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	AF-0017	A. BUILDING _____ B. WING _____	10/29/2014

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FALLS CHURCH HEALTHCARE CENTER	900 SOUTH WASHINGTON ST SUITE 300 FALLS CHURCH, VA 22046

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T 000	12 VAC 5- 412 Initial comments An unannounced Licensure Biennial survey was conducted 10/27/2014 through 10/29/2014. Two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)	T 000		
T 035	12 VAC 5-412-150 Policy and procedure manual. Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics: 1. Personnel; 2. Types of elective and emergency procedures that may be performed in the facility; 3. Types of anesthesia that may be used; 4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge; 5. Obtaining written informed consent of the patient prior to the initiation of any procedures; 6. When to use ultrasound to determine gestational age and when indicated to assess patient risk; 7. Infection prevention; 8. Risk and quality management; 9. Management and effective response to medical and/or surgical emergency; 10. Management and effective response to fire; 11. Ensuring compliance with all applicable federal, state and local laws; 12. Facility security;	T 035		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Rosemary W Codding | TITLE: Director | (X6) DATE: 12-10-14

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T 035	Continued From Page 1 13. Disaster preparedness; 14. Patient rights; 15. Functional safety and facility maintenance; and 16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable. These policies and procedures shall be based on recognized standards and guidelines. This RULE: is not met as evidenced by: Based on document review and interview the facility failed to implement their policies and procedure to annually update the policy and procedure manual. The findings included:	T 035	Policy and procedure manual **12 VAC 5 – 412-150** Correction: Notation of the Governing Body's December 2013 review of over 1000 pages of the 5 Policy Manuals is now posted in the Annual Review Documentation. Not been posted due to clerical issue of the form being revised to multiyear and new form not returned to the Manual. Notation of the Governing Body's December 2014 review of over 1000 pages of the 5 Policy Manuals is posted in the Annual Review Documentation. *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. Revised Annual Review Documentation form reviewed with QAC and Co-Administrators *Measures to maintain compliance:* Governing Body will review annually and address any	12/10/14 12/11/14

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T 035	Continued From Page 2 Review of the facility's policies and procedures on 10/27/2014 through 10/29/2014 did not contain evidence the policy and procedure manual had been reviewed and updated since 2012. Review of the policy/procedure manual did not include policies for when to use ultrasound to determine gestational age and when indicated to assess patient risk. An interview was conducted on 10/28/2014 at 6:30 p.m., with Staff #1. The surveyor requested documentation that the governing body or the administrator had reviewed the facility's policy and procedure manual annually. Staff #1 stated, "I didn't realize they needed to be reviewed annually. On 10/29/2014, Staff #1 reported the facility did not have policies and procedures to reflect the updated State licensure requirements for ensuring when to use ultrasound to determine gestational age and when indicated to assess patient risk and evidence the manual is annually reviewed and updated.	T 035	emergent issues and take corrective actions as outlined in existing policies. Policies will be clarified as needed. *Revised Annual Review Documentation Form attached.* No patients were affected by this paperwork deficiency Administrator **12 VAC 5 – 412-160 B** 6: Use of sonography to assess patient risk PLAN OF CORRECTION: Review of updated State Licensure requirements completed. A policy memorializing the FCHC Best Practices of when to use ultrasound to determine gestational age and assess patient risk of ectopic pregnancy when no sac seen will be developed. These policies and procedures shall be based on recognized standards and guidelines. FCHC will continue to utilize the Best Practices from NAF and ACOG currently used and these will be incorporated in the new policy. Copy of the policies and procedures approved by the governing body and revisions thereto shall be made available to the OLC upon request. *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. *Measures to maintain compliance:* Staff will be trained to and Policies will be clarified as needed. No patients were affected by this deficiency	12/08/14 01/01/15
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 facility failed to notify the Office of Licensure and Certification of the appointment of a new administrator. The Findings Included: The Surveyors were informed on entering the	T 050		

