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	AF-0006	A. BUILDING _____ B. WING _____	03/19/2014

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 unannounced Licensure Biennial survey was conducted March 17, 2014 through March 19, 2014. Three Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. One consumer complaint (2014-AC0022) was investigated and substantiated during 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 010	12 VAC 5-412-140 A Organization and management A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility. This RULE: is not met as evidenced by: Based on document review and interview the governing body failed to ensure the facility's quality assurance program was comprehensive, integrated and evaluated the adequacy and appropriateness of services. The governing body failed to ensure the facility operations, policies, and procedures reflected the updated regulations effective June 20, 2013. The findings included: 1. Review of documents and interview revealed the facility's quality assurance (QA) program failed to identify unacceptable and unintended trends in three of the seven required areas of evaluation. These areas included: a) Review of information during the survey	T 010		

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

State of Virginia

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T 000	12 VAC 5-412 Initial comments	T 000		

An unannounced Licensure Biennial survey was conducted March 17, 2014 through March 19 2014. Three Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the survey. One consumer complaint (2014-AC0022) was investigated and substantiated during the survey. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 06/20/2013)

T 010 12 VAC 5-412-140 A Organization and management

T 010

A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility

This RULE was not met as evidenced by:
Based on document review and interview the governing body failed to ensure the facility's quality assurance program was comprehensive, integrated and evaluated the adequacy and appropriateness of services. The governing body failed to ensure the facility operations, policies, and procedures reflected the updated regulations effective June 20, 2013.

The findings included:

1. Review of documents and interview revealed the facility's quality assurance (QA) program failed to identify unacceptable and unintended trends in three of the four required areas of evaluation. These areas included:
a) Review of information during the survey

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Administrator 4/24/14

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T 010	Continued From Page 1	T 010		

process revealed the QA program failed to identify, track and trend concerns related to incomplete patient medical records. Eleven (11) of the sixteen medical records for surgical patients reviewed the records failed to contain a required nursing progress note. Review of twenty (20) patient medical records revealed all had documentation within the record, which did not have authentication by name, date, and time.

b) Review of the medical records for Patient #5 and Patient #11 revealed documented concerns that the facility failed to identify, track and trend as complaints. The facility's complaint log contained only one complaint. The one complaint was documented as occurring in 2013. The facility's QA failed to identify the complaint investigation had been documented.

c) Review of the complication log revealed for the month of January 2014 of the eighteen complications fifteen involved medical termination of pregnancy. The facility documented fifteen patients were given an injection of an antiprogesteron (mifepristone) and instructed to use misoprostol related to an incomplete termination of their pregnancy. The facility's complication log indicated that eleven of the fifteen patients that returned chose to receive a second dosing of mifepristone and misoprostol the four other patients opted to have surgical procedures.

2. Review of the facility's policy and procedure manual did not reveal policies, procedures or processes for the facility to report the following events to the state licensing agency: any serious injury to a patient, medication errors that necessitate a clinical intervention other than monitoring, a death or serious injury of a patient, or staff member resulting from a physical assault

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that occurred within or on the abortion facility's grounds and any other incident reported to the malpractice insurance carrier or in compliance with the federal safe Medical devices Act.

The facility had not developed policies, procedures or process, which required the above information to be reported to the state licensing agency within twenty-four hours. The facility did not have a policy, procedure or process to ensure the notice to the state licensing agency included the facility's name, the type/circumstances of the event, the date of the event and the action taken by the abortion facility to protect patients and staff and prevent the recurrence of the incidence.
The facility had not developed policies, procedure or processes for training their employees in their required role as mandated reporters of abuse and neglect.

An interview was conducted on March 19, 2014 at approximately 3:54 p.m. with Staff #1 and Staff #2. A request was made for any information related to employees' training for their role as mandated reporters of abuse and neglect. Staff #1 reported he/she was not aware of a requirement related to staff being "mandated reporters." The surveyor inquired if Staff #1 had reviewed the Regulations for the Licensure of Abortion Clinics Effective June 20, 2013. Staff #1 and Staff #2 reported they had not received notification that the regulations had been revised. Staff #1 and Staff #2 reported the facility had not developed the additional policies, procedures, or processes to encompass the new reporting requirements, staff's role as mandated reporters, nor trained their staff to comply with the required role of being mandated reporters.

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T 035	Continued From Page 3	T 035		
T 035	12 VAC 5-412-150 Policy and procedure manual.	T 035		

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;
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.

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This RULE: is not met as evidenced by:
Based on a review of the facility's policies and procedures manual, observation, and staff interview, the agency failed to implement their own policy regarding facility maintenance.

The findings included:

Upon entering the facility on March 17, 2014 at 3:30 p.m. a trash can was observed on the entrance stairway leading to the clinic. The trash can with a chux pad under it was on the landing of the stairway collecting water that was dripping from the ceiling. The ceiling had water damage that was approximately eighteen (18) inches in length in the center of the ceiling. An interview with Staff #2 on March 18, 2014 at approximately 4:00 p.m. revealed that this was a new leak and

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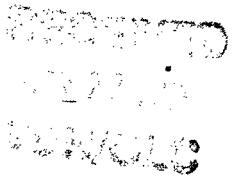
had maintenance had been notified.

A tour of the patient and visitor waiting room on March 18, 2014 revealed a damaged exterior wall due to a water leak. The ceiling had an approximately three (3) foot gaping area that was soaked with water and dripping down the wall and around an exterior window. The wood framing around the window was saturated with water and was soft. The damaged area had black colored mold growing in it, and the water drips on the wall were a pink color. The room had a moldy odor. There was a trash can on the floor with a chux pad under it to catch the leaking water. There was no barrier to prevent patients or visitors from approaching the damaged area. An interview with Staff #2 on March 18, 2014 at approximately 4:00 p.m. revealed that this leak had sprung at some point in January, 2014 and maintenance had been to the facility to do a temporary fix by pouring tar on the roof. Per Staff #2, the maintenance person said that the permanent repair could not be done until the temperature warmed and precipitation stopped enough to replace the roof. Since the temporary repair and additional snowfall the leak has continued and progressed into its moldy state. On March 18, 2014 at approximately 4:00 p.m. Staff #2 said that maintenance had been notified. On March 19, 2014 at 4:00 p.m. it was observed that the wet/moldy wall had been covered with a large plastic sheet and a maintenance person was observed leaving the facility. The waiting room still had the odor of mold, but it was evident that a air freshener or sanitizing spray had been used.

A review of the agency's policy revealed a facility maintenance segment that stated, "The office manager (Administrator) is responsible to ensure proper facility and equipment maintenance."



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T 100	Continued From Page 6	T 100		
T 100	12 VAC 5-412-170 I Personnel	T 100		

I. A personnel file shall be maintained for each staff member. Personnel record information shall be safeguarded against loss and unauthorized use. Employee health-related information shall be maintained separately within the employee's personnel file.

This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to implement the facility's policy related to maintaining health information separately within the employees' personnel files for eleven of eleven employees (Employee Files #1 - #11).

The findings included:

The agency policy and procedure manuals were reviewed on March 18, 2014 at approximately 2:00 p.m. Eleven employee files (Employee Files #1 - #11) were reviewed on March 18, 2014 at approximately 1:15 p.m. Eleven of eleven employee files reviewed had health information within the employee file.

