



2207 Peters Creek Road NW
Roanoke, VA 24017
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Planned Parenthood South Atlantic

October 26, 2016

Attn: The Acute Care Supervisors
VA Department of Health
Office of Licensure and Certification
Division of Acute Care Services
9960 Mayland Drive
Suite 401
Henrico, VA 23233-1485

RE: State Licensure Survey – AF-0011

Dear Acute Care Supervisors:

Please find enclosed the completed Plan of Correction for Planned Parenthood South Atlantic, # AB0011, located at 2207 Peters Creek Road, NW in Roanoke, Virginia.

If you have any questions or require any additional information, please feel free to contact Lorrie Detrick at lorri.detrick@ppsat.org or call (919)818-1591.

Sincerely,

Amanda Ohira
Patient Services Administrative Coordinator

enclosure

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State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AF-0011	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/10/2016
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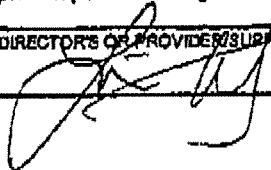
NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SOUTH ATLANTIC - ROA	STREET ADDRESS, CITY, STATE, ZIP CODE 2207 PETERS CREEK ROAD ROANOKE, VA 24017
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(T 000)	12VAC5-412 Initial Comments An unannounced First Trimester Abortion Facility (FTAF) Biennial Licensure Revisit Inspection was conducted on 09/08/2016 and 09/10/2016. (The biennial licensure inspection had been conducted on 05/18/2016 through 05/21/2016.) Two (2) Medical Facilities Inspectors with the Office of Licensure and Certification, Virginia Department of Health conducted the revisit investigation. During the inspection process observations, interviews and document review were conducted to determine compliance. The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 08/20/2013) This report includes re-cited deficiencies related to continued deficient practices.	(T 000)		
(T 035)	12VAC5-412-160 A Policies 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: 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	(T 035)	All employees have attended all mandatory trainings and emergency drills. Upon hire, it is the responsibility of the Health Center Manager to conduct and complete all mandatory trainings and drills with new employees according to the new employee orientation schedule. The Health Center Manager also follows an annual training calendar to ensure all employees receive ongoing mandatory trainings and drills. If an employee is unable to attend any mandatory training or drill, that employee will not be scheduled to work until said training or drill is completed. The Regional Director performs bi-annual audits on employee records to ensure compliance for new and regular employees in the	11.11.2016

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(continued on page 2)

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE:  TITLE: Vice President Patient Services Admin DATE: 10/26/16

STATE FORM 10/1/10 IVP812 If continuation sheet 1 of 25

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(T 035)	Continued From Page 1 Virginia prior to the initiation of any procedures; 6. When to use sonography to assess patient risk; 7. Infection prevention; 8. Quality an 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 observation, interview and document review it was determined the facility staff failed to ensure facility policies and procedures were followed that all staff working at the facility must attended mandatory trainings and emergency drills for three (3) of fifteen (15) employees (Staff	(T 035)	completion of mandatory trainings and drills. The Regional Director performs bi-annual audits on employee records to ensure compliance for new and regular employees in the completion of mandatory trainings and drills. A system has been developed to track all per diem and traveling employees' mandatory training and drills. There is a scheduling coordinator in place who is responsible for scheduling per diem and traveling employees. This person has access to an electronic shared checklist called the Staff Training Tracker. This checklist will contain information as to completion of mandatory trainings and drills. The scheduling coordinator will review the Staff Training Tracker prior to scheduling an employee in the health center. If a training or drill is not completed, the scheduling coordinator will alert the Health Center Manager. The Health Center Manager is responsible for ensuring that the training or drill is provided to the employee prior to the start of the scheduled shift. If this cannot be accomplished prior to the scheduled shift, the employee will not be allowed to work in the facility until such time that the required training or drill has been received. The Regional Director will audit the Staff Training Tracker on a monthly basis for three months, or until 100% compliance is achieved. <i>(continued on page 3)</i>	

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(T 035)	<p>Continued From Page 2</p> <p>Members #10, #11, and #12).</p> <p>The findings included:</p> <p>An interview was conducted on 09/08/2016 at 10:39 a.m., with Staff Member #2. The surveyors requested evidence of trainings and drills completed in accordance with the facility's plan of correction. The surveyors requested a list of all employees that worked at the facility and an as worked schedule for the months of July and August 2016.</p> <p>At approximately 1:10 p.m. on 09/08/2016 Staff Member #2 presented a list of employees. The surveyor inquired regarding an employee previously known to work at the facility and the initials of employees observed on 09/08/2016, which were documented on the narcotic count sheet. Staff Member #2 reported Staff Members #10, #11, and #12 had "inadvertently been left off the list."</p> <p>An interview and review of the facility's emergency drills and mandatory training documentation was conducted on 09/08/2016 at 1:23 p.m. with Staff Member #2. Staff Member #2 reported he/she used the employee list to determine whether each employee had complied with attending or reviewing the information regarding medical emergency (Hemorrhage and Hypovolemic shock) on 07/21/2016, emergency drill (active shooter) on 07/27/2016 and a mandatory staff meeting on 08/25/2016, which covered deficient practices from the facility's biennial survey, training for chemical attack and hemorrhage/hypovolemic shock. Staff Member #2 stated, "If staff misses a training or a mandatory meeting they are not allowed to work until they read and sign the training material and minutes." Staff Member #2 assisted the surveyor in determining signatures</p>	(T 035)	<p>The Staff Training Tracker will be cross-referenced with the actual facility schedule to ensure that no per diem or traveling employee has been allowed to work without having received all required trainings and drills. After three months, or when 100% compliance is achieved, the Regional Director will perform this audit bi-annually.</p>	

