STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0015	A. BUILDING _____ B. WING _____	04/05/2016

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VIRGINIA HEALTH GROUP	8316 ARLINGTON BLVD, SUITE 220 FAIRFAX, VA 22031

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T 000	12VAC5-412 Initial Comments An unannounced Complaint Licensure inspection which led to the initiation of an unannounced Biennial Licensure inspection was conducted April 4, 2016 through April 5, 2016 by two Medical Facilities Inspectors (Surveyors) from the Office of Licensure and Certification, Virginia Department of Health. The facility was not in compliance with the Rules and Regulations for the Licensure of Abortion Facilities 12VAC5-412. In addition, the surveyors exited the facility prior to completing the licensure inspection because they were to be closed for the next three (3) weekdays and then scheduled to see patients on Saturday (a day we did not plan to work), such that the license was suspended prior to completion of the Licensure inspections. Therefore, there may be additional deficiencies present that we did not inspect, observe or cite. Deficient practices were cited in the following areas: 12VAC5-412-140D, tag # 0004, Management and Administration 12VAC5-412-150A, tag # 0010, Governing Body 12VAC5-412-150E, tag # 0030, Governing Body 12VAC5-412-160A, tag # 0035, Policies and Procedures 12VAC5-412-170B, tag # 0050, Administration 12VAC5-412-170C, tag # 0055, Administration 12VAC5-412-180A, tag # 0060, Personnel 12VAC5-412-180B, tag # 0065, Personnel 12VAC5-412-180D, tag # 0080, Personnel 12VAC5-412-180F, tag # 0090, Personnel 12VAC5-412-180G, tag # 0095, Personnel 12VAC5-412-180H, tag # 0100, Personnel 12VAC5-412-220A, tag # 0190, Infection Prevention 12VAC5-412-220B, tag # 0195, Infection	T 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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T 000	Continued From Page 1 Prevention 12VAC5-412-220C, tag # 0200, Infection Prevention 12VAC5-412-220E, tag # 0210, Infection Prevention 12VAC5-412-230E, tag # 0235, Patient Services 12VAC5-412-240B, tag # 0250, Medical Testing and Laboratory Services 12VAC5-412-240C, tag # 0255, Medical Testing and Laboratory Services 12VAC5-412-260C, tag # 0315, Administration, Storage and Dispensing of Drugs 12VAC5-412-260D, tag # 0320, Administration, Storage and Dispensing of Drugs 12VAC5-412-270, tag # 0330, Equipment and Supplies 12VAC5-412-300, tag # 0355, Health Information Records 12VAC5-412-310, tag # 0360, Records Storage 12VAC5-412-340A, tag # 0400, Disaster Preparedness 12VAC5-412-350A, tag # 0410, Maintenance Significant corrections are required.	T 000		
T 004	12VAC5-412-140 D Management and Administration An abortion facility shall give written notification 30 calendar days in advance of implementing any of the following planned changes: 1. Change of location. 2. Change of ownership. 3. Change of name. 4. Voluntary closure. 5. Change of administrator. 6. Change of operator. Notices shall be sent to the attention of the	T 004		

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T 004	Continued From Page 2 director of the OLC. This RULE: is not met as evidenced by: Based on staff interview, the facility staff failed to give written notification 30 calendar days in advance of the change in Administrator. The findings included: On 4/4/16 at 2:00 p.m. the survey team entered the facility and requested to speak to the Administrator. Staff #1 introduced him/herself and the surveyor asked if he/she was the Administrator. Staff #1 stated, "No". The surveyor inquired as to who the administrator was. Staff #1 stated, "Well, we don't have one." The surveyor asked Staff #1 who was in charge. Staff #1 stated, "Well I guess that would have to be our Director of Operations." The surveyor asked Staff #1 where he/she could find the Director of Operations (DOO). Staff #1 stated, "He/she is in New Jersey." The surveyor asked the name of the DOO and Staff #1 stated, "It's (first name) but I don't know what his/her last name is." Staff #1 stated, "I used to be the Administrator but I have stepped down as of March 22. I am not the administrator any longer." The surveyor inquired as to who was the Alternate Administrator. staff #1 stated, "We don't have one." The surveyor inquired as to who was in charge at the moment. Staff #1 stated, "Well I guess I am."	T 004		
T 010	12VAC5-412-150 A Governing Body Each abortion facility shall have a governing body responsible for the management and	T 010		

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T 010	Continued From Page 3 control of the operation of the abortion facility. This RULE: is not met as evidenced by: Based on observations, staff interviews, facility document reviews, clinical record reviews and results of the survey, the facility Governing Body failed to ensure appropriate and adequate management and control of the operation of the abortion facility. Multiple areas of deficient practice were identified during the survey conducted April 4, 2016 through April 5, 2016. The facility presented a document for the meeting of the Quality/Governing Body which occurred "via phone' on 4/4/16 which did not address the areas of concern identified by the survey team. No previous meeting minutes were presented by the facility. When Staff #1 was asked about the Governing Body meetings and Quality/policy reviews, he/she stated, "I don't know. I have only been at one meeting and that was the one we had by phone today."	T 010		
T 030	12VAC5-412-150 E Governing Body The bylaws shall include at a minimum the following: 1. A statement of purpose; 2. Description of the functions and duties of the governing body, or other legal authority; 3. A statement of authority and responsibility delegated to the administrator and to the clinical	T 030		

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T 030	Continued From Page 4 staff; 4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and 5. Provision of guidelines for relationships among the governing body, the Administrator and the clinical staff. This RULE: is not met as evidenced by: Based on facility document review and staff interview, the facility staff failed to ensure a current organizational chart was available in order to identify lines of authority within the facility. The findings included: On 4/4/16 at 2:25 p.m. the survey team requested an organizational chart from Staff #1 in order to be able to identify the lines of authority within the facility. Staff #1 stated, "I will see if I can find it." On 4/5/16 at 3:10 p.m. the surveyors made a second request for this document and were given a copy of a chart which did not identify names associated with positions. The surveyors requested that Staff #1 provide the names of the current lines of authority on the organizational chart. By the end of the survey, 4/5/16 at 9:10 p.m., this document was not presented to the survey team.	T 030		
T 035	12VAC5-412-160 A Policies and Procedures Each abortion facility shall develop, implement	T 035		

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T 035	Continued From Page 5 and maintain documented policy and procedures, which shall be readily available on the premises and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but not limited to the following: 1. Personnel; 2. Types of elective services performed in the abortion facility; 3. Types of anesthesia that may be used; 4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge; 5. Obtaining informed written consent of the patient pursuant to § 18.2-76 of the Code of Virginia prior to the initiation of any procedures; 6. When to use sonography to assess patient risk; 7. Infection prevention; 8. Quality an risk management; 9. Management and effective response to medical and/or surgical emergency; 10. Management and effective response to fire; 11. Ensuring compliance with all applicable federal, state, and local laws; 12. Abortion facility security; 13. Disaster preparedness; 14. Patient rights;	T 035		