Staff #1 was informed of the findings in the employee files between 3:00 p.m. and 5:00 p.m. on March 18, 2014. Staff #1 and Staff #2 confirmed the findings in the employee files.

T 140	12 VAC 5-412-210 B Patients' rights	T 140		

B. The facility shall establish and maintain complaint handling procedures which specify the:
1. System for logging receipt, investigation and resolution of complaints; and
2. Format of the written record of the findings of each complaint investigated.

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This RULE: is not met as evidenced by:
Based on document review and interview the facility failed to document the investigation of one of one complaint included in their complaint log.

The findings included:

Review of the facility's complaint log on March 17, 2014 at approximately 3:44 p.m. revealed no complaints for 2014 and one complaint for 2013. Review of the complaint logged for 2013 did not include an investigation.

An interview conducted on March 17, 2014 at approximately 3:46 p.m., with Staff #1. When asked about the complaint log, Staff #1 stated, "That is our only complaint, we have not received any complaints for 2014." A request was made for the patient's medical record and the patient was added to the survey sample.

The patient's medical record included the same information as listed in the complaint log; there was no documentation of an investigation.

An interview was conducted on March 17, 2014 at approximately 4:49 p.m., with Staff #1 and Staff #2. A request was made for the investigative details related to the complaint. Staff #1 stated, "I met and talked to the staff about the complainant's concerns. The complainant did not want us to call back." The surveyor requested the documentation from the staff meeting. Staff #1 stated, "I didn't write anything up, I talked to them, no one admitted to inappropriately communicating with the patient." Staff #1 acknowledged the facility's form in their complaint log included a space for documenting the complaint investigation. Staff #1 stated, "I didn't write up the investigation."

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T 145	12 VAC 5-412-210 C Patients' rights C. The facility shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgement of complaints; 2. Investigation of the complaint; 3. Review of the investigation findings and resolution for the complaint; and 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. This RULE: is not met as evidenced by: Based on document review and interview the facility's designated person responsible for complaint resolution failed to identify, acknowledge and investigate complaints for three of three patients with documented concerns. (Patients #1, #5, and #11) The findings included: 1. Review of the facility's complaint log on March 17, 2014 at approximately 3:44 p.m. revealed no complaints for 2014 and one complaint for 2013. Review of the complaint logged for 2013 did not include an investigation. The surveyor requested the medical record for the patient listed in the complaint. The patient was added to the survey sample and designated Patient #1. An interview conducted on March 17, 2014 at approximately 3:46 p.m., with Staff #1. When asked about the complaint log, Staff #1 stated, "That is our only complaint, we have not received any complaints for 2014." Review of Patient #1's medical record included a progress note with the details as written in the complaint log. The progress note did not have additional information related to an investigation or	T 145		

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T 145	Continued From Page 9	T 145		

resolution of the complainant's concerns.

An interview was conducted on March 17, 2014 at approximately 4:49 p.m., with Staff #1 and Staff #2. A request was made for the investigative details related to the complaint. Staff #1 stated, "I met and talked to the staff about the complainant's concerns. The complainant did not want us to call back." The surveyor requested the documentation from the staff meeting. Staff #1 stated, "I didn't write anything up, I talked to them, no one admitted to inappropriately communicating with the patient." Staff #1 acknowledged the facility's form in their complaint log included a space for documenting the complaint investigation. Staff #1 stated, "I didn't write up the investigation."

2. Review of Patient #5's medical record on March 18, 2014 revealed a progress note dated February 25, 2014, five days after the patient's procedure. The progress note documented the patient's concerns related to not receiving a prescription for pain medications. The facility staff documented the patient's concerns related to increase pain and request for pain medication. The progress note documented the patient's concern related to how his/her discharge was handled. The progress note did not include follow-up information, investigation or resolution related to Patient #5's documented concerns. Patient #5's concerns were not included in the complaint log.

3. Review of Patient #11's medical record on March 18, 2014 revealed documentation of the patient's express concern. The documentation indicated the patient expressed concerns related to staff's "unprofessional phone etiquette." Patient #11's medical record did not include follow-up information, investigation or resolution related to the patient's documented concerns. Patient #11's

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concerns were not included in the complaint log.

An interview was conducted on March 18, 2014 at approximately 3:44 p.m., with Staff #2. The above information was presented by the surveyors. Staff #2 reviewed the patients' medical records and verified the findings. Staff #2 affirmed the person responsible for complaints had missed opportunities to identify, acknowledge, investigate, and resolve patient's complaints.

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

B. Written infection prevention policies and procedures shall include, but not be limited to:
1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community acquired infection within the facility;
2. Training of all personnel in proper infection prevention techniques;
3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;
4. Use of standard precautions;
5. Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety & Health Administration.
6. Use of personal protective equipment;
7. Use of safe injection practices;
8. Plans for annual retraining of all personnel in infection prevention methods;
9. Procedures for monitoring staff adherence to recommended infection prevention practices; and
10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.

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This RULE: is not met as evidenced by:
Based on observation, a review of The National Center for Biotechnology Information website (www.ncbi.nlm.nih.gov), and staff interview, the agency failed to comply with correct hand-washing techniques, use of standard precautions, and use of safe injection practices.

The findings included:

1. On March 19, 2014 at 7:05 p.m. Patient #19 was observed in the procedure room for a medical abortion. Staff #6 used hand sanitizer and donned non-sterile gloves and then used lubricant from a multi-use tube stored in a drawer in the procedure table/bed. Staff #6 removed an unwrapped speculum from the same drawer in the procedure table that contained the multi-use lubricant tube. This drawer contained approximately 8-10 other unwrapped speculums. Staff #6 then performed a pelvic exam. Staff #6 removed the gloves and then administered an injection of Methotrexate without wearing gloves and without having performed hand hygiene following the pelvic exam. Hand sanitizer was used by Staff #6 prior to leaving the room.

On March 19, 2014 at 7:30 p.m. Patient #20 was observed in the procedure room for a surgical abortion. Staff #6 used hand sanitizer upon entering the room and donned non-sterile gloves and removed lubricant from the multi-use tube in the procedure table/bed drawer that contains the speculums. A pelvic exam was done by Staff #6, and then the gloves were removed. No hand hygiene was done. A speculum was removed from the drawer by Staff #6 with bare hands. Staff #3 opened the sterile procedure pack and Staff #6 donned sterile gloves. Staff #6 inserted the speculum into the patient's vagina and began the dilation of the cervix. Following cervical dilation

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Staff #3 handed the suction tube (non-sterile) to Staff #6 using non-sterile gloves. Staff #6 held the non-sterile tube while wearing the sterile gloves and proceeded with the suction evacuation of the uterus. After the completion of the abortion Staff #3 brought a multi-use bottle of Ferric Subsulfate with two (2) non-sterile swabs inserted in the bottle. The bottle was held approximately three (3) inches from the perineum while Staff #6 removed the swabs and used them. The bottle of Ferric Subsulfate was then returned to the shelf and was not cleaned. Throughout the abortion procedure the patient tensed and her legs began to close and Staff #6 used hands with sterile gloves on them to push Patient #20's legs open while telling her to relax her muscles, then returned to the procedure without changing gloves.

