Planned Parenthood®
Health Systems, Inc.

Health Center
2207 Peters Creek Road, NW
Roanoke, Virginia 24017
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September 12, 2012

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: Blacksburg 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 27, 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. Should there be any questions, I will be out of the office from October 1 to October 17. Please contact Elaine Pleasants, VP for Operations, during that time. Her number is 919.833.7526 x 6131.

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-007	A. BUILDING _____ B. WING _____	07/31/2012

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BLACKSBURG PLANNED PARENTHOOD HEALTH	700-J NORTH MAIN STREET BLACKSBURG, VA 24060

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T 000	12 VAC 5- 412 Initial comments An announced Licensure Initial survey was conducted July 31, 2012 by two Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health. The agency was found not to be in compliance with 12 VAC- 412 Regulations for the Licensure of Abortion Clinics. (Effective 12/29/2011). Deficiencies were cited and follow in this report.	T 000		
T 010	12 VAC 5-412-140 A Organization and management A. Each abortion facility shall have a governing body responsible for the management and control of the operation of the facility. This RULE: is not met as evidenced by: Based on record review and interview the governing body/board failed to ensure the facility had: The required infection prevention policies, procedures and processes to prevent the spread of infections; and The required components for the quality improvement program The findings included: 1. An interview was conducted on July 31, 2012 at 8:44 a.m., with Staff #1. Staff #1 reported the facility had failed to develop infection prevention policies based on regulatory or other guidance. Staff #1 acknowledged the facility did not have a process for annual review of their infection prevention policies and procedures. Staff #1 acknowledged the facility did not have	T 010	1. The Policy & Procedures for the 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. a. There is now in place a policy for annual review of the infection prevention policies and procedures as required b. This policy covers the regulations for infection prevention, for management of equipment and supplies to prevent the spread of infection, for an employee health program, and for patient education, follow-up and reporting infections to the appropriate health agency.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	President/CEO & Administrator	09.12.2012

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T 010	Continued From Page 1 policies, procedures, or processes to address the requirements listed in the regulations at: 12 VAC 5-412-220 B (1-10) for an infection prevention plan; 12 VAC 5-412-220 (C) (1-12) for the management of equipment and supplies to prevent the spread of infection; 12 VAC 5-412-220 (D) (1-5) an employee health program; and 12 VAC 5-412-220 (E) (1-3) related to patient education, follow-up and reporting infections to the appropriate health agency. 2. Review of the facility's quality documents did not provide evidence the committee evaluated the seven required components of staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; plus staff concerns regarding patient care. The review of policies did not find evidence that all corrective action needed to be documented, that the governing body/board and the facility needed to act upon the quality report and identified deficiencies, which jeopardized patient safety needed to be reported immediately in writing. An interview was conducted on July 31, 2012 at 12:30 p.m. with Staff #2 and Staff #4. Staff #4 reviewed the regulation requirements and the governing "Board" responsibilities. Staff #4 acknowledged the govern "Board" failed to ensure the quality improvement program operated in accord with the licensing regulations and in a manner to promote patient safety.	T 010	2. 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. a. A Policy & Procedure manual has been developed 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. The Board will ensure this operates in accordance with the regulations and in a manner to promote patient safety. 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	

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T 015	Continued From Page 2 12 VAC 5-412-140 B Organization and management B. There shall be disclosure of facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership. This RULE: is not met as evidenced by: Based on record review and interview the facility's governing body failed to address the requirement to notify the state licensing agency related to any change in ownership. The finding included: Review of the policies and procedures related to the responsibilities of the facility's governing body/board did not reveal specific information to contact the state licensing agency regarding changes in ownership. An interview was conducted on July 31, 2012 at 10:20 a.m., with Staff #1 and Staff #4. Staff #4 reviewed the policies for the facility's governing "Board" responsibilities. Staff #4 reported not being able to locate the specific wording that the "Board" had the responsibility to notify the state licensing agency related to any change in ownership. Staff #1 acknowledged receipt of information, which listed the specific changes that required notification of the state licensing agency. Staff #1 reported that information had not been incorporated into the policy related to the responsibilities of the "Board."	T 015 T 015	1. There is now in place within the Regulatory Requirements for Virginia in the By-Laws the fact that the OLC will be notified of any changes in ownership of PPHS. The Facilities Coordinator will ensure this is done should it become necessary. The VP for Operations will monitor to ensure compliance.	

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T 030	Continued From Page 3	T 030		
T 030	12 VAC 5-412-140 E Organization and management E. The bylaws shall include at a minimum the following: 1. A statement of purpose; 2. Description of the functions and duties of the governing body, or other legal authority; 3. A statement of authority and responsibility delegated to the administrator and to the clinical staff; 4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and 5. Provision of guidelines for relationships among the governing body, the administrator and the clinical staff. This RULE: Is not met as evidenced by: Based on record review and interview the governing "Board" failed to incorporate a provision for selection and appointment of clinical staff and granting of clinical privileges into their bylaws. The findings included: A review of the policies, procedures and the by-laws did not reveal a documented policy, procedure, or process for credentialing physicians or other non-physician health practitioners. The facility's by-laws did not include information related to selection or determination of delineation of privileges. An interview was conducted on July 31, 2012 at 10:20 a.m., with Staff #1 and Staff #4. Staff #4 verified the facility's by-laws did not directly address a provision for physicians or other non-physician health practitioners; selection, appointment, and granting of clinical privileges by the "Board."	T 030	1. In Section 14.5 of the current By-Laws for PPHS, there is a section relative to selection and appointment of clinical staff and the granting or revocation of clinical privileges. The VP for Medical Services will ensure the Board does this for clinicians. The Administrator will monitor that this is done as required.	