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T 035	Continued From Page 6 15. Functional safety and abortion facility maintenance; and 16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable. This RULE: is not met as evidenced by: Based on document review and staff interview, the facility staff failed to ensure Policies and Procedures were reviewed /updated annually. The findings included: On 4/4/16 at 5:00 p.m., the surveyor reviewed the policy and procedure manual which was presented by Staff #1. The Policy and Procedure Manual contained a document signed by (Governing Body) which evidenced the manual had not been updated/reviewed since November 12, 2013. When Staff #1 was asked about the Governing Body meetings and Quality/policy reviews, he/she stated, "I don't know. I have only been at one meeting and that was the one we had by phone today."	T 035		
T 050	12VAC5-412-170 B Administrator Any change in the position of the administrator shall be reported immediately by the governing body to the department in writing. This RULE: is not met as evidenced by: Based on staff interview, the facility staff failed to	T 050		

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T 050	Continued From Page 7 ensure any changes in the administrator were reported immediately by the governing body to the State Agency. The findings included: On 4/4/16 at 2:00 p.m. the survey team entered the facility and requested to speak to the Administrator. Staff #1 introduced him/herself and the surveyor asked if he/she was the Administrator. Staff #1 stated, "No". The surveyor inquired as to who the administrator was. Staff #1 stated, "Well, we don't have one." The surveyor asked Staff #1 who was in charge. Staff #1 stated, "Well I guess that would have to be our Director of Operations." The surveyor asked Staff #1 where he/she could find the Director of Operations (DOO). Staff #1 stated, "He/she is in New Jersey." The surveyor asked the name of the DOO and Staff #1 stated, "It's (first name) but I don't know what his/her last name is." Staff #1 stated, "I used to be the Administrator but I have stepped down as of March 22. I am not the administrator any longer." The surveyor inquired as to who was the Alternate Administrator. staff #1 stated, "We don't have one." The surveyor inquired as to who was in charge at the moment. Staff #1 stated, "Well I guess I am."	T 050		
T 055	12VAC5-412-170 C Administrator 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 staff interview, the facility staff failed to ensure a qualified individual was appointed in writing to act in the absence of the administrator.	T 055		

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T 055	Continued From Page 8 The findings included: On 4/4/16 at 2:00 p.m. the survey team entered the facility and requested to speak to the Administrator. Staff #1 introduced him/herself and the surveyor asked if he/she was the Administrator. Staff #1 stated, "No". The surveyor inquired as to who the administrator was. Staff #1 stated, "Well, we don't have one." The surveyor asked Staff #1 who was in charge. Staff #1 stated, "Well I guess that would have to be our Director of Operations." The surveyor asked Staff #1 where he/she could find the Director of Operations (DOO). Staff #1 stated, "He/she is in New Jersey." The surveyor asked the name of the DOO and Staff #1 stated, "It's (first name) but I don't know what his/her last name is." Staff #1 stated, "I used to be the Administrator but I have stepped down as of March 22. I am not the administrator any longer." The surveyor inquired as to who was the Alternate Administrator. Staff #1 stated, "We don't have one." The surveyor inquired as to who was in charge at the moment. Staff #1 stated, "Well I guess I am." On 4/5/16 at 2:30 p.m. Staff #1 stated, "I am the acting administrator. I put in my four weeks notice on February 22nd and as of March 22nd I stepped down, but now I am the acting administrator." The surveyor verified with Staff #1 that yesterday 4/4/16 he/she had informed the survey team that he/she was not the administrator and that there "was not one". Staff #1 stated, "Yes, I said that."	T 055		
T 060	12VAC5-412-180 A Personnel Each abortion facility shall have a staff that is	T 060		

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T 060	Continued From Page 9 adequately trained and capable of providing appropriate service and supervision to patients. The abortion 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 staff interview and facility document review, the facility staff failed to ensure each staff member received necessary training to provide appropriate service to patients. The findings included: Upon review of the personnel records for staff, there was no documentation that the staff had received documented education or training on the examination and verification that tissues removed from the resulting abortion procedure contained villi or fetal parts. Staff #2 stated, on 4/5/16 at 5:43 p.m., "Well (name of Staff #7) came and showed me how a couple of times and then the rest I learned from other staff members. I catch on quick...." Staff #1 stated on 4/5/16 at 6:30 p.m. that "All staff rotate through each assignment..."	T 060		
T 065	12VAC5-412-180 B Personnel The abortion facility shall obtain written applications for employment from all staff. The abortion facility shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable.	T 065		

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T 065	Continued From Page 10	T 065		

This RULE: is not met as evidenced by:
Based on staff interview and facility document review, the facility staff failed to ensure all staff members had a written application for employment for all staff.

The findings included:

When reviewing the list of staff employed by the facility and personnel records, Staff #7 (Director of Operations) did not have a personnel file maintained at the facility.

The surveyor requested the personnel file and credentials for Staff #7 in order to verify the education/training and qualifications as Staff #7 was documenting he/she was providing multiple areas of training for staff.

Staff #1 stated on 4/5/16 at 1:50 p.m., that he/she did not have that (credentials) for Staff #7. On 4/5/16 at 2:05 p.m., Staff #1 stated that Staff #7 was on the phone and requested to speak to the surveyor. The surveyor spoke to Staff #7 who questioned: "Why do you need my information? The information you get is available to the public and I am not going to send you my personal information to be broadcast to the public." The surveyor informed Staff #7 that his/her personal information was not something that was available to the public, but that the surveyor needed to examine his/her credentials in order to verify his/her qualifications for the training of staff. Staff #7 stated, "I am a doctor so I am qualified." The surveyor questioned Staff #7 as to whether he/she had a license to practice in the State of Virginia. and Staff #7 stated, "I have passed all my tests but I do not have a license..."

At 2:45 p.m. on 4/5/16 Staff #1 brought the survey

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T 065	Continued From Page 11 team a faxed resume for Staff #7. No verification of education other than the resume was presented. The survey team reviewed documentation under the Department of Health Professionals website (www.dhp.virginia.gov) and no professional license was listed for Staff #7.	T 065		
T 080	12VAC5-412-180 D Personnel The abortion facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training. This RULE: is not met as evidenced by: Based on employee record review and staff interview, the facility staff failed to ensure on-going training and education for staff that was directly related to their duties was provided/documented and failed to ensure staff participated in annual fire safety and inservice training. The findings included: 1. Upon review of the personnel records for staff, there was no documentation that the staff had received documented education or training on the examination and verification that tissues removed from the resulting abortion procedure contained villi or fetal parts. Staff #2 stated, on 4/5/16 at 5:43 p.m., "Well (name of Staff #7) came and showed me how a couple of times and then the rest I learned from other staff members. I catch on quick...." When interviewed as to what he/she	T 080		

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T 080	Continued From Page 12 would do if he/she were unable to identify the POC (products of conception) Staff #2 stated, "I have not had a problem, but I guess I would let the doctor or someone else look at it..." Staff #1 stated on 4/5/16 at 6:30 p.m. that "All staff rotate through each assignment..." 2. The surveyor asked Staff #1 for documentation of the facility's fire drill and emergency preparedness inservice/training. Staff #1 submitted a notebook for review which documented the last fire drill practice as done in 2014, and stated "I haven't done one since I have worked here."	T 080		
T 090	12VAC5-412-180 F Personnel A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable. This RULE: is not met as evidenced by: Based on staff interview and facility document review, the facility staff failed to ensure all staff members had a personnel record which was contained within the employee file. The findings included: 1. When reviewing the list of staff employed by the facility and personnel records, Staff #7	T 090		

