State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-008	A. BUILDING _____ B. WING _____	05/09/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VIRGINIA WOMEN'S WELLNESS	224 GROVELAND ROAD VIRGINIA BEACH, VA 23452

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 000	12 VAC 5- 412 Initial comments An announced Initial Licensure Abortion Facility inspection was conducted at the above referenced facility on May 8 & 9, 2012 by four (4) Medical Facility Inspectors from the Virginia Department of Health's, Office of Licensure and Certification. The facility had multiple complaints which were also investigated during the initial inspection. Compliant Identification numbers were: 2012-AC001 through AC005, 2012-AC007 through AC010, AC012 and AC013. Ten of the eleven complaints were UNSUBSTANTIATED. Complaint # 2012-ACO10 was SUBSTANTIATED with associated deficiencies cited in this report. VA Women's Wellness Center, which is located in Virginia Beach was found out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's, effective December 29, 2011. Deficiencies were identified and cited, and will follow in this report.	T 000		
T 015	12 VAC 5-412-140 B Organization and management B. There shall be disclosure of facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership. This RULE: is not met as evidenced by: Based on review of the policy and procedure manual and interview, it was determined that the facility failed to identify and document who the	T 015	A Separate statement of ownership will be provided to the OLC	6-15-12

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

Operations Business Manager 6-7-12

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T 015	Continued From Page 1 owner(s) of the facility are. The findings were: On 5/9/12 during the entrance conference to the facility at approximately 9 AM, the corporate representative was asked who the owner or owners of this facility are. The representative stated, we are owned by a corporation. Again later that day the representative was asked who the owner(s) of this facility are. The representative would only say it's a corporation under another corporation. The Organizational chart in the policy and procedure manual was reviewed with the corporate representative on 5/10/12 at approximately 5:55 PM in the administrator's office. The chart did not have the name of the facility, a date, or any names in the job title/position boxes. On 5/10/12 on or about 6 PM in the administrator's office the corporation representative was asked again, who the owner of this facility is. The representative again said, "It's a corporation," when asked to be more specific the representative said, "I think it's ... (name)." When asked the percentage of interest or ownership that that person has in the corporation, the representative said, "I don't know."	T 015		
T 070	12 VAC 5-412-170 C Personnel C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.	T 070	Criminal background checks have been obtained on all staff/ clinicians with access to controlled substances. These documents have	6-7-12

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T 070	Continued From Page 2 This RULE: is not met as evidenced by: During the survey the facility was assessed for compliance with the provisions of the Code of Virginia, 1950 as amended and (Section 32.1-162.9:1 as amended. The Code Section requires that licensed home care organizations or home care organizations exempt under 32.1-162.8:3 (a) (b) (c) of the Code of Virginia conduct criminal records check for compensated employees hired after July 1, 1992. These same Code sections also prohibit the employment, by abortion facility's, of persons convicted of certain crimes specified in Section 32.1-126:02. That same Section requires employees not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility must have a criminal record report through the Virginia State Police. The above Statue was not met as evidenced by: Based on the review of personnel files, and interview with the Administrator, it was determined that nine (#1 - #4, #9, #12 - #13, #17 and #19) of nine (#1 - #4, #9, #12 - #13, #17 and #19) personnel that had the potential to dispense narcotics failed to have criminal record checks for the Surveyor to review as required in Section 12 VAC 5-412-170.C. The Surveyors reviewed all personnel files at various times on 5/8/12. The staff included: 1. Personnel #1 - #4 were Physicians. 2. Personnel #9 and #17 were Registered Nurses. 3. Personnel #13 - #14 and #19 were Licensed Practical Nurses.	T 070	been inserted in their personnel file.	

