Planned Parenthood®
Health Systems, Inc.

Health Center
2207 Peters Creek Road, NW
Roanoke, Virginia 24017
Ph (540) 562-2370 Fax (540) 562-1567
www.pphsinc.org

August 23, 2012

RECEIVED
AUG 24 2012
VDH/OLC

FedEx Overnight Delivery

Mr. Erik Bodin, Director
Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, Virginia 23233-1485

RE: Roanoke Health Center – Planned Parenthood Health Systems, Inc.
Plan of Correction in Response to Abortion Facility Initial Licensure Survey

Dear Mr. Bodin:

Relative to the Licensure Inspection Report received on August 6, 2012, enclosed herewith is this report with our Plan of Correction. This Plan of Correction has been signed by our President/CEO & Administrator, Walter Klausmeier.

Should there be any questions regarding information contained within our Plan of Correction, please contact me at 540.562.2370 x 7030 or e-mail me at Linda.Riddle@pphsinc.org. Mr. Klausmeier appointed me to serve in his stead during the inspection.

Cordially yours,

Linda D. Riddle
Facilities Coordinator/Acting Administrator

Enclosure: Plan of Correction

CC: Walter Klausmeier, President/CEO & Administrator
Elaine Pleasants, Vice President for Operations

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-006	A. BUILDING _____ B. WING _____	07/21/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ROANOKE PLANNED PARENTHOOD HEALTH SYS	2207 PETERS CREEK ROAD ROANOKE, VA 24017

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T 000	12 VAC 5- 412 Initial comments An announced Initial Licensure Abortion Facility inspection was conducted at the above referenced facility on July 20 through 21, 2012 by two (2) Medical Facilities Inspectors from the Virginia Department of Health's, Office of Licensure and Certification. Eleven personnel files and one clinical record were reviewed.. A tour of the facility was conducted with staff interviews. The facility was out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies were identified, cited, and will follow in this report.	T 000	RECEIVED AUG 24 2012 VDH/OLC	
T 070	12 VAC 5-412-170 C Personnel C. 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. This RULE: is not met as evidenced by: Based on review of personnel files and interview with Staff #11, it was determined that four (#3,#4 and #10-#11) of four (#3-#4 and #10-#11) staff members who have access to narcotics failed to provide criminal record checks from the Department of Virginia State Police for the Surveyor to review as required in Section 12 VAC 5-412-170. The findings included: 1. On July 20, 2012, at 11:00 a.m., the Surveyor reviewed personnel files in the facility's office. Four (#5-#6 and #10-#11) staff members who	T 070	1. All staff not licensed but with access to controlled substances will have a Criminal History record check pursuant to 32.1-126.02 of the Code of Virginia. This criminal record check will be done through the Department of Virginia State Police as required. Forms have been completed and submitted for Roanoke staff not licensed but who have access to controlled substances. These will be done prior to August 31, 2012. This process is now part of the Policy for the HR Department and will be followed going forward.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Walter W Allen	President & CEO/Administrator	08-23-2012

State of Virginia

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T 070	Continued From Page 1 dispense and administrator narcotics failed to have results of criminal records checks in their personnel files, except from local courts and out of state criminal records checks, in the personnel file for the Surveyor to review. 2. Staff Member #11 acknowledged that the results of the criminal records checks were not available for the Surveyor to review from the State Police. This interview occurred in the facility's office on July 20, 2012, at 12:10 p.m.	T 070		
T 095	12 VAC 5-412-170 H Personnel H. Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors; 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions. This RULE: is not met as evidenced by: Based on employee record review and staff interview, the center staff failed to ensure job performance was reviewed at least annually for one (#10) of eleven (#1-#11) employee records reviewed and the agency did not have a policy and procedure for reporting licensed and certified	T 095	1. The one staff person whose evaluation was not present will be reviewed. While this oversight occurred during the tenure of a manager no longer employed, the HR department will now also keep a log noting when staff are due annual reviews and will send reminders of the event to supervisors along with a due date for the review. The HR Manager will monitor this to ensure this does not occur going forward. 2. There is now in place a Policy and Procedure for reporting licensed and certified staff to the Department of Health Professionals which includes the form to be completed and submitted along with directions including to first discuss with immediate supervisor. The HR Department will be notified of any	

