State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0019	A. BUILDING: ______ B. WING ______	01/25/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ANNADALE WOMEN & FAMILY CENTER	**2839 DUKE STREET ALEXANDRIA, VA 22314**

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T 000	Initial Comments - 4 An unannounced First Trimester Abortion Facility (FTAF) Biennial Licensure inspection was conducted January 15, 2019 through January 16, 2019 and January 25, 2019. Two (2) Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health, conducted the January 15, 2019 through 16, 2019 investigation. Two (2) additional Medical Facilities Inspectors conducted the abortion procedure observation on January 25, 2019. 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 (Effective November 2018). The deficiencies cited follow in this report.	T 000		
T 060	12 VAC5-412-180 A Personnel Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided. This RULE: is not met as evidenced by: Based on observation, interview, and document review, it was determined facility staff failed to ensure a medical assistant had documented training to perform sonograms for one (1) of one (1) staff observed performing sonograms. (Staff	T 060		2/6/19

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

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T 060	Continued From page 1	T 060		

Member #4)

The findings included:

On January 15, 2019 at 10:55 a.m., the surveyor obtained consent for the observation of Patient #13's sonogram. During the observation, Staff Member #4 performed an abdominal sonogram, which did not provide positive indication of the patient's pregnancy. Staff Member #4 informed Patient #13 a transvaginal sonogram would need to be performed. Staff Member #4 performed the transvaginal sonogram and after taking measurements informed Patient #13, the physician would give the exact determination. Staff Member #4 informed Patient #13 an estimate of gestation was [redacted]

During the review of Staff Member #4's personnel record, the surveyor could not find documentation of the employee's sonogram training. Staff Member #4's job description titled "Medical Assistant" did not include the employee's tasks of performing ultrasounds/sonograms.

An interview was conducted on January 16, 2019 at approximately 12:08 p.m., with Staff Member #1. The surveyor inquired if Staff Member #4 had documentation of sonogram training. Staff Member #1 reported that the physicians had trained Staff Member #4 over the years. Staff Member #1 reported Staff Member #4's job duties included performing sonograms. The surveyor informed Staff Member #1 that Staff Member #4's Medical Assistant job description did not include performing sonograms as a job duty. The surveyor inquired if the facility had a sonogram/ultrasound job description. Staff Member #1 reported the job description should be

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T 060	Continued From page 2 in the (red) binder. The job description for sonogram/ultrasound was not located. Staff Member #1 acknowledged Staff Member #4's employees file did not contain documented training to perform sonograms.	T 060		
T 090	12 VAC5-412-180 F Personnel A personnel file shall be maintained for each staff member. The records shall be completely and accurately documented, readily available, including by electronic means and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's in-service education, and professional licensure, if applicable. This RULE: is not met as evidenced by: Based on observation, interview, and document review, it was determined facility staff failed to ensure the employee files for two (2) of three (3) nursing staff included a current verification of their license. The findings included: On January 15, 2019, surveyors reviewed the facility's personnel files. The review revealed the employee files for Staff Members #1 and #5 did not include a current verification of their nursing license. The verifications in the employee files for Staff Members #1 and #5 were dated "2016." On January 16, 2019, at approximately 12:14	T 090		2/6/19

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T 090	Continued From page 3 p.m., the surveyor informed Staff Member #1 of the findings. Staff Member #1 asked Staff Member #2 to locate the verification of the nursing license. At 12:22 p.m. on January 16, 2019, Staff Member #2 handed the surveyor the verification of the nursing license for Staff Members #1 and #5. The verifications indicated they were obtained on January 16 2019. The surveyor asked Staff Member #2 regarding the facility's process for verification of license. Staff Member #2 reported the verifications were performed on the staff's birthday or when the license on file expired. Staff Member #2 verified Staff Members #1 and #5 previous license expired in 2018 and the current license had not been verified.	T 090		
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 interview and document review, it was determined the facility's Administrator failed to ensure the complaint logging system was complete and accurate. The findings included:	T 140		2/6/19

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On January 15, 2019 at 9:10 a.m., the surveyor requested the facility's complaint log. Staff Member #2 reported the complaint log was included in the "red binder." On review of the "red binder", the surveyors were unable to identify the facility's complaint log.

