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	AF-0014	A. BUILDING _____ B. WING _____	12/09/2014

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ALEXANDRIA WOMEN'S HEALTH CLINIC	101 S. WHITING ST. SUITE #215 ALEXANDRIA, VA 22304

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	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 12/08/2014 through 12/09/2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013).	T 000	T000 Plan of Correction	
T 050	12 VAC 5-412-160 B Administrator B. Any change in the position of the administrator shall be reported immediately by the licensee to the department in writing. This RULE: is not met as evidenced by: Based on interview and document review, it was determined the agency failed to develop a policy related to reporting changes of the position of administrator. The findings included: Review of the agency policy and procedure manual on 12/08/2014, revealed there was no policy requiring the governing body to notify the Office of Licensure and Certification in writing of a change in the position of administrator. During an interview conducted on 12/08/2014, at approximately 6:00 PM, Staff #2 acknowledged there was no policy related to notifying the OLC of changes in the position of administrator.	T 050	T050 The governing body will develop a policy and procedure for reporting any changes in writing of any change in position of the administrator to the Office of Licensure and Certification.	12/30/14
T 060	12 VAC 5-412-170 A Personnel A. Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients.	T 060		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Thomas Gresinger MD — (X6) DATE: JAN 17 2015

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T 060	Continued From Page 1 The facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided. This RULE: is not met as evidenced by: Based on observation, interview and document review, it was determined the agency failed to ensure staff training was documented in employee files. The findings included: In the recovery room on 12/09/2014 at approximately 11:00 AM, Staff #6 was observed taking vital signs of clients. During an interview with Staff #6 on 12/09/2014, at approximately 12:25 PM, Staff #6 stated that he/she was currently taking classes required to attend nursing school, and that he/she had been trained to perform vital signs by Staff #4. During an interview conducted on 12/09/2014 at approximately 12:40 PM, Staff #4 stated that he/she had trained Staff #6 how to perform vital signs. A review of the employee file of Staff #6 did not include supporting documentation of training for performing vital signs.	T 060	T060 The facility will update employee files with updated documentation of training related to their duties and will be included in the policy and procedure manual.	12/30/14
T 095	12 VAC 5-412-170 H Personnel H. Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors;	T 095	T095 3. A policy and procedure will be developed for annual evaluation of employees. There will be an annual self-evaluation documentation of employee performance in each	12/30/14

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T 095	Continued From Page 2 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. This RULE: is not met as evidenced by: Based on document reviews and staff interviews it was determined the facility failed to perform an annual employee performance for one (1) of seven (7) employees in the survey sample (Staff #3). The findings included: At the entrance conference on 12/08/2014 at 1:00 p.m., the administrator was asked to provide a list of new employees hired since the last inspection and to include date of hire and title for the surveyor to review. The review of personnel records on 12/08/2014 at 3:15 p.m. failed to contain evidence that verify one (1) of seven (7) staff (Staff #3) had no evidence of an annual performance evaluation. The seven (7) staff members had been employed over one (1) year. An interview was conducted on 12/08/2014 at 4:15 p.m., with Staff #1 and Staff #2. The surveyor requested documentation showing the facility would have an annual evaluation for employee performances. Staff #2 reported he/she was unsure if the facility did have policies and procedures to reflect the State licensure requirements for ensuring an annual employee performance evaluation would be conducted; however he/she would like to continue	T 095	T095 continued. employee file. The process for evaluating employees' annual performance and competency will be reviewed by the Quality Assurance Program and the Governing Body providing a report of review, results and recommendations, if any.	12/30/14

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T 095	Continued From Page 3 investigating. The agency's policy titled, "Credentialing" was reviewed on 12/08/2014. The policy read in part: "The facility staff shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member." The review of the facility's policies and procedures on 12/08/2014 at 2:30 p.m. did not include policies for evaluating employee performances annually. The findings related to implementing the policy for evaluating employees were discussed with Staff #1 and Staff #2 on 12/09/2014 at 1:30 p.m. Staff #2 acknowledged that although the agency has a process to complete employee annual performance evaluations, he/she knew the personnel file should have contained these documents but failed to do so. Staff #2 reported he/she was not aware Staff #3's annual evaluation was not in the personnel file until it was brought to his/her attention by the surveyor. During the exit interview on 12/09/2014, Staff #2 acknowledged that the facility has a process to obtain an annual employee performance evaluation, but failed to maintain the facility's system in the manner required by this regulation.	T 095		
T 170	12 VAC 5-412-220 B Infection prevention B. Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community acquired infection	T 170	T170 All employees will be reminded in a staff meeting about infection prevention techniques regarding the use of standard precautions and correct hand-washing techniques.	12/30/14