According to The World Health Organization, Safe Abortion, 2nd edition, Technical and Policy Guidance for Health Systems; 2012, (http://www.ncbi.nlm.nih.gov/books/NBK138196/), "All staff should wash their hands thoroughly before and after coming into contact with the woman, as well as immediately following any contact with blood, body fluids or mucous membranes. High-level disinfected or sterile gloves should be worn and replaced between contacts with different patients and between vaginal (or rectal) examinations of the same woman. After completing the care of one woman and removing gloves, the health-care provider should always wash their hands, as gloves may have undetected holes in them."

#2. An observation was conducted on March 18, 2014 at 9:14 a.m., with Staff #2 to review the facility's controlled medication and medication storage. The observation revealed a box twenty-five vials of Pitocin 1-mL (milliliter) vials,

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VIRGINIA WOMEN'S WELLNESS	224 GROVELAND ROAD VIRGINIA BEACH, VA 23452

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each containing 10 units of oxytocin. One of the vials had been opened, dated "3/15/14" and placed back in the box. The package identification was listed as NDC (National Drug Code) 42023-116-25. Review of the package insert did not indicate the vial was for multiple dosing. Staff #2 stated, "We use each vial for multiple patients." Staff #2 reviewed the package insert with the surveyor and reported the NDC 42023-116-25 was not listed as a multi-dose vial. Staff #2 called the facility's medication supplier and was referred to the drug's manufacturer. On March 18, 2014 at 10:47 a.m. Staff #2 and the surveyor placed a call to the manufacturer. The manufacturer indicated NDC 42023-116-25 was a single dose vial not to be utilized on multiple patients.

[According to <http://www.Drugs.com> Pitocin is indicated for the initiation or improvement of uterine contractions ... (3) as adjunctive therapy in the management of incomplete or inevitable abortion. In the first trimester, curettage is generally considered primary therapy ...]

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

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);

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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 review the facility failed to implement proper cleaning of environmental surfaces between patients and to properly store cleaning agents.

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The findings included:

1. An observation conducted on March 18, 2014 at 9:45 a.m., with Staff #2 revealed a cloth chair was utilized in the laboratory (lab) area. Staff #2 acknowledged the cloth chair was where patient's sat to have their blood drawn. Staff #2 affirmed the cloth chair could not be disinfected between patients. Staff #2 verified if a patient bled and the blood entered the surface of the cloth chair that would present a mode of cross-contamination and a means for transmission of potentially infectious agents.

2. Appropriate storage for cleaning agents:

An observation conducted on March 18, 2014 at approximately 9:45 a.m., with Staff #2 in the lab area revealed staff stored cleaning supplies and other items under the lab sink in an unlocked cabinet. The observation revealed the following items had been stored under the lab sink: an opened gallon container of bleach, an empty water jug, a can of insecticide, a plunger and a flower. Also stored under the sink were two red sharps containers; one container had a vase with blacken material inside and the other container had a flexible hose with connector caps inside. Staff #2 acknowledged the items found were improperly stored under the lab sink.

Three Cavacide (disinfectant) bottles, one Cidex (high level disinfectant), and two distilled waters were found stored on the floor in the autoclave room on March 18, 2014 at 3:00 p.m. One of the Cavacide bottles was opened with no date documented on the bottle. One distilled water was opened with no date documented on the bottle.

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3. Procedures in place for the processing of each type of reusable medical equipment between uses on different patients.

Staff #1 reported instruments were being autoclaved in the "closed" position during the initial tour of the facility at approximately 9:25 am on March 18, 2014.

Staff #1 was present during the findings of the undated open bottles of cleaning solution and distilled water found in the autoclave room. Staff #1 confirmed the instruments were being autoclaved in the "closed" position.

T 255 12 VAC 5-412-250 H Anesthesia service — T 255

H. Discharge from anesthesia care is the responsibility of the health care practitioner providing in anesthesia care and shall occur only when the patient has met specific physician-defined criteria.

This RULE: is not met as evidenced by:
Based on documentation and interview the facility failed to have written specific physician- defined criteria for discharge for twenty of twenty medical records reviewed (Patient Record #1 - #20).

The findings included:

The policy and procedure manuals were reviewed on March 19, 2014 at approximately 5:00 pm. No specific physician defined discharge criteria was located. Twenty of twenty (Patient Records #1 - #20) medical records reviewed during the survey on March 17, 2014 and March 18, 2014 had no evidence of written discharge criteria.

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T 255	Continued From Page 17 Staff #2 was asked about physician-defined discharge criteria on March 19, 2014 at approximately 5:15 pm Staff #2 reported the facility does not have any specific discharge criteria.	T 255		
T 275	12 VAC 5-412-260 C Administration, storage and dispensing of dru C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10 This RULE: is not met as evidenced by: Based on observation, document review, and interview the facility failed to implement the facility's policy related to properly storing medications. The findings included: Approximately 75 packages of birth control medications were found unsecured in a closet across from the procedure room at 9:40 a.m. on March 18, 2014. This area could be accessed by patients. Staff #2 was present during the findings. Staff #2 confirmed the medication was unsecured.	T 275		
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	T 290		

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include:
1. A bed or recliner suitable for recovery;
2. Oxygen with flow meters and masks or equivalent;
3. Mechanical suction;
4. Resuscitation equipment to include; as a minimum, resuscitation bags and oral airways;
5. Emergency medications, intravenous fluids, and related supplies and equipment;
6. Sterile suturing equipment and supplies;
7. Adjustable examination light;
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 staff interview, the agency failed to maintain medical equipment appropriate to care for patients based on the level, scope and intensity of services provided.

The findings included:

During the facility tour on March 18, 2014 at approximately 9:15 a.m. the facility's procedure room was inspected. A one inch tear was noticed at the seam of the vinyl on the procedure table/bed. This tear was an infection control issue, as it would be impossible to properly clean the area between patients. Staff #3 acknowledged the presence of the tear in the vinyl, and stated that the procedure table is cleaned with disinfecting spray (Cavicide) and wiped down between patients.

T 295 12 VAC 5-412-280 Emergency equipment and supplies — T 295

An abortion facility shall maintain medical equipment, supplies and drugs appropriate and

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adequate to manage potential emergencies based on the level, scope and intensity of services provided. Such medical equipment, supplies and drugs shall be determined by the physician and shall be consistent with the current edition of American Heart Association's Guidelines for Advanced Cardiovascular Life Support. Drugs shall include, at a minimum, those to treat the following conditions:

1. Cardiopulmonary arrest;
2. Seizure;
3. Respiratory distress;
4. Allergic reactions;
5. Narcotic toxicity;
6. Hypovolemic shock; and
7. Vasovagal shock.

This RULE: is not met as evidenced by:
Based on observation and interview the facility failed to maintain all drugs needed to manage potential emergencies consistent with the current standards of ACLS (Advanced Cardiac Life Support).

The findings included:

A tour of the facility was done on March 18, 2014 at approximately 9:30 am. The facility does have some emergency drugs. No drugs were located to treat a seizure. No Atropine (used to treat a slow heartrate) was located. No Sodium Bicarbonate (used to treat acidosis) was located. Lidocaine (anti- arrhythmic alternative drug to Amiodarone which is the first line drug) was located (both drugs used to treat life threatening heart rhythms).