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(T035)	<p>Continued From Page 3</p> <p>that were not legible. Review of the signatures did not include Staff Members #10, #11, and #12. Staff Member #2 reported that Staff Members #10, #11, and #12 had mistakenly been left off the employee list, but had not worked since the trainings.</p> <p>Staff Member #2 and the surveyor reviewed the facility's as worked schedules for the months of July and August 2016. The schedules documented that Staff Member #10 had worked on 09/03/2016, Staff Member #11 had worked 07/23/2016 and 07/30/2016, and Staff Member #12 had worked 08/13/2016. The schedule documented Staff Members #10, #11, and #12 had worked without having reviewed mandatory trainings for 07/21/2016 and 07/25/2016 or documenting he/she had reviewed the mandatory staff meeting minutes for 08/25/2016. Staff Member #2 reported he/she had not thought about Staff Members #10, #11, and #12 because they had been left off his/her employee list. Staff Member #2 verified the facility's policy and procedure related to emergency drills and mandatory meetings had not been followed.</p> <p>An interview and review of training presentation for the facility's complaint process was conducted on 09/10/2016 at 11:30 a.m. with Staff Member #2. Staff Member #2 stated, "We already know [Names of Staff Members #10, #11, and #12] were left off of the employee list and are not going to be on the sign-in sheets for the complaint training." Staff Member #2 verified Staff Members #10, #11, and #12 had worked since the training had been presented but had not reviewed the required complaint process training.</p> <p>An interview and review of "re-training" documentation was conducted on 09/10/2016 at 2:01 p.m. with Staff Member #2. The "re-training"</p>	(T035)		

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(T 035)	Continued From Page 4 documents included proof of training related to offering STI screening, infection prevention practices, proper personal protective equipment (PPE), and hand hygiene. Staff Member #2 verified Staff Members #10, #11, and #12 did not attend or review the refresher course training documents and had worked since the trainings had been presented. An interview and review of the facility's training documentation for narcotic counting was conducted on 09/10/2016 at 2:19 p.m. with Staff Member #2. Staff Member #2 stated, "[Names of Staff Members #10, #11, and #12] didn't attend the training and all of them, [the first names for Staff Members #10, #11, and #12] have worked since the training, without reviewing the information."	(T 035)		
(T 045)	12VACS-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	(T 045)	The facility's administrator will hold monthly meetings with the Health Center Manager, designated Administrator en Absentia pursuant to 12VACS-412-170(C)), and Regional Director for three months, or until 100% compliance has been achieved, to monitor for compliance in all areas related to expired medications, narcotic counts, employee attendance at mandatory trainings and drills, and compliance with obtaining Virginia State police criminal background checks on all employees with access to narcotics. After three months, or once 100% compliance is achieved, the facility's administrator will delegate ongoing <i>(continued on page 6)</i>	11.11.16

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(T045)	<p>Continued From Page 5</p> <p>5. Maintaining compliance with applicable laws and regulations and implementing corrective action.</p> <p>This RULE: is not met as evidenced by: Based on observations, interviews and document review it was determined the facility's administrator had failed to ensure:</p> <p>1. Medications available for use were not expired, narcotic counts were performed.</p> <p>2. All employees had attended the required mandatory trainings and meetings; three (3) of fifteen (15) worked without attending. (Staff Members #10, #11, and #12).</p> <p>3. Criminal background check by the Virginia State police was performed on three (3) of eight (8) employees with access to narcotics. (Staff Members #10, #12, and #13).</p> <p>The findings included:</p> <p>1. Observations and interviews were conducted on 09/08/2016 from 10:58 a.m. through 12:08 p.m., with Staff Member #2 and two surveyors.</p> <p>The observations started at 10:58 a.m. in the area designated as the "Recovery area." Staff Member #2 reported the 10 ml (milliliter) vial of Diazepam for emergency cart was kept in the secured cabinet with the other narcotics. Staff Member #2 located the 10 ml vial of Diazepam. Staff Member #2 verified the 10 ml vial of Diazepam had expired on "1 Sep 16." Staff Member #2 verified procedures were performed on 09/03/2016 and staff had failed to remove the expired medication. Staff Member #2 reported since the 10 ml vial of</p>	(T045)	<p>oversight for compliance to the Regional Director.</p> <p>The facility administrator also attends the Roanoke RQM meetings for the purpose of additional monitoring of ongoing compliance with all abortion facility regulations.</p>	

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{T 045}	<p>Continued From Page 6</p> <p>Diazepam was not on a weekly count sheet the staff might not have looked for the vial unless there was an emergency. Staff Member #2 verified the expired 10 ml vial of Diazepam was available for emergency use on 09/03/2016 during procedures.</p> <p>Observations were conducted on 09/08/2016 at 11:10 a.m., with Staff Member #2 in the room designated as the "Lab." The observation revealed two opened undated medications within the refrigerator. One (1) 1 ml vial of Tuberculin Purified Protein Derivative 5 TU/0.1 ml approximately half full and one (1) 5 ml vial of Tuberculin Purified Protein Derivative approximately three-fourth full. Staff Member #2 verified the vials were opened and did not have an opened date. Staff Member #2 verified the amounts within each vial and that Tuberculin Purified Protein Derivative could only be opened for 28 to 30 days, then needed to be discarded. Staff Member #2 acknowledged without a date the vials were opened it would "be hard to tell if the vials were opened for 28 days."</p> <p>The narcotic count documents included a form titled "[Name of facility] Controlled Substance Log: Stock Inventory Diazepam 10 mg (milligram) Crash Cart ... 100 tab (tablet) box." The form did not have a licensed staff signature or initials as verification for the nineteen (19) counts performed by a non-licensed staff member. Staff Member #2 stated, "I started to count them they had been part of the crash cart." Staff Member #2 verified his/her count was monthly from 08/11/2016 to 07/12/2016 and then fluctuated from daily to every two or three days with the last count documented on "8/13/16." Staff Member #2 stated, "I stopped counting them in August because it was a crash cart medication." Staff Member #2 verified Diazepam 10 mg tablets were not listed on the</p>	{T 045}		