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T 050	Continued From Page 3 facility on 10/27/14, that a new Administrator had been appointed. During an interview on 10/29/14 at approximately 12:30 PM, Staff #1 was unable to provide evidence that notification was sent to the Office of Licensure and Certification of a change in Administrator.	T 050	T050 Page 3 12 VAC 5-412-160 - B: Administrator Change *Background:* FCHC has been undergoing a staffing reorganization and been in transition since September 2014, reassessing duties, leadership positions and resultant job descriptions modifications. The administrative changes will be finalized and staff trained to new alignments on December 9, 2014. After the changes and positions are finalized notification will be mailed. PLAN OF CORRECTION: The positions have been finalized and OLC will be notified of change. *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. *Measures to maintain compliance:* Staff will be trained to new organization chart. *(see attached)* and Policies will be updated and clarified as needed. No patients were affected by this paperwork deficiency	12/09/14 12/15/14
T 065	12 VAC 5-412-170 B Personnel B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member. This RULE: is not met as evidenced by: Based on interview and document review, it was determined the facility failed to implement a mechanism to verify professional licensure of three (3) of three (3) staff licenses in the survey sample. (Employee file #1, #8, #13) . The findings included: Review of personnel records on 10/28/14, revealed that the agency failed to provide evidence of license verification for three (3) of three (3) licensed employees. (Employee file # 1, #8, and #13). During an interview on 10/28/14, at approximately 6:00 PM, Staff #1 acknowledged that professional licenses had not been verified, and that they were not aware this was required.	T 065	Personnel **12 VAC 5 – 412-170 B** Correction: Verifications for professional licensure are done in December on a yearly basis then place in personnel files. See attached policy. Prevent recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency. Verifications for professional licensure are located in the employee's file. Measures to maintain compliance: Co-Administrators will review annually and address any emergent issues and take corrective actions as outlined in existing policies. The governing body will review biennially and address any emergent issues and take corrective actions as outlined in existing policies. No patients were affected by this deficiency.	01/15/15

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T 095	Continued From Page 4	T 095		
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; 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 interview and document review, it was determined that the agency did not have required personnel policies and procedures. The findings included: Review of the policies and procedures on 10/28/14 and 10/29/14 revealed that there were no personnel policies and procedures for: 1. Verifying current professional licensing or certification 2. Process for annually evaluating employee performance 3. Process for verifying that contractors and their employees meet the personnel qualifications of the facility 4. Process for reporting licensed and certified health care practitioners for violations of their	T 095	Personnel **12 VAC 5 – 412-170 H** Correction: Verifications for professional licensure are done in December on a yearly basis. Annual evaluations for employee performance are also done on a yearly basis. We have policy and procedures in place for these requirements. We will make adjustments to our policies and procedures to further clarify. The corrective actions taken will prevent recurrence of deficiency. We will include the process for verifying contractors and their employees meeting personnel qualifications of our facility. As well as clarify the process for reporting licensed and certified healthcare practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. Measures to maintain compliance: The governing body and co-administrators will review annually and address any emergent issues and take corrective actions as outlined in existing policies. VDH complaints filed by anti-choice individuals were unsubstantiated. No patients were affected by this deficiency.	01/15/15

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T 095	Continued From Page 5 licensing or certification standards to the appropriate board within the Department of Health Professions. During an interview on 10/29/14 at approximately 12:30 PM, Staff #1 acknowledged the findings.	T 095		
T 135	12 VAC 5-412-210 A Patients' rights A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission. This RULE: is not met as evidenced by: Based on interview and document review, it was determined that patients were not given a copy of their rights and responsibilities upon admission. The findings included: Review of patient records for 12 of 12 patients (#1-#12) on 10/27/14 and 10/28/14, it was revealed there was no evidence that patients had received a copy of rights and responsibilities on admission. The admission packet did not contain a copy of the rights and responsibilities for patients. During an interview on 10/28/14, at approximately 5:00 PM, Staff #1 stated that patients were given a laminated copy of rights and responsibilities to review upon admission, and that the rights and responsibilities were in a binder in the waiting	T 135	Patients' rights **12 VAC 5 – 412-210 A** Correction: *Background: Patients, as noted, are given a summary copy of Patients' Rights and Responsibilities including the complaint processes when they check in. They sign acknowledging they have reviewed and had opportunity to read the more detailed information on the clipboard. The full 7 page text is available in binders in the waiting room. The full 7 page text is available at the front desk to take if they want. Additionally, the Patient Rights are published on our website which an estimated 80% of our patients utilize. The patient signs the handout and it is included in her medical record (chart).* PLAN OF CORRECTION: The Patient Rights Handout will be revised to include a check off box for the patient to request or decline taking home a copy of the Patient Rights. It also includes a reminder that the full text of our Patient Rights Policies is on our website (see attached). Additionally, the receptionist will ask if patient wants a copy. Copies of the "How to file compliments or complaints" portion of the Patient Rights will be available on the reception counter for patients to take home. Our brochure of Patients' Rights and Responsibilities is also available in the waiting room and patient lounge. *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. The chart now evidences that patients receive and could have selected to take home a copy upon admission. *Measures to maintain compliance:* The various Expanded forms and Staff training to Policies will maintain compliance. No patients were affected by this deficiency	12/30/14