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T 070	Continued From Page 3 The Administrator verified that the results of the criminal record checks were mailed the day before the Inspection. This interview occurred on 5/8/12, in the agency's office at 4:26 p.m.	T 070		
T 155	12 VAC 5-412-210 E Patients' rights E. The facility shall provide each patient or her designee with the name, mailing address, and telephone number of the: 1. Facility contact person; and 2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The facility shall display a copy of this information in a conspicuous place. This RULE: is not met as evidenced by: Based on interview and record review the facility failed to provide the patients or patient's designees with the name, address, and toll-free complaint telephone number of the state licensure agency. The findings included: An interview with Staff #13 on May 8, 2012 at approximately 9:15 a.m. revealed each patient received patient rights and complaint information as part of the admission process. Review of the admission packs for medical and surgical procedure patients did not include the name, address, and toll-free complaint telephone number of the state licensure agency (Office of Licensure and Certification). The information given to the patients or patient's designee did not include information regarding their ability to filing anonymous complaints with the state licensure	T 155	All patients are given a copy of the "Your Rights as a Patient" form which describes proper complaint procedures. This document includes the name, address and toll free phone number for the OLC. 5-9-12	

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T 155	Continued From Page 4 agency. An interview was conducted on May 8, 2012 at 3:30 p.m. with Staff #13 and Staff #21. Staff #13 and Staff #21 reviewed the admission packs. Staff #13 reported the patient or the patient's designee only received the information included in the admission packs. Staff #13 and Staff #21 verified the complaint information given did not include name, address, and toll-free complaint telephone number of the state licensure agency or related to filing an anonymous complaint with the state licensure agency.	T 155		
T 175	12 VAC 5-412-220 C Infection prevention C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following: 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers); 2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies; 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures); 4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment; 5. Procedures for handling/temporary storage/transport of soiled linens; 6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations; 7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:	T 175	VWW maintains that our excellent track record of safe patient care proves that our infection prevention practices adequately protect our patients. In a span of more than 15 years, VWW has not had a single patient with a documented serious infection and no known cases of patient-to-patient transmission of infection. VWW vigorously disputes that any area of our office is "dirty". All aspects of the facility are cleaned daily and the DOH did not identify any portion of the facility that was soiled	

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T 175	Continued From Page 5 (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: 12 VAC 5-412-220 (C) (4), (5), (7), (10), and (12) Based on observation, interview and record review the facility failed to have infection control procedures to prevent cross-contamination related to: 1. Facility staff's handling of clean and dirty equipment between patients and staff's knowledge of manufacturer's recommendations for cleaning re-usable equipment between patients. 2. Transporting clean linen/ blankets, for handling, temporary storage/transporting soiled linens; and 3. Cleaning environmental surfaces. The findings included: 1. Observations conducted on May 9, 2012 from	T 175	or inadequately cleaned, we believe the nomenclature used to identify "clean" and "dirty" rooms is fully inaccurate. No areas of the facility are dirty and the entire facility is clean. For each and every patient, all instruments that enter the patient's body have been sterilized prior to use and all patients are safely protected from infection by appropriate practices. In particular our scrub room is especially clean, having been scrubbed and disinfected twice daily. Despite the above disclaimer, VWW supports the goals of continuously improving infection prevention procedures and we will implement the changes suggested by the DOH.	

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T 175	Continued From Page 6 6:26 p.m. to 8:35 p.m. revealed the facility utilized re-useable glass vacuum jars for procedures; passed by staff through an in-wall opening between the "clean" procedure room and the "dirty scrub" room. The facility staff did not set up separate clean and dirty areas for handling instruments and equipment. Staff #20 located within the "dirty scrub" room, placed a disposable pad on the counter top. Staff #20 retrieved a clean vacuum jar from above the designated dirty sink and placed the clean vacuum jar on the pad. From the "clean" procedure room the physician reached through the in-wall opening and placed the "dirty" instruments used during the procedure onto the pad next to the clean vacuum jar. Staff #20 retrieved the dirty instruments from the pad and placed them in the sink. Staff #20 did not change the pad on the counter top. Staff #12 located in the "clean" procedure room passed the vacuum jar utilized during the procedure with the collected conception material through the in-wall opening. Staff #12 placed the "dirty" vacuum jar on the pad. Staff #20 handed the clean vacuum jar to Staff #12. Staff #12 did not change gloves prior to receiving the clean vacuum jar. An interview was conducted on May 9, 2012 at 6:45 p.m. with Staff #20. Staff #20 reported the enzymatic soaking time for the dirty instruments as "a couple of minutes." The label on the enzymatic cleaner read "Recommended contact time 5 minutes." Staff #20 did not have a timer or clock available to ensure the manufacturer's recommendations were followed. Staff # 20 reported the concentration of enzymatic cleanser was one (1) ounce to one (1) gallon of water. Staff #20 did not have measuring devices and could not state how much water or enzymatic cleaner had been placed in the sink. An observation and interview on May 9, 2012 at 8:30 p.m., by two surveyors and Staff #12 revealed the facility utilized a cloth pillow between	T 175	(1) All reusable equipment is cleaned as per the manufacturer's recommendations. All items labeled for single use are disposed of after each patient use. Staff has been properly retrained in the handling of equipment between patients. G312 (2) The Policy and Procedures manual has been updated to include the proper transport of linen in disposable bags for laundering. The linens are returned to the facility in a covered container and stored in the recovery room in the same covered container allowing them to remain fully protected from the environment. G312 (3) The Policy and Procedures manual has been modified to include the following revisions. Staff has G312	

