/14 at approximately 2:30 PM, revealed seven (7) out of ten (10) (patients #2, #3, #5, #7-#10) did not document condition of patients at discharge or have documentation verifying that infection prevention instructions had been provided to the patient. On 10/21/14 at approximately 9:45 AM, Staff #5 took responsibility of not completing the patient record with the patient condition at discharge. Staff #5 stated, "That was me. I didn't complete it." 2. Staff #2 was present during the record review and acknowledged the findings above. During an</p>		<ul style="list-style-type: none"> • AHCW does have a policy for documenting the patient's condition at discharge. Staff 5 violated this policy in the presence of inspectors by failing to complete the patients chart. Other charts were also found to be lacking this information. The Medical Director will provide counseling of all facility physicians regarding this regulation. • Discharge / Follow-up instructions are provided to patients by the recovery room nurse. The P&P will be updated to reflect that the patient will be provided 2 copies of this form. One retained by the patient and one signed by the patient which is placed in the patient record. • The inspectors assert that the facility does not have a policy for tracking infections, and reporting findings to the local health department. AHCW has P&P 2.4.1 which documents tracking infections and P&P 2.4.5 which describes necessary reporting to the local health department including timeliness for this reporting. 	<p>12/18/14</p> <p>12/18/14</p> <p>10/21/14</p>

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T 185 Continued From Page 27

interview of on 10/21/14, at approximately 5:00 PM, Staff #2 revealed that the agency had not developed and implemented procedures for documenting and tracking infections. The agency had not developed a policy and procedure for reporting conditions to the local health department, including outbreaks of disease. Staff #2 was unaware of the requirement, and stated that a person would need to be hired to process this information.

T 185

T-285 12 VAC 5-412-260 E Administration, Dispensing and Storage of Drugs

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

10/23/14

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 observation and record review, the person responsible for administering controlled medications, failed to keep the narcotic log current and accurate: and

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

The findings included:

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

T 285

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

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T 285	Continued From Page 28 bottle of dilauded had no remaining tablets. The narcotic log indicated that on 10/10/14, there was one tablet remaining. The narcotic log indicated there were 264 xanax tablets on 10/14/14. The patient identification for the last tablet administered was not documented. A count by Staff #2 revealed 263 tablets remaining. The narcotic log indicated there were 364 vicodin tablets on 10/17/14. Staff #2 counted 363 vicodin tablets. During an interview conducted on 10/20/14 at approximately 3:00 PM, Staff #2 acknowledged the medication count did not equal the narcotic log. Staff #2 stated that "the girls didn't document in the record" after administrating the medications. Patient files with procedures performed on 10/14/10 were reviewed and one patient had received one 0.5 xanax tablet that was not documented on the narcotics log. Patient files with procedures performed on 10/18/14 were reviewed. One 2 mg dilauded and one 10 mg vidodin tablets were administered but not noted on the log. Patient record documentation resolved the differences in the log count and the actual remaining medications. Staff #4, interviewed on 10/21/14 at approximately 3:30 PM, acknowledged that the medication administered on 10/14/10 and 10/18/14 had not been documented on the log. Staff #4 said not enough time was given after the procedures to document the medications administrated. 2. An interview was conducted on October 21, 2014 at 9:50 a.m. with Staff #4. The surveyor requested to observe the preparation of injectable medications utilized during the procedure. Staff #4 stated, "I don't prepare the Lidocaine injections. [Name of Staff #1] prepares the Lidocaine injections in the room just prior to the procedure."	T 285	

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T 285 Continued From Page 29

T 285

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

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

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

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

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

T 315

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

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

T-315 12VAC 5-412-210 A Quality Management

- Following the 2012 inspection AHCW conducted quality assurance meetings which are reported in the minutes of the meetings. However, the meetings and reporting conducted since 6/20/2013 did not follow the format specified in the regulations in effect. The P&P manual will be updated to reflect the current regulation regarding format and content.

12/18/14

- A description of the quality program within the P&P Manual will be revised to reflect evaluation of factors identified within 12VAC5-412-210 B.

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T 315 Continued From Page 30

T 315

quality committee failed to ensure the facility maintained an ongoing, comprehensive, integrated, self-assessment program.

The findings included:

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

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

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

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T 315 Continued From Page 31 T 315

This is a re-cite from 2012.

T 320 12 VAC 5-412-300 B Quality assurance T 320

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

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

The findings included:

An interview and review of the facility's quality program documents was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 and the surveyor reviewed the facility's quality program documentation. The facility's documentation did not include the required seven elements of: staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; and staff concerns regarding patient care. Staff #2 reported the quality committee had not collected or evaluated dated for the seven

T-320 12VAC 5-412-210 B Quality Management Complete

Date: 12/18/14

- The facilities Quality P&P will be updated to reflect the required elements data collection, and analysis which will enable the Quality Committee to identify Patient Safety concerns, facility deficiencies and make recommendations to the Governing Board and Licensee, when required.