Staff #2 was present during the findings and confirmed the findings. Staff #1 reported on March 19, 2014 at approximately 9:40 p.m. the Atropine and Sodium Bicarbonate are on back

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T 295	Continued From Page 20 order. http://www.heart.org/HEARTORG/CPRAndECC/Science/Guidelines/Guidelines_UCM_303151_SubHomePage.jsp	T 295		
T 315	12 VAC 5-412-300 A Quality assurance A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise policies and practices, as necessary. This RULE: is not met as evidenced by: Based on document review and interview the facility failed to have a comprehensive quality assurance (QA) program, which performed self-assessment to identify concerns, and analyzed data. The findings included: 1. Review of twenty (20) patient medical records revealed the facility's QA program missed three identified patient complaints. Review of sixteen medical records for surgical patients revealed eleven (11) missed opportunity to ensure nurse's documented nursing progress notes. Review of twenty patient medical records revealed documentation within the record, which did not have authentication by name, date or time the documentation had been made. The QA program failed to implement a self assessment to identify and correct the information discovered during the	T 315		

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survey process.

An interview was conducted on March 18, 2014 at approximately 3:39 p.m., with Staff #2. Staff #2 reviewed the facility's QA with the surveyors. The information found during survey was shared with Staff #2. Staff #2 verified the information had not reached QA. Staff #2 affirmed the concerns identified by the surveyors had not been identified by the facility's QA process.

2. Review of the complication log revealed for the month of January 2014 of the eighteen complications fifteen involved medical termination of pregnancy. The facility documented fifteen patients given an methotrexate and instructed to use misoprostol returned related to an incomplete termination of their pregnancy. The facility's complication log indicated that eleven of the fifteen patients that returned chose to receive a second dosing of methotrexate and misoprostol the four other patients opted to have surgical procedures.

An interview was conducted on March 18, 2014 at approximately 4:08 p.m., with Staff #3. Staff #3 reported he/she collected the data for the complication log. Staff #3 reviewed the complication log with the surveyors. Staff #3 stated, "We had a lot of complications in January this year there were eighteen." During the review it was determined that fifteen of the complications were related to medical terminations of pregnancy. When asked related to the ratio or analysis of the data compared to the number of medical terminations of pregnancy performed in January 2014 or with other months. Staff #3 responded, "I just collected the data, I don't know how many medical terminations occurred in January." A request was made for the number of medical terminations of pregnancy performed in

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T 315	Continued From Page 22 January 2014. Staff #3 returned at approximately 4:29 p.m. and reported the facility performed "forty-four medical" terminations. From the information listed in the facility's complication log; the data revealed for 36.6 percent of the patients either additional medication or a surgical procedure was required to complete the termination of pregnancy. An interview was conducted on March 19, 2014 at approximately 8:39 p.m., with Staff #2 and Staff #6. The findings were reviewed. Staff #6 reported the facility's QA program needed to address the issues found by the survey team. Staff #2 acknowledged the QA program's failure to perform an appropriate self-assessment of the facility's performance.	T 315		
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 facility's quality assurance (QA) program failed to identify unacceptable and unintended trends in three of the seven required areas of evaluation.	T 320		

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The findings included:

1. Review of information during the survey process revealed the QA program failed to identify, track and trend concerns related to incomplete patient medical records. Eleven (11) of the sixteen medical records for surgical patients reviewed failed to contain a required nursing progress note. Review of twenty (20) patient medical records revealed all had documentation within the record, which did not have authentication by name, date, and time.

An interview was conducted on March 19, 2014 at approximately 8:39 p.m., with Staff #2 and Staff #6. The findings were reviewed. Staff #2 verified the nursing staff had failed to perform progress notes related to the patient's condition or progress throughout their stay. Staff #6 reported the documentation on the inside covers of the medical records were part of the patient's legal medical record. Staff #6 reported the notes were made by him/her and other staff. Staff #6 acknowledged the documentation was not signed, dated or timed. Staff #6 agreed the patient medical records were not complete or accurate without the proper authentication. Staff #2 acknowledged the QA program's failure to perform an appropriate self-assessment of the facility's performance.

2. Review of the medical records for Patient #5 and Patient #11 revealed documented concerns the facility failed to identify, track and trend as complaints. The facility's complaint log contained only one complaint. The one complaint was documented as occurring in 2013. The facility's QA failed to identify the complaint investigation had not been documented.

An interview was conducted on March 18, 2014

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from approximately 3:44 p.m. to 3:56 p.m., with Staff #2. Staff #2 initially reported on all seven of the required areas. Staff #2 reported the QA program did not find concerns with the assessment of the facility's patient records, handling of complaints or with complications. The surveyors presented the information discovered during the survey process. Staff #2 reviewed the findings and patient medical records with the surveyors. Staff #2 stated "We failed to pick up on the concerns you found."

3. Review of the complication log revealed for the month of January 2014 of the eighteen complications fifteen involved medical termination of pregnancy. The facility documented fifteen patients given an injection of an antiprogesteron (mifepristone) and instructed to use misoprostol returned related to an incomplete termination of their pregnancy. The facility's complication log indicated that eleven of the fifteen patients that returned chose to receive a second dosing of mifepristone and misoprostol the four other patients opted to have surgical procedures.

An interview was conducted on March 18, 2014 at approximately 4:08 p.m., with Staff #3. Staff #3 reported he/she collected the data for the complication log. Staff #3 reviewed the complication log with the surveyors. Staff #3 stated, "We had a lot of complications in January this year there were eighteen." During the review it was determined that fifteen of the complications were related to medical terminations of pregnancy. When asked related to the ratio or analysis of the data compared to the number of medical terminations of pregnancy performed in January 2014 or with other months. Staff #3 responded, "I just collected the data, I don't know how many medical terminations occurred in January." A request was made for the number of

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medical terminations of pregnancy performed in January 2014. Staff #3 returned at approximately 4:29 p.m. and reported the facility performed "forty-four medical" terminations. From the information listed in the facility's complication log; the data revealed for 36.6 percent of the patients either additional medication or a surgical procedure was required to complete the termination of pregnancy.

T 340 12 VAC 5-412-310 Medical records

T 340

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,
   i. Patient instructions, preoperative and postoperative; and
   j. Names of referral physicians or agencies.

This RULE: is not met as evidenced by:

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Based on document review and interview the facility failed to:
1. Maintain complete and accurate medical records for twenty of twenty medical records reviewed (Patients #1 - #18 and #22 - #23);

2. Ensure nurses made progress notes for eleven of sixteen surgical medical records reviewed (Patients #1, #4, #7, #8, and #10- #16); and

3. Have a signed physician's orders for one of twenty medical records reviewed. (Patient #3)

The findings included:

1. Review of twenty (20) patient medical records for Patients #1 - #18, #22, and #23 revealed handwritten notes on the inside covers of the file folder that are used as the patient's medical record. The notations were in different handwriting styles and ink colors. The documentation did not have signatures to indicate or authenticate who had written the note. The documentation did not have a date or a time that the information had been documented in the patient's medical record.

2. Review of sixteen surgical patient medical records revealed eleven (11) failed to contain a required progress note by nursing staff. The medical records for Patients #1, #4, #7, #8, and #10- #16 did not contain progress documentation by nursing.

