| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 000 | INITIAL COMMENTS | Q 000 | | |

A recertification survey of Gynemed Surgical Center was conducted on April 9, 10, 11, and 12, 2018.

The survey included: an observational tour of the physical environment; interview of staff; observation of a surgical procedure; 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.

The facility included one operating room and two procedure rooms. Gynelogical surgery is the surgical specialty performed at the facility.

A total of twenty patient clinical records were reviewed. The procedures were performed between May 2017 and April 2018.

A key code for the patients and staff was provided to the facility.

A conference via telephone was conducted with administrative staff from the Office of Health Care Qualities with the program manager for the ambulatory care program unit, program coordinator of ambulatory care, chief nurse, and the medical director on 4/12/18 at 9:50 am prior to exit.

Conditions for Coverage for Governing Body and Management 416.41, Quality Assessment and Performance Improvement 416.43, Nursing Services 416.46, Pharmaceutical Services

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 05/07/2018

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients . (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 000 | Continued From page 1<br>416.48, and Infection Control 416.51 were not met. A 90 day termination process will be implemented.<br><br>Findings in this report are based on data present at the time of review. The agency's administrative staff was kept informed of the survey findings as the survey progressed. The agency was given the opportunity to present information relative to the findings during the course of the survey. | Q 000 | | |
| Q 040 | GOVERNING BODY AND MANAGEMENT<br>CFR(s): 416.41<br><br>The ASC must have a governing body that assumes full legal responsibility for determining, implementing,and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the policy and procedure manual, interview of staff, review of governing body meeting minutes and review of the quality assessment and performance improvement (QAPI) program documentation, the governing body failed to oversee and monitor the day to day operation of the ambulatory surgery center (ASC).<br><br>The failure of the governing body to oversee and monitor the day to day operation of the ASC | Q 040 | | 5/25/18 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
| --- | --- | --- | --- |
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
| --- | --- |
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
| --- | --- | --- | --- | --- |
| Q 040 | Continued From page 2<br>placed the staff at risk of not identifying and addressing clinical and/or administrative issues that would impact the safe functioning of the ASC.<br><br>The findings include:<br><br>1. Review of the policy and procedure manual on 4/12/18 at 1:00 pm revealed policy, "GOVERNING BODY...The function of the Governing Body (GB) of GSC is to oversee all activities of the ASC. The GB is responsible for establishing the ASC's polices, making sure the policies are implemented, monitoring internal compliance with the policies, and reevaluating the policies routinely to determine whether revision is needed. The GB has oversight and accountability for the quality assessment and performance improvement program, ensure the facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.......The governing body will meet quarterly at a minimum to review overall operations of the center and more often if needed. Minutes of the meetings will be maintained in the GB binder."<br><br>2. Interview of staff on 4/9/18 at 9:30 am revealed that the governing body meetings were not held that he/she is aware. There was no documented evidence presented that any governing body meetings were held in 2016, 2017, or 2018.<br><br>3. Review of the policy and procedure manual, review of the quality assessment and performance improvement (QAPI) program documentation, interview of staff on 4/12/18 at 11:00 am revealed the QAPI program was not implemented and maintained. | Q 040 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 040 | Continued From page 3<br>This deficiency also applies to Federal tags Q080, Q140, Q180, and Q240<br><br>Cross reference to State tags 290, 300, 310, 520, 550, 570, 1030, 1650, 1680, 1820, 2060, and 2070 | Q 040 | | |
| Q 080 | QUALITY ASSESSMENT AND PERFORMANCE<br>CFR(s): 416.43<br><br>The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program.<br>This CONDITION is not met as evidenced by:<br>Based on review of the policy and procedure manual, review of the quality assessment and performance improvement (QAPI) program documentation and interview of staff, the ambulatory surgery center (ASC) failed to maintain an ongoing, data-driven QAPI program.<br><br>The failure to maintain an ongoing, data-driven QAPI program placed the patient at risk for injury, as the quality of patient care was not evaluated.<br><br>The findings include:<br><br>1. Review of the policy and procedure manual, review of the QAPI program and interview of staff on 4/11/18 at 11:00 am revealed that the ASC failed to maintain an ongoing data-driven QAPI program to improve patient health outcomes and patient safety.<br><br>2. Review of the QAPI program documentation and interview of staff on 4/11/18 at 11:00 am revealed the administrator failed to ensure annual performance improvement projects were completed at the facility. | Q 080 | | 5/25/18 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| **GYNEMED SURGI CENTER** | **17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237** |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 080 | Continued From page 4<br><br>3. Review of the policy and procedure manual, review of governing body meeting minutes, interview of the staff on 4/11/18 at 12:00 pm revealed the governing body failed to ensure that a QAPI program was implemented and maintained.<br><br>This deficiency also applies to Federal tags: Q081, Q181, Q083, and Q084<br><br>Cross reference to State tags: 580, 620, and 1590 | Q 080 | | |
| Q 081 | PROGRAM SCOPE; PROGRAM ACTIVITIES<br>CFR(s): 416.43(a), 416.43(c)(1)<br><br>(a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.<br><br>(a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.<br><br>(c)(1) The ASC must set priorities for its performance improvement activities that -<br>(i) Focus on high risk, high volume, and problem-prone areas.<br>(ii) Consider incidence, prevalence, and severity of problems in those areas.<br>(iii) Affect health outcomes, patient safety, and quality of care. | Q 081 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 081 | Continued From page 5 | Q 081 | | |

