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T 000	Initial Comments Two (2) Medical Facilities Inspectors from the Virginia Department of Health's Office of Licensure and Certification conducted an unannounced First Trimester Abortion Facility (FTAF) biennial licensure inspection and complaint investigation on June 11, 2018 and June 12, 2018. The surveyors conducted observations, interviews and document reviews during the investigation process to determine compliance. The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Amended 3/22/2017). The deficiencies cited follow in this report.	T 000		
T 035	12 VAC5-412-160 A Policy and Procedures Each abortion facility shall develop, implement and maintain documented policy and procedures, which shall be readily available on the premises and shall be reviewed annually and updated as necessary by the governing body. The policies and procedures shall include but not limited to the following topics: 1. Personnel; 2. Types of elective services performed in the abortion 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 informed written consent of the patient pursuant to § 18.2-76 of the Code of Virginia prior to the initiation of any procedures;	T 035		

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

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T 035	Continued From Page 1 6. When to use sonography to assess patient risk; 7. Infection prevention; 8. Quality and risk 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. Abortion facility security; 13. Disaster preparedness; 14. Patient rights; 15. Functional safety and abortion facility maintenance; and 16. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable. This RULE: is not met as evidenced by: Based on document review and interview, it was determined the governing body failed to review annually and update as necessary the facility's policies and procedures. The findings included: The need to review the facilities policies and procedures was discussed, with Staff Member #1,	T 035		

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T 035	Continued From Page 2 during the entrance conference on June 11, 2018 at 12:07 p.m. While conducting that review, surveyors asked Staff Member #1 on several occasions for official documentation of an annual review of the facility's policy and procedures by the governing body as provided in this regulation. Surveyors asked one last time on June 12, 2018 at 6:37 p.m. prior to the exit conference. During the exit conference on June 12, 2018 at 6:47 p.m., Staff Member #1 provided an email from a member of the governing body that advised the required documentation of the annual review is not onsite.	T 035		
T 045	12 VAC5-412-170 A Administrator The governing body shall select an administrator who shall be responsible for the managerial, operational, financial, and reporting components of the abortion facility including but not limited to: 1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights; 2. Employing qualified personnel and ensuring appropriate personnel orientation, training, education, and evaluation; 3. Ensuring the accuracy of public information materials and activities; 4. Ensuring an effective budgeting and accounting system is implemented; and 5. Maintaining compliance with applicable laws and regulations and implementing corrective action.	T 045		

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T 045	Continued From Page 3	T 045		

This RULE: is not met as evidenced by:
Based on document review and interview, it was determined the facility administrator failed to ensure the completion of appropriate training for all staff members, namely, annual fire safety training for two (2) out of twenty-two (22) staff members.

The findings included:

On June 12, 2018 surveyors provided Staff Member #1 with a form to document clinic personnel medical licensure, privileges, required training, etc. to include annual annual fire safety training. That same day at 4:19 p.m., Staff Member #1 returned the completed form to surveyors. Surveyors reviewed the document with Staff Member #1 and noticed blank spaces in the fire drill training section for several clinic employees. Staff Member #1 advised they would be deficient in annual fire drill training because some members have not completed the required training. Staff Member #1 identified two persons based on their tenure at the clinic who did not complete the fire safety training as required, Staff Member #7 and Staff Member #8. Staff Member #1 further advised that Staff Member #8 is a part-time employee but advised there is no reason why Staff Member #7 did not complete the training.

Surveyors requested the facility's policy and procedure that outlines the requirement for annual fire safety training during the meeting above. Additionally, later that evening at 6:37 p.m., surveyors asked again for the policy and procedure that outlines the requirement for annual fire safety training. Prior to the entrance conference at 6:47 p.m. Staff Member #2 advised

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T 045	Continued From Page 4 they could not locate a document that details the protocol for this training requirement.	T 045		
T 080	12 VAC5-412-180 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 interview and document review, it was determined the facility failed to develop, implement and maintain a policy and procedure for annual participation of fire safety training for all clinic employees. The findings included: On June 12, 2018 surveyors provided Staff Member #1 with a form to document clinic personnel medical licensure, privileges, required training, etc. to include annual annual fire safety training. That same day at 4:19 p.m., Staff Member #1 returned the completed form to surveyors. Surveyors reviewed the document with Staff Member #1 and noticed blanks in the fire drill training section for several clinic employees. Staff Member #1 advised they would be deficient in annual fire drill training because some members have not completed the required training. Staff Member #1 identified two persons based on their tenure at the clinic who did not complete the fire safety training as required, Staff Member #7 and Staff Member #8. Staff Member #1 further advised	T 080		