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T 135	Continued From Page 6 room. Staff #1 acknowledged that patients were not given a copy and did not know that this was required.	T 135		
T 150	12 VAC 5-412-210 D Patients' rights D. The patient shall be given a copy of the complaint procedures, in a language or manner she understands, at the time of admission to service. This RULE: is not met as evidenced by: Based on interview and document review, it was determined that 12 of 12 patient files (#1-#12) did not provide evidence that a copy of the complaint procedure was given at the time of admission to service. The findings include: Review of patient records for 12 of 12 patients (#1-#12) on 10/27/14 and 10/28/14, it was revealed there was no evidence that patients had received a copy of the complaint procedure on admission. The admission packet provided to the surveyors did not contain a copy of the complaint procedure. During an interview on 10/28/14, at approximately 5:00 PM, Staff #1 stated that patients were given a laminated copy of the complaint procedure upon admission to review. Staff #1 acknowledged that patients were not given a copy.	T 150	Patient's rights **12 VAC 5 – 412-210 D** Correction: *Background: Patients, as noted, are given a summary copy of Patients' Rights and Responsibilities including the complaint processes when they check in. They sign acknowledging they have reviewed and had opportunity to read the more detailed information on the clipboard. The full 7 page text is available in binders in the waiting room. The full 7 page text is available at the front desk to take if they want. Additionally, the Patient Rights are published on our website which an estimated 80% of our patients utilize. The patient signs the handout and it is included in her medical record (chart). Additionally the Complaint process is posted on bulletin boards in the waiting room and patient lobby.* PLAN OF CORRECTION: The Patient Rights Handout will be revised to include a check off box for the patient to request or decline taking home a copy of the Patient Rights. It also includes a reminder that the full text of our Patient Rights Policies is on our website (see attached). The receptionist additionally will ask if patient wants a copy. Copies of the "How to file compliments or complaints" portion of the Patient Rights will be stacked on the reception counter available for patients to take home. Our brochure of Patients' Rights and Responsibilities is also available in the waiting room and patient lounge. *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. The chart now evidences that patients receive and could have selected to take home a copy upon admission. *Measures to maintain compliance:* The various Expanded forms and Staff training to Policies will maintain compliance. No patients were affected by this deficiency	12/30/14
T 165	!2 VAC 5-412-220 A Infection prevention A. The abortion faciity shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the provisions of the current	T 165		

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T 165	Continued From Page 7 edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards. 1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented. 2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing. 3. A designated person in the facility shall have received training in basic infection prevention, and shall also be involved in the annual review. This RULE: is not met as evidenced by: Based on document review and interview the facility failed to ensure all infection prevention policies and procedures are reviewed annually and the designated person shall participate in the annual review. Note: This is a re-cite from 2012 related to staff's failure to ensure infection prevention policies and procedures will be reviewed annually with documented recommendations changes and updates. The findings included: An interview and review of the facility's infection prevention plan was conducted on 10/28/2014	T 165	Infection prevention **12 VAC 5 – 412-220 A** Correction: All infection prevention policies and procedures will be reviewed annually by the Governing Body. The ongoing responsibility for the program is assigned to the Nursing Administrator who is trained in infection control. The annual review and recommendations will be presented to the Quality Assurance Committee. This committee includes OB/GYN physicians. Documentation in writing in our Annual Review Documentation. Prevention Recurrence of deficiency: The corrective action will prevent any recurrence. The Nursing Administrator will monitor and report to the Governing Body any emergent issues that need corrective action. Policies will be expanded to clarify reviews and infection control staff. Measures to Maintain Compliance: The surgical and gynecological coordinators will continue to train staff to any new process or procedure. The staff will continue training through CDC, BLR webinars, ACN and NAF. OSHA and Blood borne Pathogens training will continue to be required of all employees and training documented. No patients were affected evidenced by no increase in adverse events during the period of this paperwork deficiency.	01/01/15

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T 165	Continued From Page 8 beginning at 12:30 p.m., with Staff #5. Staff #5 acknowledged the infection prevention plan did not include the administrator, appropriate members of the clinical staff and the designated qualified person would review the infection prevention policies and procedures annually as required in the Virginia licensure regulations. Review of the facility's policies and procedures on 10/27/2014 through 10/29/2014 did not contain evidence the policy and procedure manual had been reviewed and updated since 2012. An interview was conducted on 10/28/2014 at 6:30 p.m., with Staff #1. The surveyor requested documentation that demonstrated the governing body or the administrator had reviewed the facility's policy and procedure manual annually. Staff #1 stated, "I didn't realize they needed to be reviewed annually. On 10/29/2014, Staff #1 reported the facility did not have policies and procedures to reflect the updated State licensure requirements for ensuring the manual is annually reviewed and updated by the administrator, appropriate members of the clinical staff and designated qualified person.	T 165		
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	T 175		