- The administrator was incorrect when responding that data was not collected and analyzed. This information will be gathered and placed into a Quality Data Folder for review and analysis by the quality committee and the Governing Body.

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T 320 Continued From Page 32 T 320

required areas.

During an interview conducted on October 21, 2014 at 5:01 p.m. the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 denied awareness of the updated State licensure regulations. Staff #2 reported the quality committee had not collected, analyzed, or trended data for the required areas to identify unacceptable or unexpected outcomes.

This is a re-cite from 2012.

T 330 12 VAC 5-412-300 D Quality assurance

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

This RULE: is not met as evidenced by:
Based on document review and interview the quality committee failed to ensure measures were implemented to resolve identified problems and concerns.

The findings included:

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

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

T 330

T-330 12VAC 5-412-210 D Quality Management Complete Date: 12/18/14

The Correction of identified deficiencies will be reported to the Quality Committee and reflected within the Meeting minutes. This change to the P&P will be updated and the P&P reviewed at the next Quality Meeting.

12/18/14

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NAME OF PROVIDER OR SUPPLIER AMETHYST HEALTH CENTER FOR WOMEN, INC	STREET ADDRESS, CITY, STATE, ZIP CODE 9380-B FORESTWOOD LANE MANASSAS, VA 20110	CORRECTED COPY
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the facility's quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were implemented.

This is a re-cite from 2012.

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

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

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

The findings included:

An interview and review of the facility's quality program was conducted on October 21, 2014 at 5:06 p.m., with Staff #2. Staff #2 initially stated he/she did not understand the State licensure

T-335 12VAC 5-412-210 E Quality Management Complete Date: 12/18/14

12/18/14

• Following all meetings of the Quality Committee, a meeting report will be prepared and forwarded to the Governing Body. The format for this report and an exemplar of the transmittal letter to the Governing Body will be reflected in updates to the AHCW P&P manual.

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T 335 Continued From Page 34 T 335

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

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

This is a re-cite from 2012.

T 340 12 VAC 5-412-310 Medical records

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

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

T 340

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

12/18/14

• Following review of the deficiencies an immediate review of the Patient Procedure Chart will be conducted and changes discussed with the Medical Director and Physicians. Revision will take place and instruction on utilization will take place. Additionally, persons responsible for entering information into the chart will be counseled regarding proper completion of required information.

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

This RULE: is not met as evidenced by:

Based on interview and document review, the facility patient records were incomplete and did not contain sufficient information:

1. Seven (7) out of ten (10) patient records (#2, #3#, #5, #7-10) did not have the systems assessment completed,
2. Ten (10) out of ten (10) patient records (patients #1-#10) did not have physician or nurse progress notes from the procedure through discharge.
3. Seven (7) out of ten (10) patient records (#2, #3#, #5, #7-10) did not have the condition at discharge documented.
4. Nine (9) out of ten (10) patient records (#2-#10), patient instructions, preoperative and postoperative were not documented.

The findings included:

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

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T 340

medical records reviewed. The medical records did not provide a space for the nurses to document the patient's status and progress.

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

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

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

T 355 12 VAC 5-412-330 B Reports

T 355

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

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

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

T-355 12VAC 5-412-320 Required Reporting Complete Date: 12/18/14

The AHCW P&P Manual will be updated to reflect Regulations Effective 6/20/13. The Administrator, Quality Committee, Governing Body and Licensee will review this updated policy.

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T 355	<p>Continued From Page 37</p> <p>of Virginia §63.2-1509 for seven (7) of seven (7) employees. (Employee files #1 -#7)</p> <p>The findings included:</p> <p>1. Review of the facility's policy and procedure manual on 10/20/2014 through 10/21/2014 did not reveal the following policy and procedures:</p> <p>(B). The abortion facility shall report the following events to OLC:</p> <ol style="list-style-type: none"> 1. Abortion facilities shall report all patient, staff or visitor deaths. 2. Any serious injury to a patient. 3. Medication errors that necessitate a clinical intervention other than monitoring; 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and 5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990. <p>2. Review of the facility's policy and procedure manual on 10/20/2014 through 10/21/2014 did not reveal the following policy and procedures:</p> <p>(C). Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the following:</p> <ol style="list-style-type: none"> 1. Abortion facility name; 2. Type and circumstance of the events being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence. <p>An interview was conducted on 10/21/2014 at</p>	T 355		

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

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

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

5. Review of seven employee files did not reveal documentation of education, training and acknowledgement related to being Mandated reporters of suspected child abuse or neglect as

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defined under the Code of Virginia §63.2-1509.

An interview was conducted on 10/21/2014 at 5:01 p.m. with Staff #2. Staff #2 acknowledged the facility had failed to develop policies and procedure related to staff being mandated reporters of suspected child abuse or neglect.

On October 21, 2014 at 5:01 p.m., the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 reported they had not received notification that the regulations had been revised. The surveyor informed Staff #2 that the State licensure office did not send out notices to each facility related to changes in the licensure regulations. The surveyor informed Staff #2 that it was the facility's responsibility to occasionally check the State's website for updated licensure regulations.

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