STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
Office of Health Care Quality
Spring Grove Center • Bland Bryant Building
55 Wade Avenue • Catonsville, Maryland 21228-4663
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

March 26, 2013

Ms.. ..
Administrator
Prince Georges Reproductive Health Services
7411 Riggs Rd, Suite 300
Hyattsville, MD 20783

RE: NOTICE OF CURRENT DEFICIENCIES

Dear :

On February 14, 2013, a survey was conducted at your facility by the Office of Health Care Quality to determine if your facility was in compliance with State requirements for Surgical Abortion Facilities, Code of Maryland Regulations (COMAR) 10.12.01. This survey found that your facility was not in compliance with the requirements.

All references to regulatory requirements contained in this letter are found in COMAR Title 10.

I. PLAN OF CORRECTION (PoC)

A PoC for the deficiencies must be submitted within 10 days after the facility receives its State of Deficiencies State Form. Your PoC must contain the following:

- What corrective action will be accomplished for those patients found to have been affected by the deficient practice;
- How you will identify other patients having the potential to be affected by the same deficient practice and what corrective action will be taken;
- What measures will be put into place or what systemic changes you will make to ensure that the deficient practice does not recur;
- How the corrective action(s) will be monitored to ensure the deficient practice will not recur, i.e., what quality assurance program will be put into place and;
- Specific date when the corrective action will be completed.

- References to staff or patient(s) by staff identifier only, as noted in the staff and patient rosters. This applies to the PoC as well as any attachments to the PoC. It is un-acceptable to include a staff or patient's name in these documents since the documents are released to the public.

III. ALLEGATION OF COMPLIANCE

If you believe that the deficiencies identified in the State Form have been corrected, you may contact me at the Office of Health Care Quality, Spring Grove Center, Bland Bryant Building, 55 Wade Avenue, Catonsville, Maryland 21228 with your plan of correction and any written credible evidence of compliance **(for example, attach lists of attendance at provided training and/or revised statements of policies/procedures).**

If you choose and so indicate, the PoC may constitute your allegation of compliance. We may accept the written allegation of compliance **and credible evidence** of your allegation of compliance until substantiated by a revisit or other means.

If, upon the subsequent revisit, your facility has not achieved compliance, we may take administrative action against your license or impose other remedies that will continue until compliance is achieved.

IV. INFORMAL DISPUTE RESOLUTION

You have one opportunity to question cited deficiencies through an informal dispute resolution process. To be given such an opportunity, you are required to send your written request, along with the specific deficiency(ies) being disputed, and an explanation of why you are disputing those deficiencies, to Dr. Patricia Nay, Acting Executive Director, Office of Health Care Quality, Bland Bryant Building, Spring Grove Center, 55 Wade Avenue, Catonsville, Maryland 21228. This request must be sent during the same 10 days you have for submitting a PoC for the cited deficiencies. An incomplete informal dispute resolution process will not delay the effective date of any enforcement action.

If you have any questions concerning the instructions contained in this letter, please contact Joyce Janssen at 410-402-8018 or fax 410-402-8213.

Sincerely,

Barbara Fagan/LC

Barbara Fagan
Program Manager

Enclosures: State Form

cc: License File

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	SA000017	A. BUILDING: _____ B. WING _____	02/14/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PRINCE GEORGES REPRODUCTIVE HEALTH :	7411 RIGGS RD, SUITE 300 HYATTSVILLE, MD 20783

(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
A 000	Initial Comments An initial survey of Prince Georges Reproductive Health Services was conducted on February 14, 2013. The survey included the following: interview of the clinical staff; observational tour of the facility's physical environment; observation of the facility's sterilization equipment reprocessing; policy and procedure review; review of the facility's patient clinical records; review of the physicians credentialing; review of employee personnel files; review of the facility's Quality Assurance program and review of the facility's infection control program. The facility has two procedure rooms. A total of five patient clinical records were reviewed. The clinical patient records reviewed had procedures done between November 2012 and February 2013.	A 000		
A 450	.05 (A)(2)(a) .05 Administration (2) The administrator shall ensure that: (a) The facility's policies and procedures as described in §C of this regulation are: (i) Reviewed by staff at least annually and are revised as necessary; and (ii) Available at all times for staff inspection and reference; and This Regulation is not met as evidenced by: Based on facility documentation and interview of the facility administrator, it was determined that the facility failed to keep policies and procedures available at all times in the facility for staff reference. The findings include:	A 450		