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T 090	Continued From Page 13 (Director of Operations) did not have a personnel file maintained at the facility. The surveyor requested the personnel file and credentials for Staff #7 in order to verify the education/training and qualifications as Staff #7 was documenting he/she was providing multiple areas of training for staff. Staff #1 stated on 4/5/16 at 1:50 p.m., that he/she did not have that (credentials) for Staff #7. On 4/5/16 at 2:05 p.m., Staff #1 stated that Staff #7 was on the phone and requested to speak to the surveyor. The surveyor spoke to Staff #7 who questioned: "Why do you need my information? The information you get is available to the public and I am not going to send you my personal information to be broadcast to the public." The surveyor informed Staff #7 that his/her personal information was not something that was available to the public, but that the surveyor needed to examine his/her credentials in order to verify his/her qualifications for the training of staff. Staff #7 stated, "I am a doctor so I am qualified." The surveyor questioned Staff #7 as to whether he/she had a license to practice in the State of Virginia. and Staff #7 stated, "I have passed all my tests but I do not have a license..." At 2:45 p.m. on 4/5/16 Staff #1 brought the survey team a faxed resume for Staff #7. No verification of education other than the resume was presented. The survey team reviewed documentation under the Department of Health Professionals website (www.dhp.virginia.gov) and no professional license was listed for Staff #7. 2. Review of the employee files for Staff # 1, 2, 3, 4, 5, and 6 revealed no current job description contained within the employee files.	T 090		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0015	A. BUILDING _____ B. WING _____	04/05/2016

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T 095	Continued From Page 14	T 095		
T 095	12VAC5-412-180 G Personnel Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors; 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. This RULE: is not met as evidenced by: Based on staff interview and facility document review, the facility staff failed to ensure each employee had a written job description contained in the personnel file. The findings included: Review of the personnel files for Staff 1 who stated he/she was previously the administrator, then the "acting administrator" revealed no job description for either job title. Staff #2, 4, and 5 who were identified as "Health Care Team Members" did not have a job description . Staff #	T 095		

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T 095	Continued From Page 15 4, identified as the Licensed Practical Nurse, did not have a job description in the personnel file which evidenced the staff were aware of their duties and responsibilities.	T 095		
T 100	12VAC5-412-180 H Personnel A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and 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 staff interview and facility document review, the facility staff failed to maintain a personnel record for each employee. The findings included: When reviewing the list of staff employed by the facility and personnel records, Staff #7 (Director of Operations) did not have a personnel file maintained at the facility. The surveyor requested the personnel file and credentials for Staff #7 in order to verify the education/training and qualifications as Staff #7 was documenting he/she was providing multiple areas of training for staff. Staff #1 stated on 4/5/16 at 1:50 p.m., that he/she did not have that (credentials) for Staff #7. On 4/5/16 at 2:05 p.m., Staff #1 stated that Staff #7 was on the phone and requested to speak to the	T 100		

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T 100	Continued From Page 16 surveyor. The surveyor spoke to Staff #7 who questioned: "Why do you need my information? The information you get is available to the public and I am not going to send you my personal information to be broadcast to the public." The surveyor informed Staff #7 that his/her personal information was not something that was available to the public, but that the surveyor needed to examine his/her credentials in order to verify his/her qualifications for the training of staff. Staff #7 stated, "I am a doctor so I am qualified." The surveyor questioned Staff #7 as to whether he/she had a license to practice in the State of Virginia. and Staff #7 stated, "I have passed all my tests but I do not have a license..." At 2:45 p.m. on 4/5/16 Staff #1 brought the survey team a faxed resume for Staff #7. No verification of education other than the resume was presented. The survey team reviewed documentation under the Department of Health Professionals website (www.dhp.virginia.gov) and no professional license was listed for Staff #7.	T 100		
T 190	12VAC5-412-220 A Infection Prevention The abortion facility shall have an infection prevention plan that encompasses the entire abortion 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.	T 190		

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T 190	Continued From Page 17 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. This RULE: is not met as evidenced by: Based on facility document review and staff interview, the facility staff failed to ensure the infection control/ prevention policies and procedures were reviewed at least annually by the facility administrator and appropriate members of the clinical staff. The findings included: On 4/4/16 at 5:00 p.m., the surveyor reviewed the policy and procedure manual containing the Infection Control/Prevention policy/plan which was presented by Staff #1. The Policy and Procedure Manual contained a document signed by (Governing Body) which evidenced the manual had not been updated/reviewed since November 12, 2013. When Staff #1 was asked about the Governing Body meetings and Quality and policy reviews, he/she stated, "I don't know. I have only been at one meeting and that was the one we had by phone today."	T 190		

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T 195	12VAC5-412-220 B Infection Prevention 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 indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-borne 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.	T 195		

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T 195	Continued From Page 19 This RULE: is not met as evidenced by: Based on observations, staff interview and facility document review, the facility staff failed to ensure proper infection control practices were followed and adhered to in relation to: Cleanliness of patient areas and equipment, proper use of personal protective equipment and sanitary use of patient supplies and failed to ensure that procedures to prevent transmission of community-acquired infection within the facility were followed. The findings included: 1. Upon entrance to the facility on 4/4/16 at 2:00 p.m., the survey team observed the patient waiting area to be unclean. The carpet was dirty and had large dark stains in multiple areas. There was debris on the floor and black smudges on multiple areas on the walls. There were fifteen (15) chairs which were made of a black strap type cloth/elastic type material that could not be adequately cleaned or disinfected. Nine (9) metal folding chairs were available with cloth seats and back rest, several of which were stained and dirty and could not be adequately cleaned nor disinfected. Further observations made during a tour of the facility patient care areas revealed the following: In Exam Room one (1), also the procedure room (where the surgical procedures were performed), the cabinet doors were taped together with a micropore tape which was adhered to the cabinet doors. When the surveyor attempted to open the cabinet to view the contents, the door fell off. In the bottom of this cabinet was a blue chux (pad) which had debris and dried brown material (betadine) that had leaked all over the pad. There was a box of exam gloves and two boxes of	T 195		

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T 195	Continued From Page 20 tissues which had brown splatters dried on the packaging. The ultrasound machine in this room was dusty and contained areas of debris which was yellowish and brown in color. The bottom of the machine which was on casters, was dirty and had dried liquid which had collected dust and debris. The area where the ultrasound probe was kept had a wadded paper towel which appeared to have dried material on it. The keyboard was also dusty and contained debris and dried splatters of some foreign material. In the room designated as the "sterilization room" (where instruments were taken for sterilization and packaging), the monthly cleaning log for the autoclave machine (the machine used to sterilize instruments used during the surgical procedure) had the last cleaning date recorded as "January 19, 2016". There were surgical instruments inside the autoclave that had not been cleaned and the door was ajar. Staff #1 stated "I did not have any distilled water." In a room identified as the "physician's office" the surveyors observed blue surgical scrubs rolled up lying on a cabinet. At 6:15 p.m., the physician arrived and "dressed" and the rolled up scrubs were gone, and the physician was observed wearing blue scrubs. There was yellow liquid on the wall which appeared to be in a splatter pattern behind the desk near a plastic cart where various medications were kept. On 4/5/16 at approximately 2:00 p.m., this "yellow" material was identified by Staff #1 as "Methotrexate" (a medication used to induce abortion for the medical procedure) which had "accidentally been sprayed onto the wall when it was drawn up." On 4/5/16 at 5:00 p.m., the survey team observed the blue scrubs lying on the side cabinet in the physicians	T 195		