An interview was conducted on March 19, 2014 at approximately 8:42 p.m., with Staff #2 and Staff #6. The findings were reviewed. Staff #2 verified the nursing staff had failed to perform progress notes related to the patient's condition or progress throughout their stay. Staff #6 reported the documentation on the inside covers of the medical

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records were part of the patient's legal medical record. Staff #6 reported the notes were made by him/her and other staff. Staff #6 acknowledged the documentation was not signed, dated or timed. Staff #6 agreed the patient medical records were not complete or accurate without the proper authentication. Staff #2 acknowledged the QA program's failure to perform an appropriate self-assessment of the facility's performance.

3. Patient #3's chart was reviewed on March 18, 2014 and revealed that the patient had come in for an abortion procedure on January 4, 2014, selecting to have twilight sedation (intravenous Fentanyl and Versed) during the procedure. The medication was given to the patient prior to the procedure, and then a local anesthetic was administered by the physician into the patient's cervix (a combination of Pitocin, Vasopressin, and Lidocaine). These medication administrations are documented in the patient's record. The record states that after the administration of the sedation and local anesthetic but prior to the operative procedure Patient #3 had a panic attack and the abortion could not be done. The patient was scheduled to return for the procedure on January 8, 2014. Documentation of the procedure and medication administration was in the record for January 8, 2014, signed by the physician. The order for the medications on January 4, 2014, however, was not signed by the physician, but the medications were documented as being administered.

T 345 12 VAC 5-412-320 Record storage

T 345

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

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T 345	Continued From Page 28 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 observation, interview, and document review the facility failed to implement the policy related to the safe storage of medical records. The findings included: Multiple plastic bins containing medical records were found in a unsecured closet on March 19, 2014 at approximately 9:40 a.m., during a tour of the facility. This area could be accessed by patients. The policy and procedure manuals were reviewed on March 19, 2014. A policy was located related to the safe storage of medical records. Staff #2 was present during the findings and confirmed the bins contained medical records. Staff #1 was told of the findings and confirmed the door to the closet was unsecured.	T 345		
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: The facility failed to develop policies, procedures or process for reporting required information to the state licensing office and failed to train their employees regarding their role as mandated reporters of abuse and neglect. The findings included:	T 355		

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1. Review of the facility's policy and procedure manual did not reveal policies, procedures or processes for the facility to report the following events to the state licensing agency: any serious injury to a patient, medication errors that necessitate a clinical intervention other than monitoring, a death or serious injury of a patient, or staff member resulting from a physical assault that occurred within or on the abortion facility's grounds and any other incident reported to the malpractice insurance carrier or in compliance with the federal safe Medical devices Act.

The facility had not developed policies, procedures or process, which required the above information to be reported to the state licensing agency within twenty-four hours. The facility did not have a policy, procedure or process to ensure the notice to the state licensing agency included the facility's name, the type/circumstances of the event, the date of the event and the action taken by the abortion facility to protect patients and staff and prevent the recurrence of the incidence.

2. Review of eleven employee files did not reveal evidence of training of their required role as mandated reporters of abuse and neglect.

An interview was conducted on March 19, 2014 at approximately 3:54 p.m. with Staff #1 and Staff #2. A request was made for any information related to employees' training for their role as mandated reporters of abuse and neglect. Staff #1 reported he/she was not aware of a requirement related to staff being "mandated reporters." The surveyor inquired if Staff #1 had reviewed the Regulations for the Licensure of Abortion Clinics Effective June 20, 2013. Staff #1 and Staff #2 reported they had not received notification that the regulations had been revised. Staff #1 and Staff #2 reported the

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T 355	Continued From Page 30 facility had not developed the additional policies, procedures, or processes to encompass the new reporting requirements, staff's role as mandated reporters, nor trained their staff to comply with the required role of being mandated reporters.	T 355		
T 360	12 VAC 5-412-340 Policies and procedures "The abortion facility shall develop, implement and maintain policies and procedures to ensure safety within the facility and on its grounds and to minimize hazards to all occupants. The policies and procedures shall include, but not limited to: 1. Facility security; 2. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services; and 3. Provisions for disseminating safety-related information to employees and users of the facility. This RULE: is not met as evidenced by: Based on observation and interview the facility failed to implement policies to ensure safety practices pertaining to supplies. The findings included: Two unpackaged needles were found in a drawer in the procedure room on March 18, 2014 at approximately 9:30 am. Staff #2 was present during the findings and disposed of the needles.	T 360		
T 375	12 VAC 5-412-360 A Maintenance A. The facility's structure, its component parts, and all equipment such as elevators, heating,	T 375		

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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 a review of the agency's policies and procedures manual, observation, and staff interview, the agency failed to keep the facility's structure in good repair and operating condition. The agency failed to maintain areas used by patients in good repair and kept free of hazards. The agency failed to keep all wooden surfaces sealed in such a way to allow sanitation.

The findings included:

Upon entering the facility on 3/17/14 at 3:30 p.m. a trash can was observed on the entrance stairway leading to the clinic. The trash can with a chux pad under it was on the landing of the stairway collecting water that was dripping from the ceiling. The ceiling had water damage that was approximately eighteen (18) inches in length in the center of the ceiling. An interview with Staff #2 on 3/18/14 at approximately 4:00 p.m. revealed that this was a new leak and had maintenance had been notified.

A tour of the patient and visitor waiting room on 3/18/14 revealed a damaged exterior wall due to a water leak. The ceiling had an approximately three (3) foot gaping area that was soaked with water and dripping down the wall and around an exterior window. The wood framing around the window was saturated with water and was soft. The damaged area had what appeared to be a

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back colored mold growing in it, and the water drips on the wall were a pink color. The room had a moldy odor. There was a trash can on the floor with a chux pad under it to catch the leaking water. There was no barrier to prevent patients or visitors from approaching the damaged area. An interview with Staff #2 on 3/18/14 at approximately 4:00 p.m. revealed that this leak had sprung at some point in January, 2014 and maintenance had been to the facility to do a temporary fix by pouring tar on the roof. Per Staff #2, the maintenance person said that the permanent repair could not be done until the temperature warmed and precipitation stopped enough to replace the roof. Since the temporary repair and additional snowfall the leak has continued and progressed into its moldy state. On 3/18/14 at approximately 4:00 p.m. Staff #2 said that maintenance had been notified. On 3/19/14 at 4:00 p.m. it was observed that the wet/moldy wall had been covered with a large plastic sheet and a maintenance person was observed leaving the facility. The waiting room still had the odor of mold, but it was evident that a air freshener or sanitizing spray had been used.

A review of the agency's policy revealed a facility maintenance segment that stated, "The office manager (Administrator) is responsible to ensure proper facility and equipment maintenance."

Virginia Women's Wellness – Plan of correction

TAG 010

1. A – All surgical charts now include a progress note to permit documentation by the staff, nurses or physicians. All staff have been retrained to authenticate all documentation in the medical record with name, date and time.

This has been completed on 04/23/2014.

The Administrator & Assistant Administrator will continuously monitor the medical records to ensure the presence of a progress not and the authentication of all documentation.