This STANDARD is not met as evidenced by:
Based on review of the policy and procedure manual, review of the quality assessment and performance improvement (QAPI) program documentation and interview of staff, the administrator failed to maintain an ongoing data - driven QAPI program to improve patient health outcomes and patient safety.

The failure to maintain an ongoing data - driven QAPI program to improve patient health outcomes and patient safety, placed the patients at risk for injury, as the quality of patient care was not evaluated.

The findings include:

Review of the policy and procedure manual on 4/12/18 at 2:00 pm revealed, "policy...QUALITY ASSESSMENT AND IMPROVEMENT......The Quality Assurance and Improvement (QAI) Committee is responsible for establishing and implementing a quality improvement plan. The office administrator also shall delegate responsibilities for monitoring, action, evaluation and reporting......The QAI Committee will report all quality improvement activities to the Governing Body for review and recommendations..Policy..Provide for a program that assures the facility designs processes well and systematically measures, assesses and improves its performance to achieve optimal patient health outcomes in a collaborative and interdisciplinary approach."

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 081 | Continued From page 6<br><br>Review of the QAPI program documentation on 4/9/18 at 12:00 pm revealed that the program was not maintained on an ongoing basis. There was no documented evidence presented by the facility for QAPI with the exception of monitoring for Infection Control which was dated prior to the last survey of 5/6/16. The "Patient Satisfaction Survey Results" were last evaluated in 2015.<br><br>Interview of staff on 4/9/18 at 12:15 pm revealed that he/she acknowledged that the QAPI program had not been maintained on an ongoing basis.<br><br>This deficiency also applies to Federal tags: Q080, Q083, and Q084<br><br>Cross reference to State tags: 580, 620, and 1590 | Q 081 | | |
| Q 083 | PERFORMANCE IMPROVEMENT PROJECTS<br>CFR(s): 416.43(d)<br><br>(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.<br><br>(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality assessment and performance improvement (QAPI) program | Q 083 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| **GYNEMED SURGI CENTER** | **17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237** |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 083 | Continued From page 7<br>documentation and interview of staff, the administrator failed to ensure annual performance improvement projects were completed at the facility.<br><br>The failure to complete annual performance improvement projects placed the staff at risk for not identifying and addressing clinical or administrative issues that would impact patient care.<br><br>The findings include:<br><br>Review of the QAPI program documentation on 4/10/18 at 1:30 pm revealed, no documented evidence of any annual performance improvement projects ever being conducted or completed.<br><br>Interview of staff on 4/10/18 at 1:30 pm revealed that annual performance improvement projects had not been completed at the facility that he/she is aware of.<br><br>This deficiency also applies to Federal tags: Q040, Q080, Q081, and Q084<br><br>Cross reference to State tags: 290, 300, 310, 580, 620, and 1590 | Q 083 | | |
| Q 084 | GOVERNING BODY RESPONSIBILITIES<br>CFR(s): 416.43(e)<br><br>The governing body must ensure that the QAPI program-<br>(1) Is defined, implemented, and maintained by the ASC.<br>(2) Addresses the ASC's priorities and that all | Q 084 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| **GYNEMED SURGI CENTER** | **17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237** |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 084 | Continued From page 8 | Q 084 | | |

improvements are evaluated for effectiveness.
(3) Specifies data collection methods, frequency, and details.
(4) Clearly establishes its expectations for safety.
(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

This STANDARD is not met as evidenced by:
Based on review of the policy and procedure manual, review of governing body meeting minutes and interview of staff, the governing body failed to ensure that a QAPI program was implemented and maintained.