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T 175	Continued From Page 9	T 175		

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;
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 observations, interview and document

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T 175	Continued From Page 10 review it was determined that the facility failed to: 1. Ensure linens and other items were handled in a manner to prevent contamination and were washed at the correct temperature to prevent the spread of infections; 2. Develop policies and procedures that encompassed the procedures for handling, storing and transporting clean and soiled linens; 3. Ensure the process of cleaning, disinfecting, and sterilizing has been achieved according to the recommended level of disinfection/sterilization; and 4. Perform appropriate infection prevention procedures necessary to prevent/control transmission of an infectious agent. Note: This is a re-cite from 2012 related to staff's failure to ensure linens and other items were handled in a manner to prevent contamination and to prevent the spread of infections; and infection prevention polices and procedures are developed and implemented. The findings included: 1. Observations and interviews were conducted on 10/27/2014 from 12:50 p.m. to 1:30 p.m., with Staff #1 and Staff #3. An observation at 1:05 p.m. with Staff #1 in the "Surgical Suite - Local" procedure room revealed an oxygen tank with a piece of gauze strip attached to the cylinder wrench (metal cylinder key to open the oxygen tank). Staff #1 stated, "They tie this gauze to the key so it won't get lost." In the "Surgical Suite - IV Sedation" procedure room a second oxygen tank was observed with a gauze strip attached to the cylinder wrench. The observation revealed gauze strip attached to two (2) cylinder wrenches. Staff #1 verified the findings. Staff #1 affirmed the gauze strip could not be disinfected and that it would present a mode of cross-contamination and	T 175	Infection prevention **12 VAC 5 – 412-220 C** Correction: 1. The small gauze tie was removed from O2 tanks. Only items that can be cleaned according to existing FCHC policies in order to minimize cross contamination will be used in the surgical suites. 2. All PPE will be stored in the cabinets or in protective plastic bags. This will minimize cross contamination from environmental sources. 3. The metal cart in the clean autoclave alcove has been removed. A cart with an intact surface that can be disinfected has replaced it. Personnel entering the clean autoclave alcove will don full PPE including gown, gloves, mask, head cover and shoe cover. This will minimize contamination from environmental sources. 4. The surgical straps in the surgical suites are to be replaced with ones that can be disinfected between patients or disposable straps. The Nursing Administrator is investigating different options to assist in immobilizing the patients for their safety and which would meet infection control protocols without jeopardizing patient health. 5. The soiled linen container will be replaced	10/29/14 01/01/15 12/10/14 01/01/15 01/01/15

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T 175	Continued From Page 11 a means for transmission of potentially infectious agents. 2. Observations and interviews were conducted on 10/27/2014 at 1:00 p.m. to 1:30 p.m., with Staff #1. The observations revealed the following personal protective equipment (PPE) stored on an open shelf un-protected from environmental contamination: A stack of head covers, face mask and shoe covers in the "Surgical Suite - Local" procedure room and main hallway by the entrance door into the "Surgical Suite - IV Sedation" procedure room. An interview conducted on 10/27/2014 at 1:15 p.m., with Staff #1 revealed he/she was not aware this supply of PPE on the shelf should be covered to prevent contamination from environmental sources until it was brought to his/her attention by the surveyor. The main supply of PPE are stored in cabinets. 3. On 10/29/2014 at 10:45 a.m. an observation was conducted in the "Clean" scrub room (where instruments are packaged and sterilized as appropriate for use again) with Staff #9. The observation revealed a metal cart with shelf #1 and #2 covered in shelf contact paper and metal instruments placed on shelf #1. Multiple tears were observed in the contact paper on shelf #2. Staff #9 failed to don full PPE including: gown, gloves, mask, head cover and shoe covers prior to entering into a clean environment. Staff #9 reported the sterilized instruments were ready to be removed from the autoclave machine (pressure chamber used to sterilize equipment and supplies by subjecting them to high pressure saturated steam). An interview conducted with Staff #9 revealed he/she was not aware full PPE should be donned before entering the "Clean" scrub room to prevent contamination from environmental sources. Staff #9 reported he/she	T 175	with one that is labeled, has a cover, and a disposable transport bag. Soiled laundry will be transferred to the janitor's room in this closed disposable bag. This policy will be updated in the Policy for processing laundry and Guidelines for Best Practices manual. A thermometer will be purchased to monitor the hot water temperature. The temperature is maintained at 160 degrees by the landlord. A temperature log will be maintained and reviewed by the MA staff. Any deviations from the 160 degree temperature will be reported to the Nursing Administrator and corrective actions will be taken. Offsite laundry services and disposable supplies are being explored as an alternative. Prevention Recurrence Deficiency: The corrective action will prevent any reoccurrence. The Nursing Administrator will monitor and report to the Governing Body any emergent issues that need corrective action. Measures to maintain Compliance: Update to laundry manual to reflect changes. Staff trained/retrained to new process/procedure. Governing Body will review infection prevention policy annually, address any emergent issues and take corrective actions. Documentation will be shared with QAC as part of their annual review. No patients were affected evidenced by no increase in adverse events during the period of deficiency.	01/01/15 01/01/15

