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	AF-0005	A. BUILDING _____ B. WING _____	10/17/2014

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A CAPITAL WOMENS HEALTH CLINIC	1511 STARLING DRIVE HENRICO, VA 23229

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T 000	12 VAC 5- 412 Initial comments An unannounced Biennial Licensure for a First Trimester Abortion Facility was conducted on October 14, 2014 and October 17, 2014 by two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health conducted the revisit survey. The agency was not in compliance with the provisions of the Code of Virginia, and the State Board of Health 12 VAC 5-381 Regulations for the Licensure of Abortion Facilities. (Rev. 06/20//2013). Deficiencies were identified and follow in the State Form.	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 their policies and job descriptions reflected the appointment/approval of non-licensed staff having access to the facility's narcotic cabinet and accepting delivery of narcotics. The findings included: Observations were conducted on 10/14/14, at approximately 11:00 a.m., with Staff #1 and #2. During the initial tour of the facility, the observation revealed Staff #1 and #2 were in control of the keys to the locked narcotic cabinet. Staff #2 prepared to count the narcotics with the surveyors.	T 010	12 VAC 5-412-140 A On October 27, 2014, a meeting of the Governing Authority was called by the Administrator and Medical Director of the facility. Prior to the inspection and discussions with the Virginia Department of Health inspectors, The Governing Authority was unaware that in addition to having the State required criminal background check, which both the Administrator and Acting Administrator had on file, it was also required they have specific verbiage regarding access to the keys for the locked narcotic cabinet and the receiving and securing narcotic medications in their job descriptions. To comply with this requirement, The Governing Authority then created appropriate new verbiage for the	11/10/14

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

Shelley Abrams — November 13, 2014

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T 010	Continued From Page 1 Staff #1 informed Staff #2 and the surveyors that he/she had accepted delivery of narcotic medications, which "have not been added to the count." Staff #1 stated, "The narcotics I received today are in a plastic bag inside the [narcotic] cabinet." Review of personnel files revealed Staff #1 and Staff #2 were not licensed healthcare professionals. The personnel files for Staff #1 and Staff #2 did not have documented approval from the governing body to accept the delivery of narcotics and to possess keys to the locked narcotic cabinet. An interview was conducted on 10/17/14, at 4:48 p.m., with Staff #2. Staff #2 agreed the job descriptions of Staff #1 and #2 failed to document they had been approved by the governing body to have access to the keys for the locked narcotic cabinet. Staff #2 verified their job descriptions did not include the responsibility for receiving and securing narcotic medications. Staff #2 acknowledged the governing body failed to ensure the facility had a policy, which allowed for non-licensed healthcare professionals to have access to the locked narcotic cabinet.	T 010	already existing Administrator job description to appropriately authorize the Administrator/back up Administrator to have access to the keys for the locked narcotic cabinet and to receive and secure narcotic medications. This new job description was then approved by the Governing Authority, a copy of the description was placed in the two listed employees' files, and a copy was given to each of the two employees.	
T 170	12 VAC 5-412-220 B Infection prevention B. Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including	T 170	12 VAC5-412-220 B After our inspection and discussions with inspectors from the Department of Health, the facility has implemented a formal policy effective immediately of the recommended "one needle, one syringe, one time" method for use during any preparations of injections in the facility. All Staff members who are	10/2014

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T 170	Continued From Page 2 indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety & Health Administration. 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: is not met as evidenced by: Based on observations and interview the facility failed to ensure staff used safe injection practices for eleven of eleven prepared injections. The findings included: An observation was conducted on 10/17/2014 at approximately 6:40 p.m. with Staff #4 as he/she prepared Lidocaine/Vasopressin injections to be used during procedures. The observation revealed Staff #4 removed the caps covering the vial of Vasopressin and without disinfecting the vial's septum withdrew the medication. Staff #4 removed the cap from a multi-dose vial of Lidocaine and without disinfecting the vial's septum injected the Vasopressin into the vial of Lidocaine. Staff #4 did not change the needle on the syringe prior to injecting the Vasopressin into the Lidocaine vial. After injecting the Vasopressin into the Lidocaine vial Staff #4 used the same syringe to prepare a Lidocaine/Vasopressin dose for injection. Staff #4 removed the prepared syringe from the needle hub leaving the needle in	T 170	engaged in preparations of injections have been individually advised of this policy, provided a copy of the deficiency report, and have formally agreed to follow this policy without deviation. Furthermore, these staff members were educated about the requirement of and method to disinfect the septum of all vials before withdrawing medication.	