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T 095	Continued From Page 2 staff to the Board of Nursing or Board of Medicine as required in Section 12 VAC 5-412-170. H.3 and 5. The findings included: 1. On July 20, 2012, at 11:00 a.m., the Surveyor reviewed personnel files in the facility's office. One (#10) staff members failed to have an annual review of his/her performance. Staff member #10 was hired on April 4, 2009. No annual performance review was available for the Surveyor to review. Review of the Policy and Procedure manual had no process for reporting to the Department of Health Professions any violations by licensed and certified employees. 2. Staff Member #11 acknowledged during interview, that Staff #10 did not have an annual performance review conducted and no process existed for reporting licensed staff. This interview occurred in the facility's office on July 20, 2012, at 12:20 p.m.	T 095	submission with a copy of the information submitted and will also keep a log of such submissions. The HR Manager will monitor these submissions and the confidential log will be maintained in the HR Department.	
T 145	12 VAC 5-412-210 C Patients' rights C. The facility shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgement of complaints; 2. Investigation of the complaint; 3. Review of the investigation findings and resolution for the complaint; and 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. This RULE: is not met as evidenced by: Based on review of the Patients Rights Document and staff interview, the center staff failed to ensure that complaints were resolved within thirty days as	T 145	1. There is now a policy in place to ensure that complaints surrounding Patients' Rights will be resolved within thirty (30) days. This has been changed on the document of Patients' Rights which is posted in the waiting room. There will also be a notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint. There will be a log maintained of such complaints and resolutions. The QM Manager will monitor this log to ensure that deadlines are met.	

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T 145	Continued From Page 3 required in Section 12 VAC 5-412-210.C.4. The findings included: 1. On July 20, 2012, at 08:40 a.m., the Surveyor reviewed the Patient Rights Document in the facility's office. The Patient's Rights Document failed to address the resolution of complaints within thirty (30) days. 2. Staff Member #11 acknowledged during interview, that the Patients Rights Document failed to state when the complaint investigation would be completed. This interview occurred in the facility's office on July 20, 2012, at 09:20 a.m.	T 145		
T 165	12 VAC 5-412-220 A Infection prevention A. The abortion facility shall have an infection prevention plan that encompasses the entire facility and all services provided, and which is consistent with the provisions of the current edition of "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", published by the U.S. Centers for Disease Control and Prevention. An individual with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures and shall review them to assure they comply with applicable regulations and standards. 1. The process for development, implementation and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based shall be documented. 2. All infection prevention policies and procedures shall be reviewed at least annually by the administrator and appropriate members of the clinical staff. The annual review process and recommendations for changes/updates shall be documented in writing. 3. A designated person in the facility shall have	T 165	1. There is now in place a PPHS Policy & Procedure for Infection Prevention. The process for development of this policy has been documented by the QM Manager. 2. The Policy & Procedures for Infection Prevention shall be reviewed at least annually by the administrator/acting administrator and appropriate members of the clinical staff. Such review will be documented as to the process and with any recommendations for changes/updates also noted. 3. The QM Manger will have further training in infection prevention in order to train the HCM and both shall be involved in the annual review. 4. It shall be the duty of the QM Manager to schedule the annual review with all staff involved and to prepare an agenda for this review to cover all aspects required.	

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received training in basic infection prevention, and shall also be involved in the annual review.

This RULE: is not met as evidenced by:
Based on interview and record review the facility failed to develop written policies, procedures and processes for infection prevention and control.

1. The facility did not have a process for the development, implementation or maintenance of infection prevention policies based on regulatory or other guidance.

2. The facility did not have a process for annual review of their infection prevention policies and procedures.

The findings included:

1. An interview was conducted on July 20, 2012 at 9:10 a.m., with Staff #11. Staff #11 offered two binders titled "Infection Prevention" for the surveyor's review.

Review of the binders labeled "Infection Prevention" revealed guidance documents. The binders did not contain policies, procedures or processes for infection prevention.

An interview conducted on July 20, 2012 at 2:19 p.m., with Staff #12 revealed the facility did not have written policies, procedures and process for infection prevention.

2. An interview and review was conducted on July 20, 2012 at 2:19 p.m. to 4:26 p.m., with Staff #12. Staff #12 and the surveyor reviewed the facility's binders titled "Infection Prevention". One binder had a signature page. Staff #12 reported the signature page documented the administration had reviewed the information within the binder.

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T 165	Continued From Page 5 Staff #12 reported he/she was not aware that policies, procedures and processes had to be developed. Staff #12 reported being unaware of the need to ensure the implementation of the policies, procedures and processes. Staff #12 reported the facility had failed to have a system in place to develop, maintain and implement infection prevention policies, procedures and processes.	T 165		
T 170	12 VAC 5-412-220 B Infection prevention B. Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety & Health Administration. 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: is not met as evidenced by:	T 170	1. All expired items have been removed from the Emergency Cart and from other areas within the facility. The HCM will monitor all areas going forward to prevent this from occurring. As a second, the QM Manager will also check all items on visits to the facility. 2. The Policy & Procedures for the ten required infection prevention components has been developed. It shall be the responsibility of the HCM and RM to ensure that this policy is adhered to by all staff and shall also be responsible for staff training on these items. The QM Manger will provide additional training on visits to the facility. 3. The donning of Personal Protective Equipment covered in the aforementioned Policy & Procedures will adhere to the Centers for Disease Control and Prevention (CDC) sequence for donning such PPE. There will be on-going training with staff to ensure this is followed. The HCM and RM will monitor this to ensure policy is followed. 4. It shall be the duty of the QM Manager to also monitor and ensure that all Policy & Procedures are followed. Any training done shall be documented and trainees will sign the training document. 5. Staff are now instructed and trained to clean the top of multi-dose vials with an alcohol pad	

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Based on observations, interview and record review the facility failed to have infection prevention policies, procedures and processes to prevent/control the spread of infections.