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was only aware gloves were to be donned while working in that area. An interview was conducted with Staff #1 on 10/29/2014 at approximately 11:00 a.m. Staff #1 acknowledged the non-intact surface prevented disinfection of the cart; however the cart really had no purpose in this area and could be moved. Staff #1 reported the cart could not be cleaned and could see why this could be a means for transmission of potentially infectious agents. Staff #1 reported it was not the facility's policy to don full PPE during the removal of sterilized instruments from the autoclave.

4. Observations and interviews were conducted on 10/28/2014 from 5:10 p.m. to 5:40 p.m. during an abortion procedure in the "Surgical Suite - IV Sedation" procedure room with Staff #3, Staff #5 and Staff #6. The observation revealed two (2) blue cloth strips attached to the procedure table used to hold the patient's legs stable. Staff #1 verified the findings. Staff #1 affirmed the blue cloth strips could not be disinfected and cleaned between patients.

5. Observations and interviews were conducted on 10/28/2014 from 5:05 p.m. to 6:00 p.m., with Staff #5. An observation at approximately 5:30 p.m. revealed a vertical storage container with no label and several pieces of linen uncovered located in the hallway by the entrance door of the "Surgical Suite-IV Sedation" procedure room. The observation revealed soiled linen from a post procedure in the "Surgical Suite-IV Sedation" procedure room. Staff #5 reported the soiled linen items included: a sheet from "Recovery Room #1;" a patient cloth gown; and a pillowcase that is placed under the patient during the procedure to assist staff with transferring the patient post procedure from the procedure table to a stretcher. Staff #5 reported at the end of the procedures or when the container is full, it is then transported to

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T 175	Continued From Page 13 the closet marked janitor. Staff #5 reported that all linens were washed on site. The observation revealed a standard washer/dryer combination unit. Staff #5 reported the linens were washed on the appropriate setting for the material. Staff #5 reported the washer was connected to the general hot water supply for the building and he/she thought it was set to the required hot water temperature of 160 degrees Fahrenheit. Staff #5 reported the washer did not currently have a thermometer to verify the required temperature. An interview conducted on 10/28/2014 with Staff #1 revealed he/she was not aware the soiled linen container should be covered to prevent contamination. Staff #1 reported the facility did not have a written policy and procedure related to handling, storing and transporting clean and/or soiled linen. An exit interview was conducted on 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 stated, "I didn't realize the soiled linen container needed to be covered. Staff #1 reported the facility needed to address the issues found by the survey team.	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	T 180		

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T 180	Continued From Page 14 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 documentation and interview, it was determined that the facility failed to provide evidence that screening and immunizations were offered/received by 11 of 13 employees. (Employee files #1,-#4, #6-#8, and #11-#13) The findings included: Document review and staff interviews reveal the facility failed to documented screenings and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities for 11 of 13 employees. During an interview on 10/28/14, at approximately 6:00 PM, Staff #1 stated "Screening for tuberculosis and immunization for Hepatitis B and flu are offered to all employees, once when hired and annually thereafter." Staff #1 stated that the immunization information is kept in the employee health file, but has been misplaced and cannot be located at this time.	T 180	Infection prevention **12 VAC 5 – 412-220 D** Correction: *Background: our SSHP (Staff Safety and Health Program) staff medical files are renewed each September – October or within the Orientation Program for new Staff. That renewal was completed. But as noted in the deficiency report the "files" were misplaced. NOTE: the staff member #13 was cited but there was not a staff #13. Staff member #6 is a new employee and still in orientation. Staff #8 and #11 are consultants.* PLAN OF CORRECTION: The staff file of their various testing's and/or declinations have been located. The staff medical files have been updated and are current. The new Staff member's SSHP orientation is now scheduled. The Consultants medical files will be completed and brought to consistency with staff policies. *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. *Measures to maintain compliance:* The various steps for the staff medical charts have been consolidated to the activity of one staff person, our Gynecology Coordinator. No patients were affected by this deficiency	01/01/15
T 290	12 VAC 5-412-270 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:	T 290		

