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

Administrator
Germantown Reproductive Health Services
13233 Executive Park Terrace
Germantown, MD 20874

RE: NOTICE OF CURRENT DEFICIENCIES

Dear

On Febraury 11, 12 and 13, 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/rc

Barbara Fagan
Program Manager

Enclosures: State Form

cc: License 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
	SA000001	A. BUILDING: _____ B. WING _____	02/13/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
GERMANTOWN REPRODUCTIVE HEALTH SEF	13233 EXECUTIVE PARK TERRACE GERMANTOWN, MD 20874

(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 survey of Germantown Reproductive Health Services was conducted on February 11, 12 and 13, 2013. 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 three procedure rooms. A total of ten patient clinical records were reviewed. The procedures were performed between July 2012 and January 2013.	A 000		
A 420	.05 (A)(1)(e)(i) .05 Administration (e) Ensuring that all personnel: (i) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties, including proper infection control practices; This Regulation is not met as evidenced by: Based on interview of the Medical Director, review of the policy and procedure manual and review of staff personnel and training files, it was determined that the administrator failed to ensure the nursing staff had experience and training sufficient to demonstrate competency in the administration and monitoring of intravenous (I.V.) sedation medications. The findings include: Interview of the Medical Director on 2/12/13 at 10:30 am revealed that he and the staff RNs (Registered Nurses) administer I.V. sedation medications to patients receiving surgical	A 420	All registered nurses working with sedation patients will be taking an online course ensuring they are competent in administering and monitoring patients under sedation. RN's only perform this function under the direct supervision of the medical director. This will be completed and documented by June 1st 2013.	

OHCQ

Clinic Administrator 04-23-13
TITLE (X6) DATE

LABORATORY DIRECTOR'S OR PR([illegible]VE'S SIGNATURE

STATE FORM 6899 UZEY11 If continuation sheet 1 of 8

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A 420	Continued From page 1 abortion procedures. These medications include Versed, Fentanyl and Valium. Review of the policy and procedure manual revealed, "Preoperative Analgesia and Sedation: Patients at Germantown Reproductive Health Services are offered a choice of local anesthesia and twilight (IV) sedation...Personnel and Staffing Guidelines- Nurses: The functions of Nurses at Germantown Reproductive Health Services include: Overseeing the dispensing, drawing and administering of pre-op and post-op medications." Review of staff 2 and 3's personnel and training files on 2/11/13 at 12:00 pm revealed no documented evidence that they had been trained and were competent in the administration and monitoring of I.V. sedation medications.	A 420		
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 professional credentialing files, review of the policy and procedure manual, and interview with the administrator, it was determined that the administrator failed to collect, review, and document data provided by the National Practitioner Data Bank (claims against the physician, dentist, or podiatrist) for one of one physician reviewed. The findings include: Review of Staff #1's credentialing file on 2/11/13 at 11:30 am revealed that the file contained no evidence of documentation of data provided by the National Practitioner Data Bank. Review of the facility's policies and procedures titled "Physicians Qualifications Policy" and "Personnel and Staffing Guidelines- Physicians"	A 790	We submitted an application to the NPDB on on 3-15-13. It was accepted on 4-15-13. We will have a Complete Credentialing file for our Medical Director by June 1st, 2013. This will also be ammended in our policy and procedure manual as a requirement for all physicians employeed at GRHS.	