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T 175	Continued From Page 7 patients. The observation revealed the disposal pillowcase did not completely cover the pillow. Staff #12 reported with the pillow became soiled it was taken home by staff and washed. An interview was conducted on May 9, 2012 at 8:35 p.m. with Staff #21. Staff #21 was informed of the findings related to the cross-contamination of clean and dirty re-useable instruments/equipment between the scrub and procedure rooms. Staff #21 acknowledged the cloth pillow was not completely covered by the disposable pillowcase and could not be wiped down between patients. 2. An observation and interview with Staff #13 on May 8, 2012 at approximately 9:59 a.m. with Staff #13 revealed the sterilized instrument pack were stored on a wire rack above the freezer used to store conception material. Staff #13 reported the freezer would be considered part of the designated dirty side of the scrub room. An observation and interview with Staff #13 on May 8, 2012 at approximately 10:15 a.m. revealed four brown blankets stored uncovered on a wire rack in the Recovery room. Staff #13 reported the blankets were used to cover patients during recovery. Staff #13 reported the blankets were not cleaned/washed between patients. Staff #13 reported when the blankets became "obviously" soiled staff took "the blankets home, washed, them and brought them back." Review of the facility's policy and procedure manual did not have procedures related to handling, temporary storage and transporting the soiled blankets. The facility did not have a procedure directing staff how to temporarily store the soiled blankets, wash the blankets at home and how to transport the clean blankets back to the facility. An interview was conducted on May 8, 2012 at 3:30 p.m. with Staff #13 and Staff #21. Staff #21 acknowledged the facility did not have a detailed	T 175	been retrained in all aspects of cleaning of environmental surfaces. The pass-through window located between the procedure room a scrub room is only used for passing instruments and the specimen jar through. All sterile material is returned to the procedure room via the doorway. All staff have been retained on hand hygiene and the frequency of changing gloves. The especially clean scrub room is equipped with a timer & measuring cup to assure strict adherence to manufacturer recommendations for diluting and soak time of enzymatic detergent. The cloth pillow has been replaced with a fluid resistant, antimicrobial, cleanable pillow.	C-2512

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T 175	Continued From Page 8 policy or procedures related to their practice of laundering the blankets. Staff #13 verified the facility did not have procedures for handling and transporting soiled or clean linens (blankets). 3. An observation and interview related to environmental surface cleaning was conducted on May 8, 2012 at approximately 11:30 a.m. with Staff #21. Staff #21 discussed the two cleaning products used to disinfect environmental surfaces. The products in use had different surface contact times. An observation of the recovery chair recliners revealed four of the four recliners had food particles beneath the removable seat cushion. Staff #21 acknowledged the four recliners were not clean. Review of the facility's policy and procedure manual did not have procedures related to how to clean environmental surfaces. During an interview conducted on May 8, 2012 at 3:30 p.m. Staff #21 reported the facility did not have a detailed procedures related to cleaning environmental surfaces.	T 175	All sterile packs are stored in clean rooms. Although recovery room chairs were always cleaned, an additional thorough cleaning and disinfecting has been performed. The Policy + Procedures Manual has been updated to include the proper cleaning of same.	6/23/12
T 265	12 VAC 5-412-260 A Administration, storage and dispensing of dru A. Controlled substances, as defined in 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18 VAC 110-30). This RULE: is not met as evidenced by: Based on observation, interview and record review the facility failed to follow manufacturer's directions for administration of controlled	T 265	All medications used for multiple patients will be drawn from multi-dose bottles. ~~If~~ a bottle/vial is labeled for single use, it will be used for only one patient and unused portions will be discarded Proper	6/23/12

