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
Silver Spring Family Planning
1111 Spring Street, G2
Silver Spring, MD 20910

RE: NOTICE OF CURRENT DEFICIENCIES

Dear

On February 27, 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

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
	SA000010	A. BUILDING: _____ B. WING _____	02/27/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SILVER SPRING FAMILY PLANNING	1111 SPRING STREET, G2 SILVER SPRING, MD 20910

(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 Silver Spring Family Planning was conducted on February 27, 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 two procedure rooms. A total of five patient clinical records were reviewed. The procedures were performed in February 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 I.V. (intravenous) sedation medications for two of two RNs (registered nurses, identified as Staff: #2, and 3) reviewed. The findings include: Interview of the Medical Director on 2/27/13 at	A 420		

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A 420	Continued From page 1 Interview of the Medical Director on 2/27/13 at 9:30 am revealed that the staff RNs administers I.V. sedation medications to patients receiving surgical abortion procedures. These medications include Versed, Fentanyl and Valium. Review of the policy and procedure manual revealed, "Roles and responsibilities for Registered Nurses: To administer oral and intravenous medication preoperatively intraoperative and postoperatively as indicated by physician orders. Review of staff #2 and 3's personnel and training files on 2/27/13 at 11:00 am 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 610	.05(C)(6) .05 Administration (6) Pertinent safety practices, including the control of fire and mechanical hazards; This Regulation is not met as evidenced by: Based on review of the policy and procedure manual and interview of the medical director, it was determined that the administrator failed to develop policies and procedures for fire safety in the facility. The findings include: Review of the policy and procedure manual on 2/27/13 revealed it contained information from OSHA (Occupational Safety and Health Administration) regarding fire prevention plans. However, there were no policies and procedures for a fire prevention plan specific to the facility. Interview of the medical director on 2/27/13 at 1:00 pm revealed that policies and procedures for a fire plan specific to the facility had not been	A 610		

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A 610	Continued From page 2 developed.	A 610		
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 2/27/13 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 procedure manual revealed no policies and procedures regarding the collection, review, or documentation of data provided by the National Practitioner Data Bank. Interview of the medical director on 2/27/13 at 1:00 pm revealed that he 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	A 810		

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A 810	Continued From page 3 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 medical director, it was determined that the administrator failed to establish and implement a procedure for the biennial reappointment of physicians for one of one physician's reviewed. The findings include: Review of the facility's policies and procedure manual revealed no policies and procedures regarding the biennial reappointment of physicians to the facility. Review of Staff #1's credentialing file on 2/27/13 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 medical director on 2/27/13 at 1:00 pm revealed the facility had no policy and procedure for the biennial reappointment of physicians to the facility.	A 810		
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 manual, review of staff training records and interview of the medical director, it was determined that the administrator failed to develop and implement policies and procedures to ensure staff were trained in the emergency	A 980		

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A 980	Continued From page 4 transfer of a patient to the hospital from the facility for seven of seven staff reviewed. The findings include: Review of the facility's policy and procedure manual revealed no policies and procedures 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 on 2/27/13 at 11:00 am revealed no documented evidence that they were trained on the emergency transfer of a patient to the hospital from the facility. Interview of the medical director on 2/27/13 at 1:00 pm revealed the staff were not trained on the emergency transfer of a patient to the hospital from the facility.	A 980		
A1000	.07(B)(8) .07 Surgical Abortion Services (8) Safety. This Regulation is not met as evidenced by: Based on a tour of the facility and interview of the medical director, it was determined that the administrator failed to implement their policy on emergency equipment to ensure patient safety. The findings include: A tour of the facility on 2/27/13 at 1:30 pm revealed that the suction equipment used to clear a patient's airway did not have an inspection/maintenance sticker on it. Preventative maintenance is required on all electrical medical equipment to ensure the equipment is operational, calibrated and safe.	A1000		

