

Office of Health Care Quality

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 21C0001370 | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____ | (X3) DATE SURVEY COMPLETED 07/15/2016 |
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| NAME OF PROVIDER OR SUPPLIER FEMI-CARE SURGERY CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 66 PAINTERS MILL ROAD #106 OWINGS MILLS, MD 21117 |
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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 |
|--------------------|--|---------------|---|--------------------|
| A 000 | <p>Initial Comments</p> <p>A re-licensure survey was conducted on July 12, 13 and 14, 2016 at Femi-Care surgery Center, LLC. An exit interview was conducted on July 15, 2016.</p> <p>The center performs gynecologic surgical procedures. The facility includes one operating room and one procedure room.</p> <p>The survey included: an on-site visit; an observational tour of the physical environment; review of the instrument cleaning/sterilization process; two surgical procedure observations; interview of the physician/owner/infection preventionist, registered nurse and medical assistants; review of patient record forms; policy and procedure manual; quality assurance performance improvement (QAPI) projects; governing body meeting minutes; fire drill and disaster drill documentation; infection control program; admission and clinical record process; one professional credentialing file and nine personnel files.</p> <p>A total of twenty clinical records were reviewed. The surgical procedures that were performed between January 2015 to July 2016 were reviewed.</p> <p>Findings in this report are based on data present in the administrative records at the time of review. The physician/owner was kept informed of the survey findings as the survey progressed. The physician/owner was given the opportunity to present information relative to the findings during the course of the survey.</p> <p>A key code for patients, medical staff and staff</p> | A 000 | | |

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| OHCA LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
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If continuation sheet 1 of 4

Office of Health Care Quality

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| A 000 | Continued From page 1 contained herein was provided to the physician/owner. Femi-Care Surgery Center is not in compliance with the Code of Maryland Annotated Regulations COMAR 10.05.01 and 10.05.05 for Ambulatory Surgical Centers. | A 000 | | |
| A 290 | .06 (A) .06 Administration A. The licensee is responsible for the overall conduct of the facility and for compliance with applicable laws and regulations. This Regulation is not met as evidenced by: Based on a review of the administrative documents, policy and procedure manual, interview of the physician/owner, registered nurse and medical assistants and two procedure observations, it was determined that the governing body failed to oversee the day to day operations of the surgery center and failed to update/maintain the policy and procedure manual on an annual basis, failed to perform Quality Assessment and Performance Improvement (QAPI) projects, failed to implement an infection control program and failed to remove expired supplies and medications. See tags: Q0040, Q0080, Q0100, Q0180 and Q0240. | A 290 | A 290 ① The administrator will ensure the governing body follows its responsibility to oversee daily operations, update the policy and procedure manual and implement a comprehensive QAPI program. ② The governing body will review the manual annually and QA will meet quarterly for QAPI, the gov. body will oversee daily operations and compliance with regulations | |
| A 620 | .08 (B) .08 Quality Assurance Program B. The facility shall conduct ongoing quality assurance activities and document the activities on a continuous basis, but not less than quarterly. This Regulation is not met as evidenced by: | A 620 | ③ 8/22/16 ④ 8/22/16 completed ⑤ administrator ⑥ quarterly, and annually ⑦ quarterly; annually. | |

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| A 620 | Continued From page 2 Based on a tour of the ambulatory surgical center (ASC), interview of the owner/physician/infection preventionist, medical assistant (MA), observation of two surgical procedures, review of administrative documents and review of policy and procedures it was determined that the governing body failed to develop, implement and maintain a data driven on-going Quality Assessment and Performance Improvement (QAPI) program. See tags: Q0080 and Q0081. | A 620 | A 620 ① The administrator will implement a new comprehensive QA program that is data driven ② QA will meet quarterly and participate in QAPI activities ③ 8/22/16 ④ 8/22/16 completed ⑤ administrator ⑥ Quarterly meetings ⑦ Quarterly |
| A 760 | .08 (E) (1) .08 Quality Assurance Program E. Equipment Quality Control. (1) The administrator shall ensure that the facility develops a quality control procedure to monitor the safety and performance of all biomedical equipment. This Regulation is not met as evidenced by: Based on a tour of the ambulatory surgical center (ASC), interview of the owner/physician/infection preventionist, medical assistant (MA), observation of two surgical procedures, review of administrative documents and review of policy and procedures the facility failed to ensure that patients and staff were free of the risk of exposure to infection and communicable diseases. See tags: Q0240 and Q0242. | A 760 | A 760 ① The administrator will ensure bio med is done annually and the equip is maintained according to manufacturer. ② The bio-med will be done annually, equip accord. to manufacturer ③ 8/22/16 ④ 8/22/16 completed ⑤ administrator ⑥ Annually reviewed ⑦ Annual |
| A2070 | .10 (B) (1) .10 Pharmaceutical Services B. Administration of Drugs. (1) Staff shall prepare and administer drugs according to established policies and acceptable | A2070 | |

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A2070 Continued From page 3
standards of practice.

This Regulation is not met as evidenced by:
Based on an observational tour of the ambulatory surgery center (ASC), it was determined that the physician/owner failed to monitor for expired medications and failed to discard expired medications.
See tags: Q0180 and Q0181.

A2070

A2070
① The administrator will ensure all RN staff understand proper medication handling.
② All staff will be delegated areas to monitor for expired medications on a monthly basis.

A2220 13 (A) .13 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 an observational tour of the ambulatory surgical center (ASC), it was determined that the physician/owner failed to monitor for expired supplies and failed to discard expired supplies.
See tags: Q0100 and Q0101.

A2220

A2220
③ 8/22/16
④ 8/22/16 Completed
⑤ Administrator
⑥ Monthly review
⑦ Monthly

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A2220

A2220
① The administrator will ensure all staff have delegated areas to monitor for expired supplies
② All staff will monitor an area to ensure no expired supplies are on the shelves
③ 8/22/16

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④ 8/22/16 Completed
⑤ administration
⑥ monthly review
⑦ monthly

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