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T 265	Continued From Page 9 substance single dose vials. The findings included: An observation and interview conducted on May 8, 2012 at 10:00 a.m. with Staff #13 during review of the facility's system for controlled substances. Staff #13 reported the facility's patient had a choice between local anesthesia and conscious sedation (moderate sedation). Staff #13 reported the facility used an injection of Fentanyl and Midazolam (Versed). Staff #13 opened the locked box, on inspection the box contained: an opened vial of Fentanyl 2500 mcg (micrograms)/50 ml (milliliters). The staff had not documented the opened date on the vial. Staff #13 reviewed the log sheet and reported the vial was last used on May 5, 2012 and the vial count changed on May 2, 2012. Staff #13 reported the vial " was probably opened on May 2, 2012; but there is no way to know for sure. " Staff #13 reported the nurse could draw up to twenty-five (25) doses from a fifty (50) ml vial. Staff #13 reported that each dose drawn would be used for a different patient. When asked, Staff #13 read the vial label, which read: " Single dose vial. " Staff #13 replaced the partially used vial of Fentanyl into the lock box. The observation revealed five vials of Midazolam 5 mg (milligrams)/5 ml. One vial was opened without a documented opened on date. The vial label read " Single use vial. Discard unused portion. " Staff #13 reported that each Midazolam and Fentanyl vials were used for multiple patients. [Fentanyl is a short duration analgesic. Midazolam is a preoperative sedative.] Review of the controlled substance log was conducted on May 8, 2012 at 10:09 a.m. with Staff #13. Staff #13 reported the recorded amounts of medication left in the Fentanyl vial and the Midazolam vial were " guesstimates. "	T 265	Calculation of the remaining medication left in vials will be made by subtracting the amount drawn from the starting volume of an unopened bottle/vial.	

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T 265	Continued From Page 10 The estimation of the medication left in the single use vials for later use ranged from 4/5 to 19/20. Staff #13 reported the staff had not calculated the amount left but had " eyeballed " the amount. Staff #13 agreed that 4/5 for one person could be different for another person estimating the same amount. Review of the package insert for Fentanyl indicated the medication " Contained no preservatives " and listed the 50 ml vial as a single dose vial. The package insert for Midazolam indicated the vial was for single use and unused portions of the vial were to be discarded.	T 265		
T 280	12 VAC 5-412-260 D Administration, storage and dispensing of dru D. 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 observations made during the initial tour of the facility and interviews, it was determined that the facility's staff failed to ensure that injectable medications for local anesthesia were mixed and labeled in accordance with the regulations for the Board of Medicine, 18 VAC 85-20-400. More specifically, 23 multi-dose 50 cc vials of 1% Lidocaine each had a label attached to them that stated two additional drugs had been added to each the vials. The attached label did not contain the amount or strength of the medications added or the date the additional medications were added. The findings were:	T 280	All medications will be mixed by an RN or MD, or by a trained staff member with a second check performed by a registered nurse or physician. These mixed medications will be properly labeled with the amounts of medications mixed, date and time of mixing, and the initials of the person mixing the medications. If a second check is performed then	

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T 280	Continued From Page 11 An initial tour of the facility was conducted on May 8, 2012 beginning at 9:55 AM. The Recovery room, a room used for patients to recover from their procedure in, contained a large locked metal cabinet. The Administrator was asked if she could open the cabinet for this inspector to view its content. The Administrator opened the cabinet, the cabinet contained various types of injectable and oral medications. On the second shelf were multiple boxes of medications that are used during procedures. In the back on the right hand side of the shelf was an open box containing 23 vials; each had a manufacturer's label on it that read, "1% Lidocaine, 50 ml (amount)." Each vial also had an additional label attached to it that read: "Lidocaine 1%, Pitocin, Vassopressin Date mixed:____ ." All 23 vials with the attached labels failed to have the amount or strength of the Pitocin or Vassopressin written on the labels and also failed to have the "Date mixed," filled in. On the side of each vial was a date, 5/2/12, and a set of initials written with black magic marker. The administrator was shown one of the vials and asked who mixed these vials; the administrator stated it was employee #25, an LPN (Licensed Practical nurse). The administrator was also asked where was it written on the vials the amount of Pitocin (a hormone) and Vassopressin (constricts blood vessels) that was added and when; she replied, "It's not," and then pointed to the handwritten date with initials on the side of the vial and said, "here's when she mixed them." When asked who was the person who mixed the vials the administrator said (name) an LPN. The administrator was asked what the vials were used for and she replied, every patient gets this, it's their local anesthetic that the doctor injects.	T 280	Registered Nurse or Physician providing the second check will also initial. Mixed medications will be disposed of if not used within 10hrs of mixing. All medications will be mixed, diluted or drawn in a designated sanitary area.	6/25/12