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T 035	12 VAC 5-412-150 Policy and procedure manual. Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics: 1. Personnel; 2. Types of elective and emergency procedures that may be performed in the 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 written informed consent of the patient prior to the initiation of any procedures; 6. When to use ultrasound to determine gestational age and when indicated to assess patient risk; 7. Infection prevention; 8. Risk and quality 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. Facility security; 13. Disaster preparedness; 14. Patient rights; 15. Functional safety and facility maintenance; and 16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable. These policies and procedures shall be based on recognized standards and guidelines.	T 035		

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T 035	Continued From Page 5	T 035		

This RULE: is not met as evidenced by:
Based on record review and interview the facility failed to ensure a documented method was developed for the annual review of policies and procedures for personnel and failed to develop infection prevention policies, procedures and process.

The findings included:

1. The facility had a separate binder for personnel policies, procedures and process. The binder was reviewed on July 31, 2012 at 9:10 a.m. The review did not reveal evidence the personnel policy and procedure manual had been reviewed or revised since approved June 17, 2006.

Review of the facility's policy and procedure manual did not include a policy, procedure or process for the annual review of the personnel

1. While there was a review of the Personnel Policy Manual in February 2012, this was done at an informal meeting of the Board and this was not noted in the minutes. There is now policy in place that an annual review of Personnel Policies will be done annual by the Board and this will be contained in the minutes. The HR Manager will see this is presented to the Board. The VP for Operations will monitor to ensure compliance.

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T 035	Continued From Page 6 policy and procedure manual. An interview was conducted on July 31, 2012 at 10:27 a.m., with Staff #1 and Staff #4. Staff #4 acknowledged the personnel policy and procedure manual did not have evidence of annual review. Staff #4 placed a call to the facility's corporate office. Staff #4 reported the personnel policies had been reviewed during a February 2012 meeting. Staff #4 requested confirmation from the corporate office. An interview and review of the information forwarded from the facility's corporate office was conducted on July 31, 2012 at approximately 1:33 p.m., with Staff #1, Staff #2 and Staff #4. Staff #1 presented the information to the surveyor. Review of the information did not provide evidence the facility's personnel policy and procedure manual had been annually reviewed. The information presented a discussion of staff diversity and whether a staff diversity policy should be developmented. Staff #1 and Staff #4 reviewed the information presented and acknowledged the Information did not confirm the personnel policy and procedure manual had been annually reviewed. 2. The facility failed to develop infection prevention policies, procedures and processes. An interview conducted on July 31, 2012 at 8:44 a.m., with Staff #1 revealed the corporate Infection Preventions (Staff #12) was still working on the development of the facility's Infection Prevention policies, procedures and processes. Staff #4 at approximately 1:18 p.m. on July 31, 2102 requested an interview. Staff #4 revealed Staff #12 had forward a draft of the proposed Infection Prevention policies, procedures and	T 035	2. As written under T 010, there is now in place an infection prevention policy which includes annual review of said policy.	

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T 035	Continued From Page 7 processes, which had not been reviewed by the governing body/board. Staff #1 and Staff #4 acknowledged the facility did not currently have infection prevention policies/procedures or a process for annual review of infection prevention policies, procedure, and processes.	T 035		
T 050	12 VAC 5-412-160 B Administrator B. Any change in the position of the administrator shall be reported immediately by the licensee to the department in writing. This RULE: is not met as evidenced by: Based on record review and interview the facility failed to develop policy, procedure or process for reporting immediately changes in administrators to the state licensing agency in writing. The findings included: Review of the facility's policy and procedure manuals on July 31, 2012, did not provide evidence of a policy, procedure or process for reporting a change in administrators. An interview and review of the facility's policy/procedure manuals was conducted on July 31, 2012 at 10:52 a.m., with Staff #1 and Staff #4. Staff #1 reported awareness of the need to report changes to the state licensing agency. Staff #4 reviewed the facility's policy and procedure manuals. Staff #4 could not find a policy and procedure for reporting any change in administrators immediately to the state licensing agency.	T 050	1. There is a policy stating that there will be notification to OLC of any changes in administrator. This is stated in the By-Laws also.	
T 095	12 VAC 5-412-170 H Personnel H. Personnel policies and procedures shall	T 095		

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T 095	Continued From Page 8 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 record review and interview the facility failed to develop a policy, procedures or process for reporting health care practitioners to their appropriate board in case of violations. The finding included: A review of the facility's policy and procedure manuals on July 31, 2012, did not provide evidence of a method to report health care practitioners to their appropriate board, if violations occurred. An interview and review of the facility's policy/procedure manuals was conducted on July 31, 2012 at approximately 11:00 a.m. with Staff #1 and Staff #4. Staff #4 acknowledged the facility did not have a 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.	T 095	1. There is now in place a Policy & Procedure for reporting health care practitioners to the Department of Health Professionals. The HCM will ensure all staff have the necessary forms to submit a report. The RM will monitor to ensure compliance along with the HR Manager who will maintain a log of such reports which will be kept locked for confidentiality.	

