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	AF-0017	A. BUILDING _____ B. WING _____	11/17/2016

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T 000	12VAC5-412 Initial Comments An unannounced Biennial Licensure Inspection was conducted 11/14/16 through 11/17/16 by two (2) Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics (amended 2013). Deficiencies cited follow in this report.	T 000		
T 080	12VAC5-412-180 D Personnel The abortion facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training. This RULE: is not met as evidenced by: Based on staff interview and document review, the facility staff failed to ensure all employees participated in annual infection control training for 13 of 13 staff members, 2 of 2 Anesthesia Providers, and 5 of 5 physicians. There was also no documentation that 1 Anesthesia Provider had annual fire safety training. The findings included: During a review of the training provided for staff, there was no evidence of annual training for infection control contained in the staff records. On 11/17/16 at 12:10 p.m., Staff Member # 9	T 080		

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

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T 080	Continued From Page 1 stated, "We had our last Infection Control training in July of 2105. I have been trying to get (name of person) back to do training, but haven't been able to because of his/her schedule." Review of the personnel and training record for Staff Member #5 (Anesthesia Provider) revealed no evidence of participation in fire safety or emergency/disaster training. On 11/17/16 at 12:50 p.m., the inspectors discussed the findings with Staff Member #1 and #4. No further evidence was provided by the end of the inspection. Please refer to tag T 195 for more information on infection control observations during the inspection.	T 080		
T 195	12VAC5-412-220 B Infection Prevention Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions;	T 195		

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T 195	Continued From Page 2 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration; 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: is not met as evidenced by: Based on observation, staff interview, and facility document review, the facility staff failed to ensure that medications were administered using aseptic technique, that reusable non-critical medical equipment was cleaned appropriately prior to use on another patient, proper PPE (personal protective equipment) was used, and that manufacturer's recommendations for use of cleaning and disinfection products was followed . Also the facility staff failed to ensure all employees participated in annual infection control training for 13 of 13 staff members, 2 of 2 Anesthesia Providers, and 5 of 5 physicians. The findings included:	T 195		

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T 195	Continued From Page 3 1. Consent was obtained, and the surveyor observed the following during the surgical procedure for Patient #17 on 11/15/16 between 4:25 PM and 4:50 PM: A) Staff Person #5, a CRNA (Certified Registered Nurse Anesthetist) placed a plastic caddy containing IV (intravenous) supplies, including syringes which had been removed from the protective covering, on the exam table beside Patient #17's head. Staff Person #5 retrieved supplies, and started an IV for Patient #17, and then set the plastic caddy on a cart with the emergency portable respiratory suction machine. Staff Person #5 did not clean or disinfect the caddy prior to placing it on the cart. B) Prior to the start of the procedure, three (3) 250 ml (milliliter) IV bags of LR (Lactated Ringers) ,which were spiked with IV tubing, were observed hanging on an IV pole in the exam room. Staff Person #5 touched the IV pole wearing gloves he/she wore while starting Patient #17's IV and connected the bag of LR to the IV; the other two (2) bags were left hanging on the IV pole during the procedure. C) The surveyor observed Staff Member #5 withdraw two (2) medications for sedation into two (2) syringes without wiping off the septum with alcohol prior to withdrawing the medication. At approximately 4:29 PM, Staff Member #5 injected the first medication via a port in the IV line without wiping the port with alcohol prior to puncturing the septum. After administering the first medication, Staff Member #5 administered the second medication, in divided doses, accessing the port multiple times without using alcohol to disinfect the port before or after medication administration between approximately	T 195		

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T 195	Continued From Page 4 4:30 PM and 4:31 PM. D) After Patient #17 was transferred to a stretcher and moved to recovery, Staff Member #5 picked up the IV caddy from the cart and left the room. E) The surveyor interviewed Staff Member #7 regarding the three (3) IV bags of LR spiked with IV tubing and hanging on the IV pole in the room labeled "Exam Room" and two (2) bags on an IV pole in the room labeled "Surgery I" at 4:00 PM on 11/15/16, and he/she stated "We have 3 patients scheduled in the exam room and 2 in the surgery room, so we do one for each". 2. Neither Staff Member #3, who assisted with the procedure, nor Staff Member #6, the physician, wore goggles during the procedure. Staff Member #3 did not wear eyeglasses; Staff Member #6 was wearing prescription eyeglasses during the procedure. The CDC (Centers for Disease Control) "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care" states in part the following: "...The selection of PPE is based on the nature of the patient interaction and potential for exposure to blood, body fluids or infectious agents. Examples of appropriate use of PPE for adherence to Standard Precautions include: use of gloves in situations involving possible contact with blood or body fluids, mucous membranes, non-intact skin or potential infectious material; use of a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated; use of mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids...". The facility's Infection Control manual included a	T 195		