1. Observations revealed outdated supplies available for patient use; staff failed to follow the correct method of donning and removing personal protective equipment and staff's failure to use safe injection practices.

2. The facility did not have ten required infection prevention policy/procedure components:
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;
Training of all personnel in proper infection prevention techniques;
Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;
Use of standard precautions;
Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety & Health Administration.
Use of personal protective equipment;
Use of safe injection practices;
Plans for annual retraining of all personnel in infection prevention methods;
Procedures for monitoring staff adherence to recommended infection prevention practices; and
Procedures for documenting annual retraining of all staff in recommended infection prevention practices.

The findings included:

1. Observations conducted on July 20, 2012 from 10:00 a.m. to 11:02 a.m., with Staff #10 and Staff #11 revealed the following outdated supplies

prior to inserting a needed into the vial. This will be monitored by the HCM, RM or staff designee to ensure this policy if followed.

6. As stated in a previous section, there is now in place a PPHS Policy & Procedures for Infection Prevention.

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available for patient use in the:
"Emergency Cart": Two (2) Cuffed tracheal tubes size 7.5 [used to provide a patient with an open airway] had expired 02/2004; Three (3) Angiocath 20 gauge 1-1/4 in (inch) [used to start a patient's intravenous line] had expired 08/2000 and One (1) Angiocath 18 gauge 1.16 in had expired 09/2006.
"Clean" utility area the "Indicator Strips" for steam and chemical vapor sterilization had expired "04/12". Staff # 10 stated, "An indicator strip was used in each pack" that was autoclaved. Staff #10 read the expiration date on the package and stated, "These expired in April."
Exam room (B) the Ethilon 18 sutures 3-0 had four (4) had expired in "07/08" and a full box had expired "07/10". Staff #11 verified the dates on the boxes of sutures. Staff #10 verified ten (10) Synevac vacuum curettes (eight -8 millimeter and two 11 millimeter) had expired "2010-12." Staff #10 reported the vacuum curettes were used to dilate the cervix during a procedure.

Observations conducted on July 21, 2012 at 9:08 a.m., with Staff #4 as he/she put on his/her PPE. Staff #4 put on gloves first, followed by shoe covers, then gown and finally mask. Staff #4 wore eyeglasses and chose not to wear a face shield. Staff #4 did not change his/her gloves prior to arranging items in the "POC (Products of Conception) Lab ["Dirty scrub room]" preparing for the receipt of the first procedure jar. Staff #4 reported he/she always put on his/her gloves first then the rest of his/her PPE. Staff #4 reported when he/she removed his/her PPE; he/she removed his/her gown, then shoe covers and gloves last. An observation of Staff #4 leaving the "POC Lab" removed his/her gown then his/her gloves.
[A "Dirty" scrub room is a room designated to receive, clean and disinfect used instruments and or equipment following a procedure. After

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instruments are cleaned and disinfected in the "Dirty" scrub room, they are taken to the "Clean" scrub room where instruments are packaged and sterilized as appropriate for use again.]

Review of the facility's infection guidance documents revealed the Centers for Disease Control and Prevention (CDC) information related to the sequence for donning and removal of PPE.

"The Centers for Disease Control and Prevention (CDC) sequence for donning PPE indicates the person should put on gown first then mask or mask face shield with gloves being the last item put on. The CDC's sequence for removing PPE should be gloves, gown, goggles/face shield, and then mask.
http://www.cdc.gov/HAI/pdfs/ppe/ppeposter148.pdf'

Observations conducted on July 21, 2012 at 10:35 a.m. revealed Staff # 13, obtained a multi-dose vial of Lidocaine 2%, which had been opened and accessed. Staff #13 did not clean the top of the multi-dose vial, prior to inserting the needle with syringe and drawing up 8 cc (cubic centimeters) of Lidocaine 2% to administer to a patient during a procedure.

An interview was conducted on July 21, 2112 at 11:30 a.m., with Staff #10. Staff #10 reported Staff #13 should have cleaned the top of the multi-dose vial of Lidocaine 2% with an alcohol pad prior to inserting the needle into the vial.

2. An interview and review was conducted on July 20, 2012 at 2:19 p.m. to 4:26 p.m., with Staff #12. Staff #12 and the surveyor reviewed the facility's binders titled "Infection Prevention". Staff #12 reported he/she was not aware that policies, procedures and processes had to be developed.