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T 170	Continued From Page 3	T 170		

the vial of Lidocaine mixed with Vasopressin. Staff #4 attached four syringes in succession to the hub to prepare Lidocaine/Vasopressin injections to be used during the scheduled procedures. Staff #4 did not disinfect the hub of the needle, which protruded from the septum of the Lidocaine mixed with Vasopressin vial, prior to attaching each syringe. Staff #4 used the same manner of preparing Lidocaine/Vasopressin syringes as sited above; for a total of eleven injections.

An interview was conducted on 10/17/2014 at approximately 6:49 p.m., as Staff #4 prepared to begin procedures. The surveyor asked Staff #4 regarding his/her process for preparing syringes. Staff #4 reported all the connections between the needle and syringes were "sterile." Staff #4 reported the septum of the new vials were sterile.

An interview was conducted on 10/17/2014 at 7:40 p.m., with Staff #2. Staff #2 was informed of the findings during the observation. Staff #2 was informed of the standards for safe injection practices.

A second interview was conducted on 10/17/2014 at 7:43 p.m., with Staff #4. The surveyor provided Staff #4 with the current best practice guidelines for safe preparation of injections. Staff #4 acknowledged he/she had thought the septum of a newly opened vial was sterile and did not need to be disinfected. Staff #4 verified he/she had not used the best practice of "one needle, one syringe, one time."

According to the Association for Professionals in Infection Control and Epidemiology, Inc. American Journal of Infection Control 2010: "The transmission of bloodborne viruses and other microbial pathogens to patients during routine

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T 170	Continued From Page 4 health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication vial practices by health care professionals in various clinical settings throughout the United States. Breaches in safe injection, infusion, and medication vial practices continue to result in unacceptable and devastating events for patients. Always use a new sterile syringe and new needle/cannula when entering a vial. Never enter a vial with a syringe or needle/cannula that has been previously used (eg, to inject a patient or access a medication vial). Cleanse the access diaphragm of vials using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab. Allow the diaphragm to dry before inserting any device into the vial. Never leave a needle, cannula, or spike device (even if it has a 1-way valve) inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination... Use a new syringe and a new needle for each entry into a vial or IV bag ..."	T 170		
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;	T 320	12 VAC 5-412-300 B Quality assurance After our inspection and discussions with inspectors from the Department of Health, the Medical Director and Administrator called a meeting of the Quality Improvement Committee to discuss the findings. An assessment of the facility's Quality Assurance program revealed that some aspects were not	11/13/14

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T 320	Continued From Page 5 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 program failed to perform the required evaluation of supervision appropriate to the level of service, Patient records, and infections, complications and other adverse events to identify unacceptable or unexpected trends. The findings included: Review of Patient #13's medical record revealed a note detailing a telephone call from the patient's family member. The note detailed Patient #13's visit to a local hospital's emergency department and treatment for an infection and possible incomplete abortion. Review of the facility's "Complication Log" revealed information related to Patient #13's report of an infection and possible incomplete abortion. An interview and review of the facility's quality program was conducted on 10/17/2014 at 5:15 p.m., with Staff #2. Staff #2 reviewed the data submitted to the facility's outside entity for quality purposes. The surveyor asked to review the data for the months of May 2014 and June 2014 to determine if Patient #13's infection/complications had been captured in the data. Review of April 2014 through June 2014 did not indicate the facility had documented any infections. Staff #2 and the surveyor reviewed Patient #13's medical record and the facility's "Complication Log." Staff #2 reported the physician had reviewed Patient	T 320	adequate and appropriate to the level of services provided. New policies regarding patient complication reporting and resolution were then drafted and implemented. The resulting process for gathering and documenting data related to the supervision of patient complications in our facility was installed. As a result, the Administrator and Medical Director will now have timely and more direct oversight of all reported patient complications. Documentation was created for the Administrator to record all charts that are reviewed, the outcomes, or needed improvements/changes. Quality indicator definitions were assessed, updated, and refined to ensure patient care appropriate to the level of services provided. In addition to our current practice of timely consult and review with the M.D. of each patient problem, a Monthly assessment of all patient problems will be conducted and documented by the Medical Director and Administrator to identify unacceptable or unexpected trends in patient complications or other adverse events. In the event unexpected trends in patient complications or other adverse events are identified, a meeting of the Quality Improvement Committee will immediately be called. The results of	

