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 SER	13233 EXECUTIVE PARK TERRACE GERMANTOWN, MD 20874

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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		

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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	A 790		

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A 790	Continued From page 2 "Personnel and Staffing Guidelines- Physicians" 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		
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.	A 810		

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A 810	Continued From page 3 Interview of the facility's consultant on 2/12/13 at 10:00 am revealed the facility had no policy and 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		
A 980	.07(B)(6) .07 Surgical Abortion Services (6) Emergency services;	A 980		

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A 980	Continued From page 4 This Regulation is not met as evidenced by: Based on review of the policy and procedure 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		
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	A1280		

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A1280	Continued From page 5 include: 1. During a tour on 2/12/13 at 1:30 pm, eight 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		
A1430	.13 (B)(5) .13 Medical Records (5) Discharge diagnosis.	A1430		

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A1430	Continued From page 6 This Regulation is not met as evidenced by: Based on patient medical record review and 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	A1510		

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A1510	Continued From page 7 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 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		
A9999	Final Comments An exit conference was conducted with administrative staff on February 13, 2013. The survey findings were reviewed. The facility was directed to submit a written plan of correction in response to the Maryland State 767 form and following the attached guidelines, within ten days. Failure to submit an acceptable plan of correction may result in decertification from the Surgical Abortion Facilities program.	A9999		