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T 170	Continued From Page 9 Staff #12 reported being unaware of the need to ensure the implementation of the policies, procedures and processes. Staff #12 reported the facility had failed to have a system in place to develop, maintain and implement infection prevention policies, procedures and processes. Staff #12 and the surveyor reviewed the regulations at 12 VAC 5-412-220 B (1-10); Staff #12 acknowledged the facility did not have policies, procedures, or processes to address the ten requirements listed in the regulation.	T 170		
T 175	12 VAC 5-412-220 C Infection prevention C. Written policies and procedures for the management of the facility, equipment 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 dryers); 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	T 175	1. There is now a Policy & Procedure for proper cleaning and disinfecting of exam room tables and chairs. This details how to perform this, what disinfectant to be used and what PPE shall be worn. 2. The recovery room chairs have been professionally repaired. There is now in place the aforementioned Policy & Procedure to ensure that these chairs are cleaned and disinfected inbetween patients. 3. There is also a Policy & Procedure in place with the Facilities Coordinator to ensure that all furniture and equipment is maintained as per regulations. 4. The Policy & Procedures for Infection Prevention covers all items written under item T 175, Item 2.	

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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 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 facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observations, interview and record review the facility failed to:

1. Disinfect reusable equipment between patients:

(a) One of two procedure tables had various colorations of dried blood under the removable support cushion. One of two procedure table cushions was torn with exposed underlying foam;
(b) One of one staff observed performing reprocessing of equipment failed to prevent recontamination of the equipment.
(c) Five of five recovery recliners were torn and three of five recliners had a build-up of food particles and unidentifiable substances bilaterally

5. Relative to a Pest Control Program, there is currently a state licensed pest control company which performs monthly and other pest control as needed. There will be a new contract in place by August 30, 2012 detailing that this will be managed in accordance with local health and environmental regulations.

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ROANOKE PLANNED PARENTHOOD HEALTH SYS	2207 PETERS CREEK ROAD ROANOKE, VA 24017

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between the inner arm and seat cushions; and

2. The facility failed to develop infection prevention and control policies, procedures and processes for:
Hand hygiene;
The maintenance of and access to hand-washing equipment and adequate supplies;
The maintenance of and availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
The appropriate storage for cleaning agents and product-specific instructions for use of cleaning agents;
Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;
Procedures for handling/temporary storage/transport of soiled linens;
Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;
Procedures for the processing of each type of reusable medical equipment, between uses on different patients, that included the level, processes and method of cleaning/disinfection/ sterilization of each type of equipment with reference to the manufacturer's recommendations;
Procedures for appropriate disposal of non-reusable equipment;
Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;
Procedures for cleaning of environmental surfaces with appropriate cleaning products;
An effective pest control program, managed in accordance with local health and environmental regulations; and
Other infection prevention procedures necessary to prevent/control transmission of an infectious

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agent in the facility as recommended or required by the department.

The findings included:

1. (a) An observation was conducted on July 20, 2012 at 10:20 a.m. with Staff #10, Staff #11 and Staff #12 within Procedure room (D). The observations revealed a brownish red splatter approximately one (1) inch in diameter between the procedure table's main cushion and the end of the table support cushion. Staff #10 initially identified the substance as "possibly betadine." Staff #10 attempted to uses a brush and cloth to remove the substance, but was unable to maneuver the brush between the two cushions. Staff #10, Staff #11 and Staff #12 determined the end of the table support cushion was attached to a metal track and was removable. Staff #10 removed the support cushion the edge of the cushion closest to the main body of the table had multiple areas of dried blood. The undercarriage of the support cushion had multiple areas were blood had dripped and ran down the under carriage. The accumulation of dried blood varied in coloration and thickness. Staff #10 acknowledged the substance was dried blood and not betadine. Staff #10 and Staff #12 acknowledged with the accumulation of dried blood the procedure table had not been disinfected between patients.

1. At the time of this finding, the QM Manager donned proper PPE and disinfected this area of the exam table. There is now a Policy & Procedure relative to proper cleaning and disinfecting of exam tables, chairs and other equipment inbetween patients.

An observation conducted in Procedure room (B) on July 20, 2012 from 10:45 a.m. to 11:02 a.m., with Staff #10 and Staff #11 revealed the procedure table's cushion was torn. The procedure table's cushion had an approximate four (4) inch tear in the mid-back area. The tear exposed the underlying foam. Staff #10 and Staff #11 acknowledged the tear in the cushion allowed contaminates to enter the underlying foam. Staff

1. This exam table is being professionally reupholstered. The Facilities Coordinator has an updated Policy & Procedure to inspect exam tables, chairs and other equipment monthly to prevent this from occurring.

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#11 acknowledged the procedure table could not be disinfected between patients.