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A 450	Continued From page 1 Review of facility documentation on 2/14/13 9:00 am, revealed no evidence to support that the facility has any clinical policies onsite for review by staff or the surveyors. Interview of the facility administrator on 2/14/13 at 9:15 am, revealed that the facility has policies and procedures, but facility administrator had taken the policies home to update and did not bring the policies and procedures back to the facility.	A 450		
A 790	.06(B)(9) .06 Personnel (9) Data provided by the National Practitioner Data Bank. This Regulation is not met as evidenced by: Based on review of the physician credentialing files, interview with the facility administrator, it was determined that the facility failed to collect, review and document data provided by the National Practitioners Data Bank (this is a database for physicians in connection with medical liability settlements or judgments as well as adverse peer review actions against licenses, clinical privileges) for the physician reviewed. The findings include: Review of the Physician Credentialing on 2/14/13 at 11:00 am revealed that the Physician's file contented no evidence to support that data provided by the National Practitioners Data Bank was collected, documented or review. Interview of the facility administrator on 2/14/13 at 11:30 am confirmed that no data had been collected, reviewed or documented from the National Practitioners data Bank on any of the Physicians.	A 790		

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A1000	.07(B)(8) .07 Surgical Abortion Services (8) Safety. This Regulation is not met as evidenced by: Based on review of personnel files and interview of facility administrator, it was determined that the facility's Medical Director failed to ensure policies and procedures were implemented for training, orientation and competency on emergency equipment maintain ensuring patient safety. The findings include: Review of staff personnel files staff #1, 2, 3,4,5,6, and 7 on 2/14/13 at 10:30 am revealed that staff had no evidence of training, orientation or competency documented in their files of emergency equipment management or implementation of the emergency transfer policy and procedures. Interview of the facility administrator on 2/14/13 11:00 am revealed that she did not have any current evidence in the facility to support that staff had been orientated, trained or competent in emergency equipment maintain or implementation of the emergency transfer policy and procedures.	A1000		
A1270	.11 (A)(2) .11 Pharmaceutical Services (2) Develop and implement policies and procedures for pharmacy services in accordance with accepted professional practice. This Regulation is not met as evidenced by: Based on observational tour of the facility and	A1270		

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A1270	Continued From page 3 interview of the facility administrator, it was determined that the facility administrator failed to ensure that pharmacy policies were implemented and in accordance to acceptable standards of care. The findings include: During Observational tour on 2/14/13 at 2:00 pm revealed that Oxytocin (a hormone, to stimulate contractions of the uterus and smooth muscle tissue.) was being stored in the lab refrigerator at 3 degrees Celsius and the manufacturer's recommendations for storage are between 15-30 degrees Celsius. Further inspection of the medication revealed that eight vials of Oxytocin had an expiration date of August 2012. Interview of the facility administrator on 2/14/13 at 2:10 PM, revealed that she was unaware that medication are being improperly stored and had expired, and it was further stated that medication should be checked when the medication refrigerator temperature is checked.	A1270		
A1430	.13 (B)(5) .13 Medical Records (5) Discharge diagnosis. This Regulation is not met as evidenced by: Based on review of patient clinical records and interview with the facility administrator, it was determined that the facility administrator failed to ensure that the patient medical records were complete and included a discharge diagnosis for seven of seven patients records reviewed. The findings include: Review on 2/14/13 at 10 am of patient clinical records revealed, that Patients #1, 2, 3, 4, 5, 6 and 7 medical records did not content any evidence that a discharge diagnosis was	A1430		

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A1430	Continued From page 4 documented. Interview on 2/14/13 at 10:30 am of the facility administrator manager revealed that there is not a discharge diagnosis done on the patients before they are discharged to home.	A1430		
A1530	.15 (C) .15 Physical Environment C. The facility shall have a separate recovery room and waiting area. This Regulation is not met as evidenced by: Based on observation of instrument reprocessing sterilization, interview of clinical staff and policy review, it was determined that the facility failed to ensure the policies and procedures were implemented and followed, to ensure instrument reprocessing was conducted in a sanitary environment. The findings include: 1. Observation on 2/14/13 at 1:00 pm of the instrument reprocessing room revealed a basin of a clear substance with instruments in it. The reprocessing tech (Staff #8) stated that the basin contained bleach and water for cleaning the instruments. Bleach is not an Enzymatic cleaner. An Enzymatic cleaner is for instrument cleaning, a neutral or near-neutral pH detergent solution commonly is used because such solutions generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material. Enzymes in these formulations attack proteins that make up a large portion of common soil (e.g., blood, pus). Cleaning solutions also can contain lipases (enzymes active on fats) and amylases	A1530		