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T 170	Continued From Page 4	T 170	T170 continued.	12/30/14

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, it was determined the agency failed to:

1. Ensure the use of standard precautions by clinicians, when wearing gloves to prevent transmission of microorganisms

2. Develop a hand hygiene policy for clinicians when donning gloves

The findings included:

It was observed in the recovery room on 12/9/2014, at approximately 11:00 AM, that Staff #2 did not perform hand hygiene between glove changes. At approximately 11:15 AM, Staff #6 did not perform hand hygiene prior to donning gloves, when moving a stretcher to the procedure room.

The facility will require that standard precautions are followed by all employees and medical staff caring for patients to prevent transmission of infectious agents.

Effective hand hygene reduces the incidence of healthcare-associated infections by preventing the transmission of microorganisms from patient to patient and from inanimate surfaces to patients.

Hand hygene shall be practiced before and after each patient contact as well as after glove removal and before donning new gloves.

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T 170	Continued From Page 5	T 170		

During an interview on 12/09/2014, at approximately 12:20 PM, Staff #2 acknowledged that hands should be cleaned between glove changes and stated, "I guess I forgot." During an interview on 12/09/14, at approximately 12:25 PM, Staff #6 acknowledged that hands are to be cleaned prior to donning gloves with soap or alcohol rub.

It was observed in the tissue exam and equipment cleaning room on 12/09/2014, at approximately 11:00 AM, that Staff #3 did not perform hand hygiene between glove changes following two (2) procedures.

During an interview on 12/09/2014, at approximately 11:20 AM, Staff #3 stated "I wash hands before I come into the room and when I leave the room, after all procedures are done." Staff #3 acknowledged he/she would not leave the tissue room until all procedures were done for the day.

According to the Center for Disease Control (CDC), Guide To Infection Prevention For Outpatient Settings, hand hygiene should be performed:
1. Before touching a patient, even if gloves will be worn
2. Before exiting the patient's care area after touching the patient or the patient's immediate environment
3. After glove removal

Review of the agency policies and procedures manual on 12/09/2014, revealed there was no policy related to hand hygiene when wearing gloves.

During an interview on 12/09/2014, at approximately 2:00 PM, Staff #2 acknowledged

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T 170	Continued From Page 6 there was no policy related to performing hand hygiene before donning gloves and after glove removal.	T 170		
T 175	12 VAC 5-412-220 C Infection prevention C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following: 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers); 2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies; 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures); 4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment; 5. Procedures for handling/temporary storage/transport of soiled linens; 6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations; 7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment, (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection	T 175	T175 The vinyl padding in the procedure table will be replaced in order to properly disinfect and decontaminate between patient use.	12/30/14

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T 175	Continued From Page 7	T 175		

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

This RULE: is not met as evidenced by:
Based on observation, interview, and document review, it was determined the agency failed to enforce its policy on environmental cleaning related to a tear in padding, located in the procedure room.

The findings included:

It was observed during a tour of the facility on 12/08/2014, at approximately 2:00 PM, that there was a tear in vinyl padding of a structure adjoining the procedure table, above the head of the mattress padding.

During an interview conducted on 12/08/2014, at approximately 2:00 PM, Staff #1 stated that this portion of the table was used by a clinician to make notes during the procedure. Staff #1 stated, "We can get rid of this."