(b) Observations were conducted on July 21, 2012 from 9:08 a.m. to 11:30 a.m. with Staff #4 in the "POC Lab (products of conception lab)". The facility's "POC Lab" equaled the area of the facility were equipment was reprocessed after procedures and the POC identified. The observation revealed Staff #4 did not have measuring devices to ensure he/she followed manufacturer's instruction with the mixing of solutions used to clean the equipment. Staff #4 was observed to pour an enzymatic cleaner into a basin used to soak equipment after physical removal of blood and tissues. Staff #4 reported he/she did not have a measuring device but "eyeballed" the amount enzymatic cleaner needed. Staff #4 did not know the capacity of the basin and did not measure the amount of water placed in the basin. The manufacturer's instruction indicated: "1 ounce to every gallon of water." Staff #4 prepared a smaller metal basin with a water and detergent solution. Staff #4 did not measure the amount of water placed in the smaller basin. The manufacturer's instruction indicated: "1 scoop to 2 gallons of water. [A "Dirty" scrub room is a room designated to receive, clean and disinfect used instruments and or equipment following a procedure. After instruments are cleaned and disinfected in the "Dirty" scrub room, they are taken to the "Clean" scrub room where instruments are packaged and sterilized as appropriate for use again.]

1. Measuring devices have been ordered and will be in place prior to August 30, 2012. This will become part of the training procedure and will be monitored by the HCM or RM to ensure that proper measuring will be done.
2. The absorbent pads will be changed inbetween cleaning of equipment. This will become part of the training procedure and will be monitored by the HCM or RM to ensure this is being done inbetween cleaning of equipment.

The observation revealed during the first reprocessing of equipment, an area (three absorbent pads on the counter) established for cleaned equipment was splattered with blood and tissues. Staff #4 did not change the absorbent pads. Staff #4 physically cleaned each item,

1. The recliners have been professionally repaired. There is a policy now in place for the Facilities Coordinator to do a monthly inspection of exam tables,

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placed the item in the enzymatic cleaner then into the detergent followed by rinsing the equipment under running water. Staff #4 placed the cleaned equipment on the absorbent pads in contact with the splattered blood and tissue. There was an approximate 20 (twenty) minute wait until the next procedure was started and completed. During the waiting Staff #4 moved the cleaned equipment from the blood/tissue splattered pad to the clean area. Staff #4 commented and straighten the three-blood/ tissue splattered absorbent pads; "I'm usually not this messy." When asked to clarify Staff #4 explained he/she did not generally splatter blood/tissue as in the first reprocessing case. Staff #4 put the top, bottom and cap of the canister from the first procedure together. Staff #4 reported the canister was ready for a procedure.

At 10:15 a.m. Staff #4 received the instrument from the second procedure. Staff #4 followed the same cleaning process then placed the cleaned equipment on the blood/tissue splattered absorbent pads. Staff #4 was not able to verbalize the risk of spreading infection and the recontamination of the cleaned equipment by placing the items on the blood/tissues splattered absorbent pads. Staff #10 entered the "POC Lab" at 10:45 a.m., Staff #10 observed the equipment from the second procedure air-drying on the blood/tissue splattered pads. Staff #10 verified the equipment was contaminated and needed to be reprocessed. Staff #10 instructed Staff #4 to change the absorbent pads.

(c) Observations conducted on July 20, 2012 9:40 a.m. to 10:45 a.m., with Staff #10 and Staff #11 revealed five of five Recovery room recliners had torn surfaces. Staff #10 acknowledged the recliners could not be disinfected between patients since their surfaces were not intact. Staff #10,

chairs and other equipment to ensure all is in compliance. There is also a policy in place for staff to disinfect the chairs inbetween patients including down between the cushions and sides of the chair to ensure there are no food or drink debris or other contaminants. During monthly inspections by the Facilities Coordinator, this will also be inspected to ensure compliance. There is a checklist form which will be kept to note findings of these inspections.

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Staff #11 and the surveyor examined the Recovery recliners and three (3) of the recliners displayed evidence of not being cleaned between patients. The three recliners had food particles and unidentifiable substances between the inner arm and seat cushions bilaterally. Staff #11 reported the staff had "obviously not been cleaning" the surfaces of the recliners between patients.

2. An interview and review was conducted on July 20, 2012 at 2:19 p.m. to 4:26 p.m., with Staff #12. Staff #12 and the surveyor reviewed the facility's binders titled "Infection Prevention" along with the requirements listed in the State of Virginia regulations. Staff #12 reported he/she had not developed infection prevention policies, procedures and processes as required under 12 VAC 5-412-220 (c).

T 180 12 VAC 5-412-220 D Infection prevention — T 180

D. The facility shall have an employee health program that includes:
1. Access to recommended vaccines;
2. Procedures for assuring that employees with communicable diseases are identified and prevented from work activities that could result in transmission to other personnel or patients;
3. An exposure control plan for blood-bourne pathogens;
4. Documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine;
5. Compliance with requirements of the U.S. Occupational Safety & Health Administration for

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reporting of workplace-associated injuries or exposure to infection.