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(T 045)	<p>Continued From Page 7</p> <p>new "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" form for the crash cart. Staff Member #2 acknowledged recovery area staff had weekly access to the Diazepam 10 mg tablets.</p> <p>On 09/10/2016 at approximately 2:22 p.m. the surveyor informed Staff Members #4 and #5 of the findings from observations conducted on 09/08/2016. Staff Member #5 reviewed the "[Name of facility] Controlled Substance Log: Stock Inventory" for the oral Diazepam 10 mg and verified the medication had been accessible to recovery staff members on a weekly basis and a narcotic count had not been documented for three weeks since "8/13/16".</p> <p>2. An interview and review of the facility's emergency drills and mandatory training documentation was conducted on 09/08/2016 at 1:23 p.m. with Staff Member #2. Staff Member #2 reported he/she used the employee list to determine whether each employee had complied with attending or reviewing the information regarding medical emergency (Hemorrhage and Hypovolemic shock) on 07/21/2016, emergency drill (active shooter) on 07/27/16 and a mandatory staff meeting on 08/25/2016, which covered deficient practices from the facility's biennial survey, training for chemical attack and hemorrhage/hypovolemic shock. Staff Member #2 stated, "If staff misses a training or a mandatory meeting they are not allowed to work until they read and sign the training material and minutes." Staff Member #2 assisted the surveyor in determining signatures that were not legible. Review of the signatures did not include Staff Members #10, #11, and #12. Staff Member #2 reported that Staff Members #10, #11, and #12 had mistakenly been left off the employee list, but had not worked since the trainings.</p>	(T 045)		

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(T 045)	<p>Continued From Page 8</p> <p>Staff Member #2 and the surveyor reviewed the facility's as worked schedules for the months of July and August 2016. The schedules documented that Staff Member #10 had worked on 09/03/2016, Staff Member #11 had worked 07/23/2016 and 07/30/2016, and Staff Member #12 had worked 08/13/2016. The schedule documented Staff Members #10 and #11, and #12 had worked without having reviewed mandatory trainings for 07/21/2016 and 07/25/2016 or documenting he/she had reviewed the mandatory staff meeting minutes for 08/25/2016. Staff Member #2 reported he/she had not thought about Staff Members #10, #11, and #12 because they had been left off his/her employee list. Staff Member #2 verified Staff Members #10, #11, and #12 had not received their required training for emergency drills, attended the mandatory meetings, or reviewed and signed training and meeting documents.</p> <p>An interview and review of training presentation for the facility's complaint process was conducted on 09/10/2016 at 11:30 a.m. with Staff Member #2. Staff Member #2 stated, "We already know [Names of Staff Members #10, #11, and #12] were left off of the employee list and are not going to be on the sign-in sheets for the complaint training." Staff Member #2 verified Staff Members #10, #11, and #12 had worked since the training had been presented but had not reviewed the required complaint process training.</p> <p>An interview and review of "re-training" documentation was conducted on 09/10/2016 at 2:01 p.m. with Staff Member #2. The "re-training" documents included proof of training related to offering STI screening, infection prevention practices, proper personal protective equipment (PPE), and hand hygiene. Staff Member #2</p>	(T 045)		

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(T045)	<p>Continued From Page 9</p> <p>verified Staff Members #10, #11, and #12 did not attend or review the refresher course training documents and had worked since the trainings had been presented.</p> <p>An interview and review of the facility's training" documentation for narcotic counting was conducted on 09/10/2016 at 2:19 p.m. with Staff Member #2. Staff Member #2 stated, "[Names of Staff Members #10, #11, and #12] didn't attend the training and all of them, [the first names for Staff Members #10, #11, and #12] have worked since the training, without reviewing the information."</p> <p>3. An interview and review of the facility's evidence of compliance was conducted on 09/10/2016 at approximately 8:30 a.m., with Staff Member #2 with Staff Members #4 and #5 present in the room. Staff Member #2 presented the criminal background checks performed by the Virginia State Police Department (VSPD). The documents did not include completed criminal background checks by VSPD for Staff Members #10, #12 and #13. Staff Member #2 reported he/she was waiting for the sister facility where Staff Members #10 and #12 generally worked to forward proof of the Staff Members' VSPD criminal background check. Staff Member #2 acknowledged the criminal background check for Staff Member #13 had been requested in June 2016 and the facility had not received a completed form from the VSPD as of 09/10/2016.</p> <p>At approximately 3:08 p.m. on 09/10/2016 Staff Member #2 reported he/she was still waiting for proof a criminal background check had been performed by VSPD for Staff Members #10 and #12. No other documentation for Staff Members #10, #12 and #13 was presented prior to exit at 5:01 p.m. on 09/10/2016.</p>	(T045)		