A tear in vinyl inhibits the ability to disinfect the surface of microorganisms. Agency policy and procedures state "Stretcher mattresses, gurneys, wheel chairs and chairs will be examined first

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T 175	Continued From Page 8 thing in the morning and between patients for tears. If there is any damage to any mattress, gurney or chair it will be removed from use and reported to the Director of Nursing."	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; 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 five (5) of five (5) physicians. The findings included: A review of seven (7) personnel records	T 180	T180 The facility will implement a policy and procedure for an employee health program. This program will consist of, but not be limited to: • Education of personnel to recognize and protect against potential hazards to themselves and other personnel. • Provision of indicated vaccinations to all employees (including physicians). • Follow-up monitoring of exposures to communicable disease in conjuction with infection prevention. • Emphasis on maintenance of sound health habits and personal hygene. • Monitoring and provision of care to personnel with work-related illness or exposure.	12/30/14

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T 180	Continued From Page 9	T 180	T 180 Continued • Promotion of employee health education and wellness. • Bloodborne Pathogen standard implementation. Annual screening will include, but not be limited to: • An updated health history • A negative Purified Protein Derivative (PPD) or chest X-ray for positive PPD history (converters will be referred to the physician for follow-up). • Hepatitis B immunization (titer will be needed for employees that have previously received the HBV vaccination series). • Influenza immunization. If the employee refuses any vaccinations, the employee will have to sign the "Informed Refusal Form."	12/30/14

(Employee files #1-#7) and five (5) credentialing personnel records (Credentialing Employees #1-#5) failed to contain evidence verifying employees were offered/received screening for tuberculosis annually. One (1) of seven (7) personnel records (Employee #4) and four (4) of five (5) credentialing personnel records (Credentialing Employees #1, 2, 3 and 5) failed to contain evidence verifying employees had access to Hepatitis B vaccine.

The agency's policy titled, "Hepatitis B Vaccine" was reviewed on 12/08/2014. The policy read in part: "Each staff member whose position has identified them as being at risk of contracting, or there is reasonable anticipation that they may be exposed to Hepatitis B Virus (HBV) will be offered the HBV vaccination series free of charge. The vaccine will be available within 10 days of employment or assignment of a new position within the risk category. This vaccination does not have to be given if; the employee has previously received the complete HBV vaccination series, antibody testing has revealed the employee is immune, the vaccine is contraindicated for medical reasons, or the employee refused the vaccine and signs the Informed Refusal Form."

The review of the facility's policies and procedures on 12/08/2014 at 2:30 p.m. did not include policies for screening for tuberculosis.

The findings related to having screening and immunizations offered/received by employees were discussed with Staff #2 on 12/08/2014 at 4:15 p.m. Staff #2 acknowledged the facility does have a process for offering employees screening and immunizations, including Hepatitis B and the influenza vaccine. Staff #2 reported many employees refuse this offered service. The surveyor inquired if Staff #2 had documented the

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T 180	Continued From Page 10 employee's refusal. Staff #2 reported the facility had developed a decline or refusal of immunizations form, but failed to have documentation of the employees/physicians declining the screenings and immunizations. Staff #2 stated, "We don't have anything about tuberculosis screening and we don't require it because we didn't know we needed to."	T 180		
T 275	12 VAC 5-412-260 C Administration, storage and dispensing of dru C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10 This RULE: is not met as evidenced by: Based on observations, interviews and document review the facility failed to maintain drugs in the facility for daily use which are unexpired. The findings included: A tour of the facility was conducted on 12/08/2014 at approximately 1:30 p.m. with Staff #1. The observation in the facility's double locked medication cabinet revealed three (3) boxes of single use Fentanyl vials with an expired date documented as "1Dec2014." Two (2) boxes of Fentanyl were unopened and one (1) box of Fentanyl had approximately five (5) vials removed and documented by the physician in the medication log. The three (3) boxes of expired Fentanyl were removed by Staff #1 (Administrator).	T 275	T275 12/11/14 All medications will be monitored with a checklist done monthly. This checklist will include, but not be limited to: • Date and amount the medication was received. • Expiration date • Lot number All expired medications are removed and properly disposed by healthcare licensed professionals.	

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Review of the facility's policy titled "Pharmaceuticals" read in part: "The Director of Nursing, under the supervision of the Medical Director is responsible for the ordering, storing, stocking, controlling, distributing and disposing of controlled substances and all other medications. In accordance with all applicable laws, records are dept on all ordering, purchasing and dispensing of drugs."

An interview was conducted on 12/08/2014 at 1:45 p.m. with Staff #1. Staff #1 verified the date on the three (3) boxes of single use Fentanyl. Staff #1 stated, "There is something wrong because we just received this shipment from the distributor approximately one month ago and it shouldn't be expired already. I am going to contact them about this, but these boxes should be discarded immediately from this locked medication cabinet."