The QA committee will review this process and update the Governing Body. Any deviations from this practice will be brought to the attention of the Governing Body. Any employees that are found to not be compliant with this policy will be retrained and subsequently monitored by the Administrator & Assistant Administrator to ensure compliance.

1.B – The Department reviewed 21 medical records. Of the 21 medial records reviewed, the Department references 2 minor concerns expressed by patients.

Pt # 5 was asked, how did you feel about our services? Answer: "*Great personable office staff. Unprofessional phone etiquette.*" Please note that the patient was interviewed in depth about the phone etiquette issue. She could not identify how or why she was concerned, did not wish to file a formal complaint, and ultimately retracted her statement about phone etiquette, concluding that "I guess I was just nervous on the phone."

Pt # 11 called with a minor concern not a complaint. When a patient expresses a concern she is given the opportunity to file a formal complaint. Patient 11 did not file a formal complaint.

Even when provided with the highest quality of service there are instances when a patient may be unhappy. For example, sometimes patients who engage in drug seeking behavior may complain that we do not provide narcotics in sufficient dosages or quantities to make them fully happy. Likewise, it is not unknown for patients to request a lower fee. While we strive to keep our patients happy and to provide quality medical care at a fair fee, we do not consider such concerns to constitute valid formal complaints against the facility which need to be logged, investigated, and tracked.

Virginia Women's Wellness offers all patients the opportunity to file formal complaints. And we have a formal process for investigating, tracking, and following up on formal complaints. Not one of these patients chose to lodge a formal complaint, even though they were free to do so. We do not feel that fears, worries, or concerns about recognized side effects, feared complications that did not occur, or desires for oral contraceptives

constitute a formal complaint that needs to be logged into the Complaint Log, investigated, tracked, and resolved. Indeed, it is hard to see, from this set of patients, which patients the Department is even referring to.

In conclusion, none of these patients filed formal complaints, nor could VWW even identify any valid complaints amongst this set of patients. Nor do we agree that all concerns, fears, or desires voiced by patients should be logged as formal complaints in the complaint log. For example, sometimes patients who engage in drug seeking behavior may complain that we do not provide narcotics in sufficient dosages or quantities to make them fully happy. Likewise, it is not unknown for patients to request a lower fee. While we strive to keep our patients happy and to provide quality medical care at a fair fee, we do not consider such concerns to constitute valid formal complaints against the facility which need to be logged, investigated, and tracked.

All patients have the right to file a formal complaint. These formal complaints are documented in the complaint log and investigated by the Administrator. The facility will continue to document ALL formal complaints and adhere to the appropriate standards for investing and resolving these complaints.

The QA Committee will review all complaint and provide a report to the Governing Body.

1.C – Although some patients may require more medication or surgical intervention after a medical termination of pregnancy, this is a known and accepted risk of a medical termination. It is not a complication of the procedure and these cases should not have been documented in the complication log. These cases will no longer be documented in the complication log.

The QA Committee will review the complication log and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

2. Since implementation of these regulations VWW has always had policies for reporting the following adverse events to the OLC within 24 hours:

1. Any patient staff or visitor death.
2. Any serious injury to a patient.
3. Medication errors that necessitate a clinical intervention other then monitoring.
4. A death or significant injury of a staff member or patient from a physical assault that occurs on the grounds of the facility.
5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990

VWW is now aware of the recently adopted Mandatory Reporting requirement. All staff have received training on the required Mandatory Reporting. Documentation of this training has been placed in the employee or clinician file. The Administrator and/or

Assistant Administrator will monitor to ensure a;l new hires have the required Mandatory Reporting training.

The QA Committee will review the training records of the staff to ensure compliance and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This has been completed 04/23/2014.

TAG 035

While it is true that there were two leaks in the roof due to the severe and inclement weather we have experienced this winter, we have made several attempts to have this repaired. During the winter season multiple temporary repairs were done. The long term repair could not be completed until the inclement weather season had passed. This permanent repair requires several days of temperatures above 60 degrees Fahrenheit with no precipitation, obviously this could not be performed during the winter time. A temporary repair of the roof was once again performed on 03/22/14. Additionally, the drywall in the waiting area has been removed. On April 1, 2014, the Fire Marshall has inspected same and found no mold, nor mold smell in the waiting area.

The Administrator and or Assistant Administrator will continuously monitor the physical plant for any areas in need of repair. The Landlord will be immediately notified via telephone of the needs. If no response from the Landlord, a written request for repair will be sent.

The QA Committee will review the physical plant and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

The projected time line for completion of this permanent repair is 05/31/2014, weather permitting.

See attachment # 1

TAG 100

A separate employee health file has been made for each employee within their personnel file.

The Administrator and or Assistant Administrator will monitor the employee files to ensure the existence of a separate employee health file.

The QA Committee will review the employee files and separate employee health files and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 03/19/2014.

TAG 140

All complaints will be formally documented and investigated by the Administrator. The compliant, investigation, supporting documentation and resolution of this compliant will be logged appropriately on the complaint intake form and complaint investigation/resolution form.

The Director of Quality Assurance in conjunction with the Administrator and Assistant Administrator will monitor to ensure that all formal complaints are investigated properly.

The QA Committee will review the complaint log and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 03/19/2014

TAG 145

1 - All complaints will be formally documented and investigated by the Administrator. The compliant, investigation, supporting documentation and resolution of this compliant will all be logged appropriately on the complaint intake form and complaint investigation/resolution form.

2 – All staff have been retrained to forward the medical record of any patient with a complaint to the Administrator or Assistant Administrator. The Administrator or Assistant Administrator will then ensure there is proper follow-up, investigation and resolution to the patient's complaint. Not all "concerns" or "complaints" necessarily constitute valid or legitimate complaints. For example, patients, including possibly patients with a prior history of illicit drug usage, who request (or demand) inappropriate amounts of controlled substances may possibly be doing so for illegitimate and/or non-medical reasons.

The Director of Quality Assurance in conjunction with the Administrator and Assistant Administrator will monitor to ensure that all formal complaints are investigated properly.

The QA Committee will review the complaint log and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 04/23/2014.

TAG 170

1 – Proper hand hygiene was performed both before and after the procedure by the physician. All physicians and staff will continue to perform proper hand hygiene both before and after contact with each patient. Additionally, the physician will perform hand hygiene between changing of gloves while in contact with the same patient. Non-sterile gloves will be worn by the clinician when administering injectable medications.

The Administrator and Assistant Administrator will randomly observe staff to ensure they are complaint with these practices. The QA Committee will review the results of this monitoring and observation and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

2 – After contacting both the supplier and the manufacturer it was determined that although the oxytocin vial was not labeled for single- use. It was a single-use vial. VWW will contact the manufacturer of any medication that is not specifically labeled for multi-use or single-use. VWW will request from the manufacturer written confirmation of whether the vial is a multi or single-use. This documentation will be kept on file at VWW. All vials determined to be multi-use will be used for multiple patients. All vials determined to be single-use will be used for only one patient and the remainder discarded.

The Administrator and Assistant Administrator will monitor medications to ensure that single and multi dose vials are being used appropriately. The QA Committee will review the results of this monitoring and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 03/31/2014.

TAG175

1 – The cloth chair located in the laboratory has been replaced with a non-porous wipe able chair.

