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
Potomac Family Planning Center
966 Hungerford Drive, #24
Rockville, MD 20850

RE: NOTICE OF CURRENT DEFICIENCIES

Dear

On February 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 /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
	SA000011	A. BUILDING: _____ B. WING _____	02/13/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
POTOMAC FAMILY PLANNING CENTER	966 HUNGERFORD DRIVE, #24 ROCKVILLE, MD 20850

(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 Potomac Family Planning Center was conducted on February 13, 2013. The facility includes two procedure rooms . The survey included: an on-site visit; an observational tour of the physical environment; observation of one surgical procedures; observation of the instrument cleaning/sterilization process; interview of the administrator, registered nurse, medical assistants and physician; review of the policy and procedure manual; review of the personnel files; review of quality assurance and review of professional credentialing. A total of four clinical records were reviewed. The surgical procedures that had been performed between December 2012 and February 2013 were reviewed.	A 000	RECEIVED APR 16 2013 Office of Health Care Quality	
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 interview of the administrator, review of the policy and procedure manual it was determined that the administrator failed to develop a policy and procedure for safety practices. The findings include. Review of the policy and procedure manual on February 13, 2013 revealed that the administrator failed to develop a policy and procedure for patient safety practices that include the control of fire and mechanical hazards. Interview of the administrator (Staff: J) on February 13, 2013 at 4:30 PM revealed the	A 610	Fire Emergency, Power Failure and Disabled Physician (attachments 1, 2, 3) protocols are located in the policy manual under the "Emergency". The facility will conduct a fire drill bi-annually This corrective action will promote action will promote the the safety of patients, guests and staff. The fire drill will be a QA study for Q13.	04/15/13

OHCQ

TITLE (X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Office of Health Care Quality

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A 610	Continued From page 1 manager did not know that the policies had not been 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 for physicians and surgeons and interview of the administrator, it was determined that two of three physician credentialing files reviewed were incomplete and did not contain National Practitioner Data Bank information. The findings include: Review of physician's B and C's credentialing files revealed the file did not include information from the National Practitioner Data Bank regarding claims against physicians. Interview of the administrator (J) on February 13, 2013 at 4:30 PM revealed, the manager was not aware that the items were missing from the files.	A 790	Dr. A and Dr. C (attached) had National Practioner data bank (NPDB) information in their file Dr. B had a claims history report from Medical Mutual Liability Insurance Society of Maryland. Dr. B will apply to NPDB for claims history report, which will be entered in the doctor's file upon receipt. The administrator will replace the claims history report from Medical Mutual Liability Insurance Society of Maryland with the NPDB report as part of the physician's credentialing process.	05/15/13
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 individual outside the facility, except as provided by federal or State law. This Regulation is not met as evidenced by: Based on a tour of the center and interview of the administrator, it was determined that the administrator failed to protect the clinical record information from loss or misuse. The findings	A1500	To protect the confidentiality of every patient with a medical record, the recovery room file cabinet will be kept locked at all times. The files in the upstairs storage area will be placed in a locked closet. Meanwhile a carpenter will build a permanent locked enclosure to secure medical records.	4/19/13 04/15/13 06/30/13

Office of Health Care Quality

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A1500	Continued From page 2 include: During a tour of the recovery room on February 13, 2013 at 10:50 AM revealed that the top of an unlocked two draw file cabinet located inside the recovery room contained patient medical records. Interview of the registered nurse (L) revealed that the file cabinet is "never locked." During a tour of the upstairs storage area on February 13, 2013 at 1:35 PM revealed the storage area is accessed from downstairs by back stair steps that lead directly into the storage area. The door to the area is kept open with a box filled with magazines. There are fifteen unsecured boxes of medical records. The boxes are labeled 2011 and 2012. During a tour of the reception area on February 13, 2013 at 2 PM revealed that active patient medical records are stored in file cabinets in the reception area. Interview of the administrator (J) on February 13, 2013 at 4 PM revealed that the medical records in all of the storage areas are not locked or secured. There is a private cleaning company that comes in after hours on Saturdays when no staff are present in the center. The failure to safeguard medical records placed the patient's confidential medical information at risk for loss and misuse.	A1500	Current patient records are stored in the small reception office located off the front reception area. Although the office door has a lock, the sliding glass window does not. A locksmith will secure the window and the office door will be closed and locked each day to protect medical records. The office cleaning has been for many years by two employees; (Staff G and another employee, both of whom have signed confidentiality agreements. However, the aforementioned security measures should satisfy this deficiency.	05/30/13
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:	A1510	It has been the policy to use external indicator tape on every package for autoclaving. Indicator Indicator strips have been ordered and will be used in every package, therefore offering further protection to patients.	05/01/13

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A1510	Continued From page 3 Based on interview of the administrator and medical assistant and observations, it was determined that the administrator failed to implement infection control policies and failed to ensure that measures to prevent infection were practiced at the facility. These measures included failure to ensure the use of chemical indicators in each sterilized package of sterilized instrument and to maintain a clean environment. The findings include: 1. During a tour on February 13, 2013 at 9:55 AM revealed that one hundred and three peel packs (packages that are sealed and will allow the pack to be peeled open to retrieve the instruments) do not include internal steam indicator strips to ensure sterilization of the surgical instruments. Interview of the medical assistant (staff K) on February 13, 2013 at 10:05 AM revealed that internal indicator strips are not included in the peel packs and the wrapped surgical packs to assure the sterilization of the surgical instruments. The assistant stated that they do not have indicator strips to put inside the packages. Interview of the administrator (staff J) on February 13, 2013 at 4:15 PM revealed the administrator was not aware that chemical indicators needed to be used inside the instrument packets. 2. During a tour on February 13, 2013 at between 9:55 AM and 10:50 AM revealed in procedure rooms one and two there are two sets of window blinds and window ledges. The blinds and ledges have a coating of a white dusty substance. Observation of the recovery room revealed there are five sets of window blinds and window ledges. The blinds and window ledges have a coating of a white dusty substance.	A1510	Blinds will be dusted weekly as part of the cleaning process. Window ledges will be dusted at the end of each procedure day.	05/01/13

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A1510	Continued From page 4 Interview of the administrator (J) on February 13, 2013 at 4:15 PM revealed the administrator was unaware that the blinds and window ledges were dusty.	A1510		

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April 29, 2013

Potomac Family Planning Center
966 Hungerford Drive, #24
Rockville, MD 20850

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 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,

Patricia Tomsko Nay, MD

Patricia Tomsko Nay, M.D. CMD, CHCQM
FAAFP, FAIHQ, FAAHPM
Acting Executive Director and Medical Director