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(T070)	<p>12VAC5-412-180 C Personnel</p> <p>Each abortion facility shall obtain a criminal history record check pursuant to § 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.</p> <p>This RULE: is not met as evidenced by: Based on interview and document review it was determined the facility staff failed to ensure a criminal background check by the Virginia State police was performed on three (3) of eight (8) employees with access to narcotics (Staff Members #10, #12, and #13).</p> <p>The findings included:</p> <p>An interview and review of the facility's evidence of compliance was conducted on 09/10/2016 at approximately 8:30 a.m., with Staff Member #2 with Staff Members #4 and #5 present in the room. Staff Member #2 presented the criminal background checks performed by the Virginia State Police Department (VSPD). The documents included a request for Staff Member #13 criminal background check dated June 2016. The form did not indicate a criminal background check had been performed. The surveyor inquired whether Staff Member #2 had followed up with the VSPD regarding the delay in a completed criminal background check. Staff Member #2 stated, "No." Staff Member #5 asked if there was a process or time requirement for the VSPD to provide the necessary documents. The surveyor directed Staff Members #2 and #5 to contact VSPD regarding the VSPD's processes.</p> <p>The interview and review of the documents presented by Staff Member #2 did not include</p>	(T070)	<p>All employees with access to narcotics have had criminal background check requests submitted to the Virginia State police. Upon hire, it is the responsibility of the Health Center Manager to ensure that the Virginia State police background check request has been submitted either by the Organizational Development Department, or as initiated by the Health Center Manager, prior to allowing a new employee with access to narcotics to work independently in the facility. The Regional Director performs bi-annual audits on employee records to ensure compliance for new and regular employees with access to narcotics for the submission of Virginia State police background checks.</p> <p>A system has been developed to track submission of State of Virginia background checks for all per diem and traveling employees who have access to narcotics. There is a scheduling coordinator in place who is responsible for scheduling per diem and traveling employees. This person has access to an electronic shared checklist called the Staff Training Tracker. This checklist will contain information as to submission of the Virginia State police background check request for employees with access to narcotics. The scheduling coordinator will review the Staff Training Tracker prior to scheduling an employee in the health center. The scheduling coordinator will review the Staff Training Tracker prior to scheduling an employee in the health center. If a Virginia State police background check request has not been submitted, the scheduling coordinator will alert the Health Center Manager.</p> <p>The Health Center Manager is responsible for ensuring that the background check request is submitted prior to the start of the scheduled shift. If submission cannot be accomplished prior to the scheduled shift, the employee will not be allowed to work in the facility until such time that the background check request has been submitted.</p> <p style="text-align: right;">(continues on page 12)</p>	11.11.16

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(T 070)	Continued From Page 11 criminal background checks for Staff Members #10, #11, and #12. Staff Member #2 reported he/she was waiting for the sister facility where Staff Members #10, #11, and #12 generally worked to forward proof of the Staff Members' VSPD criminal background check. At approximately 3:09 p.m. on 09/10/2016 Staff Member #2 presented a copy of Staff Member #11's criminal background check performed by the VSPD. Staff #2 reported he/she was still waiting for proof a criminal background check had been performed by VSPD for Staff Members #10 and #12. No other documentation for Staff Members #10, #12 and #13 was presented prior to exit at 5:01 p.m. on 09/10/2016.	(T 070)	The Regional Director will audit the Staff Training Tracker on a monthly basis for three months, or until 100% compliance is achieved. The Staff Training Tracker will be cross-referenced with the actual facility schedule to ensure that no per diem or traveling employee with access to narcotics has been allowed to work without the Virginia State police background check request submitted. After three months, or when 100% compliance is achieved, the Regional Director will perform this audit bi-annually.	
(T 140)	12VAC5-412-200 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 interviews and document review it was determined the facility staff failed to ensure all staff members were re-trained on the facility's system for logging, investigation and resolution of complaints; three (3) of fifteen (15) employees did not receive the required training (Staff Members #10, #11, and #12). The findings included:	(T 140)	All employees have been retrained on the facility's system for logging, investigation and resolution of complaints. Upon hire, it is the responsibility of the Health Center Manager to conduct and complete training regarding the facility's system for logging, investigation and resolution of complaints with new employees according to the new employee orientation schedule. The Health Center Manager also trains all employees annually on the system for logging, investigation and resolution of complaints. If an employee is unable to attend any mandatory training or drill, that employee will not be scheduled to work until said training or drill is completed. The Regional Director performs bi-annual audits on employee records to ensure compliance for new and regular employees in the completion of training on the facility's system for logging, investigation and resolution of complaints. <i>(continue on page 13)</i>	11.11.16

