

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 C 11/16/2021
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BALTIMORE, LLC		STREET ADDRESS, CITY, STATE, ZIP CODE 7648 BELAIR ROAD BALTIMORE, MD 21236		
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A 000	<p>Initial Comments</p> <p>A Maryland state re-licensure survey of Whole Woman's Health of Baltimore was conducted on November 15 and 16, 2021.</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 credentialing 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 January 2021 and October 2021.</p> <p>A key code for the staff and patients was provided to the facility staff.</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		
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 fire drill documentation and</p>	A 380		

OHCQ

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

TITLE

(X6) DATE

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A 380	<p>Continued From page 1</p> <p>interview of staff, the administrator failed to implement the policy and procedure regarding fire drills.</p> <p>The findings include:</p> <p>Review of the policy and procedure manual revealed "Fire Safety: Fire drills will be held regularly and at least annually to ensure that staff understand the proper procedure in case of fire."</p> <p>Review of the fire drill documentation from November 2019 to current revealed that fire drills were not conducted on an annual basis.</p> <p>Interview of staff on 11/15/21 at 12:30 pm revealed that she/he confirmed that fire drills were not conducted on an annual basis.</p>	A 380		
A 420	<p>.05 (A)(1)(e)(i) .05 Administration</p> <p>(e) Ensuring that all personnel: (i) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties, including proper infection control practices;</p> <p>This Regulation is not met as evidenced by: Based on interview of staff, review of the policy and procedure manual and review of staff credentialing files, the administrator failed to ensure that two of two nursing staff had experience and training sufficient to demonstrate competency in the administration and monitoring of I.V. (intravenous) medications used for moderate sedation anesthesia.</p>	A 420		

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A 420	<p>Continued From page 2</p> <p>The findings include:</p> <p>Interview of staff on 11/15/21 at 9:30 am revealed that physicians and the staff RNs (Registered Nurses) administer I.V. medications for moderate sedation anesthesia to patients receiving surgical abortion procedures. These medications include Versed, Fentanyl and Ketamine.</p> <p>Review of the policy and procedure manual revealed "Protocol for Moderate I.V. Sedation: Pre-op IV medications are ordered by the physician. They typically include: Midazolam (Versed), Fentanyl (Duragesic), Nalbuphine (Nubain), or Ketamine (Ketalar). Monitoring of IV moderate sedation is done by a nurse that is present for monitoring only."</p> <p>Review of two staff's credentialing files revealed no documented evidence that they had been trained and were competent in the administration and monitoring of I.V. medications used for moderate sedation anesthesia.</p> <p>Interview of staff on 11/15/21 at 11:40 am revealed that she/he confirmed that there was no documented evidence that the nursing staff had been trained and were competent in the administration and monitoring of I.V. medications used for moderate sedation anesthesia.</p>	A 420		
A 450	<p>.05 (A)(2)(a) .05 Administration</p> <p>(2) The administrator shall ensure that:</p> <p>(a) The facility's policies and procedures as described in §C of this regulation are:</p> <p>(i) Reviewed by staff at least annually and are revised as necessary; and</p> <p>(ii) Available at all times for staff inspection and</p>	A 450		

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A 450	<p>Continued From page 3</p> <p>reference; and</p> <p>This Regulation is not met as evidenced by: Based on a review of the policy and procedure manual and interview of staff, the administrator failed to ensure that the policy and procedure manual was reviewed and revised, as necessary, on an annual basis.</p> <p>The findings include:</p> <p>Review of the policy and procedure manual revealed that it had last been reviewed on 1/3/18.</p> <p>Interview of staff on 11/16/21 at 11:30 am revealed that she/he confirmed that the policy and procedure manual had not been reviewed and revised, as necessary, on an annual basis.</p>	A 450		
A 550	<p>.05(C)(2)(a) .05 Administration</p> <p>(a) Procedures for the accountability of personnel involved in patient care;</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 interview of staff, the administrator failed to implement the policy and procedure regarding staff performance evaluations for two of three staff reviewed.</p> <p>The findings include:</p> <p>Review of the policy and procedure manual revealed "Employee evaluations are done after</p>	A 550		