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T 080	Continued From Page 5 that Staff Member #8 is a part-time employee but advised there is no reason why Staff Member #7 did not complete the training. Surveyors requested the facility's policy and procedure that outlines the requirement for annual fire safety training during the meeting above. Additionally, later that evening at 6:37 p.m., surveyors asked again for the policy and procedure that outlines the requirement for annual fire safety training. Prior to the entrance conference at 6:47 p.m. Staff Member #2 advised they could not locate a document that details the protocol for this training requirement.	T 080		
T 140	12 VAC5-412-200 B Patients' Rights The abortion 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. This RULE: is not met as evidenced by: Based on document review and interview, it was determined the facility failed to maintain complaint handling procedures, namely; logging of the receipt, investigation and resolution of each complaint. The findings included: On June 12, 2018 at 3:07 p.m. surveyors requested to review the facility's complaint log.	T 140		

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T 140	Continued From Page 6 Staff Member #2 provided a complaint log with the last entry dated one (1) and a half years ago in December, 2016. Staff Member #2 advised that her training at the facility included entering complaints into the log but the facility has not been logging complaints as required. Additionally, Staff Member #1 advised she usually just "takes care" of complaints and they are not placed in the complaint log. A review of the facility's policy titled "Rights and Complaint Process" states in part: "1. A patient complaint log shall be created and kept in the assistant administrator's office.... All Actions are documented on the Compliment and Complaint Log and noted in the patient's chart. All complaints are reported to the QAC."	T 140		
T 195	12 VAC5-412-220 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 7 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, interview and document review it was determined: 1. A physician utilized single dose medication vials for more than one patient. 2. A Certified Registered Nurse Anesthetist (CRNA) utilized the procedure table, within the patient's personal space, to keep and draw up medications during procedures. 3. The facility staff used a recommended single patient Ventolin HFA inhaler for more than one patient. The findings included: Observations conducted during the initial tour on June 11, 2018 at 11:22 a.m., with Staff Members #1 and #2 revealed a plastic container within the locked controlled medication area. Staff Member	T 195		

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T 195	Continued From Page 8 #1 opened the plastic container and identified the contents as two (2) opened vials of Fentanyl Citrate. Staff Member #1 stated, "[Staff Member #6's name] takes two vials out at a time and [he/she] reuses the vials until [he/she] needs more." The surveyor questioned regarding the facility's accounting for the controlled narcotics in the plastic container. Staff Member #1 reported once the Fentanyl Citrate vials were signed out to Staff Member #6 then Staff Member #6 was accountable by placing whatever was not used in the plastic container and returning the plastic container to the safe for storage. Staff Member #1 reported once the Fentanyl was removed from the facility's narcotic count it was not added back in when the plastic container was returned to the safe. The surveyor and Staff Member #2 inspected the two (2) opened vials of Fentanyl Citrate. The vial's label read in part "Fentanyl Citrate Injectable, 2 mL (milliliter) vial, 100 mcg (microgram), 50 mcg /mL, single dose vial", and the manufacturer's name. Staff Member #2 verified both vials of Fentanyl did not have a dated written to indicate when the vials had been opened. Staff Member #2 verified both vials were slightly less than half-full. Staff Member #2 verified the Fentanyl label read "single dose vial." Staff Member #1 reported Staff Member #6 maintained a log with each patient's name, date and the dose of Fentanyl, Propofol or other medications administered during each procedure. Staff Member #1 presented a red binder. Staff Member #1 reported he/she had "clipped together" Staff Member #6's log pages. Review of Staff Member #6's log sheet spanned from December 14, 2017 to June 6, 2018. An overview of Staff Member #6's documentation	T 195		

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T 195	Continued From Page 9 indicated 25 mcg/mL was the general dose of Fentanyl Citrate administered during a procedure. Staff Member #6's log documented he/she utilized portions of a Fentanyl Citrate 100 mcg /2 mL single dose vial to administered 25 mcg on the multiple dates as recorded on the log. An interview was conducted on June 12, 2018 at approximately 4:48 p.m., with Staff Members #1 and #2. The surveyor informed Staff Members #1 and #2 of the findings. The surveyor inquired regarding the possibility that Staff Member #6 wasted the additional 75 mcg Fentanyl Citrate in each single dose vial. Staff Member #1 reported the facility did not have a narcotics waste log for the number of entries on Staff Member #6's log of administrations by Staff Member #6 of only 25 mcg of Fentanyl Citrate, because "[Staff Member #6's name] splits the vials". Staff Member #1 verified the Fentanyl Citrate utilized by the facility were single dose vials that contained 100 mcg/ 2 mL. The surveyor requested the facility's policy, procedure, and best practice standard that allowed for utilizing a single dose vial for multiple patients. An interview was conducted on June 12, 2018 at 6:29 p.m., with Staff Member #1 related to the requested policies, procedure, or best practice standard for multiple medication administrations to different patients from a single dose vial. Staff Member #1 reported the facility did not have a policy, procedure or nationally recognized best practice standard, which allowed for using single dose vials as multi-dose vials. According to the Safe Injection Practice Coalition (SIPC) in conjunction with the Centers for Disease Control and Prevention (CDC) regarding safe injection practices. "IV.H.5. Do not administer medications from single-dose vials or ampules to	T 195		