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T 290	Continued From Page 15 1. A bed or recliner suitable for recovery; 2. Oxygen with flow meters and masks or equivalent; 3. Mechanical suction; 4. Resuscitation equipment to include; as a minimum, resuscitation bags and oral airways; 5. Emergency medications, intravenous fluids, and related supplies and equipment; 6. Sterile suturing equipment and supplies; 7. Adjustable examination light; 8. Containers for soiled linen and waste materials with covers; and 9. Refrigerator. This RULE: is not met as evidenced by: Based on observation and interview, the facility failed to ensure that equipment and medical supplies were appropriately maintained. The findings included: 1. Observation of Surgical Suite-Local Room, on 10/27/14, from 12:50 PM to 1:30 PM with Staff #1 and Staff #3, revealed tears on the left and right sides of the padding on the procedure table. Tears in vinyl restrict the ability to disinfect and can harbor bacteria. Staff #1 stated that the padding had recently replaced. An oxygen mask, not in a bag or packaging, was placed on the oxygen tank. Staff #1 acknowledged that the oxygen mask should be inside a bag and not open to air. Inspection of the container of emergency supplies revealed two (2) of two (2) 18 gauge needles had an expiration date of 6/2008, and one (1) 20 ml syringe had an expiration date of 5/2012. Staff #1 acknowledged the findings. 2. Observation of Recovery Room one (1) on 10/27/14, from 1:55 PM to 2:10 PM, with Staff #1, revealed tape on the vinyl pad and on the metal plate under the pad on the first gurney when entering the room. Tape was wrapped around the metal joints on both sides at the foot of the	T 290	Equipment and supplies **12 VAC 5 – 412-270** Correction: 1. The vendor for the surgical procedure table will be contacted to repair the small tears on the recently recovered procedure table. All oxygen masks are in a bag or packaged and not open to air. Consistent with our approved event related expiration policy. See attached. All medical supplies such as gloves, syringes, IV solutions, needles, cannulas, will follow event related shelf-life guidelines recognizing sterile indefinitely, unless an event causes them to become contaminated, e.g., torn or wet packaging or if the manufacturer specifies otherwise. Sterile items will no longer be evaluated by manufacturers' expiration date. 2. The tape on the gurney was removed. The pillow roll stored under the gurney was discarded. The suction catheter attached to an aspirator was bagged and not open to air. 3. All oxygen masks are in a bag or packaged and not open to air. 4. The soiled linen container will be replaced with one that is labeled, has a cover, and a disposable transport bag. Soiled laundry will be transferred to the janitor's room in this closed disposable bag. This policy will be updated in the Policy for processing laundry and Guidelines for Best Practices manual. Prevent recurrence of Deficiency: The corrective actions taken will prevent recurrence of deficiency and ensure that all items used in patient care will be cross checked at point of use before patient care. Measures to maintain compliance: Staff trained to new process/procedure. Governing Body and Co-Administrator will review annually and address any emergent issues and take corrective actions. No patients were affected evidenced by no increase in adverse events during the period of deficiency.	01/01/15 11/02/14 11/02/14 01/01/15

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gurney. Staff #1 stated that the tape was used to hold it down. The rough surface of tape restricts the ability to disinfect and can harbor bacteria. A pillow roll was stored under the gurney had tears and was dusty. Staff #1 stated that this pillow was no longer used. The end of a catheter attached to an aspirator, was placed in the original packaging that was open to air, not bagged. Staff #1 acknowledged the findings.

3. Observation of Surgical Suite-Sedation on 10/27/14, from 2:15 PM to 2:25 PM, with Staff #1, revealed an oxygen mask placed on the anesthesia equipment was open to air, not bagged. Staff #1 acknowledged the findings.

4. Observations and interviews were conducted on 10/28/2014 from 5:05 p.m. to 6:00 p.m., with Staff #5. An observation at approximately 5:30 p.m. revealed a vertical storage container with no label and several pieces of linen uncovered located in the hallway by the entrance door of the "Surgical Suite-IV Sedation" procedure room. The observation revealed soiled linen from a post procedure in the "Surgical Suite-IV Sedation" procedure room. Staff #5 reported the soiled linen items included: a sheet from "Recovery Room #1;" a patient cloth gown; and a pillowcase that is placed under the patient during the procedure to assist staff with transferring the patient post procedure from the procedure table to a stretcher. Staff #5 reported at the end of the procedures or when the container is full, it is then transported to the closet marked janitor. Staff #5 reported that all linens were washed on site. The observation revealed a standard washer/dryer combination unit.