On January 15, 2019 at approximately 11:45 a.m., the surveyors informed Staff Member #1 the complaint log was not within the "red binder." A second request was made to review the facility's complaint log. Staff Member #1 reported the facility had not received any complaints. The surveyors requested to review the complaint log as part of the required proof of a logging system. Staff Member #1 handed the surveyors two (2) notebooks and one black binder. Review of the two (2) notebooks and the black binder did not include the facility's complaint log.

On January 15, 2019 at approximately 10:30 a.m., the surveyors made a third request for the facility's complaint log. Staff Member #1 reported the facility had not had a complaint.

During the random selection of patient medical records on January 16, 2019, Patient #3's medical record contained a complaint related to services and care provided by the abortion facility.

During an interview conducted on January 16, 2019 at approximately 11:50 a.m., Staff Member #1 was informed of the findings. Staff Member #1 verified a "third-party" had filed a complaint in behalf of Patient #3. Staff Member #1 verified Patient #3's medical record also contained a response to the complaint allegations. Staff Member #1 acknowledged the complaint related

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to Patient #3 had not been logged in the facility's complaint system.

T 170	12 VAC5-412-210 B Quality Management	T 170		2/6/19

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 interview and document review, it was determined the facility's quality improvement committee failed to evaluate five (5) of the seven (7) required quality improvement components for 2018 (Staffing Patterns and Performance, Supervision Appropriate to the Level of Service, Patient Satisfaction, Complaint Resolution, and Staff Concerns Regarding Patient Care).

The findings included:

On January 15, 2019 at approximately 11:45

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T 170	Continued From page 6 a.m., the surveyors requested the facility's quality meeting minutes. Staff Member #1 handed the surveyors two (2) notebooks and one black binder. One (1) notebook was titled "QA." A review of the "QA" notebook revealed meeting minutes dated "3/16/18." The meeting minutes include an attached sheet documenting medical charts reviewed. On January 16, 2019 at approximately 9:22 a.m., Staff Member #6 handed the surveyor a typed page dated November 2018. Staff Member #6 reported a quality meeting had been held in November 2018 but the typed minutes had not been placed in the "QA" notebook. The document covered hand washing and two (2) other notations. An interview was conducted on January 16, 2019 at 12:32 p.m. with Staff Member #1. The surveyors reviewed the findings and the regulatory requirements. Staff Member #1 verified their quality improvement committee had failed to incorporate five (5) the seven (7) required quality improvement components in 2018 (Staffing Patterns and Performance, Supervision Appropriate to the Level of Service, Patient Satisfaction, Complaint Resolution, and Staff Concerns Regarding Patient Care). Additionally, a review of the facility's policy related to the required areas for quality surveillance did not include the component: "Staffing patterns and performance."	T 170		
T 200	12 VAC5-412-220 C Infection Prevention Written policies and procedures for the management of the abortion facility, equipment	T 200		2/6/19

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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 driers);

2. Availability of utility sinks, cleaning supplies, and other materials for cleaning, disposal, storage, and transport of equipment and supplies;

3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);

4. Procedures for handling, storing, and transporting clean linens, clean/sterile supplies and equipment;

5. Procedures for handling/temporary storage/transport of soiled linens;

6. Procedures for handling, storing, processing, and transporting regulated medical waste in accordance with applicable regulations;

7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
(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

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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 abortion facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observations, interviews and document review, it was determined the facility staff failed to have documented evidence of pest control services.

The findings included:

On January 15, 2019 at approximately 10:50 a.m., Staff Member #2 and the surveyor observed a brown insect on the floor in front of the facility's restroom door. The insect was approximately one (1) inch in length. The surveyor asked Staff Member #2 when the pest control service had last visited the facility. Staff Member #2 reported he/she would try to find out.