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T 280	Continued From Page 12 On 5/9/12 at approximately 6 PM, again in the Recovery room the administrator was asked where does the nurse mix the Lidocaine, Pitocin and Vassopressin vials? The administrator pointed to the desk where nurses sit and observe patients and write their progress notes and said, "Here." The desk sits in front of the recliners where patients recover after their procedures. Part IX. of the Virginia Board of Medicine, reads in part: "Mixing, Diluting or Reconstituting of Drugs for Administration. 18VAC85-20-400. Requirements for immediate-use sterile mixing, diluting or reconstituting. A. For the purposes of this chapter, the mixing, diluting or reconstituting of sterile manufactured drug products when there is no direct contact contamination and administration begins within 10 hours of the completion time of preparation shall be considered immediate-use. If manufacturers' instructions or any other accepted standard specifies or indicates an appropriate time between preparation and administration of less than 10 hours, the mixing, diluting or reconstituting shall be in accordance with the lesser time. No direct contact contamination means that there is no contamination from touch, gloves, bare skin or secretions from mouth or nose. Emergency drugs used in the practice of anesthesiology and administration of allergens may exceed 10 hours after the completion of the preparation, provided administration does not exceed the specified expiration date of a multiple use vial and there is compliance with all other requirements of this section. B. Doctors of medicine or osteopathic medicine who engage in immediate-use mixing, diluting or	T 280		

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T 280	Continued From Page 13 reconstituting shall... 3. Establish and implement procedures for verification of the accuracy of the product that has been mixed, diluted, or reconstituted to include a second check preformed by a doctor of medicine or osteopathic medicine or a pharmacist, or by a physician assistant or a registered nurse who has been specifically trained pursuant to subdivision 2 of this subsection in immediate-use mixing, diluting or reconstituting..." 4. Provide a designated, sanitary work space and equipment appropriate for aseptic manipulations;" The administrator acknowledged on 5/8/12 at 10:15 AM that the vials did not have the amount or strength of Pitocin and Vassopressin documented in the label.	T 280		
T 315	12 VAC 5-412-300 A Quality assurance A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary. This RULE: is not met as evidenced by: Based on interview and record review the facility failed to develop a quality assurance program with processes for data collection, analysis, assessment based on data, improvement and evaluation of the facility. The findings included:	T 315	We believe that we are in full compliance with 12VAC5-412-300 as written. We dispute this deficiency. VWW does have and has had an ongoing, comprehensive, integrated self-assessment program. Furthermore, staff #21 claims she was misquoted in the statements which form part of the evidence for this deficiency. 5.8.12	

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T 315	Continued From Page 14 Review of the facility's policy and procedure manual included the wording from the State of Virginia; 12VAC5-412-300 (A). The facility did not provide evidence of a quality assurance plan or documented processes for data collection, analysis, or assessment based on the data collected. The facility did not have a written process for improvement and evaluation of their overall program. An interview was conducted on May 8, 2012 at 3:40 p.m. with Staff #13 and Staff #21. Staff #21 verbally confirmed the facility did not have quality assurance processes. Staff #21 reported data had not been collected for the outcomes discussed during the May 2012 Quality Assurance Committee meeting.	T 315	The data was collected for the MAY 2012 QI meeting. This includes complication logs, chart reviews, random samples of phone interviews with patients feedback for follow-up examinations. Patient dumplaint reviews & emails, staff attendance & performance & competency evaluations. All of this formed the basis of the QI committee's analysis, assessment & evaluation. The May 2012 QI committee documented their meeting & its findings. All parties signed the minutes. 5-8-12	
T 340	12 VAC 5-412-310 Medical records An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following: 1. Patient identification; 2. Admitting information, including a patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; and 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; 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,	T 340	The operative report was updated to include the documentation of the dosing of Pitocin & Vassopressin. 5-9-12 The examination tables will be repaired or replaced to eliminate the tiny, minute tears at the bend points and at the feet. 6/25/12	