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T 115	12 VAC 5-412-180 C Clinical staff C. A physician shall remain on the premises until all patients are medically stable, sign the discharge order and be readily available and accessible until the last patient is discharged. Licensed health care practitioners trained in post-procedure assessment shall remain on the premises until the last patient has been discharged. The physician shall give a discharge order after assessing a patient or receiving a report from such trained health care practitioner indicating that a patient is safe for discharge. The facility shall develop, implement and maintain policies and procedures that ensure there is an appropriate evaluation of medical stability prior to discharge of the patient and that adequate trained health care practitioners remain with the patient until she is discharged from the facility. This RULE: is not met as evidenced by: Based on record review and interview the physician failed to write discharge orders for three of three charts reviewed (Patients #1 - #3) and the facility failed to have policies, procedures or processes, which required the physician to write discharge orders. The findings included: Review of the facility's policy and procedure manuals did not reveal policies, procedures or processes, which required the physician to write, sign, date and time discharge orders. The facility did not have a documented policy and procedure for post-procedure evaluation of the patient. Review of three medical records did not reveal a physician's discharge orders: Patient #1 admitted on July 10, 2012; Patient #2 admitted on July 24, 2012; and	T 115	1. There is now a policy in place for post-procedure evaluation of the patient. There has been a form revised to reflect that it is a Discharge Order which is given to patients when being released. The HCM will ensure the clinicians do as required. The RM will monitor to ensure compliance.	

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T 115	Continued From Page 10 Patient #3 admitted on July 24, 2012. An interview was conducted on July 31, 2012 at approximately 1:30 p.m. with Staff #1, Staff #2 and Staff #3 and Staff #4. Staff #4 had reviewed the policy and procedure manuals. Staff #2 reported the facility had not developed a policy for post-procedure evaluation because the products of conception were not expelled inside of the facility. Staff #1, Staff #2, and Staff #4 acknowledged a patient could have a reaction to the medication given while at the facility. Staff #1 and Staff #2 acknowledged the facility did not have a procedure in place for monitoring the patient after the administration of medication. The interview continued with the review of medical records forPatients #1 - #3. Staff #1, Staff #2 and Staff #4 agreed the medical records did not have documented physician discharge orders. Staff #2 acknowledged each patient admitted to the facility was admitted under the care of a physician and the physician was responsible for discharging the patient.	T 115		
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.	T 165		

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T 165	Continued From Page 11 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 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 an infection prevention plan and written policies, procedures and processes for infection prevention and control. 1. The facility did not have a plan or 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 31, 2012 at 8:44 a.m., with Staff #1. Staff #1 reported that the corporate Infection Preventions (Staff #12) was still working on the development of the facility's Infection Prevention Plan plus the policies, procedures and processes. 2. An interview conducted on July 31, 2012 at	T 165	1. As stated in T 010, there is now a Policy & Procedure for required infection prevention components. There is also a policy in place for annual review as required. Initial training has been done with staff. The HCM and RM will ensure staff adhere to the policy. The QM Manager will monitor to ensure compliance.	

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T 165	Continued From Page 12 approximately 1:18 p.m., with Staff #4 revealed Staff #12 had forward a draft of the proposed Infection Prevention policies, procedures and processes, which had not been reviewed by the governing body/board. Staff #1 and Staff #4 acknowledged the facility did not currently have a process for annual review of infection prevention policies, procedure, 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: Based on interview the facility failed to have	T 170		

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T 170	Continued From Page 13 infection prevention policies, procedures and processes to prevent/control the spread of infections. 1. 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: An interview was conducted on July 31, 2012 at 8:44 a.m., with Staff #1. Staff #1 reported the facility had failed to have a system in place to develop, maintain and implement infection prevention policies, procedures and processes. Staff #1 acknowledged the facility did not have policies, procedures, or processes to address the ten requirements listed in the regulations at 12 VAC 5-412-220 B (1-10).	T 170	1. There is now an Infection Prevention Policy & Procedure in place which addresses the ten requirements in the regulations. There has been initial training with staff by the QM Manager. The site HCM (Health Center Manager) and RD (Regional Director) will ensure new staff are trained when hired. The QM Manager will ensure that all staff are properly trained.	

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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 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;	T 175		

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T 175	Continued From Page 15 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 and interview the facility failed to: 1. Disinfect the sonogram procedure table between patients. 2. 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	T 175	1. The Infection Prevention Policy & Procedure manual dictates proper disinfecting of exam table where ultrasounds are performed. There is annual training to ensure all staff are current on this policy. New staff will be trained at hiring by HCM or RD. The QM Manager will ensure that all staff are current with training. 2. This IPP&P has policies, procedures and processes for hand hygiene, maintenance of and access to hand-washing equipment and supplies, maintenance of and availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies, appropriate storage for cleaning agents and product-specific instructions for use of cleaning agents. While this site has no linen as no surgical procedures are done here, there is a policy for handling, storing and transporting and temporary storage of clean and soiled linen. There are procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations. At this site, the only medical waste is sharps containers. There are procedures for processing of each type of reusable medical equipment between uses on different patients which includes the level, process and method of cleaning/disinfecting/sterilizing of each type with reference to manufacturers' recommendations. There are procedures	