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A 790	Continued From page 2 revealed the policies and procedures contained no information regarding the collection, review, or documentation of data provided by the National Practitioner Data Bank. Interview of the administrator on 2/12/13 at 10:00 am revealed that she acknowledged that data provided by the National Practitioner Data Bank had not been collected and documented in the physician's credentialing file.	A 790	Please see the enclosed application and acceptance email from NPDB.	
A 810	.06(D)(1) .06 Personnel D. The administrator shall establish a procedure for the biennial reappointment of a physician which includes: (1) An update of the information required in §B of this regulation; and This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, review of the professional credentialing files and interview of the facility's consultant, the administrator failed to establish and implement a procedure for the biennial reappointment of physicians for one of one physician reviewed. The findings include: Review of the facility's policies and procedures titled "Physicians Qualifications Policy" and "Personnel and Staffing Guidelines- Physicians" revealed the policies and procedures contained no information regarding the biennial reappointment of physicians to the facility. Review of Staff #1's credentialing file on 2/11/13 at 11:30 am revealed that the file contained no evidence of documentation that the physician had been appointed to practice at the facility. Interview of the facility's consultant on 2/12/13 at 10:00 am revealed the facility had no policy and	A 810	A ammendment to our policy and procedure manual will require a biennial reappointment of any/all physicians working at GRHS. This will be kept in the physicians file.	

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A 810	Continued From page 3 procedure for the biennial reappointment of physicians to the facility.	A 810		
A 880	.06(E)(1)(a)(i) .06 Personnel (i) A current license or certificate to practice in this State; and This Regulation is not met as evidenced by: Based on review of staff personnel files and interview of Staff #3, the administrator failed to verify staff maintained current Maryland state licensure to practice as an RN (registered nurse) at the facility for one of two staff reviewed. The findings include: Review of Staff 3's personnel file on 2/11/13 at 12:00 pm revealed that her Maryland state RN license expired 1/28/12. Interview of Staff #3 on 2/13/13 at 11:45 am revealed that she is aware that her RN license expired 1/28/12 and she is currently filling out an application for the Maryland Board of Nursing to get her RN license renewal. Staff # 3 stated she had done mostly administrative work (not requiring an RN license) at the facility since her RN license expired. However, she has done some work requiring an RN license at the facility, including medication management.	A 880	It is the respansibility of the clinic administrator to ensure all staff licenses are current. A spread sheet was created to identify license renewals by the month so none are missed in the future. Please see the renewed license, for staff #3.	
A 980	.07(B)(6) .07 Surgical Abortion Services (6) Emergency services; This Regulation is not met as evidenced by: Based on review of the policy and procedure	A 980	An addition to our training portion of our policy and procedures will include documentation of staff training of emergency transfer protocol. This change will be	

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A 980	Continued From page 4 manual, review of staff training records and interview of the facility's consultant, it was determined that the facility failed to develop and implement policies and procedures to ensure staff were trained in the emergency transfer of a patient to the hospital from the facility. The findings include: Review of the facility's policies and procedures titled "Patient Transfer Protocol" and "Emergency Crash Cart Protocol" revealed the policies and procedures contained no information regarding the training of staff on the emergency transfer of a patient to the hospital from the facility. Review of Staff #1, 2, 3, 4, 5, 6 and 7's training records revealed no documented evidence that they were trained on the emergency transfer of a patient to the hospital from the facility. Interview of the facility's consultant on 2/12/13 at 10:00 am revealed the staff were not trained on the emergency transfer of a patient to the hospital from the facility.	A 980	effective by June 1st 2013. An overview with staff during a staff meeting was done on 2-11-13 and documented.	
A1280	.11 (B)(1) .11 Pharmaceutical Services B. Administration of Drugs. (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice. This Regulation is not met as evidenced by: Based on an observational tour of the facility and interview of Staff #3, it was determined that the agency staff failed to appropriately use single-dose medication vials, and failed to label pre-drawn medication syringes. The findings include: 1. During a tour on 2/12/13 at 1:30 pm, eight	A1280	We are no longer ordering the 50ml SDV. We have switched to the 5ML and 10ML SDV to be used on only 1 pt. We have a protocol in Place that states: medications drawn must have medication name, and date drawn. When a identifier	