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T 195	Continued From Page 10 multiple patients or combine leftover contents for later use ... CDC guidelines call for medications labeled as "single-dose" or "single-use" to be used for only one patient. 2. Observations were conducted on June 12, 2018 from 4:08 p.m. through 4:20 p.m., with Staff Member #4. Staff Member #4 asked Staff Member #9 for the number of patients scheduled to receive monitored anesthesia care (MAC). Staff Member #9 reported five (5) patients. Staff Member #4 retrieved a plastic container from a cabinet at the nurse's station. Staff Member #9 handed a staff member a box containing Propofol vials. Staff Member #9 placed the box inside the plastic container. Staff Member #4 placed additional supplies: needles, syringes, and a specialized insert for the Propofol vials in the plastic container. Staff Member #4 requested that Staff Member #1 assist in the retrieval of the controlled narcotics from the area where such medications were stored. Staff Member #4 placed five vials of Fentanyl Citrate 100 mcg/2 mL inside the plastic container. Staff Member #4 and the surveyor waited for the first scheduled MAC patient. An observation starting at 4:20 p.m. on June 12, 2018, as Staff Member #4 and the surveyor entered the Procedure Room. Staff Member #4 introduced him/herself to the patient. Staff Member #4 attempted to place the plastic container on the top of a cart next to the suction machine, but there was not enough room. Staff Member #4 positioned the plastic container on the procedure table with Patient #12. Patient #12 was positioned on the procedure table in a manner, which allowed her head to rest on and her hair to cover the entire roll of protective paper used to cover the procedure table. Staff Members #5 and #9 assisted in re-positioning Patient #12. Staff	T 195		

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T 195	Continued From Page 11 Member #4 re-positioned his/her plastic container with medications and supplies onto the paper next to Patient #12's head. Staff Member #4 interviewed and performed Patient #12's physical examination. Staff Member #4 obtained supplies and placed Patient #12's intravenous (IV) catheter. Staff Member #4 obtained a vial of Fentanyl Citrate plastic container and utilizing Patient #12's procedure table prepared the patient's dose of Fentanyl. Staff Member #4 also utilized Patient #12's procedure table to prepare the patient's dose of Propofol. Staff Member #4 continued to store the plastic container with medications and supplies at the head of Patient #12's procedure table as he/she monitored the patient's sedation and maintained a patent airway for Patient #12. At the end of Patient #12's procedure Staff Member #4 placed the plastic container between his/her arm and body then entered the recovery area to monitor Patient #12. After Patient #12 gained consciousness, Staff Member #4 left the recovery area. Staff Member #4 entered the next procedure with the same plastic container, increasing the risk of spreading infectious agents to the next patient. An interview was conducted on June 12, 2018 at approximately 5:36 p.m., with Staff Member #4. The surveyor discussed the potential cross contamination of supplies and medications when placed in the plastic container and carried from procedure to procedure. The surveyor also discussed the best practice standard of drawing up/preparing a medication for administration in a clean area. Staff Member #4 acknowledged the procedure table with the patient on the table would not be considered a clean area. Staff Member #4 stated, "I will have to find a better place to draw up meds, the room has little extra	T 195		

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T 195	Continued From Page 12 space and I need to keep the narcotics within view." According to the Safe Injection Practice Coalition (SIPC) in conjunction with the Centers for Disease Control and Prevention (CDC) regarding safe injection practices. "...Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment ... In this context, aseptic technique refers to the manner of handling, preparing, and storing of medications and injection equipment/supplies (e.g., syringes, needles and IV tubing) to prevent microbial contamination ... Medications should be drawn up in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. ..." 3. An observation was conducted on June 11, 2018 at approximately 11:11 a.m., with Staff Members #1 and #2. Staff Member #1 and the surveyors reviewed the content of the facility's emergency cart. The emergency cart included an opened box with a Ventolin HFA inhaler. The inhaler box nor the inhaler had a documented date when the medication was opened. Staff Member #1 reported the inhaler was kept in case it was needed for a patient. The Ventolin HFA box indicated the inhaler initially had sixty metered doses. The counter on the inhaler indicated the inhaler had forty-one metered doses left. Staff Member #1 reported the inhaler was "cleaned off" after each use. The surveyor requested the policy and the Ventolin HFA package insert. Review of the package insert did not provide information the inhaler was recommended for use by multiple patients.	T 195		