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T 175	Continued From Page 16 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 agent in the facility as recommended or required by the department. The findings included: 1. An observations conducted on July 31, 2012, at 2:40 p.m., revealed rusted decorative studs on the procedure table used for sonograms. The non-intact surface of the studs prevented the disinfection of the procedure table between patients. An interview was conducted on July 31, 2012 at 3:39 p.m. with Staff #1, Staff #2 and Staff #4. Staff #2 reported awareness of the problem with the procedure table. Staff #2 acknowledged the procedure table could not be disinfected between patients related to the non-intact surface. 2. An interview was conducted on July 31, 2012 at 8:44 a.m., with Staff #1. Staff #1 reported the facility had failed to have a system in place to develop, maintain and implement infection prevention policies, procedures and processes. Staff #1 acknowledged the facility did not have policies, procedures, or processes to comply with 12 VAC 5-412-220 (C) (1-12). Staff #1 reported the facility's corporate Infection Preventions had	T 175	for appropriate disposal of non-reusable equipment, which at this site would be needles, etc for injections or blood drawing for testing. There are procedures for cleaning of environmental surfaces with appropriate cleaning products. There are procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department. 3. There will be a contract with the Pest Control company for this site instead of the letter agreement which was on file. This will be done by September 12, 2012. 1. There is a Policy & Procedure in place with the Facilities Coordinator to ensure that all furniture and equipment is maintained as per regulations. The exam table with rusted decorative studs will be reupholstered by a professional by September 12th. If upholsterer is unable to meet this deadline, the exam table will not be used until reupholstered. The HCM will inform the Facilities Coordinator of any issues with exam tables or other furniture as it occurs. The Facilities will ensure that during monthly inspections that all furniture is checked. 2. The Policy & Procedures for Infection Prevention covers all items written under item T 175.	

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T 175	Continued From Page 17 not completed the infection prevention policies, procedures and processes.	T 175		
T 180	12 VAC 5-412-220 D Infection prevention 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 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	T 180	1. There is a policy in place now relative to the employee health program to cover those items in T 180 which provides a system for access to 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 recommendation of public health authorities to include documentation of screening for tuberculosis and access to hepatitis B vaccine and a system for compliance with OSHA for reporting workplace-associated injuries or exposure to infection. This policy will be tracked as to staff and requirements by the RQ Manager who will maintain a log of staff. The VP for Medical Services will monitor to ensure compliance.	

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T 180	Continued From Page 18 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 was conducted on July 31, 2012 at 8:44 a.m., with Staff #1. Staff #1 reported the facility had failed to have a system in place to develop, maintain and implement a written employee health program. Staff #1 acknowledged the facility did not have policies, procedures, or processes to comply with 12 VAC 5-412-220 (D) (1-5). Staff #1 reported the facility's corporate Infection Preventionist had not completed the infection prevention policies, procedures and processes related to the employee health program. Staff #1 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	T 185		

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T 185	Continued From Page 19 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: An interview was conducted on July 31, 2012 at 8:44 a.m., with Staff #1. Staff #1 reported the facility had failed to have a system in place to track or trend their infection data. Staff #1 reported the facility had not developed policies, procedures for surveillance, documentation/input of data or tracking of the facility's infections. Staff #1 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. Staff #1 acknowledged the facility did not have policies, procedures, or processes to comply with 12 VAC 5-412-220 (E) (1-3).	T 185	1. There is an Infection Prevention Policy & Procedure Manual now which has the procedures for surveillance, documentation and tracking of reported infections as well as procedures for reporting conditions to the local health department. This will be monitored and maintained by the QM Manager and oversight will be by the Quality Assurance Committee.	
T 300	12 VAC 5-412-290 A Emergency services A. An abortion facility shall provide ongoing urgent or emergent care and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen and related items for	T 300		

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T 300	Continued From Page 20 resuscitation and control of hemorrhage and other complications. This RULE: is not met as evidenced by: Based on observations and interview the facility failed to have the required emergency equipment, a suction apparatus, on site. The findings included: Observations on July 31, 2012 from 7:45 a.m. to 8:30 a.m., with Staff #1 and Staff #3 did not reveal an oral suction apparatus. An interview was conducted on July 31, 2012 at 2:31 p.m., with Staff #1 and Staff #2. Staff #2 verified the facility did not have an oral suction apparatus for emergent patient care.	T 300	1. The oral suction apparatus for emergent patient care is now in place. There is a monthly inventory done to ensure all items required are in place. This will be monitored by the HCM. This site, however, only does medication abortions, not surgical, so there would be no patient on site where resuscitation or control of hemorrhage or other complications would be an issue.	
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 7. Staff concerns regarding patient care. This RULE: is not met as evidenced by: Based on record review and interview the facility's quality assurance program failed to document the evaluation of the seven require components related to adequacy/appropriateness of services	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:	

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T 320	Continued From Page 21 and identification of unacceptable/unexpected trends and occurrences. The findings included: Review of the facility's quality documents did not provide evidence the committee evaluated the seven required components of staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; plus staff concerns regarding patient care. An interview was conducted on July 31, 2012 at 12:30 p.m. with Staff #2 and Staff #4. Staff #4 reviewed the regulation requirements and the quality documents on site and requested to contact the corporate office for additional information. Staff #4 acknowledged the quality documents on site did not address the seven required components of the regulations. The facility did not present additional information prior to exit.	T 320	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. This information will be presented to the governing body for review at least once a year by the committee. The VP for Medical Services will monitor to ensure compliance.	
T 335	2 VAC 5-412-300 E Quality assurance E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.	T 335	1. A Policy & Procedure manual will be developed by September 12, 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.	