An interview conducted on 10/28/2014 with Staff #5 revealed he/she was not aware the soiled linen container should be covered to prevent

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T 290	Continued From Page 17 contamination. An interview was conducted on 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 stated, "I didn't realize the soiled linen container needed to be covered. Staff #1 reported the facility needed to address the issue found by the survey team.	T 290		
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 program documents were conducted on 10/28/2014 at 12:15 p.m., with Staff #2. Staff #2	T 320	Quality Assurance **12 VAC 5 – 412-300 B** Correction: We will continue to use the Annual Review Documentation which allows us to collect the necessary data of the seven required areas and/or identified unexpected trends/occurrences. During our QAC meetings, we will use the Annual Review Documentation to help evaluate the data collected in the documentation. Trends, actions, and relative data will be part of the QAC minutes. The corrective actions taken will prevent recurrence of deficiency. We will evaluate all the data that is collected and document review in QAC meeting minutes. Revised Annual Review Documentation form reviewed with QAC, Co-Administrators, and the governing body. Measures to maintain compliance: The QAC will review annually and address any emergent issues and take corrective actions as outlined in existing policies. No patients were affected by this deficiency.	01/01/15

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T 320	Continued From Page 18 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 10/28/2014 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		
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	T 330		

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T 330	Continued From Page 19 by the quality improvement committee. The findings included: An interview and review of the facility's quality program was conducted on 10/28/2014 at 12:15 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 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 reported the facility's quality program needed to address the issues found by the survey team. Staff #1 acknowledged the quality program's failure to implement measures to resolve problems or concerns that have been identified.	T 330	Quality Assurance **12 VAC 5 – 412-300 D** Correction: We will document in the QAC minutes any corrective actions that we implement in response to any concerns that may arise at the center. The corrective actions taken will prevent recurrence of deficiency. Measures to maintain compliance: The QAC will review all documentation annually and address any emergent issues and take corrective actions as outlined in existing policies. The QAC will also document all corrective actions that were taken upon the evaluation from the data collected documentation will be the QAC minutes. No patients were affected by this deficiency.	01/01/15
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	T 335		

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T 335	Continued From Page 20 by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee. This RULE: is not met as evidenced by: Based on document review and interview the quality committee failed to compile results of deficient practices or corrective action implemented to the governing body. 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 10/28/2014 at 12:15 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	T 335	Quality Assurance **12 VAC 5 – 412-300 E** Correction: A report for the governing body is compiled annually on the Annual Review Document and any details of corrective actions noted in QAC minutes. As per existing policy, this report is part of the QAC minutes that includes any deficiencies, recommendations, and/or improvements. The corrective actions taken will prevent recurrence of deficiency. We will submit a report to the governing body annually as documentation on the Annual Review Document. Measures to maintain compliance: The QAC will review all documentation annually, address any emergent issues, take corrective actions as outlined in existing policies, and document all corrective actions, deficiencies, recommendations, and/or improvements. With the following information, the QAC will compile a report for the governing body to review annually through the QAC minutes. No patients were affected by this deficiency.	01/01/15

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0017	A. BUILDING _____ B. WING _____	10/29/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FALLS CHURCH HEALTHCARE CENTER	900 SOUTH WASHINGTON ST SUITE 300 FALLS CHURCH, VA 22046

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T 335	Continued From Page 21 document any corrective actions that were implemented. Staff #2 reported the quality committee did not compile a report for the governing body to review at least annually. An interview was conducted on 10/29/2014 at approximately 11:30 a.m., with Staff #1. The findings were reviewed. Staff #1 reported the facility's quality program needed to address the issues found by the survey team. Staff #1 acknowledged the quality program's failure to report the deficiencies identified and recommendations for corrections and improvements.	T 335		
T 345	12 VAC 5-412-320 Record storage Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored. This RULE: is not met as evidenced by: Based on document review and interview the facility failed to provide provisions for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law. In the event of closure of the facility, the facility shall notify Office of Licensure and Certification (OLC) concerning the location where patient medical records are stored. The findings included:	T 345		