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(T 140)	Continued From Page 12 An interview was conducted during the entrance conference on 09/08/2016 at 10:39 a.m., with Staff Member #2. The surveyors requested evidence of staff training related to accepting, logging, the investigation, and resolution of complaints. The surveyors requested a list of all employees that worked at the facility and an as worked schedule for the months of July and August 2016. At approximately 1:10 p.m. on 09/08/2016 Staff Member #2 presented a list of employees. The surveyor inquired regarding an employee previously known to work at the facility and the initials of employees observed on 09/08/2016, which were documented on the narcotic count sheet. Staff Member #2 reported Staff Members #10, #11, and #12 had "inadvertently been left off the list." An interview and review of training presentation for the facility's complaint process was conducted on 09/10/2016 at 11:30 a.m. with Staff Member #2. Staff Member #2 reported he/she had used the employee list to determine whether each employee had complied with attending or reviewing the information regarding the facility's complaint process. Staff Member #2 stated, "We already know [Names of Staff Members #10, #11, and #12] were left off of the employee list and are not going to be on the sign-in sheets for the complaint training." Staff Member #2 verified Staff Members #10, #11, and #12 had worked since the training had been presented but had not reviewed the required complaint process training.	(T 140)	A system has been developed to track all per diem and traveling employees' training on the facility's system for logging, investigation and resolution of complaints. There is a scheduling coordinator in place who is responsible for scheduling per diem and traveling employees. This person has access to an electronic shared checklist called the Staff Training Tracker. This checklist will contain information as to completion of the facility's system for logging, investigation and resolution of complaints. The scheduling coordinator will review the Staff Training Tracker prior to scheduling an employee in the health center. If the facility's complaint system has not been trained on, the scheduling coordinator will alert the Health Center Manager. The Health Center Manager is responsible for ensuring that the training is provided prior to the start of the scheduled shift. If this cannot be accomplished prior to the scheduled shift, the employee will not be allowed to work in the facility until the required training has been received. The Regional Director will audit on a monthly basis for three months, or until 100% compliance is achieved, the "Eligible to Work" list as cross-referenced with the actual facility schedule to ensure that no per diem or traveling employee has been allowed to work without training on the facility's system for logging, investigation and resolution of complaints completed. After three months, or when 100% compliance is achieved, the Regional Director will perform this audit bi-annually.	
(T 195)	12VAC5-412-220 B Infection Prevention Written infection prevention policies and	(T 195)	All employees have received infection prevention training. <i>(continue on page 14)</i>	11.11.16

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(T 195)	Continued From Page 13 procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-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:	(T 195)	Upon hire, it is the responsibility of the Health Center Manager to conduct and complete infection prevention training with new employees according to the new employee orientation schedule. The Health Center Manager also follows an annual training calendar to ensure all employees receive ongoing infection prevention training. If an employee is unable to attend a mandatory infection prevention training, that employee will not be scheduled to work until said training is completed. The Regional Director performs bi-annual audits on employee records to ensure compliance for new and regular employees in the completion of mandatory trainings, including infection prevention. A system has been developed to track all per diem and traveling employees' infection prevention training. There is a scheduling coordinator in place who is responsible for scheduling per diem and traveling employees. This person has access to an electronic shared checklist called the Staff Training Tracker. This list will contain information as to completion of infection prevention training. The scheduling coordinator will review the Staff Training Tracker prior to scheduling an employee in the health center. If infection prevention training is not completed, the scheduling coordinator will alert the Health Center Manager. <i>(continued on page 15)</i>	

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(T 195)	<p>Continued From Page 14</p> <p>Based on interview and document review it was determined the facility staff failed to ensure four (4) of fifteen staff members received infection prevention training (Staff Members #10, #11, #12 and #14).</p> <p>The findings included:</p> <p>An interview and review of the facility's infection prevention "re-training" documentation was conducted on 09/10/2016 at 2:01 p.m. with Staff Member #2. The information presented included an "Infection Prevention Refresher" document. One document had Staff Member #14's name printed on the top line but the document did not have Staff Member #14's signature or a date. Staff Member #2 reported Staff Member #14 had been scheduled to work on 09/10/2016 but canceled.</p> <p>Staff Member #2 reported he/she had used the employee list to determine whether each employee had complied with attending or reviewing the infection prevention re-training and staff members. Staff Member #2 stated, "We already know [Names of Staff Members #10, #11, and #12] were left off of the employee list and are not going to be on the sign-in sheets for infection prevention and wearing the correct PPE (personal protective equipment)." Staff Member #2 verified Staff Members #10, #11, and #12 had worked after the training had been presented. Staff Member #2 verified Staff Members #10, #11, and #12 had worked without reviewing the required training for infection prevention practices, hand hygiene, and wearing the proper personal protection equipment (PPE).</p> <p>Staff Member #2 presented observation audits conducted to ensure staff were wearing proper PPE and performing hand hygiene. The audits</p>	(T 195)	<p>The Health Center Manager is responsible for ensuring that the training is provided prior to the start of the scheduled shift. If this cannot be accomplished prior to the scheduled shift, the employee will not be allowed to work in the facility until such time that the required infection prevention training has been received. The Regional Director will audit the Staff Training Tracker on a monthly basis for three months, or until 100% compliance is achieved. The Staff Training Tracker will be cross-referenced with the actual facility schedule to ensure that no per diem or traveling employee has been allowed to work without all required trainings completed, including infection prevention. After three months, or when 100% compliance is achieved, the Regional Director will perform this audit bi-annually.</p>	

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(T 195)	Continued From Page 15 listed dates, but did not include which staff member had been observed, whether the staff member being observed required corrective action, or what corrective action was offered if needed. The audits did not provide a means to collect, track, and trend staff member behaviors regarding wearing proper PPE and performing hand hygiene. Staff Member #2 acknowledged the findings.	(T 195)		
(T 245)	12VAC5-412-240 A Medical Testing and Laboratory Services 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 § 18.2-78 of the Code of Virginia, shall be completed for each patient. 1. Use of any additional medical testing shall be based on assessment of patient risk. The clinical criteria for such additional testing and the actions to be taken if abnormal results are found shall be documented. 2. Medical testing shall include a recognized method to confirm pregnancy and determination or documentation of Rh factor. 3. The abortion facility shall develop, implement and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention. The policies and procedures shall address appropriate responses to a positive screening test. 4. A written report of each laboratory test and	(T 245)	All employees have received training to offer patients screening for sexually transmitted infections (STIs). Upon hire, it is the responsibility of the Health Center Manager to conduct and complete training regarding offering patients screening for STIs with new employees according to the new employee orientation schedule. The Health Center Manager is also responsible for training of all regular employees in the area of offering patients screening for STIs. If an employee is unable to attend a mandatory training, that employee will not be scheduled to work until said training is completed. The Regional Director performs bi-annual audits on employee records to ensure compliance for new and regular employees in the completion of mandatory trainings, including offering patients screening for STIs. A system has been developed to track all per diem and traveling employees' <i>(continue on page 17)</i>	11/1/16