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On January 15, 2019 at 3:40 p.m., the surveyors informed Staff Member #1 of the findings and made a second request for proof of the pest control service's last visit. Staff Member #1 reported the pest control services was part of the building agreement and was performed by the building maintenance.

On January 16, 2019 at 11:57 p.m., the surveyor made a third request for information related to the pest control service's last visit. Staff Member #1 presented a typed document indicating the building management performed the pest control service. The document did not have a date and did not specify how often the pest control service was offered. Staff Member #1 reported the facility did not have further documentation of the pest control service visits.

T 245	12 VAC5-412-240 A Medical Testing and Laboratory Services	T 245		2/6/19

Prior to the initiation of any abortion, a medical history and physical examination, including a confirmation of pregnancy, and completion of all requirements of informed written consent pursuant to § 18.2-76 of the Code of Virginia, shall be completed for each patient.

1. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor.

2. Use of any additional medical testing shall be based on assessment of patient risk.

3. The abortion facility shall develop, implement and maintain policies and procedures for offering

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screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention or at a minimum referring patients to clinics that provide such testing.

4. A written report of each laboratory test and examination shall be a part of the patient's record.

This RULE: is not met as evidenced by:
Based on interview and document review, it was determined the facility staff failed to ensure a current medical history was performed prior to a surgical abortion procedure for one (1) of twelve (12) reviewed patient medical records. (Patient # 12)

The findings included:

On January 16, 2019 at 11:00 a.m., the surveyor reviewed Patient #12's medical record. Patient #12 was admitted to the facility on March 14, 2018 for [redacted] performed on [redacted] Patient #12's medical record documented the patient called the facility [redacted] Patient #12's medical record documented the patient [redacted]. Patient #12's medical record documented the patient called the facility on April 6, 2018 [redacted]. The facility scheduled [redacted] for [redacted] to terminate Patient #12's pregnancy. The history and physical attached to the April 6, 2018 operative report was dated [redacted] and

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T 245	Continued From page 11 documented [redacted] The surveyor reviewed Patient #12's medical record with Staff Member #1 at 11:54 a.m., on January 16, 2019. Staff Member #1 verified Patient #12 did not have a current history and physical performed prior to [redacted]	T 245		
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 temperatures in accordance with definitions in 18 VAC 110-20-10. This RULE: is not met as evidenced by: Based on observation, interview and record review, it was determined the facility staff failed to ensure expired medications were not available for administration to patients. The findings included: A facility tour was conducted on January 15, 2019 starting at approximately 11:30 a.m., with Staff Member #1. An observation of the non-narcotic storage are for medications revealed two (2) packages of Methylergonovine maleate 0.2 mg (milligram/mL (milliliter). One (1) opened package had one (1) vial with an expiration date	T 315		2/6/19

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of "12/2018." The second unopened package contained ten (10) vials of Methylergonovine maleate with an expiration date of "3/2018." Staff Member #1 reported the facility had just received the unopened package of Methylergonovine maleate from their medication supplier.

[According to www.drugs.com Methylergonovine maleate is used in "Prevention and treatment of postpartum hemorrhage in the presence of uterine atony"-[a loss of muscle tone].

Staff Member #1 verified the vials of Methylergonovine maleate were all expired and still available for potential administration to a patient. The surveyor requested documentation related to the last administered dose of Methylergonovine maleate.

During an interview on January 16, 2019 at approximately 12:11 p.m., Staff Member #1 reported the only way to determine when the last dose of Methylergonovine maleate had been administered would be to review every chart from 2018. Staff Member #1 denied the facility had a system to document the administration of Methylergonovine maleate with the amount given other than within the patient's medical record. Staff Member #1 reported the facility did not have a system/process to document when a vial of Methylergonovine maleate was removed for the medication storage shelf or other accounting system.