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T 195	Continued From Page 13 An interview was conducted on June 12, 2018, at 6:29 p.m., with Staff Member #1. The surveyor made a second request for the facility's policy for use and cleaning of the inhaler, a best practice standard, or evidence of the manufacturer's recommendation for multiple patient use of a single inhaler. Staff Member #1 reported the facility did not have a policy or best practice standard regarding the use of the inhaler for multiple patients. The surveyor contacted the manufacturer of the Ventolin HFA inhalers for recommended use of a single inhaler. The manufacturer emailed the surveyor the following information: "SUMMARY: Individual MDIs [Metered Dose Inhalers] manufactured by [Name of Manufacturer] including ... Ventolin HFA are intended for use by individual patients. Administering inhalations from a single MDI to multiple patients, often referred to as common MDI canister protocol (CCP), is outside the recommended labeling for MDIs manufactured by [Name of the Manufacturer] ..."	T 195		
T 300	12 VAC5-412-250 H Anesthesia Services The abortion facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria, and those criteria have been documented within the patient's medical record.	T 300		

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T 300	Continued From Page 14 This RULE: is not met as evidenced by: Based on interviews and document reviews, it was determined the anesthesia service providers failed to document the patient's stability for discharge from the Recovery Area to the "Lounge" for three (3) of five (5) surgical abortion patients. (Patients #2, #3, #10) The findings included: 1. Review of Patient #2's medical record indicated she was admitted to the facility on February 2, 2018 for a monitored anesthesia care (MAC) surgical abortion. The anesthesia service provider did not document, by check box, clearance for Patient #2 to move from the Recovery area to the secondary monitoring area in the "Lounge." An interview conducted at 12:13 p.m. on June 12, 2018, Staff Member #1 verified the anesthesia provider failed to check the box "Cleared for the Lounge." The surveyor requested the facility's policy for post anesthesia care. 2. Review of Patient #3's medical record indicated she was admitted to the facility on January 6, 2018 for a MAC surgical abortion. The anesthesia service provider did not document, by check box, clearance for Patient #3 to move from the Recovery area to the secondary monitoring area in the "Lounge." 3. Review of Patient #10's medical record indicated she was admitted to the facility on December 15, 2017 for a MAC surgical abortion. The anesthesia service provider did not document, by initial, in the space provided for the	T 300		

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T 300	Continued From Page 15 sedation provider, to discharge the patient from anesthesia care. During an interview at 12:23 p.m. on June 12, 2018, regarding Patient #10, Staff Member #1 advised the block requiring an initial for the sedation provider to discharge the patient from anesthesia care should not be on the form. Additionally, at 12:27 p.m., Staff Member #1 verified the findings for Patient #2 and Patient #3. Staff Member #1 presented the facility's policy titled "First Stage Recovery Attendant" on June 12, 2018. The policy documented the duties of the "Recovery Attendant" but included "RN/CRNA (Registered Nurse/Certified Registered Nurse Anesthetist) directs ALL actions ... Assist RN/CRNA as needed while [he/she] monitors the first minutes of first recovery..." The surveyor requested Staff Member #1's assistance regarding the inability to find information within the policy related to the responsibilities of the anesthesia provider's responsibilities. Staff Member #1 provided two (2) additional policies "12. Post-Procedure Care" and "Post-Operative Care." Review of these policies documented the responsibilities of the "nurse," the training requirements for non-licensed staff, and post-procedure discharge process. No additional information was provided prior to exit on June 12, 2018.	T 300		
T 315	12 VAC5-412-260 C Administration, Storage, Dispensing of Drugs Drugs maintained in the abortion 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	T 315		

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T 315	Continued From Page 16 temperatures in accordance with definitions in 18 VAC 110-20-10. This RULE: is not met as evidenced by: Based on observations, interviews and document review it was determined the facility staff failed to ensure expired medications were not available for use in one (1) of one (1) emergency cart and one (1) of two (2) procedure rooms. The findings included: 1. Observations and interview were conducted during the initial tour on June 11, 2018 at approximately 11:11 a.m., with Staff Members #1 and #2. The observation revealed the emergency medication cart was housed in a storeroom. Staff Member #1 stated, "We follow a no expiration policy." Staff Member #1 reported the facility had documentation that expiration date did not matter. The surveyor attempted to clarify if the "no expiration date" practice was for supplies or medications. Staff Member #1 reported for supplies and medications. The surveyors discussed the concern that not all medications had preservatives, which allowed extension past the manufacturer's date of expiration. The surveyors requested to review the facility's documentation regarding not needing to abide by the manufacturer's expiration date for medications and supplies. Staff Member #1 inspected the medications with the surveyor. The observation revealed the following expired medications within the facility's emergency cart: One (1) bag of 5% Dextrose 250 mL (milliliter) Intravenous Solution (IV) - with an expiration date "Nov 2015" One (1) bag of 9% Sodium Chloride 250 mL not within a protective outer cover - with an expiration date "May 2018"	T 315		