[According to www.drugs.com: Fentanyl is an opioid medication. An opioid is sometimes called a narcotic. Fentanyl is used as part of anesthesia to help prevent pain after surgery or other medical procedure.]

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

E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in 54.1-3404 of the Drug Control Act of the Code of Virginia.

This RULE: is not met as evidenced by:
Based on document review, observation and interviews the facility failed to keep records of all

T285 — 12/30/14

Only healthcare licensed professional will keep record of all drugs received, administered, dispensed or disposed.
The medical director will be responsible for ordering, stocking, controlling, distributing and disposing of controlled substances

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T 285	Continued From Page 12 drugs in Schedules I-V received in accordance with federal and state laws. Note: This is a re-cite from 2012. The findings included: A tour of the facility was conducted on 12/08/2014 at approximately 1:30 p.m. with Staff #1 (Administrator). Staff #1 reported all narcotics are stored in the double locked medication cabinet. Staff #1 confirmed only patients who receive sedation have an IV (intravenous line which is inserted into the vein to receive fluids or medications) started prior to the procedure. Staff #1 confirmed he/she is not licensed as a health professional. Staff #1 confirmed the narcotics are received by him/her from the vendor; however medications are removed from the locked cabinet by the physicians and CRNA (certified nurse anesthetist) and documented in the medication logs. Staff #1 acknowledged all narcotics are accounted for by documentation in each patient's record and by the medication logs signed by the physicians and/or CRNA, which is overseen by the Medical Director. Staff #1 verified the narcotics are counted at the above named facility by the physicians prior to each use and documented on the medication log. Staff #1 and Staff #2 count the narcotics monthly and document the count on a separate ledger from the physicians but compare counts. Staff #1 again confirmed he/she and Staff #2 are not licensed as health professionals. A review of the medication logs and ledgers were conducted on 12/08/2014 with Staff #1. Medication logs showed evidence the physicians and CRNA signed each entry for narcotics dispensed. A review of the monthly ledger showed evidence Staff #1 and Staff #2 initialed	T 285	T285 Continued and other medications as stated in the facility's policy and procedure manual. Monthly narcotic count will be done by a healthcare lisensed professional and verified by the director of nursing and/or medical director.	12/30/14

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the monthly narcotics count co-signed by the Medical Director. Staff #1 confirmed he/she and Staff #2 are not licensed as health professionals.

An interview was conducted with Staff #5 on 12/09/2014 at approximately 9:10 a.m. Staff #5 verified a narcotics count is done at the beginning of each clinic and documented on the medication log. Staff #5 acknowledged there have been no problems; however if any problems were encountered with the count, he/she would notify the Administrator and the Medical Director immediately and his/her obligation is to report it the proper authorities.

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

A review of the facility's policy titled "Pharmaceuticals" read in part: "The Director of Nursing, under the supervision of the Medical Director is responsible for the ordering, storing, stocking, controlling, distributing and disposing of controlled substances and all other medications. In accordance with all applicable laws, records are kept on all ordering, purchasing and dispensing of drugs. The Medical Director and/or the Director of Nursing is responsible for the correct, safe storage of medications, IV solutions and chemicals. Access to drug storage is limited to licensed Medical and Nursing personnel. Adequate space, cabinetry and refrigeration shall be made available tin the pharmacy area to house all pharmacy medications and related supplies." Nowhere in the policy does it state unlicensed personnel shall have access to controlled substances.

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During a review of Staff #5's credentials file on 12/08/2014 it was noted the documentation indicated Staff #5's DEA (drug enforcement agency) number expires on 10/31/2016.

A review of Staff #1 and Staff #2's employee file were conducted on 12/08/2014. Staff #1's date of hire was 07/01/2000. Staff #1 has no professional license which would allow him/her to handle controlled substances. Staff #1 has no evidence of training in medications in his/her employee file. Staff #1 has a job description for administrator. Staff #2's date of hire was 09/04/2004. Staff #2 has no professional license which would allow him/her to handle controlled substances. Staff #2 has evidence of attending nursing school and training in medications in his/her employee file. Staff #2 has job descriptions for alternate administrator and surgical and laboratory technician.