This RULE: is not met as evidenced by:
Based on interview and record review the facility failed to have four of the five requirements related to its employee health program. The facility's employee health program did not have written protocols or procedures to ensure employees had:

a system to access the recommended vaccines;
a procedures for employees with communicable diseases to be identified and prevented from work activities that could result in transmission to other personnel or patients;
a system for documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine; and
a system for compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.

The findings included:

An interview and review was conducted on July 20, 2012 at 2:19 p.m. to 4:26 p.m., with Staff #12. Staff #12 and the surveyor reviewed the facility's binders titled "Infection Prevention". Staff #12 reported he/she was not aware that policies, procedures and processes had to be developed for employee health. Staff #12 reported the facility had failed to have a written employee health program. Staff #12 and the surveyor reviewed the regulations at 12 VAC 5-412-220 D (1-5); Staff #12 acknowledged the facility did not have

1. There will be a policy put into place by the HR Department and QM Manager to ensure that there is a system to access the recommended vaccines; procedures for employees with communicable diseases to be identified and prevented from work activities that could result in transmission to other personnel or patients; a system for documentation of screening and immunizations offered/received by employees in accordance with statute, regulation or recommendations of public health authorities, including documentation of screening for tuberculosis and access to hepatitis B vaccine and a system for compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection. This policy will dictate how employees will be monitored and a log maintained of vaccines with notations made for booster vaccines or recurring vaccines needed. This log will also record OSHA reporting of workplace-associated injuries or exposure to infection. This log will be monitored by the HR Manager and the QM Manager to ensure the policy is followed and that reminders are sent to employees requiring further vaccines or testing.

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T 180	Continued From Page 17 documentation for how employees would access recommended vaccines or how the facility would ensure that employees with communicable diseases were identified and prevented from working to curb the spread to other employees and the patients. Staff #13 reported the facility did not have a system for documenting screening and immunizations or a method to ensure compliance with requirements of the U.S. Occupational Safety & Health Administration for reporting of workplace-associated injuries or exposure to infection.	T 180		
T 185	12 VAC 5-412-220 E Infection prevention E. The facility shall develop, implement and maintain policies and procedures for the following patient education, follow-up, and reporting activities: 1. Discharge instructions for patients, to include instructions to call or return if signs of infection develop; 2. A procedure for surveillance, documentation and tracking of reported infections; and 3. Policies and procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12 VAC 5-90), including outbreaks of disease. This RULE: is not met as evidenced by: Based on interview and record review the facility failed to have a procedure for surveillance, documentation and tracking of reported infections; and policies/procedures for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12 VAC 5-90), including outbreaks of disease. The findings included:	T 185	1. A policy has been implemented regarding the following items: a) discharge instructions for patients to include instructions to call or return if signs of infection develop; b) a procedure for surveillance, documentation and tracking of reported infections; and c) policy and procedure for reporting conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12 VAC 5-90), including outbreaks of disease. This will ensure the proper information is provided and that tracking is properly done to be compliant with the regulation. The QM Manager will develop a log relative to infections and reporting as required. The VP for Medical Services will routinely monitor this log to ensure compliance. For any patient with a positive screening test, a written report of each laboratory test and examination shall be a part of the patient's record. Those patient records will be reviewed by the HCM to ensure compliance. These records will be monitored by the RM to ensure compliance.	

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T 185	Continued From Page 18 An Interview and review was conducted on July 20, 2012 at 2:19 p.m. to 4:26 p.m., with Staff #12. Staff #12 and the surveyor reviewed the facility's binders titled "Infection Prevention." Staff #12 reported the facility gathered information related to infections via the corporation,s software. Staff #12 had not tracked or trended the infection data. Staff #12 reported information specific to the facility needed to be entered by facility staff and the software listed the infections. Staff #12 had not developed policies, procedures for surveillance, documentation/input of data or tracking of the facility's infections. Staff #12 acknowledged the facility did not have written policies/procedures for reporting conditions or disease outbreaks to the local health department in accordance with the regulations for disease reporting and control.	T 185		
T 195	12 VAC 5-412-240 A Medical testing, patient counseling and labor A. Prior to the initiation of any abortion, a medical history and physical examination, to include confirmation of pregnancy, shall be completed for each patient. 1. Use of any additional medical testing, including but not limited to ultrasonography shall be based on an 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 pregnancy test and determination on Rh factor. 3. The 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	T 195	1. There are policies in place relative to medical testing and patient counseling reflecting that prior to the initiation of any abortion, a medical history and physical examination to include confirmation of pregnancy shall be completed for each patient. Use of any additional medical testing, including but not limited to ultrasonography, shall be based on an 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. Medical testing shall include a recognized pregnancy test and determination on Rh factor. We have policies in place for screening of sexually transmitted diseases consistent with the current guidelines issued by the US Centers for Disease Control and prevention and there are procedures for addressing appropriate responses to a positive screening test. A written report of each laboratory test and examination shall be a part of the patient's record. Results of testing and monitoring of patient records shall be done by the HCM. Any positive results will be logged appropriately and reported as required.	