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T 195	Continued From Page 21 office. When the physician arrived and "dressed" for procedures, the scrubs were gone. Surgical procedures were performed on both days and the physician did not wear any other covering during all procedures performed other than the blue scrubs. During the tour and subsequent observations on 4/4/16 the survey team did not observe any other scrubs stored at the facility and upon arrival to the facility on 4/4/16, the physician was not observed carrying in any scrubs. On 4/5/16 the surveyor accompanied Staff #2 in the "pathology room" in order to observe the process of receipt and examination of the products of conception (POC) and handling/cleaning of surgical instruments. Staff #2 donned a yellow PPE (personal protective equipment) gown, goggles and gloves. After completing the examination, weighing and packaging of the POC, Staff #2 removed the gloves, goggles and gown. Present on the gown was blood stains. Staff #2 held up the gown and looked at it and proceeded to hang it on the back of the door for future use stating "Oh it's not that bad", referring to the amount of blood on the gown. The policy and procedure regarding the cleaning of the autoclave documented, "Cleaning of Autoclave: "...this task shall be performed monthly." The facility had no specific policies or procedures regarding cleaning. Staff #1 stated, "We (staff) clean the (patient care) equipment and the building housekeeping cleans the floors and bathrooms..." 2. On 4/4/2016 at 3:45 PM the surveyors observed a plastic basket of instruments sitting on a wire rack in the sterilization room. Staff #1 was	T 195		

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T 195	Continued From Page 22 asked whether the instruments were clean, he/she stated "They are disinfected but not sterilized, they need to be repackaged. We usually sterilize them at the end of every day, but we didn't sterilize those on Saturday because there was no distilled water for the autoclave." When asked where the distilled water was at that time, he/she stated "it's in my car." On 4/4/2016 at 3:50 PM, the surveyors observed a tray on the counter in the sterilization room which contained sterilization integrators for use in the autoclave. Steam integrators detect critical sterilization parameter failures for exposure time, temperature and steam quality. Fourteen of the sterilization integrators available for use Expired 10/20/2015. At 5:45 PM on 4/4/2016 the surveyors observed paper towels and ultrasound gel stored under the sink of exam room 2. At 6:00 PM on 4/5/2016 the surveyor, after talking with Patient #6 and obtaining permission, entered exam room 1 to observe a surgical procedure. Staff #1 poured 2 Misoprostol tablets into the cap of the bottle and placed cervical swabs into a bottle of Monsel's solution in preparation for the procedure, while Staff #6 spoke with the patient. Staff #6 told Patient #6 that because of a slightly lower than normal hematocrit (the proportion of total blood volume that is composed of red blood cells), she was at increased risk of death and or complications related to the procedure. Patient #6 stated "I want to call my husband," and picked up her cell phone. Staff #6 asked if the patient's husband was in the waiting room, and she said, "No, he is in the car." Staff #6 told Staff #1 and Patient #6 he would "talk to (patient's name) and husband in his/her office." While preparing for the procedure, Staff #1 poured 2 Misoprostol tablets into the cap of the bottle, and placed 2 cervical swabs into a multi-dose bottle of Monsel's	T 195		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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T 195	Continued From Page 23 solution. Staff #1 then poured the 2 Misoprostol tablets back into the bottle but left the swabs sitting in the Monsel's solution. The facility staff exited the exam room, leaving the inspector with the patient. At 6:10 PM on 4/5/2016 while standing outside the patient bathroom the surveyor heard Staff #1 and 2 having a discussion about the toilet in the patient bathroom being stopped up. Staff #1 stated "that happens all the time in that bathroom." The surveyor observed Staff #2 don gloves, retrieve a plunger from the staff bathroom, go into the patient bathroom and use the plunger to unstop the toilet. Staff #2 then walked back down the hallway to the staff bathroom carrying the plunger with gloves on, he/she put down the plunger, removed the gloves, and cleaned his/her hands with hand sanitizer. Staff #2 was then approached by Staff #6 and asked if he/she wanted to go into the next procedure to translate for a Spanish speaking client, or whether he/she wanted to assist and translate. Staff #2 stated "It will be easier to translate and let (Staff #1's name) assist." Staff #2 then went into exam room 1 where he/she stood beside Patient #7 during the surgical procedure to translate and also held the patient's hand during the procedure. Staff #2 did not change scrubs or don PPE prior to entering the exam room where the procedure took place. On 4/5/2016 at 6:25 PM the surveyor observed the surgical procedure for Patient #7. The surveyor observed Staff #1 setting up while Staff #6 was talking with Patient #7. He/she poured 2 Misoprostol tablets into the cap of a multi dose bottle leaving the bottle open and sitting on the counter during the procedure until pouring the tablets from the cap into the gloved hand of Staff #6. Staff #6 , while wearing gloves visibly soiled with blood, removed cervical swabs which had been sitting in the multi-dose bottle of Monsel's solution since 6:00 PM where they were placed	T 195		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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T 195	Continued From Page 24 preparation for a procedure which was canceled. On 4/5/2016 at approximately 6:30 PM, the surveyor observed that exam room 1, where a surgical procedure was being performed, did not have a sink available for handwashing. While performing the surgical procedure, Staff #1's gloves were observed to be visibly soiled with blood. After the procedure, Staff #1 removed his/her gloves and used hand sanitizer. The surveyor did not observe Staff #1 wash his/her hands with soap and water after exiting the procedure room. On 4/5/2016 at approximately 6:35 PM the surveyor observed Staff #1 clean exam room 1 after Patient #7's surgical procedure. The surveyor noted that the rolling exam light which was touched by Staff #6 while wearing contaminated gloves during the procedure was not cleaned, the ultrasound machine sitting in the room beside the patient was not cleaned, neither the can of Hurricane numbing spray nor the bottle of Monesl's solution were wiped off after having been used, and only the top of the vacuum suction machine was cleaned.	T 195		
T 200	12VAC5-412-220 C Infection Prevention Written policies and procedures for the management of the abortion 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 driers); 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.,	T 200		

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T 200	Continued From Page 25 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 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;	T 200		

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T 200	Continued From Page 26 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 abortion facility as recommended or required by the department. This RULE: is not met as evidenced by: Based on observation, the facility staff failed to ensure the availability of sinks for proper handwashing, proper cleaning of environmental surfaces, proper disinfection of equipment, ability to verify the recommended level of sterilization was achieved and periodic and ongoing maintenance of equipment. The findings included: 1. The surveyors observed multiple pieces of equipment being used for patient care which included the following: Exam light (2) Exam Table (2) Suction Machine -gomco recovery room Pulse oximeter AED/Defibrillator (used in the event of a cardiac arrest) Datascope-vital signs monitor Heating pad (2) Autoclave Centrifuge Gel warmer Vacuum Suction machine in procedure room used during the surgical procedures All of the equipment listed above with the	T 200		

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VIRGINIA HEALTH GROUP	8316 ARLINGTON BLVD, SUITE 220 FAIRFAX, VA 22031