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T 355	12 VAC5-412-300 Health Information Records	T 355		2/6/19

An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to

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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;
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 a facility physician failed to provide a discharge order for two (2) of twelve (12) patients included in the survey sample for medical record review. (Patients #3 and #7)

The findings included:

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(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 355	Continued From page 14	T 355		
	Patient #3 was admitted to the facility on June 30, 2018. Patient #3's medical record documented the patient was scheduled for [redacted] on [redacted]. The medical record documented [redacted] Patient #3's medical record documented the patient [redacted] A review of the post procedure physician's orders did not include an order for discharge once discharge criteria was achieved.			
	Patient #7 was admitted to the facility on July 24, 2018 and scheduled for [redacted] on [redacted]. Review of Patient #7's post procedure physician's orders did not include an order for discharge once discharge criteria was achieved.			
	An interview and review of the medical records for Patients #3 and #7 was conducted on January 16, 2019 at 11:55 a.m., with Staff Member #1. Staff Member #1 verified the physician had failed to complete the check box for discharge order.			
T 370	12 VAC5-412-320 B Required Reporting	T 370		2/6/19
	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			

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0019	A. BUILDING: ______ B. WING ______	01/25/2019

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T 370	Continued From page 15	T 370		

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 and interview, it was determined the facility failed to report a serious injury to a patient to the Office of Licensure and Certification (OLC).

The findings include:

On January 16, 2019 at 10:02 a.m., surveyors reviewed the medical record for Patient #3. During that review, surveyors learned the facility Patient #3 on the patient . The physician and Patient #3

As noted in the medical record, Patient #3

On January 16, 2019 at 12:35 p.m., surveyors asked Staff Member #1 about the event and if he/she reported the event to OLC. Staff Member #1 advised he/she did not report the event to OLC and further inquired about the definition of a serious injury. Staff Member #1 did advise that he/she believed the event was a complication and should be placed in the complication log.

ANNANDALE WOMEN and FAMILY CENTER

2839 DUKE STREET, ALEXANDRIA, VA 22314, (703) 751-4702

Douglas Middlebrooks, PhD
Supervisor Div of Acute Care Services
Commonwealth of Virginia, Dept of Health
9960 Mayland Drive Suite 401
Henrico, Virginia 23233-1485

February 18, 2019

Mr. Middlebrooks,

I have completed our plan for correcting deficiencies cited. These are enclosed. Please let me know if there is need for further clarification.

We would appreciate clarification regarding the reportable event: serious injury.

Thank you for your assistance in this review.

Sincerely,

Gail Frances, MSN, NP
Practice Administrator

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Annandale Women & Family Center; License AF-0019
Answers to Deficiencies.
February 18, 2019

T 060. 12=VAC5-412-180 A Personnel Adequately Trained Staff
Job description of performing ultrasounds has been written, reviewed by Administrator added to the manual. Job training of ultrasound has been documented, reviewed and added to each staff member personnel file who has been trained according to job description. This was completed 2/1/2019. Training and documentation of training will be reviewed and filed appropriately in personnel file at completion of individual training. The Practice Administrator will implement and review this policy effective 2/1/2019.

T090. 12-VAC5-412-180-F=Personnel

Policy in manual is to verify each licensed personnel on or before expiration date. This was established in Jan 2012. Staff #1 and staff #5 verification was obtained and filed in appropriate personnel file. Licensure expiration is based on date of birth of the licensee. A tickler file with birthdates was established 2/4/2019 and will be checked monthly by the Practice Administrator and verifications obtained when due. Personnel records are reviewed and any areas of incompleteness are corrected on an annual basis by the Practice Administrator effective Jan 2012.

T140 12VAC5-412-200B. Patients Rights
A policy to keep records regarding patient complaints was established Jan 2012 and is documented in Policy Manual. The complaint regarding patient #3 was a letter written by a business consumer organization. It did not contain any release of record signature by the patient. Therefore, in keeping with HIPAA regulations, we did not answer the letter from the business organization. We had telephone conversations with the patient and resolved her concerns which were documented in the chart; but not in the log. This chart was reviewed by the Quality Control supervisor and the Practice Administrator on 2/6/2019. This was documented in the complaint log 2/6/19. All complaints will be brought to the attention of the Quality Control Supervisor who will oversee resolution. This change is effective 2/6/2019. The Practice Administrator will review and document all complaints in the log effective Jan 2012.