The failure of the governing body to ensure that a QAPI program was implemented and maintained placed the patients at risk for injury, as the agency staff may not have identified and addressed clinical and administrative issues impacting patient care.

The findings include:

Review of the policy and procedure manual on 4/12/18 at 1:30 pm revealed, "GOVERNING BODY.... The function of the Governing Body (GB) of GSC is to oversee all activities of the ASC. The GB is responsible for establishing the ASC's policies, making sure that the policies are implemented, monitoring internal compliance with policies, and reevaluating the policies routinely to determine whether revision is needed. The GB has oversight and accountability for the quality assessment and performance improvement program, ensure that facility policies and programs are administered so as to provide

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|

Q 084 — Continued From page 9

quality health care in a safe environment, and develops and maintains a disaster preparedness plan.......The governing body will meet quarterly at minimum to review overall operations of the center and more often if needed. Minutes of the meetings will be maintained in the GB binder."

Review of the governing body meeting minutes on 4/9/18 at 11:45 am revealed that the last meeting was held and documented in 2015. There was no other documented evidence presented during this survey that any governing body meetings were held in 2016, 2017, or 2018. Several activities of the quality assurance performance improvement program were last performed in 2012.

Interview of staff on 4/12/18 at 12:00 pm revealed that the governing body meetings were not conducted on a quarterly basis or maintained on an on-going basis.

This deficiency also applies to Federal tags: Q040, Q080, Q081, and Q083

Cross reference to State tags: 290, 300, 310, 580, 620, 1590, and 1650

Q 104 — SAFETY FROM FIRE
CFR(s): 416.44(b)

(1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 104 | Continued From page 10 | Q 104 | | |

January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federalregister/code_of_federal-regulations/ibr_locations.html.
Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 104 | Continued From page 11 | Q 104 | | |

dispensers in its facility if:
(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;
(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;
(iii) The dispensers are installed in a manner that adequately protects against inappropriate access; and
(iv) The dispensers are installed in accordance with the following provisions:
(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);
(B) The maximum individual dispenser fluid capacity shall be:
(1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors
(2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms
(C) The dispensers shall have a minimum horizontal spacing of 4 feet (1.2m) from each other;
(D) Not more than an aggregate of 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;
(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, Flammable and Combustible Liquids Code;
(F) The dispensers shall not be installed over or directly adjacent to an ignition source;
(G) In locations with carpeted floor

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 104 | Continued From page 12 | Q 104 | | |

coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

This STANDARD is not met as evidenced by:
Based on review of the policy and procedure manual, review of fire and disaster drill documentation, and interview of staff, the administrator failed to ensure that staff performed required fire and disaster drills.

The failure to perform quarterly fire drills and annual disaster drills to evaluate the staff response time and ability to evacuate the patients in a timely manner placed the patients and staff at risk for injury. This citation was issued on the last survey dated 05/06/2016.

The findings include:

Review of the policy and procedure manual on 4/12/18 at 1:00 pm revealed, "The staff will participate in quarterly fire drills and this will be documented and filed in the fire safety manual.""EDUCATION AND TRAINING...POLICY Personnel will be prepared for their responsibilities in the provision of ambulatory care through appropriate education, training programs and in-services. PROCEDURE..All facility personnel will receive annual update training that include, but are not limited to, general safety, hazardous material and wastes,