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(T 245)	<p>Continued From Page 16</p> <p>examination shall be a part of the patient's record.</p> <p>This RULE: is not met as evidenced by: Based on interview and document review it was determined the facility staff failed to ensure all staff members received training to offer patients screening for sexually transmitted infections [(STIs) (Staff Members #10, #11, and #12)].</p> <p>The findings included:</p> <p>An interview and review of the facility's infection prevention "re-training" documentation for STI screening was conducted on 09/10/2016 at 2:01 p.m. with Staff Member #2. Staff Member #2 presented a "Refresher" course document with a sign-in sheet attached. Staff Member #2 reported the course was offered on 07/21/2016 and he/she had used the employee list to determine staff compliance with attending or reviewing the information. Staff Member #2 stated, "You already know (Names of Staff Members #10, #11, and #12) are not going to be on the sign-in sheets for this training. I already told you they were accidentally left off the employee list." Staff Member #2 stated, "All of them, [the first names for Staff Members #10, #11, and #12] have worked since the training, without reviewing the information."</p> <p>The information presented included a document with Staff Member #14's name printed on the top line. The document had a signature that Staff Member #2 verified was Staff Member #14's signature. Staff Member #2 also verified the signature had not been dated.</p>	(T 245)	<p>training regarding offering patients screening for STIs. There is a scheduling coordinator in place who is responsible for scheduling per diem and traveling employees. This person has access to an electronic shared checklist called the Staff Training Tracker. This checklist will contain information as to completion of training regarding offering patients screening for STIs. The scheduling coordinator will review the Staff Training Tracker prior to scheduling an employee in the health center. If training regarding offering patients screening for STIs is not completed, the scheduling coordinator will alert the Health Center Manager. The Health Center Manager is responsible for ensuring that the training is provided prior to the start of the scheduled shift. If this cannot be accomplished prior to the scheduled shift, the employee will not be allowed to work in the facility until such time that the training is completed. The Regional Director will audit the Staff Training Tracker on a monthly basis for three months, or until 100% compliance is achieved. The Staff Training Tracker will be cross-referenced with the actual facility schedule to ensure that no per diem or traveling employee has been allowed to work without all required trainings completed, including offering patients screening for STIs. After three months, or when 100% compliance is achieved, the Regional Director will perform this audit bi-annually.</p>	

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(T 325)	Continued From Page 17	(T 325)		
(T 325)	<p>12VAC5-412-260 E Administration, Storage, Dispensing of Drugs</p> <p>Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Code of Virginia.</p> <p>This RULE: is not met as evidenced by: Based on observations, interviews and document review it was determined facility staff failed to ensure:</p> <ol style="list-style-type: none"> Expired and opened undated medications were not available for use. The narcotic count was performed on narcotics within the locked storage and the required second staff verification of the narcotic count was by a licensed staff. All staff received training related to accurately performing the weekly narcotic count. <p>The findings included:</p> <p>Observations and interviews were conducted on 09/08/2016 from 10:58 a.m. through 12:08 p.m., with Staff Member #2 and two surveyors. The observations started at 10:58 a.m. in the area designated as the "Recovery area."</p> <ol style="list-style-type: none"> Staff Member #2 stated, "We have a new form for the emergency cart and count." The form titled "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" had a pre-printed list of medications and supplies, which 	(T 325)	<p>There are no expired or opened undated medications available for use. A licensed staff member conducts a complete inventory on a monthly basis of all medications in the health center. Any medications identified as near expiration are immediately ordered so that the expired medications can be replaced. Any opened medications not marked with an "opened" date are disposed of and immediately replaced. The Health Center Manager is responsible for monitoring that the licensed staff member completes the inventory of medications on a timely basis. After three months, or when 100% compliance is achieved, the Regional Director will perform bi-annual audits of the monthly medication inventories to ensure ongoing compliance in this area.</p> <p>The narcotic count has been performed on narcotics within the locked storage and the required second staff verification of the narcotic count was by a licensed staff person as required. Narcotic counts will be performed at the beginning and end of every AB clinic day. The Health Center Manager is responsible for ensuring that the narcotic count in the locked storage is done with verification by a second staff person who is licensed and documents</p> <p><i>(continue on page 19)</i></p>	11.11.16