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T 335	Continued From Page 22 This RULE: is not met as evidenced by: Based on record review and interview the facility's quality improvement policies failed to include that: all corrective action needed to be documented; the governing body/board and the facility needed to act upon the quality report; and identified deficiencies, which jeopardized patient safety was reported immediately in writing. The findings included: An interview and review of the facility's quality improvement program was conducted on July 31, 2012 at 12:34 p.m. with Staff #2 and Staff #4. Staff #2 and Staff #4 reviewed the regulations and compared the facility's quality improvement documents. Staff #4 verified the facility's documents and policies did not include that all corrective action needed to be documented; the governing body/board and the facility needed to act upon the quality report; or that the quality committee reported immediately in writing identified deficiencies, which jeopardized patient safety.	T 335		
T 340	12 VAC 5-412-310 Medical records An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following: 1. Patient identification; 2. Admitting information, including a patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; and 5. Procedure report to include: a. Physician orders;	T 340		

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T 340	Continued From Page 23 b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses' progress notes, h. Condition at time of discharge, i. Patient instructions, preoperative and postoperative; and j. Names of referral physicians or agencies. This RULE: is not met as evidenced by: Based on record review and interview the facility failed to develop policies, procedures and processes that identified the contents of an accurate and complete medical record. The findings included: An interview and review of the facility's policy and procedure manuals was conducted on July 31, 2012 at 12:44 p.m., with Staff #1, Staff #2 and Staff #4. The review did not reveal evidence of policies, procedures or processes for the contents of a complete medical record or requirements for an accurate medical record. Staff #4 verified the findings and reported the policies would need to be developed.	T 340	1. There is in place a policy, procedure and process to identify the contents of an accurate and complete medical record. This will be monitored by the HCM with the QM Manager ensuring that on site visits random charts will be reviewed to ensure compliance with the policy.	
T 350	12 VAC 5-412-330 A Reports A. Abortion facilities shall comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12 VAC 5-550-120).	T 350	RECEIVED SEP 13 2012 VDH/OLC	

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BLACKSBURG PLANNED PARENTHOOD HEALTH	700-J NORTH MAIN STREET BLACKSBURG, VA 24060

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T 350	Continued From Page 24 This RULE: is not met as evidenced by: Based on interview the facility did not have policies, procedures or documentation that induced terminations of pregnancies were reported to the appropriate health department agency. The findings included: An interview conducted on July 31, 2012 at 2:39 p.m., with Staff #2, Staff #3 and Staff #4 revealed the facility did not have a policy, procedure or documentation that reports regarding induced terminations of pregnancies were sent to the appropriate health department agency. Staff #3 reported completing the required forms and forwarding the forms to their sister facility. Staff 33 reported the forms were counted along with the sister facility's numbers. Staff #4 reported he/she did not document or maintain a log separate from the sister facility. Staff #4 verified the facility did not have policies and procedures related to the reporting of induced termination of pregnancies and reporting to the required health department agency.	T 350	1. There appears to have been some miscommunication during this interview. This site does complete and submit as required to the proper agencies the Report of Induced Termination of Pregnancy (Form VS-5A 10-02). These are done at the site and mailed from the site. 2. There is now in place a policy and procedure for completion of the forms which will be monitored by the HCM to ensure these are routinely done in a timely manner. This process will have oversight by the RD.	
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 record review and interview the facility did not have policies, procedures and processes for reporting the death of patients, visitors or staff to the state licensing agency within twenty-four hour of the occurrence. The findings included:	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 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.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-007	A. BUILDING _____ B. WING _____	07/31/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BLACKSBURG PLANNED PARENTHOOD HEALTH	700-J NORTH MAIN STREET BLACKSBURG, VA 24060

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 355	Continued From Page 25 Review of the facility's policy and procedure manuals did not provide evidence of a policy, procedure or process for reporting within twenty-four hours the death of a patient, visitor or staff to the Office of Licensure and Certification. An interview conducted on July 31, 2012 at 2:39 p.m., with Staff #2, Staff #3 and Staff #4 revealed the facility did not have a policy, procedure, or process for reporting to the Office of Licensure and Certification all patient, visitor or staff deaths within twenty-four hours of the occurrence.	T 355		
T 400	12 VAC 5-412-380 Local and state codes and standards Abortion facilities 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 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.	T 400		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-007	A. BUILDING _____ B. WING _____	07/31/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BLACKSBURG PLANNED PARENTHOOD HEALTH	700-J NORTH MAIN STREET BLACKSBURG, VA 24060

(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 26	T 400		

This RULE: is not met as evidenced by:
Based on observation, interviews 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:

The facility's record did not reveal an attestation from an architect that the building met the required (FGI) guidelines. The facility did not have documentation that the heating and cooling system provided two exchanges of outside air every hour.

Exam Room #1 has lessthan the required 120 square feet. Treatment Room #2 has less than the requirement of 120 square feet. The facility has corridor widths less than the requirement of 60 inches.

Heating, venting and air conditioning was not verified to meet the 30 % efficiency rating of MERV (MERV- the minimum efficiency reporting value) level 7 for Treatment Rooms #1 and #2.

Storage Room for sterile supplies failed to meet the requirement for ventilation, humidity and temperature control by a MERV 7 rating.

No glazing material on glass windows and doors was noted during the initial tour of the facility on 8/31/12,

Sinks failed to have valves that can be opened without hands (single handle or wrist blades).

1. The Blacksburg PPHS Health Center does not provide surgical abortions. This site provides medication abortions only. Medication abortion is a non-surgical process, in which the patient takes oral medications; there is no "procedure" and no sedation or anesthesia. Attached is the process followed for a medication abortion (Attachment A), which makes clear the non-surgical nature of the service; essentially, the patient has an ultrasound and a physical examination, and then is given an oral medication by the physician, and additional oral medications to take at home. Also attached is a policy and procedure confirming that Blacksburg provides no surgical services (Attachment B) [This is first 3 pages of a 30-page policy; these are pertinent pages which detail Blacksburg being a medication abortion only site].