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T 195	Continued From Page 19 and procedures shall address appropriate responses to a positive screening test. 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 review of the Policy and Procedure Manual, and interview with Staff #11, it was determined that the facility failed to have a policy and procedure for reporting violations to the Board of Nursing and the Board of Medicine if inappropriate behaviors occurs as required in Section 12 VAC 5-412-240.A. The findings included: 1. The Surveyor reviewed the facility's Policy and Procedure Manual at various times on July 20, 2012, in the facility's office. 2. Staff Member #11 acknowledged that the results of the criminal records checks were not available for the Surveyor to review from the State Police. This interview occurred in the agency's office on July 20, 2012, at 12:10 a.m.	T 195	As noted under T 095, there is now a Policy and Procedure in place for reporting licensed and certified staff to the Department of Health Professionals. The HR Department will be notified of any submission and a log will be kept of same. The HR Manager will monitor these submissions and the confidential log will be maintained in the HR Department. As noted under T 070, there is now a policy for the HR Department regarding the Criminal History record check pursuant to 32.1-126.02 of the Code of Virginia. The HR Manager will monitor and ensure such background checks are done and logged.	
T 320	12 VAC 5-412-300 B Quality assurance B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance; 2. Supervision appropriate to the level of service; 3. Patient records; 4. Patient satisfaction; 5. Complaint resolution; 6. Infections, complications and other adverse events; and	T 320	1. There has been established a Quality Assurance Committee which will evaluate to assure adequacy and appropriateness of services and which will identify unacceptable or unexpected trends or occurrences in: staffing patterns and performance; supervision appropriate to level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events, and; staff concerns regarding patient care.	

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T 320	Continued From Page 20 7. Staff concerns regarding patient care. This RULE: is not met as evidenced by: Based on review of the Policy and Procedure Manual and interview with Staff #11, it was determined that no policy and procedure were developed to ensure all the subjects of the Quality Assurance Committee would be addressed as required in Section 12 VAC 5-412-300. B.#2-#5 and #7. The findings included: 1. On July 20, 2012, the Surveyor reviewed the Policy and Procedure Manual at various times in the facility's office. No policy and procedure to list the subjects that would be discussed in the Quality Assurance Committee meeting as Supervision appropriate to the level of service, Patients Records, Patient satisfaction, Complaint resolution and Staff concerns regarding patient care. 2. Staff #11 acknowledged during interview that no policies and procedures were developed that would address all the subjects that would be discussed in the Quality Assurance Committee Meeting. This interview occurred in the facility's office, on July 20, 2012, approximately at 4:15 p.m.	T 320	1. A Policy & Procedure manual will be developed by August 30, 2012 to address all subjects to be discussed at the Quality Assurance Committee meetings. This committee will then have meetings and keep minutes and any information will be provided to the Board at least once a year. This will be monitored by the Facilities Coordinator and the VP for Medical Services as this committee is specific to the Virginia sites of PPHS only.	
T 355	12 VAC 5-412-330 B Reports B. Abortion facilities shall report all patient, staff or visitor deaths to the OLC within 24 hours of occurrence. This RULE: is not met as evidenced by: Based on review of policies and staff interview, it was determined that no policy and procedure for	T 355	1. A Policy & Procedure has been developed in order to report any patient, staff or visitor deaths to the OLC within 24 hours of occurrence. The report initially will be made to the Facilities Coordinator who will then prepare a letter to be faxed to	

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T 355	Continued From Page 21 reporting deaths were available for the Surveyor to review as required in Section 12 VAC 5-412-330. B. The findings included: 1. On July 20, 2012, the Surveyor reviewed the Policy and Procedure Manual at various times in the facility's office. No polity and procedure to address how deaths of visitors, staff or patients would be reported to the Office of Licensure and Certification (OLC) within twenty four (24) hours was available for the Surveyor to review. 2. Staff #11 acknowledged during interview, that no policy and procedure were developed that addressed when and how deaths would be disclosed to OLC. This interview occurred in the facility's office, on July 20, 2012, approximately at 4:21 p.m.	T 355	804.527.4502 to Mr. Erik Bodin, Director of OLC, within 24 hours of the occurrence. A log will be kept of such incidents with all pertinent information for future OLC inspections. The VP for Operations will monitor this log to ensure compliance.	
T 400	12 VAC 5-412-380 Local and state codes and standards Abortion faculties shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001. Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their	T 400	PPHS has two years from the date of licensure to comply with the requirements of 12 VAC 5-412-380 and its plan of compliance for each of the findings is to be completed within the two years from licensure. Attached is Appendix A, which is an updated letter from our architect, which states how compliance will be handled for the two (2) outside	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-005	A. BUILDING _____ B. WING _____	07/21/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ROANOKE PLANNED PARENTHOOD HEALTH SYS	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 400	Continued From Page 22	T 400		

current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.
Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements.