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(T 325)	Continued From Page 18 should be available. Staff Member #2 determined Staff Member #15 had performed the "Aug. 2016" documentation. Staff Member #15 had placed a check mark at each medication except "Flumazenil (Romazicon), Vasopressin (Pitressin), and Diazepam (Vallium). The surveyor inquired regarding the medications left without a check mark. Staff Member #2 reported the count was generally "performed by two staff one (1) licensed and one (1) non-licensed according to our policy." Staff Member #2 stated, "I was not here on the 31st (August 2016). I was at a meeting at (Name of a sister facility). (Staff Member #15's name) performed the count alone for the emergency cart. (He/she) may not have known where the Vasopressin and Diazepam were kept." Staff Member #2 obtained the key for locked narcotic cabinet. Staff Member #2 reported the 10 ml (milliliter) vial of Diazepam for emergency cart was kept in the secured cabinet with the other narcotics. Staff Member #2 located the 10 ml vial of Diazepam. Staff Member #2 verified the 10 ml vial of Diazepam had expired on "1 Sep 16." Staff Member #2 verified procedures were performed on 09/03/2016 and staff had failed to remove the expired medication. Staff Member #2 reported since the 10 ml vial of Diazepam was not on a weekly count sheet the staff might not have looked for the vial unless there had been a medical emergency. Staff Member #2 verified the expired 10 ml vial of Diazepam was available for emergency use on 09/03/2016 during procedures. Staff Member #2 was not able to locate the Flumazenil and Vasopressin in the locked cabinet. Staff Member #2 reported the Flumazenil and Vasopressin "might be in the refrigerator in the Lab." Observations were conducted on 09/08/2016 at 11:10 a.m., with Staff Member #2 in the room	(T 325)	the completion of this process with signatures of both parties on a weekly basis. After three months, or when 100% compliance is achieved, the Regional Director will perform bi-annual audits of the narcotic counts to ensure ongoing compliance in this area. All staff has been trained on accurately performing the narcotic count prior to and after every AB clinic day. All new employees are trained on accurately performing the narcotic count prior to the start of their first shift. All traveling and per diem staff will have indication on the Staff Training Tracker that they have received the required training on accurate AB clinic day narcotic counts. After three months, or when 100% compliance is achieved, the Regional Director will perform bi-annual audits of training on weekly narcotic counts to ensure ongoing compliance in this area.	

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(T 325)	<p>Continued From Page 19</p> <p>designated as the "Lab." The observation revealed two opened undated medications within the refrigerator. One (1) 1 ml vial of Tuberculin Purified Protein Derivative 5 TU/0.1 ml approximately half full and one (1) 5 ml vial of Tuberculin Purified Protein Derivative approximately three-fourth full. Staff Member #2 verified the vials were opened and did not have an opened date inscribed. Staff Member #2 verified the amounts within each vial and that Tuberculin Purified Protein Derivative could only be opened for 28 to 30 days, and then needed to be discarded. Staff Member #2 acknowledged without a date the vials had been opened it would "be hard to tell if the vials were opened for 28 days."</p> <p>2. Review on 09/08/2016 at approximately 11:05 a.m., with Staff Member #2 of the narcotic count documents did not include a count sheet for the Diazepam 10 ml vial. Staff Member #2 stated, "it (Diazepam vial) is not on our weekly count sheets." Staff Member #2 reported the 10 ml vial of Diazepam was on the monthly count sheet. Staff Member #2 acknowledged the 10 ml vial of Diazepam was housed with the weekly medications and recovery area staff members had weekly access to the 10 ml vial of Diazepam. Staff Member #2 acknowledged the 10 ml vial of Diazepam listed on the 08/2016 "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" had not been checked.</p> <p>The narcotic count documents included a form titled "9 (Name of facility) Controlled Substance Log: Stock Inventory Diazepam 10 mg (milligram) Crash Cart ... 100 tab (tablet) box." The form did not have a licensed staff signature or initials for the nineteen (19) counts performed by a</p>	(T 325)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AP-0011	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/10/2016
NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SOUTH ATLANTIC - ROA		STREET ADDRESS, CITY, STATE, ZIP CODE 2207 PETERS CREEK ROAD ROANOKE, VA 24017		
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(T 325)	<p>Continued From Page 20</p> <p>non-licensed staff member. Staff Member #2 stated, "I started to count them they had been part of the crash cart." Staff Member #2 verified his/her count was monthly from 06/11/2016 to 07/12/2016 and then fluctuated from daily to every two or three days with the last count documented on "8/13/16." Staff Member #2 stated, "I stopped counting it in August because it was a crash cart medication." Staff Member #2 verified Diazepam 10 mg tablets were not listed on the "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" form for the crash cart. Staff Member #2 acknowledged recovery area staff had weekly access to the Diazepam 10 mg tablets. Staff Member #2 was not able to locate the Flumazenil and Vasopressin listed on the emergency cart count sheet.</p> <p>An interview was conducted on 09/10/2016 at 2:18 p.m., with Staff Member #4 with Staff Members #2 and #5 present in the room. Staff Member #4 verified a patient could request oral Diazepam instead of the generally offered Ativan as a pre-procedure medication. Staff Member #5 stated, "The oral Valium (Diazepam) tablets need to be counted along with the weekly narcotics."</p> <p>On 09/10/2016 at approximately 2:22 p.m. the surveyor informed Staff Members #4 and #5 of the findings from observations conducted on 09/08/2016. Staff Member #5 reviewed the 08/2016 "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services." Staff Member #5 verified Staff Member #15 should have entered the expiration dates on the form. Staff #5 reported he/she was not sure of what "Loc:" meant and would clarify with the affiliate organization. Staff Member #5 reviewed the "(Name of facility) Controlled Substance Log: Stock Inventory" for the oral Diazepam 10 mg and verified the medication had been accessible to</p>	(T 325)		