(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 200	Continued From Page 27 exception of the Suction machine used in the procedure room for surgical procedures had not had an annual preventative maintenance check since January 2015 as per a document presented to the survey team by Staff #1 on 4/5/16 at 4:10 p.m.. The vacuum suction machine used for the surgical procedures contained a sticker which documented no preventative maintenance check since 2012. 2. The survey team requested information for the facility pest control and prevention plan. Staff #1 stated, "We do not have one. The building has one, but it is for the whole building, not just this area. 3. At 2:30 PM on 4/4/2016 the surveyors observed that the ultrasound machine in exam room one (1) was stained, and the keyboard had dried particles of debris between the keys. On 4/4/2016 at 3:45 PM the surveyors observed a plastic basket of instruments sitting on a wire rack in the sterilization room. Staff #1 was asked whether the instruments were clean, he/she stated "They are disinfected but not sterilized, they need to be repackaged. We usually sterilize them at the end of every day, but we didn't sterilize those on Saturday because there was no distilled water for the autoclave." When asked where the distilled water was at that time, he/she stated "It's in my car." On 4/4/2016 at 3:50 PM, the surveyors observed a tray on the counter in the sterilization room which contained sterilization integrators for use in the autoclave. Steam integrators detect critical sterilization parameter failures for exposure time, temperature and steam quality. Fourteen of the sterilization integrators available for use Expired 10/20/2015.	T 200		

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T 200	Continued From Page 28 At 6:00 PM on 4/5/2016 the surveyor, after talking with Patient #6 and obtaining permission, entered exam room one (1) to observe a surgical procedure. Staff #1 poured 2 Misoprostol tablets into the cap of the bottle and placed cervical swabs into a bottle of Monsel's solution in preparation for the procedure, while Staff #6 spoke with the patient. Staff #6 told Patient #6 that because of a slightly lower than normal hematocrit (the proportion of total blood volume that is composed of red blood cells), she was at increased risk of death and or complications related to the procedure. Patient #6 stated, "I want to call my husband," and picked up her cell phone. Staff #6 asked if the patient's husband was in the waiting room, and she said "No, he is in the car." Staff #6 told Staff #1 and Patient #6 he would "talk to (patient's name) and husband in his/her office." While preparing for the procedure, Staff #1 poured 2 Misoprostol tablets into the cap of the bottle, and placed 2 cervical swabs into a multi-dose bottle of Monsel's solution. Staff #1 then poured the 2 Misoprostol tablets back into the bottle but left the swabs sitting in the Monsel's solution. The facility staff exited the exam room, leaving the inspector with the patient. On 4/5/2016 at approximately 6:30 PM, the surveyor observed that exam room 1, where a surgical procedure was being performed, did not have a sink available for handwashing. While performing the surgical procedure, Staff #1's gloves were observed to be visibly soiled with blood. After the procedure, Staff #1 removed his/her gloves and used hand sanitizer. The surveyor did not observe Staff #1 wash his/her hands with soap and water after exiting the procedure room. On 4/5/2016 at approximately 6:35 PM the inspector observed Staff #1 clean exam room 1 after Patient #7's surgical procedure. The inspector noted that the rolling exam light which	T 200		

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T 200	Continued From Page 29 was touched by Staff #6 while wearing contaminated gloves during the procedure was not cleaned, the ultrasound machine sitting in the room beside the patient was not cleaned, and only the top of the vacuum suction machine was wiped down.	T 200		
T 210	12VAC5-412-220 E Infection Prevention The abortion facility shall develop, implement and maintain policies and procedures for the following patient education, follow up, and reporting activities: 1. A procedure for surveillance, documentation and tracking of reported infections; and 2. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90), including outbreaks of disease. This RULE: is not met as evidenced by: Based on record review, and staff and patient interview, the facility staff failed to ensure that the facility implemented policies and procedures for surveillance of reportable infections. Findings include: 1. A review of the medical record for Patient #1 included documentation on the patient information form that he/she had a history of chlamydia. The CDC (Centers for Disease Control and Prevention) screening recommendations for STI's (sexually transmitted infections), including chlamydia states "sexually active women aged 25 years and older is recommended if a patient is at increased risk". ACOG (The American College of	T 210		

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T 210	Continued From Page 30 Obstetricians and Gynecolologists) FAQ-009 (frequently asked questions)-gynecologic problems- lists previous infection with an STI as an increased risk factor for acquiring an STI. During an interview with Staff #2 about what STI testing the facility offered on 4/4/2016 at 3:50 PM, he/she stated "We don't offer STI testing. We refer them out for that. The doctor would decide if they need that, if they are high risk, they might send them to be tested/treated before the procedure." During an interview on 4/5/2016 at 5:45 PM with Patient #6 regarding whether she was offered STI testing by facility staff , she stated "No, they just told me my blood was ok. I signed a lot of papers, they didn't ask me about testing." The facility's STI Screening Consent Form states that for patients who choose to undergo STI testing lab fees could cost between $50.00 and $150.00 per test in addition to $45.00 per test for (name of facility's) professional fee, plus the cost of supplies, for performing the tests, receiving the results, and counseling." There was no documentation that patients received information about STI testing through low cost or free clinics.	T 210		
T 235	12VAC5-412-230 E Patient Services; Patient Counseling The abortion facility shall offer each patient seeking an abortion, in a language or manner she understand, appropriate counseling and instruction in the abortion procedure and shall develop, implement and maintain policies and procedures for the provision of family planning and post-abortion counseling to its patients. This RULE: is not met as evidenced by: Based on a patient interview, the facility staff failed	T 235		

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T 235	Continued From Page 31 to ensure that a patient seeking an abortion procedure was counseled in a language or manner she understood. Findings include: 1. At 6:00 PM on 4/5/2016 the surveyor, after talking with Patient #6 and obtaining permission, entered exam room one (1) to observe a surgical procedure. Staff #6 asked the patient if she consented to the procedure, and told her that because of a slightly lower than normal hematocrit (proportion of total blood volume that is composed of red blood cells), she was at increased risk of death and or complications. Patient #6 stated "I want to call my husband," and picked up her cell phone. Staff #6 asked if the patient's husband was in the waiting room, and she said "No, he is in the car." Staff #6 told Staff #1 and Patient #6 he would "talk to (patient's name) and husband in his/her office." The facility staff exited the exam room, leaving the inspector with the patient. Patient #6 looked at the surveyor and stated, "Can you tell me what he was talking about?" The surveyor explained that he/she was not an employee of the facility and could not explain the procedure/complications, but that Staff #6 would talk with both she and her husband when he arrived." The surveyor interviewed Patient #6 and asked if she received counseling about the procedure and what to expect during and after the procedure, and she stated, "No, they just told me my blood was ok and I signed a lot of papers." 2. Staff #6 spoke with Patient #6 and her husband about possible complications related to a low hematocrit and counseled them that she had time to think about what she wanted to do and could reschedule the procedure if she chose to do so. While speaking to Patient #6, her husband	T 235		

