STATE OF M CYLAND
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
Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

December 3, 2015

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

Dear

Enclosed is a list of deficiencies resulting from a relicensure survey that was completed at your facility on October 15, 2015.

Please note that an Acceptable Plan of Correction (POC) for the identified deficiencies must include the following information:

1. **State how the management team will evaluate the scope of each deficiency cited.**
2. **State what process changes the management team will make to correct each specific deficiency identified.**
3. **Define the projected time line for each step in the corrective action plan for each deficiency cited.**
4. **Define the projected completion date for each deficiency cited.**
5. **Identify who will be responsible for assuring each step in the plan of correction is implemented.**
6. **State what specific quality indicators that the management team will monitor and evaluate the effectiveness of the corrective actions.**
7. **Define what will be the on-going schedule of the quality monitoring activities for each deficiency cited.**

IT IS IMPERATIVE THAT YOUR POC CONTAIN THE ABOVE COMPONENTS.
Please complete Forms CMS 2567 as follows:

1. **Use the official form provided to you for your response.**
2. **Your Plan of Correction must be entered in the appropriate column on the right.**
3. **An authorized representative of your facility must sign and date the form in the designated space provided.**

PLEASE RETURN COMPLETED CMS 2567:

Barbara Fagan, Program Manager
Ambulatory Care Programs
Office of Health Care Quality
Spring Grove Center
Bland Bryant Building
55 Wade Avenue
Catonsville, Maryland 21228

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. Tricia Nay, 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.

Please submit a Plan of Correction within 10 calendar days of receipt of this letter. Please be advised that failure to submit an <u>acceptable POC</u> could result in a recommendation to terminate your facility from the Medicare program.

If you have any questions regarding these instructions, please call the undersigned at (410) 402-8040.

Sincerely,

Barbara Fagan

Barbara Fagan
Program Manager
Ambulatory Care
Office of Health Care Quality

Cc: file

Office of Health Care Quality

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 _____	10/15/2015

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

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A 000	Initial Comments A relicensure survey of Prince Georges Reproductive Health Services was conducted on October 15, 2015. The survey included: interview of the staff; an observational tour of the physical environment; observation of reprocessing of surgical equipment; review of the policy and procedure manual; review of clinical records; review of professional credentialing; review of personnel files and review of the quality assurance and infection control programs. The facility included two procedure rooms. A total of five patient clinical records were reviewed. The procedures were performed between July 2014 and September 2015. A key code for the patients and staff was provided to the facility staff. Findings in this report are based on data present at the time of review. The agency's staff was kept informed of the survey findings as the survey progressed. The agency staff was given the opportunity to present information relative to the findings during the course of the survey.	A 000	A meeting was held on 10/15/15 between the Clinic Owner, Medical Director and Clinic Administrator. During this meeting we discussed the deficiencies brought to my attention by the DHMH inspectors and developed the following plan of correction to ensure we are compliant with Maryland DHMH Surgical Abortion Facilities code 10.12.01.	
A 380	.05 (A)(1)(a) .05 Administration (a) Consulting with the staff to develop and implement the facility ' s policies and procedures in accordance with §C of this regulation; This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, review of staff credentialing files for five of six staff, interview of staff #7 and review of QA (quality assurance) / Staff Meeting Minutes, it was	A 380	A380 It is the responsibility of the Clinic Administrator to hold quarterly quality assurance meetings with all staff. These meetings must include a disaster/emergency training and/or protocol review. During staff meetings we failed to keep our disaster/emergency protocols current on a quarterly basis. So this doesn't happen again the quality assurance meetings will be reviewed by the physician on a monthly basis to ensure that we have met our requirements for disaster/emergency training. A spreadsheet has been created to keep in the front of the QA meeting binder to have proof of the physicians review, date, and signature. This protocol is in effect as of 01/11/16. Employee files were updated with information regarding their Hepatitis B vaccinations or declined vaccinations. Some employees had proof of vaccination in their files at our sister location, some new employees need testing, and some staff have declined to be tested/vaccinated. All staff members will have completed information in their employee files no later than 06/15/16. We request this amount of time to be compliant due to the time needed to complete the 3 part series.	

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A 380	Continued From page 1 determined that the administrator did not implement policies and procedures for infection control measures and disaster/fire (emergency) drills. Staff: 1, 2, 3, 5, and 6 The findings include: 1) Review of the policy and procedure manual on 10/15/15 at 12:00 PM revealed, "The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated. However, if an employee refuses to decline vaccination, the employee must sign a declination form. ...Documentation of refusal is kept at Prince Georges Reproductive Health." There was no policy and procedure regarding TB (tuberculosis) screening for staff. Review of Staff 3 and 6's credentialing files on 10/15/15 at 10:00 am revealed no documented evidence that they had ever been vaccinated for Hepatitis B, or had been offered the Hepatitis B vaccination by the facility. Additionally, there was no documented evidence that Staff 1, 2, 3, 5, and 6 had ever been tested for TB (tuberculosis). Interview of Staff 7 on 10/15/15 at 1:00 PM revealed that s/he acknowledged s/he did not have documented evidence for hepatitis B for these staff. Tuberculosis testing is mandatory for all staff who provide clinical care to patients in the facility.	A 380	Tuberculosis testing protocol and consent form for all employees has been created. Tb testing has been added to our Exposure Control Plan as well. We have already ordered and began testing staff. Please see TB Consent form, Exposure Control Plan Protocol and Henry Schein invoice number 25345251 included. We will have all staff tested and documentation in employee files by 01/30/16. It is the Clinic Administrators responsibility to ensure that new employees and existing employees have current and complete documentation of vaccinations and necessary testing in their employee files. As a way to ensure this is not overlooked in the future we have added TB testing to our employee packet along with our other terms of employment check offs. Having this documentation added to this quality assurance protocol will ensure that all staff are current in their Tb testing along with their annual training. A1150 In addition to our current emergency supplies we have ordered a Yankauer Tubing system for airway suction purposes. We have also researched suction machines compatible with the Yankauer tubing system and will have on one site by 01/30/16. Please see Henry Schein invoice number 25345251. It is the responsibility of the physician/medical director to ensure that all emergency equipment necessary per the Maryland Regulations for Surgical abortion clinics is on site and in proper working order.	