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T 315	Continued From Page 17 Four (4) bags of 5%Dextrose 500 mL IV Solution - with an expiration date: "Jan 2016" Two (2) packages of Lidocaine HCL 2% injectable -with an expiration date: "May 2018" One (1) bottle of Nitrostat 0.4 mg (milligram) - with an expiration date: "04/18" Three (3) vials Dopamine HCL 5 mL single dose 200 mg (40 mg/mL) - with an expiration date: 1 June 2018. 2. The same tour also revealed the following expired medications available for patients in procedure room #2. Staff Member #1 provided the same explanation as above that the facility follows a no expiration policy. One (1) bag of 5% Dextrose 250 mL (milliliter) Intravenous Solution (IV) - with an expiration date "Jan 2015" One (1) bag of Lactated Ringers 250 mL (milliliter) Intravenous Solution (IV) - with an expiration date "April 2015" On June 11, 2018, Staff Member #1 presented the facility's policy titled "Expiration of items to be used for patient care" for the surveyors to review. The policy read in part "Purpose: To provide safe and appropriate patient care consistent with Infection Control and Quality Assurance policies all staff and healthcare workers will help to ensure suitability of medications, solutions, reagents, supplies and equipment used in patient care. Policy: Staff will provide best practices to monitor medications, solutions, reagents, supplies and equipment used in patient care and ensure sequence cross checks for rotation of stock and dated items ... Before patient use or administration all medications, IV solutions, equipment, and supplies will be rechecked at point of use for expirations and condition in accordance with expiration and maintenance procedures ... 4. Sterile items will no longer have an expiration date	T 315		

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T 315	Continued From Page 18 ...All medical devices and instruments will be cleaned and/or sterilized, dated, and initialed by instrument tech who prepared the items ... Event-related shelf life for sterilized items recognizes that autoclaved medical instruments or those received from the manufacturer sterile would remain sterile indefinitely, unless an event caused them to be contaminated ... 5. All medical supplies such as gloves, syringes, IV solutions, needles, cannulas will follow event related shelf-life guidelines recognizing they would remain sterile indefinitely, unless an event causes them to become contaminated e.g., torn or wet packaging or if the manufacturer specifies otherwise ..." Attachments to the facility's policy included a document regarding "self-life for sterilized materials" and a document with Centers for Disease Control and Prevention (CDC) guidelines for event-related management of sterilized/processed instruments. On June 12, 2018, the surveyor discussed the facility's policy with Staff Member #1. The surveyor discussed the facility's policy titled "Expiration of items to be used for patient care" primarily focused on management of sterilization medical equipment. Staff Member #1 reported the policy's inclusion of "all medications" and "IV solution." The surveyor discussed with Staff Member #1 the policy also directed cross checks for expiration dates and following manufacturers' specified expiration recommendation. Staff Member #1 stated, "I have other proofs, articles for no expiration and indefinite shelf life for medications." The surveyor requested the additional information and best practice standard for utilizing medication beyond the manufacturer's documented expiration date. No additional information was presented to the surveyors prior to exit.	T 315		

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T 315	Continued From Page 19 According to CDC's Frequently Asked Questions (FAQ): "If a single-dose or single-use vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date." According to drugs.com, "The expiration date is the final day that the manufacturer guarantees the full potency and safety of a medication. Drug expiration dates exist on most medication labels, including prescription, over-the-counter (OTC) and dietary (herbal) supplements. U.S. pharmaceutical manufacturers are required by law to place expiration dates on prescription products prior to marketing. For legal and liability reasons, manufacturers will not make recommendations about the stability of drugs past the original expiration date ..."	T 315		
T 355	12 VAC5-412-300 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. If medically indicated, it shall include, but not be limited to the following: 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;	T 355		

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T 355	Continued From Page 20 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); j. Names of referral physicians or agencies; and 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 interview and document review, it was determined the facility staff and physicians failed to ensure patient's medical records were complete and accurate, including progress notes, the doses of administered medications, the authentication of signatures and administration of medications with dates and/or times, discharge orders and patient consents/notifications for eleven (11) out of eleven (11) patients included in the survey sample. (Patients #1, #2, #3, #4, #5, #6, #7, #8, #9, #10, and #11} The findings included: 1. Review of Patient #1's medical record documented the patient was admitted to the facility on February 3, 2018 for a monitored anesthesia care (MAC) procedure. Staff Member #1 reviewed the medical record with the surveyor at 1:06 p.m. on June 12, 2018. Staff Member #1 verified the informed consent form dated January 23, 2018 did not have the patient's initials acknowledging her right to speak with a physician about the abortion services. Staff Member #1 also verified no physician notes were present on the	T 355		