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T 235	Continued From Page 32 translated in their native language so that Patient #6 understood what Staff #6 was saying. 3. At 6:20 PM the surveyor interviewed Staff #1 and Staff #6 as to whether Patient #6 was aware of the timeframe she had in which to make a decision. Staff #1 stated "I don't know. I believe on the phone they tell them in Virginia they have until 12 weeks, but I'm not sure if she knows that." Staff #6 stated, "I would assume she has a base knowledge about things like that, but no, I can't say that. I know she has 4 to 5 weeks to make a choice."	T 235		
T 250	12VAC5-412-240 B Medical Testing and Laboratory Services Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) (42 CFR Part 493). 1. Facilities for collecting specimens shall be available on site. 2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA-88 and shall be performed in compliance with CLIA-88 standards. 3. All laboratory supplies shall be monitored for expiration dates, if applicable, and disposed of properly. This RULE: is not met as evidenced by: Based on facility document review and review of outside resources, the facility staff failed to ensure the person who was named as the laboratory	T 250		

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T 250	Continued From Page 33 director met the qualifications of a director. The findings included: During the survey conducted 4/4 through 4/5/16 the survey team examined the CLIA (Clinical Laboratory Improvement Amendments) document for Laboratory Services. The document listed (Name identified as Staff # 8 for identification purposes) as the laboratory director with a title of MD (physician). Upon review of the facility personnel records and staff list, Staff #8 was not employed at the facility. Staff #1 was interviewed previously (4/4/16 at 2:15 p.m.) as to who the medical director was for the facility and he/she first stated (name of Staff #8) but then said it was Staff #6. The surveyors accessed the Department of Health Professionals for the State of Virginia and were unable to locate a license for Staff #8. According to the regulations at 493.1405 for CLIA regarding the qualifications for laboratory director, the following was evidenced: The laboratory director must be(b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications	T 250		

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T 250	Continued From Page 34 that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; and 493.1407: (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. If the director cannot practically provide personal, on-site supervision it must be demonstrated that the director: · Provides direction and consultation by telephone or electronic means (e.g. email, text message or fax), as necessary; or · Delegates to qualified personnel specific responsibilities as provided in the regulations. The survey team was unable to validate the credentials of the laboratory Director (Staff #8) as the personnel file was not accessible/on site and there was no evidence that any person had been delegated to fulfill the responsibilities.	T 250		
T 255	12VAC5-412-240 C Medical Testing and Laboratory Services All tissues removed resulting from the abortion procedure shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy, and referred appropriately. This RULE: is not met as evidenced by:	T 255		

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T 255	Continued From Page 35 Based on staff interview and facility document review, the facility staff failed to ensure each staff member received necessary training to provide appropriate service to patients. The findings included: Upon review of the personnel records for staff, there was no documentation that the staff had received documented education or training on the examination and verification that tissues removed from the resulting abortion procedure contained villi or fetal parts. Staff #2 stated, on 4/5/16 at 5:43 p.m., "Well (name of Staff #7) came and showed me how a couple of times and then the rest I learned from other staff members. I catch on quick...." When interviewed as to what he/she would do if he/she were unable to identify the POC (products of conception) Staff #2 stated, "I have not had a problem, but I guess I would let the doctor or someone else look at it..." Staff #1 stated on 4/5/16 at 6:30 p.m. that "All staff rotate through each assignment..."	T 255		
T 315	12VAC5-412-260 C Administration, Storage, Dispensing of Drugs Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10. This RULE: is not met as evidenced by: Based on observation and staff interview, the facility staff failed to ensure drugs maintained in	T 315		

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T 315	Continued From Page 36 the facility were not expired and properly stored with access limited to authorized personnel only. The findings included: 1. On 4/4/16 at 2:45 p.m. the surveyors observed in the "Recovery Room" a cabinet which was unlocked and contained the following: Diphendydramine 50mg (milligram) vial three (3) vials which had the following expiration dates: 2 vials 12/2013, 1 vial 10/2014. Naloxone 0.4mg/ml (milligrams per milliliter) 1 ml vial (4) with the expiration date 1 March 2015. Digoxin 500mcg.2ml (micrograms per milliliter) 2 ml ampoule (0.5mg/2ml) expired 12/2014. Clonidine 0.1mg tablet (2) expiration 1/2014 Furosemide 20mg vial 10mg/ml expired 1 August 2014 Sodium Bicarb 8.4% (2) expired 1 May 2014 Diazepam 10mg/2ml injection expired 1 May 2014 Atropine Sulfate 1mg syringe expired 1 May 2015 ProAir HFA Albuterol Inhaler 90mcg (micrograms) per activation expired September 2014 Also contained in the unlocked cabinet were: Acetaminophen 500mg bottle (opened and not dated as to when opened) Metronidazole tablets 500mg 50 tablet bottle opened 8/18/15 Ibuprofen 800mg tablets 500 tablet bottle opened 2/6/16 Doxycycline 100mg tablets 500 tablet bottle opened 1/19/16 On 4/5/16 at 3:15 p.m., the surveyors observed the cabinet had been locked, however the doors still opened with enough space to allow a hand to be inserted into the cabinet where any medications stored could be easily accessed.	T 315		

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T 315	Continued From Page 37 Diphenhydramine (Bendaryl) - an antihistamine used for the treatment of allergic reactions. Naloxone is used to treat a narcotic overdose in an emergency situation. Digoxin helps make the heart beat stronger and with a more regular rhythm. Clonidine is used to treat hypertension (high blood pressure). Furosemide (Lasix) treats fluid retention (edema) and is also used to treat high blood pressure (hypertension). Soduim Bicarb buffers excess hydrogen ion concentration, raises blood pH and reverses the clinical manifestations of acidosis. Used to reverse acidosis in an emergency situation. Diazepam- is used to treat anxiety disorders, alcohol withdrawal symptoms, or muscle spasms. Diazepam is sometimes used with other medications to treat seizures. It is a schedule IV (four) controlled substance. Atropine Sulfate is used to treat bradyasystolic cardiac arrest. ProAir HFA is indicated for the treatment or prevention of bronchospasm. Acetaminophen (Tylenol) an analgesic for mild to moderate pain relief. Ibuprofen- a non-steroidal antiinflammatory medication used to treat mild to moderate pain. Doxycycline- an antibiotic. Metrodinazole (Flagyl) an antibiotic. Medication list per www.drugs.com accessed 4/8/16 at 11:41 a.m. In the "physician's office" the surveyors observed Lidocaine for injection (multiple vials), Pitocin and Methotrexate on a plastic cart. The door to the office could not be locked as there was tape over the latch preventing the door from locking. Staff #2 stated, "That door doesn't lock. It's broken."	T 315		

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T 315	Continued From Page 38 2. At 2:15 PM on 4/4/2016, the surveyors observed vials of Lidocaine and Pitocin sitting on top of a plastic rolling cabinet behind a desk in the physician's office. The latch on the door to the office was was broken and the door could not be locked. 3. At 2:30 PM on 4/4/2016, the surveyor observed a key hanging in a door between the reception area and the nursing station where a printer and blank paperwork sat on a counter. The surveyor entered the door with Staff #1 and observed office supplies and multiple bottles of Misoprostol 100 mg (milligram) tablets with "prescription only" written on the label. The key remained in the door throughout the inspection. 4. During the course of the physical plant tour on 4/4/2016 at 2:50 PM, the following observations were made by the surveyors in the laboratory area: -Methergine (4 vials) stored in the refrigerator with blood samples and lab testing controls. -6 prefilled syringes of Hepatitis B vaccine which expired 2/2016 -Tubersol PPD derivative with an open date of 12/5/2015 written on the box, and a manufacturer's expiration date of 12/17/2015. -An unlocked drawer of the desk in the laboratory room contained an open container of Methotrexate which was not labeled with an open date. 5. In a cabinet of exam room 1 where procedures where were performed the following expired items were observed by the surveyors to be available for use on 4/5/2016 at 3:30 PM: -2 bottles of Ferric Subsulfate solution expired 10/2015 and 3/12/16.	T 315		