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T 320	Continued From Page 6 #13's medical record and did not find anything out of the ordinary. Staff #2 acknowledged Patient #13's medical record and the facility's "Complication Log" offered detailed information regarding the patient having an infection. Staff #2 stated, "I think we may have just interpreted this wrong." Staff #2 verified the facility failed to capture data regarding infections for its quality evaluation. During the interview and review Staff #2 acknowledged he/she reviewed "100%" of the facility's medical records but did not maintain a written document related to what was reviewed, the outcomes, or needed improvements/changes. Staff #2 verified the facility did not have a process or gather data related to supervision appropriate to the level of service.	T 320	this meeting and changes in protocol were then reported to and approved by the Governing Authority.	
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;	T 340	12 VAC 5-412-310 Medical records After our inspection and discussions with inspectors from the Virginia Department of Health, the facility created new progress notes in narrative form to document each patient's progress from admission to discharge. All licensed staff were made aware that any signature must have the date and time documented. The layout of the new notes clearly demonstrate when the physician has seen and established the patient was stable for discharge. Furthermore, the new nurse's progress notes in narrative form make clear the exact time of admission, the exact time of discharge, and all observations of the patient's status while in recovery.	11/13/14

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T 340	Continued From Page 7	T 340		

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:
Based on document review and interview the facility:
1. Failed to ensure physicians and nurses completed progress notes, which detailed the patient's progress from admission to discharge for twelve (12) of twelve (12) patients included in the survey sample. (Patients #1-#12) and

2. Failed to ensure direct care staff documented the date and time patients were discharged from the facility for twelve (12) of twelve (12) patients included in the survey sample. (Patients #1-#12)

The findings included:

1. Review of the medical records for Patients #1 - #12 did not reveal progress notes by the physician and the nursing staff, which detailed the patient's progress.

Review of the medical records for Patients #1-#12 revealed a form titled "Recovery Room Notes." The form contained a section titled ObservaionNote [Sic] the section was blank for all twelve patients (#1-#12). The recovery room nurse did not document observations of the patient's status while in the Recovery room.

An interview was conducted on October 17, 2014 at approximately 4:45 p.m., with Staff #2. Staff #2 acknowledged that he/she was not aware that progress notes required a narrative of the patients'

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T 340	Continued From Page 8	T 340		

status from post procedure until discharge.

2. Review of the medical records for Patients #1-#12 revealed a form titled "Recovery Room Notes." The lower portion of the form included medications prescribed and/or given to the patients at discharge. The "Recovery Room Notes" form did not indicate the time the patients had been discharged from the recovery area. The physician and nurse had signed the Recovery Room Notes" form under the area listing the discharge medications, but did not include the date and time of their signature. The surveyors could not determine when the physician had seen and established the patient was stable for discharge.

An interview was conducted on October 17, 2014 at approximately 4:45 p.m., with Staff #2. Staff #2 reviewed a sample of the twelve medical records included in the sample. Staff #2 was not able to determine when the patients had actually been discharged from the facility. Staff #2 reported he/she was not aware that licensed health care professionals' signatures needed to be timed and dated.