2. The non-surgical nature of the services provided at Blacksburg change the obligations imposed by the Guidelines.

   a. exam rooms: Blacksburg does not have any treatment rooms; rather, because of the nature of the services provided, Blacksburg has exam rooms. Attached is a revised architect's letter (attachment C) stating that because no procedures are provided at Blacksburg, it is not required under the Guidelines to have treatment rooms of at least 120 square feet, but rather is required to have exam rooms of at least 80 square feet, and that this requirement is met by both of Blacksburg's exam rooms. In providing medication abortion, the rooms are used for ultrasound and medical examinations, and for the doctor to provide an oral medication. These exam rooms are adequate in size to protect patient and staff health, safety, and comfort, for the services provided at Blacksburg.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-007	A. BUILDING _____ B. WING _____	07/31/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BLACKSBURG PLANNED PARENTHOOD HEALTH	700-J NORTH MAIN STREET BLACKSBURG, VA 24060

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T 400	Continued From Page 27 Doors width do not meet the required 36 inch width clearance. In addition, the doors do not have lever type hardware. Staff #1 verified during interview that the determination to renovate or relocate had not been made. This interview occurred in the agency's office on 7/31/12, at 3:30 p.m.	T 400	3. In the alternative, should the VDH conclude that Blacksburg is required under the Guidelines to have treatment rooms PPHS has two years from the date of licensure to comply with this requirement. We propose to seek a waiver based on the non-surgical nature of the services provided at Blacksburg. Should the waiver be unsuccessful, we would evaluate options for construction and/or moving into a new facility. During the interim period patient health, safety, and comfort are well protected by the existing exam rooms, given the non-surgical nature of the services provided. Blacksburg has been providing medication abortion services at its current facility for 2 years and has an excellent safety record. 4. Corridor width: The facility's corridors are not five feet in width; rather, as stated in our architect's letter, they are 4'10" (that is, two inches short). PPHS has two years from the date of licensure to comply with this requirement. We propose to seek a waiver of the corridor-width requirement based on the non-surgical nature of the services provided at Blacksburg, and its excellent safety record. Should the waiver be unsuccessful, we would evaluate options for construction and/or moving into a new facility. During the interim period patient and staff health, safety, and comfort are well protected by the existing corridors, especially given the non-surgical nature of the services provided. The intent behind the corridor width regulation is fire safety and emergency evacuation. Blacksburg's staff have been trained in fire safety and had refresher training on fire safety and on actually using a fire extinguisher in April 2012. Finally, there have been no emergency transfers for any reason for the 25 years this site has been	

apply, we have two years to comply and propose to seek a waiver; should the waiver be unsuccessful we will evaluate options for construction and/or moving to a new facility.

The air circulation and temperature has been and continues to be adequate in the exam rooms and other areas of the facility, without "stuffiness," ensuring patient and staff comfort. Blacksburg's strong safety record also confirms that its HVAC system is adequate to protect patient and staff health and safety, especially given the non-surgical nature of the services provided.

6. No glazing material on glass windows and doors – The doors and windows do have safety glass. We are getting quotes for a security film for the door and windows. The check-in windows already have security film covering them. Also, we have two years to meet this or ask for a waiver as patient and staff safety is not at risk due to the safety glass already in place.

7. Sinks: the sinks in Blacksburg's exam rooms are not hands-free. PPHS has two years from the date of licensure to comply with this requirement. Our plan for compliance is to evaluate options for construction and/or moving into a new facility (depending in part on the outcome of the other physical construction items at issue). **PPHS takes infection control very seriously, and has installed numerous hand sanitizer dispensers around the health center.** These dispensers, together with PPHS's current sinks, meet the intent of the requirement in maintaining patient and staff safety and comfort, especially given the non-surgical nature of services provided at Blacksburg.

Attachment A

Planned Parenthood Health Systems
Blacksburg Medication Abortion Process
August 2012

Steps for Day 1 of 2 Appointments:

1. Check-in and paperwork complete, ID and address checked, payment collected
2. Patient has Ultrasound (in compliance with VA state law, offering viewing, listening and copy of the picture).
    a. Time and date noted of Ultrasound (has to be 24hr in advance of AB).
    b. During ultrasound a vaginal probe or abdominal probe are used (depending on gestational age), afterward both of these probes are cleaned with high disinfectant cleaning solution (not required to be sterile).
3. Lab work is done for Hemoglobin & RH typing only: Single use disposable items are used such as lancets and slides.
4. Patients listen to the 24 state mandated consent
5. Patients have discussion and here full details of MAB process.
6. Patients schedule Part 2 for actual MAB appointment.

Steps for Part 2 of 2 Appointments:

1. Check-in, paperwork confirmed, ID verified, final payment collected
2. Patient reviews consents and signs forms with health center staff
3. Doctor meets with patient and reviews chart and gives the Mifeprex and Misoprostol medications upon client final consent
4. Doctor discharges patient
5. Patient schedules required follow-up appointment for within 14 days

If patient lives greater than 100 miles to the clinic, all of the above mentioned steps are the same expect for 3 things:

1. Patients must listen over the phone to the VA state-mandated consent at least 24 hours prior to the AB appt.
2. Patients must show proof of address for 100 mile address verification
3. Patients must remain on site for 2 hours from having the Ultrasound until the doctor meets with the patient to give the medications (Mifeprex and Misoprotol)

Attachment B

MIFEPRISTONE MEDICATION ABORTION

I. GENERAL INFORMATION

Initiation of Services — PPFA defines first trimester abortion services (up to 13 6/7 weeks) as a core service — surgical and/or medication — which **must** be provided by all affiliates by 1/2013. Service approval through PPFA's Medical Affairs Division is not required for core services.