This RULE: is not met as evidenced by:
Based on interview and record review the facility failed to meet the following requirements established in Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute:

The findings included:

Review on July 20, 2012 of the architect's attestation revealed the facility failed to meet the requirements of two (2) outside air exchanges per hour and to have filters with at least 30 % efficiency.

An interview was conducted on July 20, 2012 at 2:39 p.m., with Staff #11. Staff #11 reported the facility was not in compliance with the requirements as listed by the architect and were awaiting determination whether facilities were going to be "grand-fathered into compliance."

air exchanges per hour and for the 30% efficient filters. We already meet the 5' corridor width in the health center and exceed the procedure room square footage requirement.

Rife + Wood
ARCHITECTS

August 21, 2012

Linda D. Riddle, Facilities Coordinator
Planned Parenthood Health Systems, Inc.
2207 Peters Creek Road
Roanoke, Virginia 24017

phone: 540.562.2370 x 7030
fax: 540.562.1567
e-mail: Linda.Riddle@pphsinc.org

Re: Facility Compliance – Planned Parenthood -Roanoke Clinic
2207 Peters Creek Road
Roanoke, Virginia 24017

Dear Linda,,
As the original architects for the Planned Parenthood Clinic, Rife+Wood provided architectural design and construction administrative services for the Roanoke facility, located at 2207 Peters Creek Road, Roanoke, VA. The City of Roanoke issued a building permit for the construction in 1999 and upon completion of the project in 2000, the City issued a Certificate of Occupancy. A copy of this CO has been provided with previous clinic submissions. By issuing this CO, the city agreed that building was designed and constructed to meet or exceed the design standards for ambulatory clinics under of the building code at the time of construction.

In the fall of 2011, at the request of Planned Parenthood, Rife+Wood Architects reviewed the building for compliance with the FGI- Guidelines for Design and Construction of Health Care Facilities – our review was specific to sections (Part 1 and sections 3.1 and 3.7 of Part 3) 2010 Edition, as amended by the Virginia Department of Health *Regulations for Licensure of Abortion Facilities, 12 VAC 5-412.*

On August 14, 2012, under the direction of Rife+Wood Architects, the HVAC system for the clinic Procedure Rooms was examined. Air volume testing was performed by qualified contractor (Mechanical Balancing, Inc.) and the existing equipment was examined by qualified Class A Mechanical Contractor (HVAC, Inc., Roanoke VA) with the following findings:

1. Air Filtration Existing Air Handling units at the Clinic wing are equipped with washable 16 x25 air filters. **The equipment manufacturer (Trane, Inc.) has verified that the existing washable filters have an efficiency rating of 45%.** The filters were inspected and found to be clean and operating on 8/14/2012.

- The mechanical contractor (HVAC, Inc.) recommends that the clinic make periodic inspection of the filters part of all future system maintenance agreements. It is also advised that in the future, the existing filters be removed and replaced with (1" x 16" x 25') pleated-type filters that meet or exceed the required 30% efficiency rating, with a written log showing the date of each service and replacement.

2. Air Volume and Outdoor Air: The existing Procedure Rooms 135 & 136 are service by a gas fired, split system heat pump (AHU / CPU-1). The Air Handling Unit for this equipment is located in the attic space above the clinic – outdoor air (fresh air) is ducted from a dedicated roof top fan.

- Based on the design capacity of the equipment and the field measurements it was determined that the existing system is "nearly" compliant and the air flow to the Procedure rooms can likely be modified to meet air volume requirements thru conventional testing & balancing techniques (damper adjustment, diffuser settings, fan speed).

The clinic will proceed with the following work in sequence:

1. Service roof top fans (inspect, clean & lubricate motors, change belts) .
2. Interconnect Procedure room thermostat control unit with fan to assure flow of outdoor air when unit is in activated.
3. Test and balance air flow to Procedure Rooms 135 & 136 by adjusting dampers & fan speed to achieve compliant levels (> 2 outdoor air changes / hour).
4. Provide final TAB (testing & balancing report) showing compliance with requirements.

Completion of the steps described above will bring the Planned Parenthood facility into compliance with the applicable sections of the 2010 edition of the FGI-Guidelines for Design and Construction of Health Care Facilities.

Please feel free to call on me if you have any questions regarding this summary and recommendations.

Sincerely,

8/21/2012

Jeffrey R. Wood, AIA — date

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