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 104 | Continued From page 13<br>fire safety, emergency management, infection control, patient safety, HIPAA, and BCLS. Documentation of employee attendance is accomplished by using the sign-in sheep and kept on file in the training manual."<br><br>Review of the fire drill documentation on 4/9/18 at 11:30 am revealed one fire drill dated on 12/22/16 with one signature only, and one fire drill dated on 12/22/17 with no signatures. Fire drills were not performed on a quarterly basis. Additionally, there was no documented evidence of ever having conducted annual disaster drills.<br><br>Interview of staff on 4/9/18 at 12:45 pm revealed he/she acknowledged quarterly fire drills and annual disaster drills were not conducted at the facility.<br><br>This deficiency also applies to Federal tags: Q040, and Q104<br><br>Cross reference to State tags: 290, 300, 310, and 1030 | Q 104 | | |
| Q 106 | EMERGENCY PERSONNEL<br>CFR(s): 416.44(d)<br><br>Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policy and procedure manual, review of credentialing and personnel files, and interview of staff, the administrator and the physician/owner failed to assure that the | Q 106 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 106 | Continued From page 14 | Q 106 | | |

ambulatory surgery center staff are current in cardiopulmonary resuscitation (CPR), advanced cardiac life support (ACLS), and training to administer conscious sedation. This was evident for seven of eleven staff reviewed.

Failure of the physicians and the registered nurses to maintain training certification placed the patients at risk for injury and death from untrained workers during an emergency.

The findings include:

Review of the policy and procedure manual on 4/12/18 at 2:00 pm revealed, "Cardiopulmonary Resuscitation: Policy..
All medical personnel will be BCLS certified. The Medical Director, CRNP and RN will be ACLS certified."
Another policy states.."All personnel, who have direct patient contact, will maintain CPR skills as evidenced by a biannual update review or certification class."...Another policy states.."SCOPE OF SERVICES....QUALIFICATIONS OF STAFF....The facility's nursing staff maintains a current nursing license and BCLS certification. ACLS certification is required for the RN administering sedation under the direct supervision of the physician. Staff are encouraged to have a professional organization membership. A continuous program of in-service education and periodic skills for all personnel is maintained to ensure the quality of care provided is kept current with the developments in the medical, nursing and infection control fields."

The Maryland Board of Nursing recommendations concerning RN's administering

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 106 | Continued From page 15<br>conscious sedation has ruled..."The board has determined that it is within the scope of practice of a registered nurse to administer and monitor intravenous conscious sedation for a client undergoing a diagnostic and/or surgical procedure only when the following specific conditions are met:<br>1. Medications must be ordered only by a physician, or dentist, who must be immediately available in the room during the diagnostic and/or surgical procedure.<br>2. The employer must have in place an educational/credentialing mechanism which includes a process for evaluating and documenting the registered nurse's demonstration of the knowledge, skills, and abilities related to the management of clients receiving IV conscious sedation. Evaluation and documentation of competency should occur on a periodic basis."<br><br>Review of credentialing and staff files on 4/9/18 at 9:30 am revealed there is no documented evidence of current CPR for six staff members, no documented evidence of ACLS for two staff members, and no documented evidence of any RN having completed any type of training for administering conscious sedation.<br><br>Interview of staff on 4/12/18 at 11:00 am revealed that training for CPR was canceled because of a "snow storm" and has not been re-scheduled.<br><br>This deficiency also applies to Federal tag# Q040<br><br>Cross reference to State tags: 290, 300, 310, 1590, 1650, 1680, and 1870 | Q 106 | | |
| Q 140 | NURSING SERVICES | Q 140 | | 5/25/18 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ____ B. WING ____ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 140 | Continued From page 16<br>CFR(s): 416.46<br><br>The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the policy and procedure manual, review of staff personnel files, and interview of staff, the administrator failed to ensure the nursing services of the ASC (ambulatory surgery center), were directed so that the patient care needs of all patients were met for five of eight staff reviewed.<br><br>The failure of the administrator to provide new employees orientation and with skills competency assessment and the failure to follow facility policy placed the patients at risk for injury due to receiving inadequate care from unqualified individuals.<br><br>This deficiency also applies to Federal tags: Q040 and Q141<br><br>Cross reference to State tags: 290, 300, 310, and 520 | Q 140 | | |
| Q 141 | ORGANIZATION AND STAFFING<br>CFR(s): 416.46(a)<br><br>Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. | Q 141 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______<br>B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203<br>BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 141 | Continued From page 17 | Q 141 | | |

This STANDARD is not met as evidenced by:
Based on review of the policy and procedure manual, review of staff personnel files, and interview of staff, the administrator failed to ensure the nursing services of the ASC (ambulatory surgery center), were directed so that the patient care needs of all patients were met for four of eight staff reviewed. The administrator failed to provide employee orientation, and failed to follow their policy for the delivery of nursing care for two licensed nurses.