An interview with Staff #1 and Staff #2 was conducted on 12/09/2014 in regards to the findings. Staff #1 acknowledged approximately two (2) years prior to the survey a staff Registered Nurse was responsible for the task of handling all medications. After the Registered Nurse left the facility, the medication task became the responsibility of the Administrator because the physicians were not in the office everyday. Staff #1 didn't want to add more responsibilities to the physicians so he/she took the duty of ordering, storing and stocking the controlled substances and all other medications. Staff #1 stated, "I didn't realize I couldn't receive, store and count the narcotics until it was brought to my attention by the surveyor."

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T 315	Continued From Page 15	T 315		
T 315	12 VAC 5-412-300 A Quality assurance A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary. This RULE: is not met as evidenced by: Based on document review and interview the quality committee failed to ensure the facility maintained an ongoing, comprehensive, integrated, self-assessment program. Note: This is a re-cite from 2012. The findings included: An interview and review of the facility's quality program was conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 initially stated he/she did not understand the State licensure requirement of implementing "an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement." The review revealed documents titled "Quality Meeting," which listed items discussed as part of the facility's quality program meeting. The surveyor asked Staff #2 how the quality committee determined, which items to discuss and if the committee had formulated the items from data collected. Staff #2 denied that data had been collected as the basis for what was discussed	T 315	T315 The Quality Assurance Committee consists of: 1. Medical Director (Physician). 2. Administrator (non-physician healthcare practitioner). 3. Assistant Administrator (member of the administrative staff). 4. Surgical Coordinator (an individual with demostrated ability to represent the rights and concerns of patients). The Quality Assurance Committee will implement a comprehensive self-assessment program of the quality care and appropriateness of the services given to our patients. This program will consist of: 1. Staffing patterns and performance. 2. Supervision appropriate to the level of service. 3. Patient records.	12/30/14

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T 315	Continued From Page 16 during the quality committee's meetings. An interview was conducted on 12/09/2014 at 1:50 p.m., the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 denied awareness of the updated State licensure regulations. Staff #2 stated, "We have not collected data or performed a program assessment."	T 315	T315 Continued 4. Patient satisfaction (surveys, suggestion box). 5. Complaint resolution 6. Recording and reporting of infections, complications and other adverse events (monthly compilation). 7. Staff concerns regarding patient care (staff suggestion box, meetings). This program will allow the facility to correct and make improvements to patient care and in our respective duties to better serve the care of our patients.	12/30/14
T 320	12 VAC 5-412-300 B Quality assurance B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance; 2. Supervision appropriate to the level of service; 3. Patient records; 4. Patient satisfaction; 5. Complaint resolution; 6. Infections, complications and other adverse events; and 7. Staff concerns regarding patient care. This RULE: is not met as evidenced by: Based on document review and interview the quality committee failed to ensure an evaluation of the adequacy and appropriateness of services as required by the State licensure regulations. Note: This is a re-cite from 2012 related to staff's failure to ensure all subjects of the quality improvement committee would be addressed. The findings included: An interview and review of the facility's quality	T 320	T320 The adequacy and appropriateness of services will be evaluated by the Quality Assurance Committe. This evaluation will identify the unexpected or unacceptable trends or occurences. This will address the following: 1. Staffing patterns and performance 2. Supervision appropriate to the level of service	12/30/14

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T 320	Continued From Page 17 program documents were conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 and the surveyor reviewed the facility's quality program documentation. The facility's documentation did not include the required seven (7) elements of: staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; and staff concerns regarding patient care. Staff #2 reported the quality committee had collected data but had not evaluated data for the seven required areas or identified unacceptable or unexpected trends or occurrences. During an interview conducted on 12/09/2014 at 1:30 p.m. the surveyor inquired if Staff #2 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #2 denied awareness of the updated State licensure regulations. Staff #2 reported the quality committee had collected data, but had not analyzed or trended data for the required areas to identify unacceptable or unexpected outcomes.	T 320	T320 Continued 3. Patient records. 4. Patient satisfaction (surveys, suggestion box). 5. Complaint resolution 6. Recording and reporting of infections, complications and other adverse events (monthly compilation). 7. Staff concern regarding patient care (staff suggestion box, meetings). All data collected will be evaluated to correct and/or make improvements regarding patient care.	12/30/14
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. Note: This is a re-cite from 2012 related to staff's failure to ensure how problems would be resolved by the quality improvement committee.	T 330	T330 The Quality Assurance Committee will provide proper documentation of all data collected and will be evaluated to correct and/or make improvements regarding patient Care.	12/30/14