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T 340	Continued From Page 15 i. Patient instructions, preoperative and postoperative; and j. Names of referral physicians or agencies. This RULE: is not met as evidenced by: Based on observations made during the initial tour of the facility and clinical record review, it was determined that facility staff failed to ensure all medications given to each patient were documented in their clinical record. Specifically, thirteen (13) of thirteen (13) patients who had a surgical abortion performed at the facility failed to have listed in their record that received Lidocaine, Pitocin and Vassopressin medications in the local anesthetic that the doctor gave to each patient, (patient records #1, 3 - 8, 10, 11, 13 - 15 & 17). The findings were: Clinical records were reviewed in the Counseling office on 5/8/12 beginning at 12 noon. Records #1, 3 - 8, 10, 11, 13 - 15 & 17, all had documented evidence that the patients had surgical abortions performed at the facility. All of the above referenced records had documented evidence that the patient(s) received 20 cc of 1% Lidocaine. There was no mention of Pitocin or Vassopressin in the records reviewed. The administrator who is also a nurse stated in an interview on 5/8/12 that all patients who have a surgical abortion receive Lidocaine, Pitocin and Vassopressin as a local. Staff member #21 stated, "We have a policy about this." On 5/8/12 at 2:45 PM the facility's policy regarding Local Anesthesia was reviewed and read in part, "Local anesthesia consists of a series of injections into the cervix, typically with medications,	T 340		

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T 340	Continued From Page 16 Lidocaine, Oxytocin and Vassopressin. Every patient will receive local anesthesia unless allergies prohibit its administration." Cross reference to 12VAC5-412-260 D. Tag T 280.	T 340		
T 375	12 VAC 5-412-360 A Maintenance A. The facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be all 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 observations, and interview with Staff #21, it was determined that four of four (#1 - #4) of (#1 - #4) reclining chairs for the Patients in the Recovery Room, and three (#1 - #3) of three (#1 - #3) examination tables were not in good repair as required in Section 12 VAC 5-412.360. A. The findings included: Observations doing a tour of the Abortion Facility by the Surveyors and Staff #21 revealed that four (#1 - #4) of four (#1 - #4) patients' reclining chairs in the Recovery Area revealed that the reclining chairs were not cleaned and four (#1 - #4) of four (#1 - #4) reclining chairs had broken areas along the bilateral lacquered arms. Three (#1 - #3) of three (#1 - #3) patients' examination tables had tears at the bend points and at the feet, in the Exam, Ultrasound and Procedure Rooms.	T 375	Our recovery room chairs have always been and will continue to be cleaned after every patient and kept in sanitary condition. Staff #21 denies ever stating the chairs were "unclean". They have always been cleaned regularly. Furthermore, the arms of our chairs were not broken. However, the small 1 inch scratches in the Lacquer on the surface of the arms of our intact, structurally sound chairs will be sanded & resealed to eliminate all scratches in the lacquer. (a)(3)(i)(L)	

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T 375	Continued From Page 17 Staff #21 verified that the recovery room reclining chairs were unclean and had breaks in the wooded surfaces and tears were present in all Examination Tables. This interview occurred during the tour of the facility, on 5/8/12, between 10:10 a.m.-10:28 a.m.	T 375	The examination tables will be repaired or replaced to eliminate the tiny, minute tears at the bend points and at the feet.	6/3/12
T 380	12 VAC 5-412-360 B Maintenance B. When patient monitoring equipment is utilized, a written preventative maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, no less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. This RULE: is not met as evidenced by: Based on interview and tour of the facility, it was determined that the facility failed to show that there was preventative maintenance service on one (1) EKG machine, one (1) lamp and two (2) microscopes. The findings include: 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and Operations Business Manager (interviewee #21) between 9:00 am and 11:30 am. In the Recovery Room there was an EKG machine with no evidence of its preventative maintenance service. In the supply closet was a lamp with no evidence of its preventative maintenance service. There	T 380	(1) EKG machine (1) lamp & (2) microscopes have all had preventative maintenance performed by a licensed biomed technician and have been properly labeled.	5/31/12

