



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

Whole Woman's Health Of Baltimore, LLC

7648 Belair Road

Baltimore, MD 21236

RE: NOTICE OF CURRENT DEFICIENCIES

Dear :

On February 22, 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.

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Web Site: www.dhmh.maryland.gov

- 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
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: SA000003	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/22/2013
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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	Initial Comments An initial survey of Whole Woman's Health was conducted on February 22, 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 administrative coordinator, registered nurse, patient advocates 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 February 2013 were reviewed.	A 000	A1000 The administrator will be responsible for ensuring patient safety measures are strictly followed. The administrator coordinator safely removed and disposed of the sharps containers. New sharps containers were purchased and installed in the post anesthesia recovery room. Training was conducted on 3/1/13 to reeducate staff how to safely use sharps containers according to MOH Standards. No patients were affected by this error. The Administrator will designate a staff member to inspect all sharps containers on a daily basis. In addition to weekly checks the administrator will facilitate MOH training as needed to ensure staff are aware of sharps safety according to safety guidelines the staff member was counseled see	4/14/13
A1000	.07(B)(8) .07 Surgical Abortion Services (8) Safety. This Regulation is not met as evidenced by: Based on interview of the administrative coordinator and tour of the facility, it was determined that the administrator failed to secure the medical waste sharps container and protect the safety of the patients. The findings include: During a tour of the post anesthesia recovery room on February 22, 2013 at 10:50 AM observation revealed, next to two recovery rooms chairs are two tables. On at each of the tables is a sharps container (a hard plastic container that used syringes, needles and medications are disposed in after use). Each container has an	A1000		

OHCQ

LABORATORY DIRECTOR'S OR PROVIDER'S SIGNATURE	REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
			4/11/13

Office of Health Care Quality

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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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A1000	Continued From page 1 opening that can be reached into and the items withdrawn. The lids on both sharps containers were opened. One of the sharps containers was filled past the fill line with the syringes, needles and medication's at the top and easily accessible to the patient's. Interview of the administrative coordinator (staff I) on February 22, 2013 at 4:30 PM revealed, the administrator was not aware that the sharps containers needed to be in a location away from the patients.	A1000	Attached documentation	2/22/13
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 a tour of the facility, interview of the administrative coordinator and the patient advocate, it was determined that the administrator failed to implement their policy and procedures for the use and storage of medications. The findings include. A tour of the facility performed on February 22, 2013 at 11:15 AM revealed in the medication room there were forty-three syringes with five milliliters of a clear liquid solution. The syringes were not labeled. Interview of the patient advocate (staff L) on 2/22/13 at 11:15 AM revealed the patient advocate prepares five syringes a day of 0.9% sodium chloride (point nine per cent, used to dilute or dissolve medications for intramuscular or subcutaneous injection) with five milliliters of the solution. There	A1280	The administrator will be responsible for ensuring proper labeling of medications and/or mixtures. The session runner will verify all drawn medications and/or mixtures are labeled properly at the beginning of every session day. The admin administrator and administrative coordinator conducted training to ensure that all staff understood how to properly draw medications and/or mixtures and properly label them. During the inspection all unmarked syringes	3/1/13

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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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A1280	Continued From page 2 are no labels on the syringes that include the name of the solution, the date drawn, who drew the solution and the expiration date of the solution. Interview of the administrative coordinator (staff I) on February 22, 2013 at 11:15 AM revealed the administrator was not aware that the syringes were not labeled.	A1280	were removed and properly disposed of in accordance with OSHA regulations. New syringes were drawn and properly labeled with name of solution, dosage, staff initials who drew it, and date in which it was drawn. No patients were affected by this error. Retraining of all staff ensured proper drawing methods as well as proper labeling measures. On a weekly basis the Administrator or designee will inspect all mixtures as well as medication syringes to ensure proper labeling. In addition to weekly checks the administrator or designee will facilitate additional training as needed to ensure proper labeling of all syringes within the building. documentation attached for training as well as policy review	



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Martin O'Malley, Governor - Anthony G. Brown, Lt. Governor - Joshua M. Sharfstein M.D., Secretary

April 29, 2013

Whole Woman's Health of Baltimore, LLC
7648 Belair Road
Baltimore, MD 21236

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 22, 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, M.D. CMD, CHCQM
FAAFP, FAIHQ, FAAHPM
Acting Executive Director and Medical Director