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T 330	Continued From Page 18 The findings included: An interview and review of the facility's quality program was conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 initially acknowledged the quality improvement committee did discuss concerns/problems that had been identified by services provided, appropriateness of care including reports from staff, patients, performance, patterns, or any other sources of data collected. The review revealed documents titled "Quality Meeting," which listed items discussed as part of the facility's quality program meeting. Staff #2 identifies the items as concerns that were discussed during the meeting. The surveyor asked Staff #2 for documentation that measures were implemented to correct the concerns. Staff #2 reported the quality committee did not document any corrective actions that were implemented. An interview was conducted on 12/09/2014 at approximately 1:50 p.m., with Staff #2. The findings were reviewed. Staff #2 reported the facility's quality program needed to address the issues found by the survey team. Staff #2 acknowledged the quality program's failure to implement measures to resolve problems or concerns that have been identified.	T 330	T330 Continued The Quality Assurance Committee will hold meetings to discuss concerns and problems that have been identified and any corrective actions implemented to resolve problems or concerns will be documented. There will be a review of all complications and patient complaints, if any, from previous months.	12/30/14
T 335	2 VAC 5-412-300 E Quality assurance E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All	T 335	T335 All results from the Quality improvement program will be reported at least annually. These results will be reported to the Governing Body and Licensee and	12/30/14

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T 335	Continued From Page 19	T 335	T335	12/30/14

corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.

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

Note: This is a re-cite from 2012 related to staff's failure to ensure results of the quality improvement program would be reported to the licensee at least annually and deficiencies identified, recommendations and improvements were being acted upon by the governing body and the facility.

The findings included:

An interview and review of the facility's quality program was conducted on 12/09/2014 at 1:30 p.m., with Staff #2. Staff #2 initially acknowledged the quality improvement committee did discuss concerns/problems that had been identified by services provided, appropriateness of care including reports from staff, patients, performance, patterns, or any other sources of data collected.

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

Shall include any deficiencies found as well as the corrective actions implemented to resolve problems or concerns.

All corrective actions will be documented.

Deficiencies that may jeopardize patient safety shall be reported immediately in writing to the Governing Body and Licensee.

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T 335	Continued From Page 20 implemented. Staff #2 reported the quality committee did not compile a report for the governing body to review at least annually. An interview was conducted on 12/09/2014 at approximately 1:50 p.m., with Staff #2. The findings were reviewed. Staff #2 reported the facility's quality program needed to address the issues found by the survey team. Staff #2 acknowledged the quality program's failure to report the deficiencies identified and recommendations for corrections and improvements.	T 335		
T 360	12 VAC 5-412-340 Policies and procedures The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not limited to: 1. Facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and 3. Provisions for disseminating safety-related information to employees and users of the facility. This RULE: is not met as evidenced by: Based on interview and document review, it was determined the agency failed to develop policies related to safety within the facility and on the grounds. The findings included: Review of the agency policy and procedure manual on 12/08/2014, revealed there was no	T 360	T360 12/30/14 A policy and procedure has been developed to provide a safe and healthy workplace for all patients, visitors and employees. The facility shall protect all individuals from preventable occupational injuries and illnesses as well as any situation that may be hazardous or potentially hazardous to the environmental health or safety of the facility. This policy and procedure shall include, but not be limited to:	

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T 360	Continued From Page 21 policy detailing how the agency provided security for employees and patients within the facility. During an interview on 12/08/2014, at approximately 6:00 PM, Staff #2 stated that the facility had installed bullet proof glass, a video camera, and a process of locking all doors to ensure safety of staff and clients. The exterior door to the building was locked at 7:00 PM by the owners, as a safety measure. Staff #2 acknowledged there was no policy related to the security measures that had been put in place.	T 360	T360 Continued 1. Facility security (security camera installed, bullet proof glass at reception desk, passcode on all doors). 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services (in-service, drills, periodic review). 3. Provisions for disseminating safety-related information to employees and users of the facility (in-service, drills, literature, periodic review).	12/30/14