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A1530	Continued From page 5 (enzymes active on starches). The enzymatic must be EPA approved. Further observation revealed that dirty bloody suction hose were in a bucket next to the clean hoses. The reprocessing tech identified this area as the clean area. 2. Observation of the sterilization processing room on 2/14/13 at 1:00 pm revealed that the biohazards box which is open at the top, containing contaminated waste and soiled chuxs is located in the reprocessing room. The staff is touching the box with are PPE (protective personal protection) and then placing the gown on top of the clean paper that is used wipe the cleaned instruments, Further observation revealed that Staff #8 put her gloved hands into the biohazards box and did not change gloves or wash hands or use hand sanitizer. The staff then proceeded to return to reprocessing the instruments 3. Interview of Staff #8 on 2/20/13 at 1 pm during observation of cleaning of instruments, revealed that she did not know if bleach was an enzymatic cleaned and that she was just told to use bleach and water for instrument cleaner. She stated that the instruments in the basin were cleaned and ready to be wrapped for the autoclave. Further interview of Staff #3 revealed that because the reprocessing space is so small it is hard to not contaminate items and keep clean items clean, and dirty items from mixing.	A1530		

Prince Georges Reproductive Health Services Plan of Correction ID# SA000017

A450

During our inspection we failed to have our policy and procedure manual on site. To ensure this never happens again PGRHS Policy and Protocol Manual will be kept on site at all times. It is the responsibility of the Clinic Administrator to ensure that additions and revisions be done via back up driver so a hard copy will be available to employees and inspectors at all times. Failure to have our policy and procedure manuals on site could impact patients if staff has a question about a correct course of action pertaining to patient care and cannot access our policies. In the future our complete training manual and protocol manual is kept in the front administrative office assessable to all. Please see our complete training manual and protocol manual included with this plan of correction. Both the training manual and policy and procedure manual were returned to PRRHS on 03-01-13.

Training manual pages 1-11

Policy and Protocol Manual pages 1-42

A790

PGRHS failed to properly credential our Medical Director. Failure to credential our medical director could affect patients negatively if our company employees a physician that has a problematic past history or is unlicensed. We found this deficiency did no harm to patients because our physician is licensed in the State of Maryland, carries malpractice insurance, and has an extensive background in performing abortions. In the future it will be the responsibility of the Clinic Administrator to check with the Data Bank on an annual basis. We submitted an application of behalf of our company so it can be used in both offices. Our application was accepted on 4-15-13. We have begun a credentialing file for our physician that will be kept with his employee file. Revisions to our policy and procedure manual under "Personnel and Staffing Guidelines" will include mandatory initial and annual credentialing of all employed physicians. Please see our application to the Data Bank and a follow up email as proof of activation. A credentialing file for our Medical Director will be completed and documented by June 1st 2013.

National Practitioners Data Bank Company Application

National Practitioners Data Bank Activation Date

A1000

Prior to our inspection we used a shadowing method of training requiring a new employee to follow an existing employee until the new employee demonstrated they were proficient, this included no documentation process. Failure to document training of employees puts the clinic at risk of employees using improper technique and having no supporting evidence of the proper technique being taught. PGRHS has amended their training protocol to include: Initial training documentation as a baseline of skills upon employment. A 90 day evaluation with documentation of clinical skills will be done by

the Medical Director prior to the employee performing clinical duties without direct supervision. This evaluation will be repeated and documented annually for every employee and will be kept in the employee's file. The annual documentation of training is the responsibility of the Clinic Administrator. This evaluation for existing employees will be completed and documented by June 1st 2013. Training and evaluations include but are not limited to: Patient health histories, taking vitals, height and weight, laboratory testing, patient education, sterilizing and packing instruments, set up and break down of surgical room, sanitation and infection control, crash cart contents and uses, emergency transport protocol (CODE RED), etc. Please see policy and protocol manual for a complete list.