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T 315	Continued From Page 39 -A bottle of Misoprostol 200 mg with "expires 2/26/16" written on the label was in the cabinet of exam room 1 where procedures were performed. -Betadine in a bottle labeled ultrasound gel with "exp 12/2015 written handwritten in black. --(2) 23 gauge 3/4 inch butterfly needles expired 8/2015. - (1) 22 gauge angiocath expired 9/2014. 6. The surveyors observed (2) ammonia inhalants expired 9/2014 were lying on top of the counter in exam room 1 at 3:30 PM on 4/5/2016. Misoprostol is a medication used to cause an abortion. Methergine is a medication used to control bleeding after an abortion procedure. Methotrexate is a chemo (cancer) therapy drug used in this case to induce abortion. Lidocaine is a medication used to numb tissue. Ferric Subsulfate is a liquid used to stop bleeding of tissues. Tubersol PPD is a medication used to test for tuberculosis (TB). Pitocin is a medication used to induce contraction of the uterus, in this case to induce abortion. (www.drugs .com accessed 4/12/16 at 12:24 p.m.)	T 315		
T 320	12VAC5-412-260 D Administration, Storage, Dispensing of Drugs The mixing, diluting or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18 VAC 85-20-400 et seq.). This RULE: is not met as evidenced by: Based on observation, the facility staff failed to ensure medications were prepared for administration in a sanitary environment.	T 320		

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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 320	Continued From Page 40 The findings included: 1. On 4/4/16 at 2:00 p.m. the survey team entered the facility and were put into the "Physician's office" in order to have a space in which to work. The desk in the office was not clean. It contained debris, smudges of foreign dried material and the surface was not intact (worn off shellac/lacquered finish). The surveyors used hand sanitizer in order to clean the desk in order to work. When the provider arrived at approximately 6:00 p.m., the survey team was asked to move to another space in which to work as the provider "needed the office to work and see patients and change". When the surveyor returned to the office to finish collecting items, the provider was sitting at the desk, with no barrier on the desk, drawing up multiple syringes of medications and placing them together, aside, on the surface of the desk. It was also observed that none of the syringes had been labeled as to their contents and they remained on the desk surface. Staff #1 stated on 4/6/16 at 6:50 p.m. when asked if there were medications kept anywhere else in the facility, "No, the physician keeps his medications in his office and draws them up there." 2. The surveyor observed dried yellow splatter on the wall near a sharps container in the laboratory area. An interview was held with Staff #1 at 4:10 PM on 4/5/2016 regarding the yellow splatter, and he/she stated, "That's the Methotrexate. When the doctor tops it off he/she puts the cover over the end of the needle but is messy sometimes and it shoots out of the syringe and gets on stuff." Staff #1 was asked what his/her knowledge of Methotrexate and how it works, he/she stated "It stops cell growth."	T 320		

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T 320	Continued From Page 41 3. The MSDS (material safety data sheet) for Methotrexate gives the following guidance for general handling: "Avoid breathing vapor or mist. Avoid contact with eyes, skin, clothing. When handling use appropriate PPE (personal protective equipment) (see section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal methods to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems, or other equivalent controls".	T 320		
T 330	12VAC5-412-270 Equipment and Supplies An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include: 1. A bed or recliner suitable for recovery; 2. Oxygen with flow meters and masks or equivalent; 3. Mechanical suction; 4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; 5. Emergency medications, intravenous fluids, and related supplies and equipment; 6. Sterile suturing equipment and supplies; 7. Adjustable examination light;	T 330		

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T 330	Continued From Page 42 8. Containers for soiled linen and waste materials with covers; and 9. Refrigerator This RULE: is not met as evidenced by: Based on clinical record review and facility document review, the facility staff failed to maintain adequate medical equipment for the treatment of patients. Sterile suturing equipment and supplies were not available when a patient experienced prolonged bleeding after a procedure and the patient had to be transported to the local emergency department for care. The findings included: In February 2016, Patient #2 had a surgical abortion performed at the facility. Documentation in the clinical record revealed the patient experienced prolonged bleeding and had to be transported to the local emergency department for treatment. Further review of the record revealed a discussion with the facility provider and the "on call" emergency room provider which documented, "(time) laceration on internal cervix os (os is the part of the cervix that can be seen from inside the vagina during a gynecologic examination is known as the ectocervix. An opening in the center of the ectocervix, known as the external os, opens to allow passage between the uterus and vagina) sutured and patient sent home..." Review of the facility adverse occurrence log revealed "no sutures were available..." on that date but that the facility had obtained the supplies.	T 330		

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T 335	Continued From Page 43	T 335		
T 335	12VAC5-412-280 Emergency Equipment and Supplies An abortion facility shall maintain medical equipment, supplies and drugs appropriate and adequate to manage potential emergencies based on the level, scope and intensity of services provided. Such medical equipment, supplies and drugs shall be determined by the physician and shall be consistent with the current edition of American Heart Association's Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Drugs shall include, at a minimum, those to treat the following conditions: 1. Cardiopulmonary arrest; 2. Seizure; 3. Respiratory distress; 4. Allergic reaction; 5. Narcotic toxicity; 6. Hypovolemic shock; and 7. Vasovagal shock. This RULE: is not met as evidenced by: Based on an audit of the facility's emergency drugs and equipment and staff interview, the facility staff failed to ensure that appropriate emergency medical equipment, supplies, and drugs were maintained adequately to manage potential emergencies. Findings include: 1. The facility's emergency box was audited on	T 335		

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T 335	Continued From Page 44 4/5/2016 at 3:00 PM and it was noted that the following medications and supplies were expired: -Diphenhydramine 50 mg/ml (milligrams per milliliter) injectable 4 vials expired 7/2015 -Procainamide HCl 1gm/2ml (grams per milliliter) 1 vial expired 9/1/2015 -Sodium Bicarb 2 syringes -(2) 20 gauge angiocaths expired 11/2015 -(1) 22 gauge angiocath expired 9/2015 -Sodium Bicarb 8.4% 50 meq (millequivalents) expired 12/1/2015 2. The surveyor audited the facility's emergency cart located in the recovery room on 4/5/2016 at 3:00 PM and noted the following: - It was noted that the last PM (preventative maintenance) sticker on the AED (automated external defibrillator) was dated 1/12/2015. -The adult monophasic or biphasic pacing defibrillator electrodes available for use had an expiration date of 12/2013. -3 packs of EKG (electrocardiogram) electrodes available for use expired 1/2016. -The PM on the pulse oximeter was last done on 1/12/2015. -The PM on the EKG machine was last done on 1/12/2015. -The PM on the data scope monitor was last done on 1/12/2015. 3. A first aide box with bandaids and neosporin contained a single dose packet of Neosporin antibiotic ointment expired 8/2013. 3. The surveyor interviewed Staff #1 and Staff #3 and asked how often staff checked the emergency supplies and medications, and whether there was a log for documentation of the checks on 4/5/2016 at 5:30 PM. Staff #1 stated "There is no log for checking the emergency equipment." Staff #3 stated, "I haven't checked the emergency	T 335		