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T 355	Continued From Page 21 "Physician Progress Notes" and he/she advised that form should not be in the file. Staff Member #1 verified Patient #1's medical record did not have a start and stop time for the patient's surgical procedure. Staff Member #1 advised the facility gave all notes relating to the patient transfer to the EMS crew and thus the facility has an incomplete medical file. 2. Review of Patient #2's medical record documented the patient was admitted to the facility on February 2, 2018 for a monitored anesthesia care (MAC) procedure on February 3, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:13 p.m. June 12, 2018. Staff Member #1 verified Patient #2's medical record did not have a start and stop time for the patient's surgical procedure. Staff Member #1 verified the medical record did not include a documented discharge order by a physician and did not have progress notes by the physician and nursing staff. Staff Member #1 reported the top of the page was dated, but verified the line associated with the administration of Misoprostol indicated a "Date/Time" requirement. Staff Member #1 verified staff failed to date the administration of the medication. 3. Review of Patient #3 medical record documented the patient had a MAC procedure on January 13, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:27 p.m. June 12, 2018. Staff Member #1 verified Patient #3's medical record did not have a physician discharge order and progress notes by nursing staff and the physician. Patient #3 was returned to the facility on February 14, 2018 for a re-evacuation. Patient #3's re-evacuation procedure was performed utilizing a peri-cervical block with lidocaine. Staff Member #1 verified the physician failed to document the amount of	T 355		

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T 355	Continued From Page 22 lidocaine used within the operative note. Staff Member #1 verified the documentation for Patient #3's procedure on February 14, 2018 did not include nursing progress note and a discharge order by the physician. Staff Member #1 acknowledged the form utilized for re-evacuations did not have a line or check-off box for the patient's discharge home when stable. 4. Review of Patient 4's medical record documented the patient had a surgical abortion with local anesthesia (peri-cervical block) on February 13, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:31 p.m. June 12, 2018. Staff Member #1 verified Patient #4's medical record did not have progress notes by nursing staff and the physician. Staff Member #1 verified the line associated with the discharge per sedation provider related to "Lidocaine"/local procedures was blank. Staff Member #1 crossed through the line and stated, "That's an error on the form. We don't require the anesthesiologist to review theses." Staff Member #1 verified the Misoprostol administered prior to the February 13, 2018 procedure did not have a date associated with the time of administration. 5. Review of Patient 5's medical record documented the patient was had a surgical abortion with local anesthesia on November 21, 2017. Staff Member #1 reviewed the medical record with the surveyor at 12:39 p.m. June 12, 2018. Staff Member #1 verified the physician failed to document the amount of lidocaine used within the operative note. Staff Member #1 verified the "Recovery" section was blank and did not include documentation of vitals sign, nor an indication if the patient was post-operative for a lidocaine or MAC procedure. Staff Member #1 verified Patient #5's medical record did not have a nursing progress note. Staff Member #1 verified	T 355		

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T 355	Continued From Page 23 the Misoprostol administered on November 21, 2017 did not have a date associated with the time of administration. 6. Review of Patient #6 medical record documented the patient was scheduled for a medical abortion on January 24, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:42 p.m. June 12, 2018. Staff Member #1 verified the physician that administered the Mifepristone failed to document the date and time. [According to the FDA, "Mifepristone/Mifeprex is used, together with another medication called misoprostol, to end an early pregnancy."] 7. Review of Patient #7's medical record documented the patient was scheduled for a MAC procedure on March 8, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:56 p.m. June 12, 2018. Staff Member #1 verified the physician's documented observation of Patient #7's product of conception (POC) did not include whether the POC was "Normal" or "Abnormal." Staff Member #1 verified the "Recovery" section did not document whether the patient was post-operative for a lidocaine or MAC procedure. Staff Member #1 verified Patient #7's medical record did not have a physician's discharge order, physician progress note and nursing progress note. Patient #7 returned to the facility on March 22, 2018 for a re-evacuation procedure under MAC. Staff Member #1 verified nursing staff failed to document whether the patient was allowed to leave the facility on her own after sedation or accompanied by another person. Staff Member #1 verified nursing staff failed to make a progress note associated with the March 22, 2018 re-evacuation procedure. Staff Member #1 acknowledged the form utilized for re-evacuations did not have a line or check-off box	T 355		

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T 355	Continued From Page 24 for the physician's order to discharge the patient to home when stable. Staff Member #1 verified the Misoprostol administered on March 8, 2018 and March 22, 2018 did not have a date associated with the time of administration. 8. Review of Patient #8's medical record on June 12, 2018 at 9:44 a.m., revealed the patient was scheduled for a MAC procedure on March 21, 2018. On the surgical record, the physician failed to check the box denoting the patient's discharge when stable. Additionally, in the sedation record, no times were recorded for the surgical procedure. 9. Review of Patient #9's medical record documented the patient was scheduled for a medication abortion on November 14, 2017. Staff Member #1 reviewed the medical record with the surveyor at 1:00 p.m. June 12, 2018. Staff Member #1 verified the physician that administered the Mifepristone failed to document the date and time. [According to the FDA, "Mifepristone/Mifeprex is used, together with another medication called misoprostol, to end an early pregnancy."] Staff Member #1 also verified on a prescription for Vicoden ES #8, the 8 is crossed out and a 12 is written. No notation is made regarding who altered the record and when. Staff Member #1 verified two inaccuracies on the form documenting the required ultrasound. The first inaccuracy is in the area for a patient exception (lives more than 100 miles from the clinic) where the box is checked but it is not applicable to the patient. The second inaccuracy is in the area where the clinic offers the patient the ability to view the ultrasound or listen to fetal heart tones. In this section both the decline and I choose box is checked for listen to fetal heart tones. 10. Review of Patient #10's record documented	T 355		