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A1280	Continued From page 5 pre-drawn syringes of Versed mixed with Fentanyl (medications used for I.V. sedation) were observed in a locked cabinet. The syringes each contained a total of 4 milliliters of medication in them. Also in the locked cabinet was an unopened 50 milliliter single dose vial of Fentanyl. Interview of Staff #3 on 2/12/13 at 1:30 pm revealed that 50 milliliter single dose vials of Fentanyl are used to pre-draw the syringes of Versed mixed with Fentanyl. If any Fentanyl remains in the 50 milliliter single dose vial after the desired number of pre-drawn syringes are prepared, the date that the vial was opened and used is documented on the vial, and the vial is used for up to 28 days after it is opened and used. Single dose medication vials may only be used with one needle, and for one patient. After one time use, the single dose medication vial must be discarded. It may not be used as a multidose medication vial. 2. During a tour on 2/12/13 at 1:30 pm, one pre-drawn syringe was observed in a locked cabinet. The syringe contained clear liquid, and was labeled, "2/11/13." However, there was no other information documented (labeled) on the syringe in order to know the name, dose, and expiration of the medication. Interview of Staff #3 on 2/12/13 at 1:30 pm revealed that she acknowledged that the syringe was not adequately labeled.	A1280	is left off the syringe it must be thrown out. Staff retraining will include medication drawing and dosage performed and documented by June 1st 2013.	
A1430	.13 (B)(5) .13 Medical Records (5) Discharge diagnosis. This Regulation is not met as evidenced by: Based on patient medical record review and	A1430	A change was made to our pt health history / AB notes packet, to include a discharge diagnosis on 03-05-13. All pt charts after this date have a discharge diagnosis. Please see included pt hx packet (Highlighted area).	

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A1430	Continued From page 6 interview of the administrator, the administrator failed to ensure that the patient's medical records included a discharge diagnosis for ten of ten patient records reviewed. The findings include: Review of Patients A, B, C, D, E, F, G, H, I and J's medical records revealed there was no evidence that a discharge diagnosis was documented in the medical records. Interview of the administrator on 2/12/13 at 10:00 am confirmed that a discharge diagnosis was not documented in the patient medical records.	A1430		
A1510	.15 (A) .15 Physical Environment A. The administrator shall ensure that the facility has a safe, functional, and sanitary environment for the provision of surgical services. This Regulation is not met as evidenced by: Based on observation of surgical instrument reprocessing and interview of Staff #3, it was determined that the administrator failed to ensure adequate surgical instrument reprocessing in order to maintain a sanitary environment for the provision of surgical services. The findings include: Observation of surgical instrument reprocessing on 2/13/13 at 2:00 pm revealed that dirty surgical instruments were placed in a covered bin in the procedure room and carried to the reprocessing room to be cleaned and sterilized. Interview of Staff #3 on 2/13/13 at 2:00 pm revealed that the dirty surgical instruments first soak for 10 minutes in the bin containing a solution of 1 part bleach and 10 parts water. The instruments are then cleaned in the sink with brushes using dish soap and water. Then, the	A1510	We are now using Cavicide 1 as an enzymatic cleaner during step 2 of our 3part cleaning process. While researching enzymatic cleaners we found Cavicide 1 best ~~meant~~ fit our needs within the ERA guidelines. Please see our 3 Step Cleaning protocol.	

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A1510	Continued From page 7 instruments are rinsed with water, dried, and prepared to be sterilized in the autoclave machine (machine used to sterilize surgical instruments). Staff #3 was unaware that dirty surgical instruments may not be pre-cleaned with bleach, water and dish soap. Dirty surgical instruments must be pre-cleaned with an enzymatic cleaner prior to putting them in the autoclave machine.	A1510		

Germantown Reproductive Health Services Plan of Correction ID # SA000001

A420

During our clinic inspection the Clinic Administrator failed to have our staff RN's properly trained in sedation administration and monitoring. A new policy of GRHS is to have all Registered Nurses take an online course in sedation, which will be documented and placed in the employees file. Our RN's only perform this function under direct supervision of the Medical Director at all times and we feel this has had no negative impact on patients but understand how this training is a useful tool to ensure patient safety. We are currently still looking for a course acceptable by the State of Maryland but it will be completed and documented by June 1st, 2013. It will be the responsibility of the Medical Director to decide which course will be taken. It is the responsibility of the Clinic Administrator to ensure this documentation is the employees file.