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T 345	Continued From Page 22 Review of the facility's policies and procedures on 10/27/2014 through 10/29/2014 did not contain evidence the policy and procedure manual had been reviewed and updated since 2012. The facility failed to have evidence that provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law. In the event of closure of the facility, the facility shall notify Office of Licensure and Certification (OLC) concerning the location where patient medical records are stored. An interview was conducted on 10/28/2014 at 10:30 a.m., with Staff #1. The surveyor requested documentation that records were being stored according to applicable federal and state law. Staff #1 stated, "I'm not sure where the owner of the facility has them located, but I will look into that matter." On 10/29/2014 at 11:30 a.m., Staff #1 reported he/she did not have any further information for the surveyor regarding the provisions of the safe storage of medical records because he/she has been busy with other responsibilities and duties regarding the survey.	T 345	Record Storage **12 VAC 5 – 412-320** Correction: Notation of the governing Body's December 2013 review of over 1000 pages of the 5 Policy Manuals is now posted in the Annual Review Documentation. It was not posted due to clerical issue of the form being revised to multiyear. The new form was not returned to the Manual by the time of the unannounced inspection. Notation of the Governing Body's scheduled December 2014 review of over 1000 pages of the 5 Policy Manuals is posted in the Annual Review Documentation. See attached form. Safe and secure storage of Patient Records has been continually maintained on and off site according to FCHC's record retention and destruction policy. Revising storage of archived medical records is part of FCHC's ongoing administrative transition that began in September 2014. Since May of 2014, we entered into and are presently in final stages of negotiations with the landlord to obtain additional storage space. This will facilitate full on-site record storage. As well, initial planning to make electronic copies of archived files is underway. Staff is currently consolidating the archived records on site in a secure locked auxiliary room. The new procedure will be reviewed by GB and reported to QAC at their next meeting. *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. *Measures to maintain compliance:* Governing Body will review annually and address any emergent issues and take corrective actions as outlined in existing policies. Policies will be clarified as needed. Staff will be trained in the new procedures including assisting with making electronic copies. No patients were affected by this deficiency.	12/11/14 12/11/14 01/01/15
T 355	12 VAC 5-412-330 B Reports B. Abortion facilities shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence. This RULE: is not met as evidenced by: Based on document review and interview the facility failed to develop policies and procedure for reporting to the Office of Licensure and Certification (OLC) within 24 hours any occurrences, which involved: 1. Serious patient injury, medication errors, death	T 355		

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	AF-0017	A. BUILDING _____ B. WING _____	10/29/2014

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T 355	Continued From Page 23 or significant injury resulting from a physical assault, any other incident reported to the malpractice insurance carrier; 2. What the notification to OLC should include; 3. The facility's responsibility to report occurrences to law enforcement and the failure to develop policies and procedures to ensure compliance with; and 4. Confidentiality of records shared with OLC. The findings included: 1. Review of the facility's policy and procedure manual on 10/27/2014 through 10/29/2014 did not reveal the following policy and procedures: (B). The abortion facility shall report the following events to OLC: 1. Any serious injury to a patient; 2. Medication errors that necessitate a clinical intervention other than monitoring; 3. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; and 4. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990. 2. Review of the facility's policy and procedure manual on 10/27/2014 through 10/29/2014 did not reveal the following policy and procedures: (C). Notification of the events listed in subsection B shall be required within 24 hours of occurrence. Each notice shall contain the following: 1. Abortion facility name; 2. Type and circumstance of the events being reported;	T 355	Reports **12 VAC 5 – 412-330 B** Correction: NOTE: There have been no events of serious injury to a patient, medication errors that necessitate clinical intervention, death or significant injury resulting from assault at FCHC or incident reported to malpractice insurance. The reporting of NO incidents will be included as requested to OLC. The existing Policy for reporting deaths to the Office of Licensure within 24 hours will be expanded to clarify reporting sequence and process. An additional line for Reports to OLC will be added to the Annual Review Documentation. *The current policies previously approved by OLC are attached.* *Prevent recurrence of Deficiency:* The corrective actions taken will prevent recurrence of deficiency. *Measures to maintain compliance:* GB will report annually in December to OLC as requested even if no reportable events were experienced. GB will continue to review the OLC website to see any noticed changes. The GB will also review for licensure regulations that may have changed without notification from the OLC. No patients were affected by this deficiency.	01/01/15 12/11/14

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T 355	Continued From Page 24	T 355		

3. Date of the event; and
4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.

(D). Compliance with 12VAC5-412-320 does not relieve the abortion facility from complying with any other applicable reporting or notification requirements, such as those relating to law enforcement or professional regulatory agencies.

(E). Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed by the OLC except as required or permitted by law.

An interview was conducted on 10/28/2014 at approximately 6:30 p.m. with Staff #1. A request was made for any information related to reporting events to the OLC. Staff #1 reported he/she was not aware of a requirement related to reporting the events to the OLC within 24 hours of occurrence. The surveyor inquired if Staff #1 had reviewed the Regulations for the Licensure of Abortion Facilities Effective June 20, 2013. Staff #1 reported they had not received notification that the regulations had been revised. The surveyor informed Staff #1 that the State licensure office did not send out notices to each facility related to changes in the licensure regulations. The surveyor informed Staff #1 that it was the facility's responsibility to occasionally check the State's website for updated licensure regulations. Staff #1 reported the facility had not developed the additional policies, procedures, or processes to encompass the new reporting requirements to comply with the required reporting events to the OLC.