2- All materials have been removed from under the sink. These items have been discarded or properly stored in a different area.

All bottles of Cavicide and distilled water have been removed from the floor and stored in the proper area. The opened bottles of Cavicide and distilled water have been marked with the date of opening and initials of the individual that opened.

These were completed on 03/18/2014.

3 – All instruments will now be autoclaved in the open position with the exception of tenaculums. If autoclaved in the open position, these sharp metal instruments can tear the CSR wrap therefore compromising the safety of the staff and the sterility of the instruments. The nurse surveyors agreed that sharp tooth tenaculums may be autoclaved in the closed position. All staff have been retrained in the proper position of autoclaving instruments.

The Administrator and Assistant Administrator will randomly these areas to ensure the compliance. The QA Committee will review the results of this monitoring and observation and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 04/10/2014.

TAG 255

Standardized discharge criteria have been established by each physician. Nursing staff have been trained as to the standardized discharge criteria. These criteria have also been posted in the recovery room.

The Administrator and Assistant Administrator will randomly observe to ensure the standardized discharge criteria are present in the recovery area and that all recovery room personnel have been trained in the use of same.

The QA Committee will review the results of this monitoring and observation and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed 04/11/2014

TAG 275

A lock has been placed on the closet where the sample packages of birth control pills were stored. These samples of birth control pills are now securely stored.

The Administrator and Assistant Administrator will randomly observe to ensure the the lock remains and all medications are securely stored.

The QA Committee will review the results of this monitoring and observation and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 03/19/2014

TAG 290

The minute tear on the seam of the vinyl examination table has been repaired.

The Administrator and Assistant Administrator will randomly observe the equipment to ensure it is free from tears.

The QA Committee will review the results of this monitoring and observation and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 03/19/2014

See attachment # 2

TAG 295

Midazolam, sodium bicarbonate & Atropine have been ordered. These items are expected to arrive within 7 days.

The Administrator and Assistant Administrator will randomly review the stat kit monthly to ensure the presence of all emergency drugs

The QA Committee will review the results of this monitoring and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This has been completed 04/14/14.

See Attachment # 3

TAG 315

I – All surgical charts now include a progress note to permit documentation by the staff, nurses or physicians. All staff have been retrained to authenticate all documentation in the medical record with name, date and time.

The Administrator & Assistant Administrator will continuously monitor the medical records to ensure the presence of a progress note and the authentication of all documentation.

2 – Although some patients may require more medication or surgical intervention after a medical termination of pregnancy, this is a known and accepted risk of a medical termination. It is not a complication of the procedure and these cases should not have been documented in the complication log. These cases will no longer be documented in the complication log.

The Administrator and Assistant Administrator will randomly review the complication log to ensure proper documentation and recording.

The QA Committee will review the complication log and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This has been completed on 03/20/2014.

TAG 320

1 - All surgical charts now include a progress note to permit documentation by the staff, nurses or physicians. All staff have been retrained to authenticate all documentation in the medical record with name, date and time.

This has been completed on 04/23/2014.

The Administrator & Assistant Administrator will continuously monitor the medical records to ensure the presence of a progress not and the authentication of all documentation.

The QA Committee will review the results of this monitoring and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

2 – We dispute this deficiency. For a detailed explanation, please see POC for TAG 010, 1.B. In sum, none of these patients filed formal complaints. Nor could the facility even identify a valid complaint among any of the patient records reviewed by the Department. All patients have the right to file a formal complaint. These formal complaints are documented in the complaint log and investigated by the Administrator. The facility will continue to document ALL formal complaints and adhere to the appropriate standards for investing and resolving these complaints.

3 – Although some patients may require more medication or surgical intervention after a medical termination of pregnancy, this is a known and accepted risk of a medical termination. It is not a complication of the procedure and these cases should not have been documented in the complication log. These will no longer be documented in the complication log.

The QA Committee will review the results of this monitoring and observation and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

TAG 340

1 - All staff have been retrained to authenticate all documentation in the medical record with name, date and time.

The Administrator and Assistant Administrator will randomly monitor medical records to ensure all documentation has been authenticated.

The QA Committee will review the results of this monitoring and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This has been completed on 04/23/2014.

2 - All surgical charts now include a progress note to permit documentation by the staff, nurses or physicians.

The Administrator & Assistant Administrator will continuously monitor the medical records to ensure the presence of a progress note and the authentication of all documentation.

The QA Committee will review the results of this monitoring and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This has been completed on 04/23/2014.

3 – Charts will be randomly selected and reviewed by the Administrator, Assistant Administrator or Office Manager to ensure accuracy and completeness. Any deficiencies in recorded keeping will be forwarded to the appropriate staff member for completion and if required retraining will be completed.

TAG 345

Although a key is required to access the area of the facility where the records were stored, there was not a lock on the closet door where the bins containing medical records were stored. This lock was installed before the final day of inspection.

This was completed on 03/19/2014

The Administrator and Assistant Administrator will randomly check the closet where medical records may be stored to ensure it is securely locked.

The QA Committee will review the results of this monitoring and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

TAG 355

1 - Since implementation of these regulations VWW has had policies for reporting the following adverse events to the OLC within 24 hours:

1. Any patient staff or visitor death.
2. Any serious injury to a patient.
3. Medication errors that necessitate a clinical intervention other then monitoring.
4. A death or significant injury of a staff member or patient from a physical assault that occurs on the grounds of the facility.
5. Any other incident reported to the malpractice insurance carrier or in compliance with the federal Safe Medical Devices Act of 1990

These policies have been updated to assure the report includes the facility name, the type of incident, the date of event and the action taken by the facility to protect patients and staff and prevent recurrence of the incidence.

The Administrator and/or Assistant Administrator will monitor to ensure compliance with the Mandatory Reporting.

The QA Committee will review and confirm compliance and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed 04/11/2014.

2 - VWW is now aware of the recently adopted Mandatory Reporting requirement. All staff have received training on the required Mandatory Reporting. Documentation of this training has been placed in the employee or clinician file.

The Administrator and/or Assistant Administrator will monitor to ensure all new hires have the required Mandatory Reporting training.

The QA Committee will review the training records of the staff to ensure compliance and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This has been completed 04/23/2014.

TAG 360

The unused, unwrapped materials found in the drawer were immediately discarded.

The Administrator and Assistant Administrator will continuously inspect the facility to ensure there are no materials that are stored incorrectly or not disposed of correctly.

The QA Committee will review this monitoring and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

This was completed on 03/18/2014.

TAG 375

While it is true that there were two leaks in the roof due to the severe and inclement weather we have experienced this winter, we have made several attempts to have this repaired. During the winter season multiple temporary repairs were done. The long term repair could not be completed until the inclement weather season had passed. This repair requires several days of temperatures above 60 degrees with no precipitation. A temporary repair of the roof was once again performed on 03/22/14. Additionally, the drywall in the waiting area has been removed. On April 1, 2014, the Fire Marshall has inspected same and found no mold, nor mold smell in the waiting area.

The Administrator and or Assistant Administrator will continuously monitor the physical plant for any areas in need of repair. The Landlord will be immediately notified via telephone of the needs. If no response from the Landlord, a written request for repair will be sent.