PPHS initiated medication abortion services in 2003 and has maintained an excellent safety record. Medication abortion services (up to and including 63 days) are currently provided in the following PPHS health centers:

1. Blacksburg, VA
2. Charlottesville, VA
3. Columbia, SC
4. Roanoke, VA
5. Wilmington, NC
6. Winston-Salem, NC

Quality and Risk Management Activities — Affiliates **must** have a risk and quality management program. PPHS has a risk and quality management program.

1. A Quality Assurance Committee responsible for the oversight and supervision of the program is established and includes:
    a. A physician;
    b. A non-physician health care practitioner;
    c. A member of the administrative staff;
    d. An individual with demonstrated ability to represent the rights and concerns of clients (may be a staff member);
2. Results of the quality improvement program shall be reported to the affiliate leadership at least annually and shall include the deficiencies identified and corrections and improvements. The report shall be acted upon by the affiliate leadership and the staff. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the affiliate leadership by the quality improvement committee.
3. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:
    a. Staffing patterns and performance;
    b. Supervision appropriate to the level of service;
    c. Medical records;
    d. Client satisfaction;
    e. Complaint resolution;
    f. Infections, complications, and other adverse events;
    g. Staff concerns regarding client care.
4. Audits — Contact ARMS for information about the online STARS Audit tool which houses compliance audits to complement affiliate programs.

5. Incident Reports — Incident reports **must** be sent to Medical Services Administration (MSA) for review, and from there, will be forwarded by MSA to ARMS. Timely incident reporting is a required and necessary part of any risk and quality management program (See Section I-A-1, Clinical Program Structure.)
6. Adverse Events and Complication Tracking — The affiliate **must** have a complication tracking system for each provider that is reviewed on a regular basis as part of its Risk and Quality Management program. PPHS has a complication tracking system for each provider, as part of a Risk and Quality Management program that is reviewed on a regular basis. See VII-D-2 for a sample list of complications and definitions.
7. CAPS Adverse Events reporting —
   - PPHS home Clinicians are responsible for the completion of adverse event reports in their assigned health centers, submission to PPHS Medical Services Administration, where they will be reviewed and submitted to ARMS and CAPS as appropriate. Health Centers should NOT send reports directly to ARMS and CAPS- this will lead to duplication. This process for handling adverse events has been agreed to by all parties.
   - Adverse events **must** be reported soon as possible and within 30 days of learning of the event.
     - Deaths **must** be reported to ARMS and CAPS immediately after learning of the event.
     - Do *not* send reports directly to Danco — this will lead to duplication. The process for handling adverse events has been agreed to by Danco.
     - Reports will be forwarded to Danco Laboratories and Danco will report the data to the Food and Drug Administration (FDA).
     - CAPS reports back adverse event data to affiliates on a regular basis.
   - Adverse event reports **must** be submitted to PPFA/CAPS using the Mifepristone Adverse Report Form, available on the CAPS page of the Extranet.
   - Following review of reports, reports will be forwarded to CAPS. Centers should not send reports directly to CAPS as the MSA office is entering the event electronically, and this may cause duplication.
   - The adverse events reportable to CAPS are:
     - Ongoing pregnancy — a living, viable pregnancy that is growing. For example, the ultrasound shows a fetal pole with cardiac activity or a gestational sac that has grown approximately since mifepristone was given. Submit the adverse event report after the client has had surgical completion, enters prenatal care, or is lost to follow up.
     - Treatment in the Emergency Department — **any** medical or surgical treatment received in the emergency department, such as a D&C for heavy bleeding. If the client went to the ER and was reassured (with or without pain medication) and left without treatment, it is not an adverse event.
     - Hospital admission — admission to a floor for treatment and/or observation related to the abortion. Treatment and release from the emergency department is not an adverse event.
     - Transfusion — include the number of units transfused as well as pre- and post-transfusion hemoglobin and hematocrit, if known.

- Ectopic pregnancy (unrecognized) — any ectopic pregnancy that was **not** diagnosed before the client ingested mifepristone. Reports **must** include details of diagnosis and treatment, if surgery was performed, and final outcome. This definition excludes cases where an ectopic pregnancy was suspected **before** administration of mifepristone and the client was evaluated and/or referred out for care.
- Allergic reaction — any allergic reaction serious enough to be treated in the emergency department or that required admission to the hospital. Allergic reactions specific to mifepristone or misoprostol require a careful history to exclude exposure to other possible allergens.
- Infection — any infection which required treatment with IV antibiotics or admission to the hospital.
- Death — deaths **must** be reported immediately to ARMS and CAPS.
- Other — any other unusual or serious event or other major complication associated with mifepristone medication abortion. An emergent aspiration at the affiliate health center for severe bleeding or instability would warrant an adverse event if:
  - hemoglobin dropped significantly from baseline
  - non-routine, extraordinary steps were needed to control bleeding, such as multiple aspirations or injection of methylergonovine along with uterine aspiration.

8. Complication Tracking — the affiliate is required to have a complication tracking system as part of a Risk Management Program. Complications are to be reviewed every 6 to 12 months. The complication log **must** include the adverse events required to be reported above. See VII-D-2 for a Sample list of complications and definitions.
9. State reporting requirements
   a. VA Centers **must** comply with the fetal death and induced termination of pregnancy reporting provisions in the Board of Health Regulations Governing Vital Records (12VAC-5-550-120). See Appendix for statute and forms required.
   b. VA Centers shall report all patient, staff, or visitor deaths to the OLC within 24 hours of occurrence.