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T 335	Continued From Page 45 equipment since I have been here." The surveyor asked Staff #3 to demonstrate how to check the AED to assure it was working properly. Staff #3 turned the AED on, and it said "Place electrodes, replace battery."	T 335		
T 355	12VAC5-412-300 Health Information 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 be limited to the following: 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses' progress notes, h. Condition at time of discharge, i. Patient instructions, preoperative and postoperative; and j. Names of referral physicians or agencies. 6. Any other information required by law to be maintained in the health information record.	T 355		

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T 355	Continued From Page 46 This RULE: is not met as evidenced by: Based on review of 6 (six) clinical records, the facility staff failed to ensure an accurate and complete clinical record was maintained for Patient # 1, 2, and #3. The findings included: 1. For Patient #2, the clinical record did not contain any documentation of the "pathology report" documenting the examination of the Products of Conception (POC) that were removed during the procedure. There was no documentation of the medication "hurricane topical" which is a numbing spray which Staff #6 stated was "used on all patients". The patient had to be sent to the emergency room due to prolonged bleeding. There was no documentation of when the ambulance was called, or when the patient left the facility, condition at discharge or discharge vital signs. There was no "nursing notes" documentation of the events. Corrections in the chart were made by "scribbling" through the information or marking over it with a darker correction. 2. For Patient #3 there were no pre-op vital signs documented. Corrections in the chart were made by "scribbling" through the information or marking over it with a darker correction. There was no documentation of the medication "hurricane topical" which is a numbing spray which Staff #6 stated was "used on all patients". 3. A review of Patient #1's medical record included documentation that he/she was allergic to Aspirin. The abortion procedure records dated 11/14/2015 included medication orders for administration of Ibuprofen 800 mg or Acetaminophen 1,000 mg by mouth as needed for pain in recovery. Documentation on the recovery	T 355		

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T 355	Continued From Page 47 room record was that Patient #1 was administered Ibuprofen 800 mg (milligrams) at 8:51 PM. FDA (food and drug administration) postmarket drug safety information for patients and for providers for Ibuprofen includes the following: "Warnings: Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, and blister". An interview with Staff #6 on 4/5/2016 at at approximately 7:00 PM regarding whether patients who have Aspirin allergies are specifically questioned about allergies to Ibuprofen of other NSAID's (non-sterodial anti-inflammatory drugs), he/she stated, "Yes, but how often does that reaction happen due to Aspirin allergy? No, we don't usually ask if they have taken Ibuprofen if they have an Aspirin allergy." The abortion procedure record dated 11/14/2015 for Patient #1 documented that the procedure time started at 9:34 PM and the procedure time ended at 9:44 PM. Documentation of care on Patient #1's RR (recovery room) record started at 8:45 PM, ended at 9:25 PM, and the patient's discharge time was documented as 9:49 PM. The time entries on the RR record had been written over and were difficult to read. Staff #1 and #6 were interviewed on 4/5/2016 at approximately 7:00 PM about the inconsistent time documentation, and Staff #6 stated, "I noted my signature as 8:45 at the end of the abortion procedure note, and that lines up with what is on the recovery room notes corrected time. The clock must not have been right-when does the time change?" Staff #1 stated, "The procedure start and end time was just documented wrong, the time on the recovery room record is right." At approximately 7:30 PM on 4/5/2016 Staff #1,	T 355		

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T 355	Continued From Page 48 when questioned about the use of Hurricane numbing spray for surgical procedures, stated "We use Hurricane on everybody." Operative reports for Patient 4 and Patient 1 lacked documentation of the application of Hurricane numbing spray.	T 355		
T 360	12VAC5-412-310 Records Storage Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.). This RULE: is not met as evidenced by: Based on observations and staff interview, the facility staff failed to ensure that medical records were stored according to applicable federal and state laws. Findings include: 1. At 2:40 PM on 4/4/2016 the surveyor opened a door in the patient bathroom and observed boxes of patient medical records being stored in boxes. One of the boxes had the top off, was lying on its side, and records were spilling out of the side of the box. The record storage area was accessible to anyone who entered the patient bathroom. 2. At 3:00 PM on 4/4/2016 the surveyor opened an unlocked door at the end of the hall between exam room 2 and the office where patient counseling was conducted and observed boxes of patient records.	T 360		

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T 360	Continued From Page 49 3. At 7:00 PM on 4/4/2016 while speaking with Staff #1 about patient record reviews and information which the surveyors would need to access, he/she was asked about the boxes of records that had been observed in the unlocked closets in the patient bathroom and in the hallway. Staff #1 stated, "That's where we keep the records. They are in boxes by date and by patient's names alphabetically."	T 360		
T 400	12VAC5-412-340 A Disaster Preparedness Each abortion facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The policies and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster. This RULE: is not met as evidenced by: Based on staff interview and review of the facility's documentation of emergency practices, the facility staff failed to ensure that employees received training in the evacuation of all occupants in order to protect them from hazards in the event of a fire or other disaster. Findings include: 1. The surveyor asked Staff #1 for documentation of the facility's fire drill and emergency preparedness inservice/training. Staff #1 submitted a notebook for review which documented the last fire drill practice as done in 2014, and stated, "I haven't done one since I have worked here."	T 400		

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T 410	Continued From Page 50	T 410		
T 410	12VAC5-412-350 A Maintenance The abortion facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization. This RULE: is not met as evidenced by: Based on observation, the facility staff failed to maintain patient areas in good repair. The findings included: Upon entrance to the facility on 4/4/16 at 2:00 p.m., the survey team observed the patient waiting room to have chipped and peeling paint on the walls and and panel boards hanging loose around an air conditioning unit. There was a piece of the countertop missing from a small ledge which exposed sharp edges. The area was unclean. There was graffiti scratched into the wall on the left side of the room and black smudges on the paint in multiple places on the walls of the entire room. There was a plastic type vase containing some artificial flowers and decorative pebbles on the receptionist window ledge which was cracked allowing some of the pebbles to fall onto the floor. In Exam Room 1 (one), also the procedure room (where the surgical procedures were performed), the cabinet doors were taped together with a micropore tape which was adhered to the cabinet doors. When the surveyor attempted to open the	T 410		

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T 410	Continued From Page 51 cabinet to view the contents, the door fell off. Please refer to 12VAC5-412-220 (0195) for additional information. The surveyors also observed multiple pieces of equipment being used for patient care which included the following: Exam light (2) Exam Table (2) Suction Machine -gomco recovery room Pulse oximeter AED/Defibrillator (used in the event of a cardiac arrest) Datascope-vital signs monitor Heating pad (2) Autoclave Centrifuge Gel warmer Vacuum Suction machine in procedure room used during the surgical procedures All of the equipment listed above with the exception of the Suction machine used in the procedure room for surgical procedures had not had an annual preventative maintenance check since January 2015 as per a document presented to the survey team by Staff #1 on 4/5/16 at 4:10 p.m.. The vacuum suction machine used for the surgical procedures contained a sticker which documented no preventative maintenance check since 2012. The survey team also observed that there was no call system located in the patient bathroom which could be used in the event a patient required assistance.	T 410		