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T 355	Continued From Page 25 the patient was scheduled for a MAC procedure on December 15, 2017. Staff Member #1 reviewed the medical record with the surveyor at 1:02 p.m. Staff Member #1 verified none of the boxes are checked on the ultrasound verification form indicating if the patient requested or declined to view the ultrasound or listen to fetal heart tones. Additionally on that form, the patient signed the area denoting an exception to the ultrasound waiting period although she did not live more than 100 miles from the facility. Lastly, a staff member did not provide a review date on that form. Staff Member #1 advised the physician made an error in this case because they were supposed to complete the form once a cervical exam was completed. Staff Member #1 verified Patient #10's medical record did not have a start and stop time for the patient's surgical procedure. Staff Member #1 also verified the sedation provider did not initial the area denoting release of the patient from sedative care. 11. Review of Patient #11's medical record documented the patient was admitted to the facility on May 25, 2018. Staff Member #1 reviewed the medical record with the surveyor at 12:58 p.m. on June 12, 2018. The physician's operative note, for May 29, 2018 indicated, by circle, the procedure was performed under MAC. Patient #11's medical record did not include an anesthesia record. Staff Member #1 reviewed the record and stated, "This is a local not a MAC." Staff Member #1 verified the physician failed to indicate in the operative note an amount of lidocaine administered, if a peri-cervical block procedure was performed. Staff Member #1 verified Patient #11's medical record did not include a physician's progress note, or explanation the patient had initially requested a MAC and changed to a procedure managed under local anesthesia. Staff Member #1 verified the	T 355		

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T 355	Continued From Page 26 Misoprostol administered on May 29, 2018 did not have a date associated with the time of administration. Staff Member #1 presented the facility's policy titled "Guidelines for Maintaining the Medical Record as a Medicolegal Document" on June 12, 2018 for the surveyor's review. The policy read in part, "3 ... Documentation should always be precise, objective, accurate and complete ... The medical record will minimally include ... pre, intra, and post phases of the patient's visit ... physician's SOAP (an acronym for subjective, objective, assessment, and plan) notes; ... 7. All blanks and check boxes should be completed on assessment forms and consent forms ... 18. For surgery patients recovery room discharge notes should include, but not limited to: a. With whom the patient is discharged. b. Patient ambulatory by self status. c. When the patient is discharged ... f. Basic vitals ..." The policy did not address the need for a physician's order for discharging the patient once the patient had meet discharge criteria. The surveyors requested the facility's policy for discharge criteria. Staff Member #1 presented the facility's policy titled "Patient Admission and Discharge" on June 12, 2018. The policy read in part, "Patients shall be discharged only on order of the Medical Staff physician which order shall be recorded on the patient's medical record ... [Sic]" The surveyors and Staff Member #1 reviewed the regulatory requirements related to the missing medical record components for the patients included in the survey sample. The facility staff presented no additional information prior to the survey completion on June 12, 2018.	T 355		

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T 370	Continued From Page 27	T 370		
T 370	12 VAC5-412-320 B Required Reporting The abortion facility shall report the following events to OLC: 1. Any patient, staff or visitor deaths. 2. Any serious injury to a patient. 3. Medication errors that necessitate a clinical intervention other than monitoring; and 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; This RULE: is not met as evidenced by: Based on document review, interview, and complaint investigation, it was determined the facility failed to report a serious injury to a patient to Office of Licensure and Certificatin (OLC). The finding included: During the entrance conference on June 11, 2018 at 12:07 p.m., the facility administrator advised a transfer from the clinic to a hospital did occur in 2018. The administrator further advised the medical file relating to that transfer was located in his/her desk and available for surveyor review. Surveyors examined the medical file and learned the patient arrived at the clinic on February 3, 2018 for a surgical procedure to terminate pregnancy. This date aligned with the date provided in the complaint. The procedure utilized moderate sedation, and thus a CRNA (Certified Registered Nurse Anesthetist) attended the procedure for the administration and management of sedation while a medical doctor performed the surgical procedure.	T 370		

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The physician notes contained in part: "Aspirate the uterine without difficulty." "Estimated blood loss 80 ml." "Patient sent to recovery in excellent condition."

The physician notes did not contain a start or stop time for the procedure. Additionally, the physician notes ended after a brief notation on pathology. The brief pathology report also did not include a time.

The CRNA notes contained in part: The CRNA noted a series of hypotensive blood pressure readings and actions taken for patient management to include the administration of 1,000 ml of normal saline. The anesthesia record further noted "blood loss" "EMS Called 9:29 am" and "to stretcher 9:53 am."