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A 380	Continued From page 2 2) Review of the policy and procedure manual on 10/15/15 at 12:30 PM revealed "Disaster and Safety Drills...In order to maintain a safe facility and a well-trained staff, disaster/safety drills will be held at least quarterly. The clinical administrator will plan these events during staff meetings and/or as surprise events to test the employees skills in coping with the situation presented. It is the responsibility of the clinical administrator to document these events in the QA/Staff Meetings file in the front office." Review of the QA/ Staff Meeting Minutes on 10/15/15 at 10:30 am revealed a fire drill was conducted on 4/2/15, a disaster/fire drill was conducted on 6/12/13, and fire drill training was conducted on 4/27/13. Interview with the administrator on 10/15/15 at 1:00 PM revealed that s/he acknowledged disaster/fire and safety drills were not being conducted on a quarterly basis.	A 380	We have added the additional emergency equipment to our emergency crash cart log. This will ensure that we have equipment needed to ensure proper treatment of a patient during and emergency situation. The physician/medical director will be responsible for ongoing monitoring of the Emergency Crash Cart Log on a monthly basis. A1270 PGRHS has written a new narcotics protocol that modifies how often the counts are done and by whom. Narcotics are now being counted in the morning before patients are seen and at the end of the day when patients are completed. The count is performed by the Registered Nurse and the Physician and notated on a log that is kept indefinitely. We are still keeping our patient log with names, dates, and amounts given/wasted on the computer which is cross referenced with the patient charts and daily counts log. This is done on a weekly basis by a Medical Assistant. It is the responsibility of the Medical Director/Physician to ensure that these counts are correct and completed according to protocol. The physician is responsible for all protocols regarding Narcotics including daily counts, weekly reviews of computerize log which are randomly cross matched with patient charts. The physician will sign into the log all invoices of Narcotics ordered and received to update the weekly count. Please see PGRHS Narcotic Count Protocol and Narcotics Daily Count Log Sheet.	
A1150	.09(C)(5) .09 Emergency Services (5) Suction equipment; and This Regulation is not met as evidenced by: Based on a tour of the facility and interview of staff #7, the administrator did not ensure that specified emergency equipment was available at the facility. The findings include: A tour of the facility on 10/15/15 at 12:00 PM revealed that the facility did not have an airway suction machine and necessary supplies required to perform oral airway suction in an emergency. Interview of Staff #7 on 10/15/15 at 1:30 PM	A1150		

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A1150	Continued From page 3 revealed that s/he acknowledged that a suction machine and necessary supplies were not available. S/he was unaware that this equipment was necessary to have available at the facility.	A1150		
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 review of the policy and procedure manual, tour of the facility and interview of Staff 7, it was determined that the agency staff did not account for controlled medications. The findings include: Review of the policy and procedure manual revealed "In order to ensure proper counts of narcotic we keep an excel log of all medications received and given to patients. At the beginning of every week the Registered Nurse counts all narcotics and a second count is done by the Clinical Administrator to ensure the count matches. This is also done at the end of every week. Once the counts are completed it is the responsibility of the Assistant Manager to input the patient names and amount of narcotics administered. The total of narcotics given to each patient is added up from the medication administration page and documented by the physician on the surgical end sheet within the patients chart. This is where the Assistant Manager will get the totals to input in the log." A tour of the facility on 10/15/15 at 12:30 PM revealed there was one medication cabinet	A1270		

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A1270	Continued From page 4 hanging on the wall located in the ultra sound room. This cabinet was locked and contained 32 vials of Midazolam (schedule IV controlled substance), and 150 ampules of Fentanyl (schedule II controlled substance). Review of the spread sheet on the computer used for tracking Midazolam and Fentanyl revealed that a daily am (morning/beginning of shift) and PM (evening/end of shift) count was not performed and documented by two licensed staff for these two (Midazolam and Fentanyl) controlled substances. Interview of Staff 7 on 10/15/15 at 1:00 PM revealed that at the beginning of the week one registered nurse (RN) counts the Midazolam and Fentanyl. The RN documents these counts on a scrap piece of paper, and gives it to Staff 7 for review. The Medical Assistant (MA) reviews the patient chart, and records the amount of a controlled substance (Midazolam and Fentanyl) given to the patient on the spread sheet on the computer. Then, on a weekly basis, Staff 7 compares the count documented on the scrap paper by the RN to the spread sheet on the computer for accuracy of the controlled substance count. The scrap paper is then discarded. The total amount of each controlled substance medication must be counted, documented, and signed by two licensed health care providers at the facility twice daily (am/beginning of shift and PM/end of shift) whenever those medications are accessed. This count must be performed before the first patient of the day receives any of the controlled medication, and after the last patient of the day receives any of the controlled medication.	A1270		

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A9999	Continued From page 5	A9999		
A9999	Final Comments An exit conference was conducted with the administrator on October 15, 2015. The survey findings were reviewed. The facility staff was directed to submit a written plan of correction in response to the 2567 form and following the attached guidelines, within ten days. Failure to submit an acceptable plan of correction may result in revocation of license from the Surgical Abortion Facilities program.	A9999		