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A 550	<p>Continued From page 4</p> <p>the probationary period is completed (around 90 days) and at the employee's anniversary of hire date."</p> <p>Review of two staff credentialing files (RNs / Registered Nurses) revealed that their performance evaluations were performed and signed by a medical assistant. Staff performance evaluations must be performed and signed by a staff with equal or greater clinical credentials than the staff being evaluated.</p> <p>Interview of staff on 11/15/21 at 11:40 am revealed that she/he confirmed that the RN's performance evaluations were performed and signed by a medical assistant.</p>	A 550		
A1280	<p>.11 (B)(1) .11 Pharmaceutical Services</p> <p>B. Administration of Drugs.</p> <p>(1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice.</p> <p>This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, a tour of the facility and interview of staff, the agency staff failed to ensure measures for the provision of medications in a safe and secure manner. These measures included securing and accounting for controlled medications, and proper use of single dose vials of medication.</p> <p>The findings include:</p> <p>1. Review of the policy and procedure manual revealed "Controlled medications must be</p>	A1280		

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A1280	<p>Continued From page 5</p> <p>secured behind two locks, i.e. in a safe in a lockable room. Unlicensed Staff with access to these drugs must be trained to the physician's satisfaction, and a record of their training must be kept on file...Controlled medications opening count: Each day, prior to drawing up or administering any medications, two staff will open the safe and count each drug on the Controlled Medication Log...Controlled medications closing count: Each day that controlled medications are administered, at the end of the day, two staff will open the safe and count each drug on the controlled medication log."</p> <p>A tour of the facility revealed that there were two open, unlocked safes located in the medication room. The door to the medication room was locked. Inside the open safes were Midazolam (controlled medication), Fentanyl (controlled medication) and Ketamine (controlled medication). The controlled medications were not stored securely, behind two locks. Additionally, an unlicensed staff unlocked the door to the medication room, and therefore had access to the controlled medications. Review of the "Controlled Medications Log" revealed that the opening count and closing count was performed and documented by two unlicensed staff.</p> <p>Controlled medications must be securely stored behind two locks. Only licensed staff may access controlled medications. The total amount of each controlled medication must be counted, documented, and signed by two licensed health care providers at the facility twice daily (am/beginning of shift and pm/end of shift) whenever those medications are accessed.</p> <p>Interview of staff on 11/15/21 at 10:00 am revealed that she/he confirmed the findings</p>	A1280		

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A1280	<p>Continued From page 6</p> <p>regarding controlled medications.</p> <p>2. During a tour of the facility, the following single dose vials of medication were observed in the medication room:</p> <p>Two vials of Fentanyl were previously opened and some of the medication had been used.</p> <p>Multiple patient use of single dose vials is contradicted by the manufacturer's instructions, and increases the risk of patient infection.</p> <p>Interview of staff on 11/15/21 at 10:00 am revealed that she/he confirmed that the single dose vials of medication should have been discarded after one patient use.</p>	A1280		
A1500	<p>.14 (B) .14 Patients' Rights and Responsibilities</p> <p>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.</p> <p>This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, a tour of the facility and interview of staff, the administrator failed to ensure the confidentiality of the patient's medical records.</p> <p>The findings include:</p> <p>Review of the policy and procedure manual revealed "Whole Woman's Health will ensure that each patient chart is treated with confidentiality."</p> <p>A tour of the facility revealed that there were five</p>	A1500		

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A1500	<p>Continued From page 7</p> <p>open, unsecured cardboard boxes that contained patient medical records, located in the clinic manager's office. The patients' medical records were not kept secure in order to protect patient confidentiality.</p> <p>Interview of staff on 11/15/21 at 10:00 am revealed that the patients' records in cardboard boxes were being gathered to be sent to a storage facility at the end of the year. She/he confirmed that they were not being maintained in a secure, confidential manner.</p>	A1500		