The QA Committee will review monitoring of the physical plant and report on same to the Governing Body. Any further review or action required will be ordered by the GB.

The projected time line for completion of this permanent repair is 05/31/2014, weather permitting.

See attachment # 1

4/28/14

Administrator Date

Attachment #1

DICKERSON, JAMES
CONSTRUCTION
Virginia Beach, Va 23454

January 24, 2014

Re: Virginia Women's Wellness
224 Groveland Road
Virginia Beach, VA 24352
michellenelson@aol.com

2nd Story off Roof Snow Removal -	$ 200.00
Clean out all drains	$ 150.00

** Note ~ During Roof maintenance I have observed splitting or tearing of the roof membrane in several areas - mainly facing the rear portion of the building.

Recommendation 1 - New Roof
2 - Apply roof asphalt as patch in split areas -
* note for proper application - temperatures should be between 60degrees and 85degrees for three to five days - with no ~~perception~~ precipitation

My advice would be to replace the roof or repair the split areas during the mid spring early summer for suitable climate.

Pricing and quotes will vary upon time of application.

Thank you for your consideration,

Jim Dickerson

Attachment #2

Invoice

LEATHER
restore & more

AUTOMOTIVE | HOME | MARINE | OFFICE

4517 Miarfield Arc, Chesapeake, VA 23321
757.484.5250 Fax 757.484.8499

Date	Invoice #
3/20/2014	3426

Bill To
Virginia Woman's Wellness 224 Groveland Rd Virginia Beach, VA 23452

P.O. No.	Terms

Quantity	Description	Rate	Amount
1	Labor to repair exam table. OK per Terry	95.00	95.00
	Sales Tax	6.00%	0.00

RECEIVED
VDH/OLC

Total $95.00

PD 3/27/14

HENRY SCHEIN®

Attachment #3

INVOICE#	INVOICE DATE
9842977-01	4/14/14
CUSTOMER#	BOX# / PAGE#
2507631	1 of 1 / 1
CUSTOMER PO#	
ORDER#	ORDER DATE
18484932	04/14/14

BOX CONTENT LIST

SHIP TO
VIRGINIA WOMEN WELLNESS
224 GROVELAND RD
CRAIG S CROPP
VIRGINIA BEACH VA 23452-5610

BILL TO
Professional Medical Services
224 Groveland Rd
Craig Cropp
Virginia Beach,VA 23452-5610

LOCATION CODE	SHIPPED QTY	EXP. CODE	UNIT SIZE	DESCRIPTION & STRENGTH	ITEM CODE	LINE NO
-05-05-43	2 TF	06/14	1ML/VL	MIDAZOLAM HCL INJ SDV 5MG/ML 00409230801 NDC#:05258430801 LOT#:12841 TF M2 - Pedigree item. M2 - Henry Schein,Inc. distributes this drug product as an Authorized Distributor of Record for the manufacturer. NORTHEAST D.C. Dea#: RH0236667 Customer Dea#: FC0410174 HENRY SCHEIN INC. 41 WEAVER ROAD DENVER, PA 17517	248-0299	1

4/16/14 TB

VDH/OLC

OFFICE USE ONLY

BATCH# 75632-008

TotQty- 2

Size:#E2

WT - 1

FREIGHT INSTRUCTIONS MD3 4932

RED

HENRY SCHEIN®

6 Duryea Road, Melville, NY 11747
Questions: 1-800-472-4346

INVOICE

SHIP TO/SOLD TO:
Virginia Women Wellness MD
224 Groveland Rd
Craig S Cropp
Virginia Beach,VA 23452-5610

0100001017462059140951100100000005647504141 41

BILL TO:
Professional Medical Services MD
224 Groveland Rd
Craig Cropp
Virginia Beach, VA 23452-5610

Professional Medical Services
224 Groveland Rd
Craig Cropp
Virginia Beach, VA 23452-5610

RECEIVED
APR 29 2014
VEHICLE

BILL TO	SHIP TO	INVOICE AMOUNT
1017462	2507631	564.75

INVOICE#	INVOICE DATE
5914095-01	4/14/14

CUSTOMER PO#

ORDER#	ORDER DATE	ESTIMATED DUE DATE
18484932	04/14/14	05/14/14

D&B#:01-243-0880
WHSE DEA# RH0236667 Fed ID: 11-3136595

LINE NO	ITEM CODE	UNIT SIZE	DESCRIPTION & STRENGTH	QUANTITY ORDERED	QUANTITY SHIPPED	ITEM STATUS	UNIT PRICE	EXTENSION	BOX NO	REM
7	248-1288	RX 50ML/EA	SODIUM BICARB ABJ SYR N-R 8.4%	2	2		20.79	41.58		
		M2 - PEDIGREE ITEM.								
		DUE TO MANUFACTURER NO RETURN POLICY THIS ITEM IS NOT RETURNABLE								
		NDC:05258465734								
8	248-4141	RX 10ML SYR	ATROPINE SULF ABJ LFS N/R .1MG/ML	2	2	*	12.30	24.60		
		** SPECIAL CONTRACT PRICE **								
		M2 - PEDIGREE ITEM.								
		DUE TO MANUFACTURER NO RETURN POLICY THIS ITEM IS NOT RETURNABLE								
		NDC:0525840[illegible]234								
9	248-0299	1ML/VL	MIDAZOLAM HCL INJ SDV 5MG/ML	2						
		This item will ship on another invoice.								
		NDC:0525843[illegible]11								
10	113-5423	160/PK	SUPER SANI CLOTH LARGE	6	6	*P T	7.53	45.18		
11	437-7034	160/EA	EZ-KILL WIPES 6X6.75OD	6	6	*P T	7.21	43.26		
		** SPECIAL CONTRACT PRICE **								
12	315-7107	PU 25/PK	ALLERGY TRAY SYR REG 1CC 27X1/2"	6	6	T	2.85	17.10		
	105-7886	MSDS	ATROPINE SULFATE INJ MSDS ABBHOS	1						

INCLUDED IN THE BELOW FREIGHT CHARGE IS A FUEL/HANDLING SURCHARGE. FOR THE CURRENT TERMS OF SALE GOTO
HTTP://WWW.HENRYSCHEIN.COM/US-EN/MEDICAL/LEGALTERMS.ASPX
PLEASE REFER TO BACK OF PAPERWORK FOR DISCLOSURES/TERMS OF SALE
M2 - HENRY SCHEIN,INC. DISTRIBUTES THIS DRUG PRODUCT AS AN AUTHORIZED

BILL TO	SHIP TO	INVOICE#	INVOICE AMOUNT
1017462	2507631	5914095-01	564.75
ORDER#	ORDER DATE	INVOICE DATE	# OF BOXES
18484932	04/14/14	4/14/14	3
CUSTOMER PO#			PAGE#
			2

ITEM STATUS KEY
B - Backordered; Item will follow
D - Discontinued; Item no longer available
F - Special Schein Free Goods
M - Manufacturer will ship Item directly to you
P - Prescription Drug; Return Authorization Required
R - Refrigerated Item; May be shipped separately
$ - Special Schein Pricing
T - Taxable Item
U - Temporarily unavailable; please reorder
* - Item has MSDS

REM KEY
SK - School Kit
NC - No Charge

Continued on Next Page .....