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T 195	Continued From Page 5 copy of the above mentioned CDC document. 3. Staff Member #3 used running water from the hand washing sink to clear the vacuum line from the vacuum suction machine used during the surgical procedure. During an interview with Staff Member #3 on 11/15/16 at 4:40 PM, he/she told the surveyor that the sink was the "clean sink used for handwashing". 4. Staff Member #3 cleaned the room after the procedure using an unlabeled spray bottle of liquid, which Staff Member #3 stated was Terg-o-cide. Staff Member #3 applied the liquid from the spray bottle on the surface of the exam table, including the vinyl stirrup covers, and the vacuum suction machine so that it was dripping from the surfaces. The equipment was wiped off by Staff Member #3 immediately, without allowing the liquid to remain wet on the surfaces. Staff Member #3 did not clean or disinfect the IV pole, the rolling exam light used during the procedure, the sharps container, the cart with the respiratory suction machine, or the BP (blood pressure) cuff which was used to monitor Patient#17's vital signs during the procedure. Staff Member #3 provided the surveyor with manufacturer's directions and guidelines for Terg-o-cide dilution for general cleaning, sono rinse bucket, and small spray bottles located in every patient service area use. The directions state in part the following: "...As possible area cleaned should remain wet 5-10 minutes; use in cleaning exam tables, floor spills, and any non-porous surface...". The label on the original container of Terg-o-cide included the following in part: "...cleaning procedure-blood/body fluids	T 195		

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T 195	Continued From Page 6 must be thoroughly cleaned before application of this product. Treated surfaces must remain wet for at least 10 (ten) minutes for proper disinfection...". Findings were reviewed with Staff Persons #1 and #4 on 11/17/16 between 12:30 PM and 1:30 PM.. 5. During a review of the training provided for staff, there was no evidence of annual training for infection control contained in the staff records. On 11/17/16 at 12:10 p.m., Staff Member # 9 stated, "We had our last Infection Control training in July of 2105. I have been trying to get (name of person) back to do training, but haven't been able to because of his/her schedule." On 11/17/16 at 12:50 p.m., the inspectors discussed the findings with Staff Member #1 and #4. No further evidence was provided by the end of the inspection.	T 195		
T 215	12VAC5-412-230 A Patient Services; Patient Counseling Abortions performed in abortion facilities shall be performed only on patients who are within the first trimester of pregnancy based on an appropriate clinical estimate by a licensed physician. This RULE: is not met as evidenced by: Based on staff interview and clinical record review, it was determined the facility staff failed to ensure that medications administered to terminate pregnancy were not administered prior to the	T 215		

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T 215	Continued From Page 7 physician determination of whether or not the procedure would be performed, for 1 of 23 patients in the sample. Patient # 3 was administered a medication, Misoprostol, to begin the abortion procedure. After being administered the medication, the physician did not do the procedure and the patient was discharged. The findings included: A record review of Patient #3's medical record revealed that an ultrasound performed at the facility on 1/14/16 documented gestational age as 13 weeks 5 days with a CRL (crown rump length of 77.5 mm (millimeters)). On 1/15/16, the day that Patient #3 returned to the facility for a procedure, a repeat ultrasound at 2:35 PM documented a gestational age of 14 weeks 5 days +/- (plus or minus) 6 days, with a BPD (biparietal diameter) of 28.8 mm. Medical record documentation dated 1/15/16 for Patient #3 under the section "Aspiration D&C (dilation and curettage) Patients DOP (day of procedure) it was noted that Staff Person #1 had initialed that Pre-operative Misoprostol 200 mcg (micrograms)-2 tablets PO (by mouth) time 1330 (1:30 PM) was given, a pad was placed, and Pt (patient) was advised: C & B (cramping and bleeding) & Nausea. Pre-operative anti-anxiety: Librium 10 mg (milligrams) #2 PO time 1330 (1:30 PM). The space for M.D. (medical doctor) signature, was blank. The surveyor also noted a handwritten note by Staff Member #1 on the same page to "1) refer pt to (facility name) return 2 wks (weeks) FU (follow-up) OC's (oral contraceptives) generic @ FU". An interview was conducted with Staff Member #1 on 11/15/16 between approximately	T 215		