T170-12VAC5-412-210 B Quality Management.
The Policy Manual contains a policy and procedure documentation of Quality Assurance effective Jan 2012. The Policy Manual was updated Jan 15, 2019 to include all seven of the listed items of evaluation. A meeting with the Quality Control supervisor and the Practice Administrator was held 2/6/2019 to review these items and to re-iterate that each item must be assessed on an annual basis. The Quality Assurance Meetings will be reviewed and signed by the Practice Administrator to ensure the items are adequately addressed annually effective 2/6/2019.

T200-12VAC5-412-220 C Infection Prevention
The Policy Manual contains policy and procedure for annual pest control effective Jan 2012 The Condo Association performs annual pest control for the building. The last pest control was done in the summer of 2018. The report from the association did not have a date. The Practice Administrator has requested a dated letter from the association 2/1/2019 and will file this in the Infection Control Meeting and Record file. The Practice Administrator will review and document pest control on an annual basis effective Jan 2012.

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2/18/19 [signature] AWFC

T245 12VAC5-412-240 A Medical Testing and Laboratory Services
The Policy Manual contains policy and procedure to maintain current(within one year) of documentation of medical history in each patient chart effective Jan 2012. Patient #12 medical record was reviewed at a staff meeting including Practice Administrator, physician, Quality Control supervisor and nursing and clerical staff on 2/1/2019. Policy regarding current (within one year) documentation of medical history was reviewed. All staff members present acknowledged this policy. There is provision for the physician to acknowledge current medical history on the chart. The Practice Administrator and the Alternate PA will continue to do weekly chart reviews assuring all documentation is complete as established 1/2/2017.

T315 12VAC5-412-260C. Administration, Storage and Dispensing Drugs.
The Policy Manual contains policy and procedure regarding Administration, Storage and Dispensing Drugs established Jan 2012. Charts from the month of January 2019 were reviewed by the Quality Control Supervisor and the Practice Administrator. No methylergonovine was administered during this time frame. All medications administered are documented with lot number and expiration date. The methylergonovine expired was December 2018 and so no expired medication was given. The unopened box expired 3/2018 was returned to the supplier for refund and replacement. A documentation of vials administered is now established and maintained in the storage container of the methylergonovine as of 2/1/2019. The Practice Administrator makes random inspections of all stored medication with corrective measures taken as indicated effective Jan 2012. The Quality Control Supervisor will make random inspections of all stored medication and report any deficiencies to the Practice Administrator effective 2/6/2019.

T355-12VAC5-412-300 Health Information Records
The Policy Manual contains policy and procedure regarding documentation of clinical records established Jan 2012. The physicians post op notes contains provision for discharge order. The Practice Administrator, Quality Control Supervisor, physician and nursing and clerical staff reviewed chart patient #3 and #7 which had the missing check for discharge at staff meeting 2/1/2019. The importance of all documentation being completed before discharge was stressed. The Practice Administrator or Alt Administrator performs weekly chart reviews and verification of all necessary documentation established Jan 2017.

2/18/19 [signature] AWFC

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T370 12VAC 412-0320B. Required Reporting

The Policy Manual contains policy and procedure regarding reporting the four listed events established Jan 2012. Patient #3 was [redacted]. The [redacted] performed [redacted] was not to [redacted] but to [redacted], The [redacted] heals on its own and does not require any surgical intervention. It most likely occurred due to the [redacted] is a complication of surgical abortion and not considered a 'serious injury" by this practice and standards of care. The incident of [redacted] was recorded in the complication log [redacted] The complication log was updated and made current [redacted] by the Practice Administrator. The events listed in the Required Reporting are somewhat ambiguous to this practice. "Serious Injury" was not interpreted as a complication of abortion; but, rather an injury not associated with abortion such as slipping on ice and suffering a concussion. And so this was not considered in this situation. Further, the [redacted] All listed events are reported to the OLC at occurrence by the Practice Administrator as established by the Policy Manual Jan 2012.

2/18/19 [signature] ANFC

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