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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SOUTH ATLANTIC - ROA		STREET ADDRESS, CITY, STATE, ZIP CODE 2207 PETERS CREEK ROAD ROANOKE, VA 24017		
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{T 325}	Continued From Page 21 recovery staff members on a weekly basis and a narcotic count had not been documented for three weeks since "8/13/16." 3. An interview and review of the facility's training documentation for narcotic counting was conducted on 09/10/2016 at 2:19 p.m. with Staff Member #2. Staff Member #2 stated, "(Names of Staff Members #10, #11, and #12) didn't attend the training and all of them, (the first names for Staff Members #10, #11, and #12) have worked since the training, without reviewing the information."	{T 325}		
{T 330}	12VAC5-412-270 Equipment and Supplies An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include: 1. A bed or recliner suitable for recovery; 2. Oxygen with flow meters and masks or equivalent; 3. Mechanical suction; 4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; 5. Emergency medications, intravenous fluids, and related supplies and equipment; 6. Sterile suturing equipment and supplies; 7. Adjustable examination light; 8. Containers for soiled linen and waste materials with covers; and	{T 330}	The facility staff has followed their procedures for ensuring emergency cart medications and supplies were documented on the inventory sheet for all months. The Health Center Manager is responsible for monitoring the proper completion of emergency cart medication and supply inventory by a licensed staff member, and educates facility staff as to proper completion as well. The Health Center Manager audits for the proper completion of the emergency cart inventory on a monthly basis, directly following the completion of the inventory by the assigned staff person. Any issues identified by the Health Center Manager are immediately corrected and the appropriate staff persons are educated as to these areas. After three months, or when 100% compliance is achieved, the Regional Director will perform bi-annual audits of the emergency cart inventory sheets to ensure ongoing compliance in this area.	11/16/16

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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SOUTH ATLANTIC - ROA		STREET ADDRESS, CITY, STATE, ZIP CODE 2207 PETERS CREEK ROAD ROANOKE, VA 24017		
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{T 330}	Continued From Page 22 9. Refrigerator This RULE: is not met as evidenced by: Based on observation, interview and document review it was determined the facility staff failed follow their procedure for ensuring emergency cart medications and supplies were documented on the inventory sheet for one (1) of one (1) month the inventory sheet was in use (August 2016). The findings included: Observations and interviews were conducted on 09/08/2016 from 10:58 a.m. through 12:08 p.m., with Staff Member #2 and two surveyors. Staff Member #2 and a surveyor reviewed the monthly log for the facility's emergency cart. Staff Member #2 stated, "We have a new form for the emergency cart and count." The form titled "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" had a pre-printed list of medications and supplies, which should be available. The form "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" listed the medications with pre-printed dosages and annotations related to shortages of certain medications. Under the name and dosage of each medication the form provided a space for staff members to enter the medication's "Exp:" (expiration date) and "Loc:" (generally the location of the medication e.g. drawer #3). The documentation on the "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" for "Aug. 2016" the "Exp:" and "Loc:" for each medication was blank. Staff Member #2 stated, "I'm not clinical I'm not sure what the 'Exp' and 'Loc' mean." Staff Member #2 did verify the	{T 330}		

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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SOUTH ATLANTIC - ROA			STREET ADDRESS, CITY, STATE, ZIP CODE 2207 PETERS CREEK ROAD ROANOKE, VA 24017		
(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 330)	<p>Continued From Page 23</p> <p>two areas (Exp: and Loc:) under each medication had not been filled in and was blank.</p> <p>Staff Member #2 determined Staff Member #15 had performed the "Aug. 2016" documentation. Staff Member #15 had placed a check mark at each medication except "Flumazenil (Romazicon), Vasopressin (Pitressin), and Diazepam (Valium). The surveyor inquired regarding the medications left without a check mark. The surveyor inquired regarding the meaning of the check marks whether it verified simply that the medication was present or that the count of the medications were correct. Staff Member #2 reported the form was new and he/she could not provide an answer to the meaning of the check marks. Staff Member #2 reported the count is generally performed by two staff one (1) licensed and one (1) non-licensed. Staff Member #2 stated, "I was not here on the 31st (August 2016). I was at a meeting at ((Name of a sister facility). (Staff Member #15's name) performed the count alone for the emergency cart. (He/she) may not have known where the Flumazenil, Vasopressin and Diazepam were kept." Staff Member #2 was not able to locate the Flumazenil and Vasopressin in the locked cabinet. Staff Member #2 reported the Flumazenil and Vasopressin "might be in the refrigerator in the Lab."</p> <p>Observations conducted on 09/08/2016 at 11:10 a.m., with Staff Member #2 in the room designated as the "Lab" did not reveal vials of Flumazenil and Vasopressin. Staff Member #2 stated, "I guess we don't have those two medications." The surveyor inquired whether the "Monthly Emergency Box Cart Inventory for Center Providing Surgical Services" should have documented zero vials available or not applicable if the facility did not stock the two medications. Staff Member #2 reported he/she was not able to</p>	(T 330)			

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(T 330)	Continued From Page 24 provide an answer to the surveyor's question. An interview was conducted on 09/10/2016 at 2:01 p.m., with Staff Member #2. Staff Member #2 reported that Staff Member #15 was not a "regular employee" of the facility but worked within the affiliate organization. On 09/10/2016 at approximately 2:22 p.m. the surveyor informed Staff Members #4 and #5 of the 09/08/2016 observation findings. Staff Member #5 reviewed the 08/2016 "Monthly Emergency Box Cart inventory for Center Providing Surgical Services." Staff Member #5 verified Staff Member #15 should have entered the expiration dates on the form. Staff #5 reported he/she was not sure of what "Loc:" meant and would clarify with the affiliate organization. Staff Member #5 could not verify whether the check marks represented the medication was present or the count was correct.	(T 330)		

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