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T 215	Continued From Page 8 2:30 PM and 3:45 PM. Staff Member #1 was asked if he/she gave Misoprostel to Patient #3 who did not have a procedure that day, but was referred to another facility. Staff Person #1 stated "Yes, I gave it. That is in our standing orders. (He/She (the doctor)) decided (he/she) was not comfortable doing her after repeating her sono and referred her out. (He/She) was aware she got it. We go from their LMP (last menstrual period) not EDC (estimated date of conception). Most physicians talk LMP. It's different with each physician what they are comfortable doing. Our limit is 13 weeks 6 days". The package insert for Misoprostol states the following in part "..CYTOTEC (MISOPROSTOL) ADMINISTRATION TO WOMEN WHO ARE PREGNANT CAN CAUSE BIRTH DEFECTS, ABORTION, OR PREMATURE BIRTH. UTERINE RUPTURE HAS BEEN REPORTED WHEN CYTOTEC WAS ADMINISTERED IN PREGNANT WOMEN TO INDUCE LABOR OR TO INDUCE ABORTION BEYOND THE EIGHTH WEEK OF PREGNANCY...". (http://druginserts.com; accessed 11/29/16 3:14 PM). It was documented that Patient #3 had a follow-up visit on 2/1/16. The record did not include documentation that Patient #3 followed up with the facility she was referred to on 1/15/16 to complete the procedure. Documentation did note that a urine pregnancy test was negative at the follow up appointment.	T 215		
T 355	12VAC5-412-300 Health Information Records An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not be limited to the following:	T 355		

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T 355	Continued From Page 9 1. Patient identification; 2. Admitting information, including patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses' progress notes, h. Condition at time of discharge, i. Patient instructions, preoperative and postoperative; and j. Names of referral physicians or agencies. 6. Any other information required by law to be maintained in the health information record. This RULE: is not met as evidenced by: Based on clinical record review and staff interview, the facility staff failed to ensure a complete and accurate medical record was maintained for each patient and corrections made to the clinical record were done legibly. The facility staff also failed to ensure medication dosages administered during the procedures were documented in the clinical record. This involved 3 of 23 patients in the inspection sample, Patients #13,# 20 and #22. The Findings included: During a review of the clinical record for Patient #	T 355		

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T 355	Continued From Page 10 13, in the area for the documentation of "Pre-med standing orders" the staff had entered a time for the administration of the medication Misoprostol and Librium and then had scribbled through the time and wrote a different time on the record. A date underneath this documentation had also been entered and written over causing the date to be illegible. The date documented for the physician review of the sonogram had also been written over making it difficult to tell when the review was actually done. Under the section for "Health Education" the time for the administration of the Misoprostol was again scribbled through and another time written as well as the same for the Libruim. The date was also overwritten making it difficult to discern the date documented. Misoprostol is a medication used to start the abortion process. Librium is an medication used to treat anxiety. (www.drugs.com accessed 11/28/16 at 1:41 p.m.) Review of the clinical record for Patient #20 revealed a document "Recovery". At the bottom of the document the date for the patients discharge status was overwritten to the point the actual date was not identifiable. The "Follow-up" date was also overwritten and illegible. Patient #22 received the medication Lidocaine as a numbing/local anesthetic agent during the procedure on 5/21/16. The amount/dose of Lidocaine administered was not documented in the clinical record. The clinical record documented "... block using 1% (one percent) Lidocaine", however no dose was documented anywhere within the clinical record. On 11/17/16 at 12:10 p.m., the inspectors discussed the findings with Staff #1 and #4. Staff #1 stated, "We will re educate the staff regarding	T 355		

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T 355	Continued From Page 11 making corrections in the record...the Lidocaine is on our new forms and we will document that..."	T 355		
T 415	12VAC5-412-350 B Maintenance When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. This RULE: is not met as evidenced by: Based on observation, review of facility documentation, and staff interview, the facility staff failed to ensure that annual PM (preventative maintenance) was performed on one vacuum suction machine. Findings include: While touring the facility on 11/15/16 between 11:30 AM and 12:00 PM, the surveyor noted that the vacuum suction machine in Surgery Room I did not have a PM sticker. The surveyor asked Staff Member #1 if there was a PM log that might have information as to when the PM had been done on the machine. A PM log for equipment was provided to the surveyors; however, the vacuum suction machine was not included in the document.	T 415		

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T 415	Continued From Page 12 At the exit meeting on 11/17/16 at 11:55, Staff Person #1 was asked again about documentation of annual PM for the vacuum suction machine, and he/she stated "It may be that we replaced that suction machine. We have many suction machines. If it was replaced, it probably has not had a PM. We will have to call and have them check it".	T 415		