A790

GRHS 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 April 15th, 2013. 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.

A810

GRHS failed to reappoint our Medical Director and/or Physicians. We found this deficiency has had not had a negative impact on the care of our patients but understand this is a good time to be able to evaluate our physicians to ensure they are meeting the standards set forth by GRHS. We have amended our policy and procedure manual under "Personnel and Staffing Guidelines" to include biannual reappointment of all Medical Directors and/or Physicians employed at GRHS. It is the responsibility of the Clinic Administrator and Clinic Director to review and reappoint if deemed appropriate. An initial appointment of our current Medical Director will be on file by June 1st, 2013.

A880

It is the responsibility of the Clinic Administrator to ensure that all staff licenses are current and on file. We failed to have a current license for Staff #3 in her employee file. To ensure this doesn't happen again a spreadsheet was created with all employee license renewal dates in one location so nobody is

over looked again. We found this had no negative impact on patients since staff #3 worked only under the direct supervision of the physician and works mainly part time administratively. All staff licenses are current and in each employees file as of March 1st, 2013.

A980

The Crash Cart Protocol and the Emergency Transport Protocol in our policy and procedure manual were incomplete during our state inspection. We failed to outline how often training our staff to be proficient in performing these emergency protocols would take place and document the training in the employee files. We will amend our protocols to list the Medical Director as the person responsible for the training of these protocols. We will amend our protocols to list the Clinic Administrator as the person responsible to ensure the training would take place upon hiring of a staff member and annually thereafter. This shall be done with other training assessments on the anniversary of the employees start date, documented and placed in the employee's file. We have found that this deficiency hasn't negatively affected patients. We understand this is to the benefit of GRHS to have appropriate training and documentation of training to ensure staff is proficient in handling and emergency for the safety of patients. These protocols will be amended and complete training will be in place by June 1st, 2013.

A1280

During our inspection we became aware that the 50ml bottles of Fentanyl in use at the clinic we single dose vials. This error was an oversight since a 50ml bottle of Fentanyl could not be completely used on one patient it was not believed to be a single dose vial. When the inspector brought this to our attention we immediately informed the physician. When contacting our supplier to rectify the error we found the best way was to order 5ml and 10ml single dose vials use on one patient and discard the remaining Fentanyl. We have no knowledge of this negatively affecting any of our patients. In addition to our narcotics logs which list every patient seen that receives sedation, which medication, how much is used, and running totals by week, we have notated on our intake sheets if it is a single dose vial or a multi dose vial. It is the responsibility of the Registered Nurse to check in narcotics, keep running totals, draw, and label all narcotics. Our Drawn Medication Protocol requires the name, dose, and date drawn on all syringes. Staff #3 failed to properly follow our protocol which required several syringes to be thrown away. It is the policy of GRHS to immediately throw away any medication that is inadequately labeled. Retraining the Registered Nurses on medication protocols is the responsibility of the Medical Director. This is part of the staff assessments and retraining will be completed and documented by June 1st, 2013. A staff meeting was held on February 12th, 2013 to discuss proper medication drawing. We found that the mislabeled medication had no impact on patients since it was thrown away before it could be used.

A1430

GRHS failed to include a discharge diagnosis as part of our physician's notes following medical treatment. While a discharge diagnosis was not notated we do have recovery room discharge findings which document; vitals, bleeding, pain level, laps walked (up and ambulatory), mandatory recovery times, etc. We find that not having a discharge diagnosis did not negatively affect our patients. We

added discharge diagnosis on our physician's findings portion of our paperwork on March 1st, 2013. All patients' charts beyond that day will have a completed discharge diagnosis. Our recovery room protocol will be amended to include a mandatory discharge diagnosis on all patients seen at GRHS by June 1st, 2013.

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May 7, 2013

Germantown Reproductive Health Services
13233 Executive Park Terrace
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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 13, 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