



MARYLAND Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Office of Health Care Quality, 55 Wade Avenue, Catonsville, Maryland 21228

November 13, 2018

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

RE: ACCEPTABLE PLAN OF CORRECTION

Dear Administrator:

We have reviewed and accepted the Plan of Correction submitted as a result of a licensure survey completed at your facility on July 11, 2018.

Please be advised that an unannounced follow-up visit may occur prior to the standard survey to ensure continual compliance.

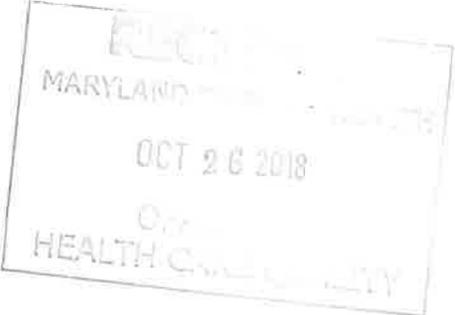
If there are any questions concerning this notice, please contact this Office at 410-402-8055.

Sincerely,

Patricia Tomsko Nay, M.D.

Patricia Tomsko Nay
Executive Director

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 07/11/2018
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BALTIMORE, L		STREET ADDRESS, CITY, STATE, ZIP CODE 7648 BELAIR ROAD BALTIMORE, MD 21236		
(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	<p>Initial Comments</p> <p>A licensure survey of Whole Woman's Health of Baltimore was conducted on July 10 and 11, 2018. An exit interview was conducted on July 11, 2018.</p> <p>The center performs surgical abortion procedures. The facility includes two procedure rooms.</p> <p>The survey included: an on-site visit; an observational tour of the physical environment; observation of the patient laboratory (blood draw) process; observation of patient ultrasound process; observation of patient education process; observation of patient discharge process; observation of hand hygiene; observation of instrument cleaning/sterilization process; interview of the facility's administrator, medical director, registered nurse, counselor's, medical assistants, patient advocates; review of the policy and procedure manual; review of clinical records; review of the personnel files; review of quality assurance and infection control program, and review of professional credentialing.</p> <p>A total of seven patient clinical records were reviewed. The procedures were performed between February 2017 and July 2018.</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. A key code for the patients was provided to the facility at exit.</p>	A000	<p>A000</p> <p>This Plan of Correction is submitted as required under Federal and State regulation and statutes applicable to abortion care providers. This Plan of Correction does not constitute an admission of liability on the part of the Whole Woman's Health of Baltimore, and such liability is hereby specifically denied. The submission of the plan does not constitute an agreement by the facility that the surveyors' findings or conclusions are accurate, that the findings constitute a deficiency, or that the scope or severity regarding any of the deficiencies cited are correctly applied.</p> 	

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

TITLE

(X6) DATE

administrator

10/24/18

Office of Health Care Quality

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A600 Continued From page 1 A 600, .05(C)(5) .05 Administration	<p>(5) Infection control for patients and staff;</p> <p>This Regulation is not met as evidenced by: Based on patient observations, review of infection control training policy, review of staff infection control training and interview of the staff, it was determined that the staff failed to implement infection control policies and failed to ensure that measures to prevent infection were practiced at the facility. These measures included failed to don gloves when cleaning patient equipment and failed to perform hand hygiene.</p> <p>The findings include: Patients: F, G, H, I</p> <p>1. Observation of Patient F's ultrasound on July 11, 2018 at 8:35 AM revealed, the staff member did not perform hand hygiene before donning gloves. The staff member performed the ultrasound, removed the gloves and did not perform hand hygiene. The staff member left the room with the patient Observation of patient F's blood draw on July 11, 2018 at 8:50 AM revealed, the staff member donned gloves without performing hand hygiene. The staff member wiped the patient's finger with an alcohol pledge, pricked the finger and collected the patient's blood on a slide. The staff member then repeated the same blood draw a second time. After the testing the patient's blood for two different tests the staff member disposed of the slides into the medical waste. The staff member documented in the patient's medical record, then cleansed the patient's finger and applied a band-aid. The staff member removed their gloves did not perform hand hygiene and 08</p>	A600 A600	<p>A600 It is the policy of Whole Woman's Health of Baltimore to establish and maintain an infection control policy designed to provide a safe, sanitary patient care, and to help prevent the development and transmission of communicable diseases and infections. It is the policy of Whole Woman's Health of Baltimore to ensure proper handwashing and hand hygiene techniques are being followed at all times. On 08/09/2018 the Clinic Administrator, and Director of Clinical Services reviewed and modified the current infection control policy to include: proper hand hygiene prior to donning gloves, after the removal of gloves, before and after direct patient contact, before and after performing patient examinations, before and after cleaning equipment, before and after contact with blood or bodily fluids, before and after using restroom, before and after eating food. (Attached) On 08/17/2018 the Clinic Administrator started monitoring proper handwashing technique daily during clinical session by having the all staff members peer-partner and demonstrate appropriate handwashing technique for 1 week. The purpose of the monitoring will be to ensure that proper hand hygiene is practiced including hand hygiene pre-donning and post-removal of gloves.</p>	08/16/2018
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A600	Continued From page 2 wiped their hands on their pants. 2. Observation of Patient's G's blood draw on July 11, 2018 at 9:30 AM revealed, the staff member donned gloves without performing hand hygiene. The staff member wiped the patient's finger with an alcohol pledge, pricked the finger and collected the patient's blood on a slide. The staff member then repeated the same blood draw a second time. After the testing the patient's blood for two different tests the staff member disposed of the slides into the medical waste. The staff member documented in the patient's medical record, then cleansed the patient's finger and applied a bandaid. The staff member removed their gloves, performed hand hygiene with hand gel. The staff member did not allow the gel to dry and the staff member wiped their hands dry on their pants. 3. Observation of the staff in the recovery room area on July 11, 2018 at 11:51 AM revealed the staff member donned gloves without performing hand hygiene. The staff member then discontinued Patient I's intravenous port. 4. Observation of the staff in the recovery room area on July 11, 2018 at 12:10 PM revealed the staff member placed a blood pressure cuff on Patient H's upper right arm. After removing the blood pressure cuff the staff member donned a glove on the right hand leaving the left hand ungloved and withdrew a germicidal disposable wipe. The staff kept the wipe in his/her right hand and cleaned the blood pressure cuff while holding the patient use items with the ungloved left hand. The staff transferred the patient used item to the ungloved hand re-contaminating the patient use item. The staff then disposed of the germicidal wipe. The staff failed to follow the manufactures	A600	Continued From page 2: The monitoring will continue until 2 consecutive weeks of zero negative findings is achieved. Afterwards, staff members will be randomly monitored on a weekly basis by the Clinic Administrator for a period of not less than 6 months to ensure ongoing compliance. After that, random monitoring will continue to occur for 12 months. Any infractions observed will be prevented or corrected as observed. The Clinic Administrator completed an in-service on 08/16/2018 for all staff members. The following was reviewed: Hand Hygiene and appropriate use of gloves—to include review of the updated facility handwashing policy and procedure as well as demonstrations completed by staff to ensure all are practicing proper technique. Any staff member who fails to comply with the points of the in-service will be further educated and or progressively disciplined as indicated. At the quarterly QA meetings, the monitoring of handwashing technique and compliance will be reviewed. If necessary, an action plan will be written by the committee. Any written action plan will be monitored by the Clinic Administrator until resolution.		