Personnel and Staffing Guidelines page 3-4

Description of Job by Location within the Clinic pages 4-6

A1270

The inspectors found expired and improperly stored medication on site. To ensure proper storage temperatures of medication PGRHS has implemented a new medication storage protocol. When supplies arrive at the clinic they are to be matched up with a medication storage spread sheet and signed off by the staff member putting away supplies. This form includes all medications used in our clinic their proper storage temperatures and requirements. In regards to the oxytocin found in the refrigerator I was able to track the last shipment and discard two boxes of single dose ampules (50 amps in total). Working backwards from the date the Oxytocin was found to the received date from our supplier I went through patient charts and found no matching lot numbers. I am confident that no patients were giving the Oxytocin that was improperly stored. We also had a staff meeting regarding the importance of checking expiration dates and discarding any/all items that are expired. This included responsibility for the assigned employee's area of work and a weekly inspection by the Clinic Administrator. All employees attended this meeting and it was logged in our Quality Assurance/ Staff Trainings folder located in the front office.

A1430

PGRHS has added an area for the Physician to include a discharge diagnosis on every patient chart. This was not part of our original patient chart but was changed on 04-08-13. All patients' charts beyond this date have a discharge diagnosis listed. It is the responsibility of the Medical Director to fill in the discharge diagnosis on every chart and a chart audit done on a weekly basis to ensure it has been completed is the responsibility of the clinic administrator. We find this deficiency didn't negatively affect our patients. Please see Physician's Notes Forms.

Post-Surgical Abortion Data Sheet

Medical Abortion Data Sheet

A1530

During our inspection it was brought to my attention that the reprocessing staff was unable to maintain adequate clean space for instruments and PPE's were being contaminated due to placement of the biohazard box. PGRHS implemented several changes to the instrument reprocessing room. First we removed one of our autoclaves to another room freeing up a large counter space to be used solely as a clean area. We also moved our clean instrument wrapping station allowing us to move the biohazard box to the adjacent wall giving the technician room to move freely without being near or touching the biohazard box. Reorganizing the reprocessing room was completed on 03-16-13. Extensive retraining in correct use of personal protective equipment was completed and documented with all employees including staff member #8 on 03-16-13. This retraining included written instruction and demonstration. We also failed to use appropriate enzymatic cleaning solution during our cleaning process. Upon researching enzymatic cleaners we found Cavicide 1 best fit our needs and the safety recommendations of the EPA. Enzymatic cleaner was purchased on 03-05-13 and was used during retraining. We soak our instruments in 9 parts water and 1 part bleach solution for 10 minutes to decontaminate, then they are moved into the basin for scrubbing which contained hot water and a enzymatic soap solution to clean, then remove to air dry, rewrap, and sterilize. This protocol is recommended by the CDC and NAF . We have our autoclaves inspected annually and use spore testing weekly. Each instrument pack has an internal heat sensor and heat indicated tape used on the outside. The Medical Director inspects all instrument packs prior to use. Close inspection of the instrument reprocessing area and employee's has become a primary focus in ensure that our instruments are safe to use on patients. The clinic administrator will be performing surprise inspection of the reprocessing process at least once a week to ensure staff is following proper guidelines per our protocol.

Henry Schein Invoice 03-05-13 (Cavicide 1 Purchase)

3 Step Reusable Instrument Cleaning Protocol

A majority of the changes outlined above have been put in effect already but some additional time for my training and retraining protocol is still needed. I will have all employee trainings completed and documented no later than June 1st, 2013 for re-inspection. We appreciate the feedback and strive to maintain a safe clinic to serve women with their reproductive needs.

Thank you,

, Clinic Administrator

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May 8, 2013

Administrator
Prince Georges Reproductive Health Services
7411 Riggs Rd, Suite 300
Hyattsville, MD 20783

RE: ACCEPTABLE PLAN OF CORRECTION

Dear :

We have reviewed and accepted the Plan of Correction submitted as a result of an initial survey completed at your facility on February 14, 2013.

Please be advised that an unannounced follow-up visit may occur prior to the standard survey to ensure continual compliance.

If there are any questions concerning this notice, please contact this Office at 410-402-8040.

Sincerely,

Barbara Fagan

Barbara Fagan, Program Manager
Ambulatory Care Programs
Office of Health Care Quality