II. MANAGEMENT OF EMERGENCIES

Emergency Call Systems — A licensed health care provider **must** be on call 24 hours a day, 7 days a week. See Section VII-B-5 for sample Telephone Contact Form. The emergency number **must** be provided on the clients written care instructions

On-call clinicians **must** be aware of all clients who have made previous calls with significant complaints. If a client calls more than once with the same significant complaint, she should be instructed to return to the clinic to be assessed in person. If an emergency cannot be evaluated and managed in a timely manner, the client **must** be referred to an emergency department.

Attachment C

Rife + Wood
ARCHITECTS

September 7, 2012

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

Re: Facility Compliance – Planned Parenthood – Blacksburg VA

Dear Linda,

At your request Rife+Wood Architects have visited the existing Planned Parenthood Clinic in Blacksburg, VA to help determine how the facility may / may not be in compliance with the newly enacted Virginia Department of Health *Regulations for Licensure of Abortion Facilities, 12 VAC 5-412.*

The clinic is one of several tenants in an existing two story commercial building in Downtown Blacksburg. Critical components of compliance are addressed herein:

CORRIDOR WIDTH:
The existing Blacksburg Clinic is served by corridors that are 4'-10" wide (typical). **The existing corridor width does not meet the standard requirement** for corridors to - minimum clear width of 60 inches (per FGI Standards Section 3.1-7.2.1 (1),(2) Corridor Width: See recommendations below.

SPRINKLER SYSTEM:
The existing multi-tenant building and the Planned Parenthood clinic is not equipped with an automatic fire suppression system. Sprinkler requirement are determined by a combination of factors: occupant use / number of occupant / building size & height and construction classification.

The Commonwealth of Virginia Building Code (VBC 2009 –IBC 2009) defines Ambulatory Health Care facilities as a Group B (Business) use and uses the criteria noted below to determine the fire safety systems and sprinkler requirements:

> Chapter 9 – Fire Protection Systems
> **[F] 903.2.2 Group B ambulatory health care facilities.** An *automatic sprinkler system* shall be installed throughout all fire areas containing a Group B ambulatory health care facility occupancy when either of the following conditions exists at any time:
> 1. Four or more care recipients are incapable of self preservation.
> 2. One or more care recipients who are incapable of self-preservation are located at other than the level of exit discharge serving such an occupancy.

The **Blacksburg Health Center is exempt** from the Virginia Building Code **requirements for a sprinkler system** based on the following:

- The Blacksburg health center provides only two exam rooms.

- The facility provides on-grade access and emergency egress (i.e., clinic located on level of discharge).
- The health center does not use sedatives (i.e., all care recipients are capable of self preservation).

TREATMENT ROOM SIZE:
The existing facility has two exam rooms for patients. We do not have treatment rooms as no surgical abortions are performed and no sedation is used. Our examination rooms meet and exceed the 80 SF rooms for an exam room.

Space	*Existing Size*	*Existing Floor Area*
Exam Room 1	9'-0" x 11'-0"	99 sq.ft.
Exam Room 2	9'-0" x 10'-0"	90 sq.ft.

HEATING VENTING AND AIR CONDITIONING (HVAC):
AIR VOLUME: The existing medical clinic serviced by a central heating plant (forced air / heat pump unit). The existing Treatment Room 1 & Treatment Room 2 are served by the same system. The volume of air delivered to these treatment rooms has not been verified. The existing HVAC equipment is has been in use for over 10 years. Whereas ASHRAE standards for air volume and outdoor air volumes in Treatment Rooms have increased with the current edition of ASHRAE it is likely that the design levels in these rooms do not meet current requirements.

OUTDOOR (FRESH) AIR:
The volume of outdoor air provided to Treatment Room 1 & Treatment Room 2 has not been verified. Field measurements by a qualified testing and balancing agency are necessary to confirm the volume of air at each treatment room. **Whereas this design standard has increased since the initial licensing this clinic began at this site it is likely that outdoor air volume does not meet the new requirements of ASARAE Standard 170-2008.** See recommendations below.

AIR FILTRATION:
Existing HVAC equipment is over 10 years. The existing filter configuration and efficiency was compliant at the time of installation, but whereas the ASHRAE standards for air filtration have increased in subsequent editions, **it is possible that the design likely does not meet the new 30% efficiency rating requirements of ASARAE Standard 170-2008.**

RECOMMENDATIONS:
The existing Blacksburg Clinic is non-compliant in several ways, most notably:

a. Corridor Width / egress width
b. Door clearances and door hardware
c. HVAC – total air volume and outside air volumes (un-determined)
d. HVAC – air filtration efficiency (un-determined).

Given the significant physical and operational constraints of this clinic, it is our recommendation that Planned Parenthood begin the process to examine two strategic planning options (i.e. Relocate or apply for waivers).

RELOCATE: Explore feasibility of relocating the clinic operations to an alternate location that provides accommodation for the deficiencies noted above.

WAIVERS: PPHS would apply for waivers regarding the corridor width / egress width, the door clearances and door hardware, the HVAC total air volume and outside air volumes, and the HVAC air filtration efficiency as this site does no surgical abortion procedures.

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

Sincerely,

Jeffrey R. Wood, AIA date

Rife+Wood Architects
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Acting Facility Administrator date
Planned Parenthood Health Systems, Inc