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A 790	Continued From page 4 The findings include. Review of physician's credentialing files revealed, the files did not include information from the National Practitioner Data Bank regarding claims against physicians. Review of the policies for personnel revealed, "Credentialing and verification: All LIP's (Licensed Independent Practitioner) (as applicable) will be checked against the National Practitioner Data Bank and enrolled in continuous query." Interview of the staff on July 10, 2018 at 2:30 PM revealed, the staff was not aware the National Practitioner Data Bank are missing from the credentialing files.	A790		
A 810 .06(D)(1) .06 Personnel	D. The administrator shall establish a procedure for the biennial reappointment of a physician which includes: (1) An update of the information required in §8 of this regulation; and This Regulation is not met as evidenced by: Based on review of the policies, physician credentialing file and interview of the staff, it was determined that the scope of procedures performed and medical staff privileges were not reappraised by the center staff for three of three files reviewed. The findings include. Review of the agency policy revealed, "The	A810	A810 Whole Woman's Health of Baltimore contracts and employs practitioners who are licensed to practice independently to provide services to patients wishing to receive medical services and treatment. Eligibility for providing patient care is determined by the extent to which the applicant meets defined requirements for education, licensure, board certification, training, clinical experience, and adequate malpractice coverage. Whole Woman's Health of Baltimore initiates credentialing of all practitioners upon employment. The credentialing is a function of the Whole Woman's Health Management Company alongside the Clinic Administrator. Biennial verification of all Primary and Secondary Source requirements is completed. This includes verification of: Verification of DEA certificate, Verification of State License, Review of Malpractice Insurance coverage, Verification of	07/10/2018

Continued A810 from page 5:

State Controlled Substance Registration, Verification of enrollment in continuous query in National Physician Data Bank, Update Curriculum Vitae, Verification of affiliation agreements or admitting privileges with local hospitals, Verification of CPR/ Life support training, update personal contact information, Complete Back up Agreement, Verify CAQH information, Review Photo ID, Review Independent Contractor Agreement, Peer Reviews, and Current Immunizations and PPD status.

Any credentialing deficiencies are addressed by the Clinic Administrator to the Director of Clinical Services, and the practitioner. The practitioner has 7 business days to comply with deficiencies.

On 07/10/2018 the Clinic Administrator, and Director of Clinical Services reviewed and modified the Whole Woman's Health of Baltimore Credentialing policy to include: A biennial review of the practitioner's credentialing documentation by the Clinic Administrator to include documentation of privileges designated by the Medical Director and Chief Executive Officer as well as the scope of procedures that the independent contracted practitioner can provide in accordance with Whole Woman's Health of Baltimore. (Attached)

The Clinic Administrator obtained documentation from the Chief Executive Officer for privileges and scope of procedures on 07/10/2018. A copy of appropriate documentation is located in the providers' files in the Clinic Administrator's office.

The Clinic Administrator will schedule an annual review for each practitioner based on their Independent Contract Anniversary date.

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A1490	Continued From page 6 The findings include. Review of the patient rights statement on July 11, 2018 at 11 AM revealed the statement does not include the patient has the opportunity to participate in planning their medical treatment. Interview of staff on July 11, 2018 at 12 PM revealed that the staff was not aware that the rights statement was incomplete.	A1490		