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
Hagerstown Reproductive Health Services
160 W Washington St, Suite 100
Hagerstown, MD 21740

RE: NOTICE OF CURRENT DEFICIENCIES

Dear

On February 28, 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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	SA000014	A. BUILDING _____ B. WING _____	02/28/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HAGERSTOWN REPRODUCTIVE HEALTH SER	160 W WASHINGTON ST, SUITE 100 HAGERSTOWN, MD 21740

(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 Hagerstown Reproductive Health Services was conducted on February 28, 2013. 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 facility's administrator, technician's, registered nurses and physician; review of the policy and procedure manual; review of the personnel files; review of quality assurance and review of professional credentialing. The facility includes two procedure rooms. A total of five clinical records were reviewed. The surgical procedures that had been performed September 2012 and February 2013 were reviewed.			
A1250	.10 (B)(5) .10 Hospitalization (5) Appropriate training for staff in the facility 's written protocols and procedures. This Regulation is not met as evidenced by: Based on interview of the administrator and review of personnel files, it was determined that the administrator failed to provide emergency training for patient transfers to the hospital for five of five employees. The findings include. Review of personnel files for staff members C, D, E, F, and G revealed that there is no documentary evidence that the members received training for emergency patient transfer's to the hospital.	A1250	The failure was corrected soon after the survey was done. A training format was developed and took place Thursday, March 14, 2013. The record for each employee's participation is included in that employee's personnel file (a sample is attached). Two employees were unable to be present that day so, upon the return of one of them, an individualized training was held March 23, 2013. A single employee remains who has not yet participated. She has not worked since February (for medical reasons). When she returns, she, too, will be trained. For this reason only, final completion cannot be assured until 5/1/2013. Going forward, this training will be updated as needed and conducted annually. It is understood that this training is only one part of the total preparation necessary to handle an emergency optimally. Additional elements include CPR certification and recertification, routine skills updates, appropriate management of medications and equipment maintenance and QA for all of it. Prior to our training, theoretical harm existed for all patients because the training had not been performed. However, we believe no actual harm came to any patient. A hospital transfer has not occurred for more than a decade. Current patients are unaffected because the Failure was rectified shortly after the survey was completed.	5-1-13

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APR 15 2013
Office of Health Care Quality

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ABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: Administrator | (X6) DATE: 4-11-13

TATE FORM 6899 KXBX11 If continuation sheet 1 of 2

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A1250	Continued From page 1 Interview of the administrator (H) on February 28, 2013 at 12:30 PM revealed the administrator acknowledged that no training had been provided. 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 interview of the administrator 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. The findings include. During a tour on February 28, 2013 between 10:45 AM and 11:25 AM observation revealed that eighty-two peel packs (surgical instrument packs that peel open) do not include internal steam indicator strips to ensure sterilization of the surgical instruments. Interview of the administrator (staff H) on February 28, 2013 at 5:15 PM revealed that the administrator was not aware that internal indicator strips were needed in the surgical packs to assure the sterilization of the surgical instruments.	A1510	This failure was discussed the day of the survey. Immediately following, indicator strips were placed in ALL newly packaged surgical instruments. On 3/11/2013, a total re-evaluation of instruments maintained in the surgery rooms was initiated to more effectively reflect numbers and types of instruments routinely used and to more easily observe and track expiration of sterility. This process resulted in the removal and relocation of surplus instruments (nearly half of the former supply!). The remaining instruments were removed from their packaging, washed and repackaged with chemical indicator strips visibly placed inside each of them. Each was then labeled to show the operator of the sterilizer, which sterilizer was used, the date sterilization was done and the date it will expire (need to be re-done). In order to ensure this procedure is consistently followed (that quality is retained in this area of our operation) periodic training for autoclave procedures now includes this additional, specific instruction. Additionally, surgery assistants have been instructed to verify that the chemical strips are in place, that color has changed appropriately when stocking these instruments and to never offer an instrument to the physician if the strip is absent or if its color change doesn't indicate sterility. Prior to this correction, harm (infection risk) may have occurred to patients whose treatment required the use of these packaged instruments. We were unable to trace any specific incident of harm to this failure. No current threat exists.	3/11/13

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April 29, 2013

Hagerstown Reproductive Health Services
160 W Washington St, Suite 100
Hagerstown, MD 21740

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 28, 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, CMD, CHCQM,
FAAFP, FAIHQ, FAAHPM
Acting Executive Director and Medical Director

cc: License File