The medical record provided no other information on the presentation and management of the bleeding. Additionally, the record did not contain documentation regarding the patient transfer, name of the receiving hospital, or if and what relevant medical information the facility provided to the hospital.

On June 11, 2018 at 2:59 p.m., surveyors spoke to the physician who performed the surgical procedure, via telephone. The physician advised the interns at the receiving hospital believed the bleeding occurred due to a perforation. The physician advised he/she believed the bleeding occurred due to previous injury from repeated C-sections. The physician advised he/she rode in the ambulance with the patient to the hospital and waited in the emergency room with her. He/she also advised the receiving hospital moved the patient to a surgical suite, and he/she attempted to go into the operating room with the patient but

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T 370	Continued From Page 29 the receiving hospital staff would not allow him/her to do so. On June 12, 2018 at 4:58 p.m., surveyors spoke with the CRNA. in person. at the facility. The CRNA advised he/she and the physician made the decision together to transfer the patient because of bleeding. The CRNA described the bleeding as "not excessive" but more than usual. The CRNA advised he/she noticed a drop in blood pressure before the discovery of the unusual bleeding, and administered 1,000 ml of normal saline. He.she further advised the patient was stable when EMS arrived and additionally the patient spoke with her family member on the telephone. On June 12, 2018 at 1:06 p.m., surveyors spoke to the facility administrator who is also a registered nurse. The administrator advised the patient never made it to the recovery area. Instead, with the physician in pathology, the staff notified him/her the patient continued to bleed and the facility then called EMS. The administrator advised the facility gave all notes relating to patient management and transfer during the bleeding to the EMS crew. He/she advised the facility had no additional medical documentation outside of that contained in the file. The facility administrator advised the physician rode in the ambulance with the patient and it is his/her understanding the receiving hospital performed a surgical procedure to identify and fix the source of the bleeding. The facility administrator assisted surveyors in reading a note placed on the front of the medical file. He/she advised the note contained documentation of the facility's attempts to contact the patient by telephone after the transfer. The notes indicated two failed attempts and a third call where the administrator did speak with the patient on the telephone. The patient advised, according	T 370		

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T 370	Continued From Page 30 to the note, of a discharge from the receiving hospital on Monday February 5, 2018. Lastly, the administrator advised the clinic did not contact the OLC because they believed they were not required to. He/she further explained the facility has had patients transferred out in the past but the clinic did not notify OLC during those events either. Surveyors examined the facility's complications log and determined that no other transfers occurred during the review period for this survey (2017 or 2018). A review of the facility's policy titled "Serious incidents/injuries/death at FCHC" states in part: "reports [sic] all serious incidents/injuries/death that may occur in the center. In the event of a serious incident/injury/death a "Serious/Injury/Death Report Form" will be submitted to VDH/OLC within 24 hours."	T 370		
T 375	12 VAC5-412-320 C Required Reporting Notification of the events listed in subsection B of this section shall be required within 24 hours of occurrence. Each notice shall contain the following: 1. Abortion facility name; 2. Type and circumstance of the events being reported; 3. Date of the event; and 4. Actions taken by the abortion facility to protect patient and staff safety and to prevent recurrence.	T 375		

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This RULE: is not met as evidenced by:
Based on document review, interview, and complaint investigation, it was determined the facility failed to report a serious injury to a patient to Office of Licensure and Certification (OLC) within twenty four hours of occurrence.

The finding included:

During the entrance conference on June 11, 2018 at 12:07 p.m., the facility administrator advised a transfer from the clinic to a hospital did occur in 2018. Surveyors examined the medical file and learned the patient arrived at the clinic on February 3, 2018 for a surgical procedure to terminate pregnancy. The procedure utilized moderate sedation, and thus a CRNA (Certified Registered Nurse Anesthetist) attended the procedure for the administration and management of sedation while a medical doctor performed the surgical procedure.

The CRNA notes contained in part: The CRNA noted a series of hypotensive blood pressure readings and actions taken for patient management to include the administration of 1,000 ml of normal saline. The anesthesia record further noted "blood loss" "EMS Called 9:29 am" and "to stretcher 9:53 am."

The medical record provided no other information on the presentation and management of the bleeding. Additionally, the record did not contain documentation regarding the patient transfer, name of the receiving hospital, or if and what relevant medical information the facility provided

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T 375	Continued From Page 32 to the hospital. The facility administrator advised the clinic did not contact the Office of Licensure and Certification (OLC) because they believed they were not required to. He/she further explained the facility has had patients transferred out in the past but the clinic did not notify OLC during those events either. A review of the facility's policy titled "Serious incidents/injuries/death at FCHC" states in part: "reports [sic] all serious incidents/injuries/death that may occur in the center. In the event of a serious incident/injury/death a "Serious/Injury/Death Report Form" will be submitted to VDH/OLC within 24 hours." Refer to T 0370 for additional information.	T 375		