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A1000	Continued From page 5 Interview of the medical director on 2/27/13 at 1:30 pm revealed that the company, Med Electronics, performs preventative maintenance on all the electrical medical equipment in the facility on a biannual basis. The medical director acknowledged that preventative maintenance had not been performed on the suction equipment.	A1000		
A1490	.14 (A) .14 Patients' Rights and Responsibilities The administrator shall ensure that the facility develops and implements written policies and procedures concerning patients ' rights and responsibilities, including but not limited to: A. The opportunity to participate in planning their medical treatment; and This Regulation is not met as evidenced by: Based on review of the policy and procedure manual and interview of the medical director, it was determined that the administrator failed to develop and implement policies and procedures regarding patient rights, including the right of the patient to participate in planning their medical treatment. The findings include: Review of the policy and procedure manual revealed there were no policies and procedures regarding patient rights. Interview of the medical director on 2/27/13 at 1:00 pm revealed that he acknowledged that policies and procedures on patient rights were not developed.	A1490		
A1500	.14 (B) .14 Patients' Rights and Responsibilities B. Confidentiality of medical records and the right to approve or refuse release of records to any	A1500		

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A1500	Continued From page 6 individual outside the facility, except as provided by federal or State law. This Regulation is not met as evidenced by: Based on review of the policy and procedure manual and interview of the medical director, it was determined that the administrator failed to develop and implement policies and procedures regarding patient rights, including the confidentiality of medical records, and the right to approve or refuse release of records. The findings include: Review of the policy and procedure manual revealed there were no policies and procedures regarding patient rights. Interview of the medical director on 2/27/13 at 1:00 pm revealed that he acknowledged that policies and procedures on patient rights were not developed.	A1500		

We reviewed your report following your site visit and survey. Below please find our Plan of Correction for addressing the deficiencies found during your visit. A review of our records found no patients adversely affected by these deficiencies. It is our intention to have these deficiencies rectified in a timely fashion. Our quality assurance program will include a periodic review of files to ensure continued compliance with COMAR 10.12.01

A420 In accordance with .05 (A)(1)(e)(i).05. The Medical Director will perform training on conscious sedation. Training will include a presentation on the levels of sedation, the side effects of sedative agents including benzodiazepines and narcotics, reversal agents, monitoring, drug interactions, complications and the management of complications. This in-service will be conducted on an annual basis. All relevant employee files will be updated to include documentation of training. This training will be completed by May 31 2013

A610 Our facility will institute a fire prevention plan in accordance with OSHA regulations including site specific information. Employees will receive online training by PROCPR (accredited we will also perform fire drills on a biannual basis. Training is scheduled to be completed by May 1st 2013. Employee files will be updated to include documentation of training and relevant certificates.

An appointment has been scheduled to have Medtronic inspect and maintain the suction machine in accordance with regulation .07 (b) .07 (8). This will be completed on April 16th 2013.

Employees will review our protocol for the transfer of patients to hospital, including notification of hospital staff, activating Emergency Medical Service, arranging transport ambulance services preparation of patient records and the safe transfer of patient to care to Paramedic staff. Training will begin immediately and be completed by April 8, 2013.Employee files will be updated to include documentation of training.

A810 / A1000 A Policy for credentialing of physicians including the medical director will be instituted. This will include a review National Practitioner Data Bank information, a period of direct observation, and review application/reappointment questionnaire. Initial credentialing will be done for new physicians at time of hire then on a biannual basis. Credentialing will be procedure specific. The policy will be instituted effective immediately. A copy of the credentialing report including the National

Practitioner Data Bank report will be kept on file. This policy will be instituted immediately and files will be updated by May 31 2013

A1490 / A1500 Open review of the Policies and Procedures Manual we have realized that information and a consent addressing patient's rights and responsibilities were not present

. We have now developed an information sheet and consent to address this. The Patient counseling process will be updated to include information and consents regarding patient's rights and responsibilities. A signed consent will be obtained and kept as a part of patients records. This will be updated effective May 1st 2013.

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May 3, 2013

Silver Spring Family Planning
1111 Spring Street, G2
Silver Spring MD 20910

RE: ACCEPTABLE PLAN OF CORRECTION

Dear

We have reviewed and accepted the Plan of Correction submitted as a result of a initial survey completed at your facility on February 27, 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