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T 380	Continued From Page 18 were two (2) microscopes, one (1) in the Procedure Room and one (1) in the Treatment Room with no evidence of preventative maintenance service 2. On May 8, 2012 an interview was conducted with the Operations Business Manager (interviewee #21) in the facility between 9:00 am and 11:30 am. The Operations Business Manager acknowledged that the one (1) EKG machine, one (1) lamp and two (2) microscopes failed to have the preventative maintenance service.	T 380		
T 385	12 VAC 5-412-370 A Fire-fighting equipment and systems A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program. This RULE: is not met as evidenced by: Based on facility tour and interview, it was determined that the facility failed to have a monitoring program for fire and safety nor a responsible employee for the monitoring program. The findings include: 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and the Operations Business Manager (interviewee #21) between 9:00 am and 11:30 am. Present were fire extinguishers and fire exit plans located throughout the facility. 2. On May 8, 2012 an interview was conducted with the Administrator (LPN, employee #13) in the facility between 1:dpm and 3:dpm. The	T 385	We dispute this deficiency. Employee #13 claims she was misquoted and that we are in full compliance with this deficiency. The designated individual to monitor the fire safety program is the Administrator. Fire Safety training & the proper use of a fire extinguisher was performed on May 04, 2012. This is documented both in the employee files & in the Emergency Disaster Plan. 5-8-12	

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T 385	Continued From Page 19 Administrator acknowledged that the facility did not have an individual responsible to monitor a fire and safety program. The Administrator acknowledged that there had been no training on the use of the fire extinguishers and/or other fire and safety activities. The Administrator acknowledged that there was no evidence to show for a monitoring program for fire/safety activities.	T 385		
T 390	12 VAC 5-412-370 B Fire-fighting equipment and systems B. All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested in accordance with current edition of the Virginia Statewide Fire Prevention Code (27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition. This RULE: is not met as evidenced by: Based on facility tour and interview it was determined that the facility failed to have evidence that the fire alarm was inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition. The findings include: 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and the Operations Business Manager (interviewee #21) between 9:00 am and 11:30 am. During the tour the Administrator identified that the fire alarm system was integrated within the safety alarm system under contract with ADT Company. 2. On May 8, 2012 an interview was conducted	T 390	All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested as required. 6.25.12	

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T 390	Continued From Page 20 with the Administrator (LPN, employee #13) in the facility between 1:00 pm and 3:30 PM. The Administrator acknowledged that ADT alarm company was responsible for the inspection and testing of the facility fire alarm system. The Administrator was unable to provide evidence that the fire alarm system had been inspected and tested in accordance with current edition of the Virginia Statewide Fire Prevention Code (27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.	T 390		
T 400	12 VAC 5-412-380 Local and state codes and standards Abortion faculties shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001. Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure. Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements. This RULE: is not met as evidenced by:	T 400	As per the Virginia Department of Health letter dated May 23, 2012, all deficiencies cited under 12VAC5-412-380 will be completed within two years of issuance our license. 5-23-12	

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T 400	Continued From Page 21 Based on interview and facility tour it was determined the facility failed to have an architect attestation, HVAC duct inspection reports, documentation of test for fire alarm system, ventilation of treatment room (MERV 7), air exchange information for treatment rooms and rating of insulation. The findings include: 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and Operations Business Manager (interviewee #21) between 9:00am and 11:30am. During the facility tour there was no evidence that the facility met the state and local codes and building ordinances. 2. On May 8, 2012 an interview was conducted with the Operations Business Manager (interviewee #21) in the facility between 2:00pm and 3:00pm. The Operations Business Manager acknowledged that the facility was unable to provide evidence that the facility met the state and local codes and building ordinances. The Operations Business Manager (interviewee #21) provided a written acknowledgment that contained the following content: "At this time we do not have the following requested documents available: architect attestation, HVAC duct inspection reports, documentation of test for alarm system, ventilation of treatment room (MERV 7), air exchange information for treatment rooms and rating of insulation."	T 400		