



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

Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

August 20, 2015

Whole Woman's Health of Baltimore

7648 Belair Road

Baltimore MD 21236

Dear

Enclosed is a list of State deficiencies resulting from a relicensure survey that was completed at your facility on July 27, 2015.

Please note that an Acceptable Plan of Correction (POC) for the identified deficiencies must include the following information:

- 1. State how the management team will evaluate the scope of each deficiency cited.**
- 2. State what process changes the management team will make to correct each specific deficiency identified.**
- 3. Define the projected time line for each step in the corrective action plan for each deficiency cited.**
- 4. Define the projected completion date for each deficiency cited.**
- 5. Identify who will be responsible for assuring each step in the plan of correction is implemented.**
- 6. State what specific quality indicators that the management team will monitor and evaluate the effectiveness of the corrective actions.**
- 7. Define what will be the on-going schedule of the quality monitoring activities for each deficiency cited.**

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IT IS IMPERATIVE THAT YOUR POC CONTAIN THE ABOVE COMPONENTS.

Please complete Forms CMS 2567 as follows:

- 1. Use the official form provided to you for your response.**
- 2. Your Plan of Correction must be entered in the appropriate column on the right.**
- 3. An authorized representative of your facility must sign and date the form in the designated space provided.**

PLEASE RETURN COMPLETED CMS 2567:

**Barbara Fagan, Program Manager
Ambulatory Care Programs
Office of Health Care Quality
Spring Grove Center
Bland Bryant Building
55 Wade Avenue
Catonsville, Maryland 21228**

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. Tricia Nay, 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.

Please submit a Plan of Correction within 10 calendar days of receipt of this letter. Please be advised that failure to submit an acceptable POC could result in a recommendation to terminate your facility from the Medicare program.

If you have any questions regarding these instructions, please call the undersigned at (410) 402-8040.

Sincerely,



**Barbara Fagan
Program Manager
Ambulatory Care
Office of Health Care Quality**

Office of Health Care Quality

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: SA000003	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/27/2015
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NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BALTIMORE, L	STREET ADDRESS, CITY, STATE, ZIP CODE 7648 BELAIR ROAD BALTIMORE, MD 21236
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(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
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A 000	<p>Initial Comments</p> <p>A relicensure survey of Whole Woman's Health of Baltimore was conducted on July 17 and 27, 2015.</p> <p>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.</p> <p>The facility included two procedure rooms.</p> <p>A total of five patient clinical records were reviewed. The procedures were performed between March 2014 and May 2015.</p> <p>A key code for the patients and staff was provided to the facility.</p> <p>Findings in this report are based on data present at the time of review. The agency's staff was kept informed of the survey findings as the survey progressed. The agency staff was given the opportunity to present information relative to the findings during the course of the survey.</p>	A 000	<p>SEP - 1 2015</p> <p>Office of Health Care Quality</p>	
A 380	<p>.05 (A)(1)(a) .05 Administration</p> <p>(a) Consulting with the staff to develop and implement the facility's policies and procedures in accordance with §C of this regulation;</p> <p>This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, review of staff credentialing files and</p>	A 380	<p>The Clinic Administrator will be responsible for ensuring the clinic's policies and procedures are enforced and followed accurately.</p>	09/02/15

OHCC LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE <i>administrator</i>	(X6) DATE <i>8/26/15</i>
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A 380	<p>Continued From page 1</p> <p>interview of Staff 11, Hepatitis B immunization were not implemented for four of ten staff reviewed.</p> <p>Staff: 1, 2, 3, 4</p> <p>The findings include:</p> <p>Review of the policy and procedure manual revealed, "In accordance with OSHA regulations, Whole Woman's Health will provide employees at risk for exposure with HBV (Hepatitis B) vaccinations, at no charge to them. While it is not mandatory that all employees participate in the free vaccination program, it is our policy that all are made aware of the HBV vaccine and the benefits of the vaccine. Employees may chose to refuse the vaccination, but they must sign the "Informed Refusal of Hepatitis B Vaccination" form."</p> <p>Review of Staff 1, 2, 3 and 4's credentialing files revealed no documented evidence that they had ever been vaccinated for Hepatitis B, or had been offered the Hepatitis B vaccination by the facility.</p> <p>Interview of Staff 11 on 7/27/15 at 10:00 am revealed that she was unaware that Hepatitis B vaccination was necessary for physicians. Hepatitis B vaccination, or the offering of the Hepatitis B vaccination to staff, is mandatory for all staff who provide clinical care to patients in the facility.</p>	A 380	<p>Whole Woman's Health of Baltimore will provide all employees at risk for exposure to HBV (Hepatitis B) vaccination at no charge to them. All employees will be made aware of the HBV vaccine and the benefits of the vaccine. Employees may choose to refuse the vaccination, but they must sign the "Informed Refusal of Hepatitis B Vaccination" form.</p> <p>Vaccination records for staff 1, 2, and 3 are currently filed in their credentialing files. Staff 4 has chosen to refuse the vaccination and will sign an Informed Refusal of Hepatitis B Vaccination form.</p> <p>The Clinic Administrator will issue a memorandum to all staff at risk for exposure to HBV (Hepatitis B) outlining Whole Woman's Health of Baltimore's policy regarding HBV vaccination in accordance with OSHA regulations.</p>	
A9999	<p>Final Comments</p> <p>An exit conference was conducted with the administrator on July 27, 2015.</p>	A9999	<p>In order to monitor compliance with this requirement, the Clinic Administrator will review all staff's vaccination records on a quarterly basis.</p>	

Office of Health Care Quality

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A9999	Continued From page 2 The survey findings were reviewed. The facility staff was directed to submit a written plan of correction in response to the Maryland State 2567 form and following the attached guidelines, within ten days. Failure to submit an acceptable plan of correction may result in revocation of license from the Surgical Abortion Facilities program.	A9999		