The failure of the administrator to provide new employee orientation with skills competency assessment and the failure to follow facility policy placed the patients at risk for injury due to receiving inadequate care from unqualified individuals.

The findings include:

1. Review of the policy and procedure manual on 4/12/18 at 1:30 pm revealed, "NEW EMPLOYEE ORIENTATION....POLICY.....Each employee will be oriented to all facets of his or her job, as well as the organization's mission, values and goals, policies and procedures and employee benefits."

Review of staff's personnel files on 4/9/18 at 11:45 am revealed no documented evidence that they had been oriented to the facility and performed a skills competency assessment during the orientation period.

It is essential that new employees participate in orientation, to include a skills competency assessment, as it is a demonstration of the employee's ability to adequately perform patient

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 141 | Continued From page 18<br>care tasks.<br><br>2. Review of the policy and procedure manual on 4/12/18 at 1:30 pm revealed, "DELIVERY OF NURSING CARE....POLICY...Registered nurses, who are qualified by relevant education and experience, shall supervise the provision of ambulatory nursing care. Staffing is based on patient acuity, census and physical facility. Two (2) licensed nurses, one of whom is an RN, shall be present at all times."<br><br>Interview of staff on 4/11/18 at 10:15 am revealed where there is one (1) licensed RN only per day. Staff was unaware of the facility policy.<br><br>This deficiency also applies to Federal tags: Q040 and Q140<br><br>Cross reference to State tags: 290, 300, 310, 520, and 550 | Q 141 | | |
| Q 180 | PHARMACEUTICAL SERVICES<br>CFR(s): 416.48<br><br>The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the policy and procedure manual, observations, narcotic log records, review of facility documentation, and interview, it was determined that the facility failed to secure and safeguard the narcotic/controlled substance box access (access by letter opener) medications | Q 180 | | 5/29/18 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 180 | Continued From page 19<br>against misuse and theft.<br><br>The facility also failed to have two licensed personnel count all narcotic/controlled substances.<br><br>This deficiency also applies to Federal tags: Q040 and Q180<br><br>Cross reference to State tags: 290, 300, 310, 1650, 2060, and 2070 | Q 180 | | |
| Q 181 | ADMINISTRATION OF DRUGS<br>CFR(s): 416.48(a)<br><br>Drugs must be prepared and administered according to established policies and acceptable standards of practice.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policy and procedure manual, observational tour of the facility, review of narcotic log documentation, and interview of staff, it was determined that the facility failed to safely secure narcotics and controlled substances at the facility, and failed to maintain accurate documentation of narcotics and controlled substances by two licensed personnel.<br><br>The failure to properly secure and maintain narcotics and controlled substances, and properly count narcotic and controlled medication, the facility cannot ensure the security of scheduled drugs and prevent abuse and/or misuse of controlled substances. | Q 181 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 181 | Continued From page 20 | Q 181 | | |

The findings include:

1. Review of the policies and procedure manual on 4/12/18 at 11:45 am revealed a policy entitled 'Controlled Drug Management....POLICY...To ensure adequate control, dispensing and accountability of all controlled substances in conformity with state and federal regulations. SECURITY..When not in use, the controlled substance storage area on each patient care unit must be kept double-locked and secure at all times.......If the keys are ever lost or misplaced, the locks to the door and narcotic cabinet will be replaced immediately."

Observation of the narcotic and controlled substance box on 4/11/18 at 12:10 pm revealed, the narcotic box is located in the medication room. On the left back upper side of the small room the narcotic box is mounted to the wall. Staff was directed to open the narcotic box and staff used what appeared to be a long letter opener to gain access to both locks on this box. Staff said, "this is the only way to open this, the keys were lost." Staff was unable to verify how long the narcotic box has been accessed this way.

Interview of staff on 4/11/18 at 1:45 pm revealed where it was acknowledged the narcotic box lock keys were lost and the narcotic box has not been corrected to working condition with a key.

2. Review of the policy and procedure manual on 4/12/18 at 12:10 pm revealed, "POLICY....To ensure adequate control, dispensing and accountability of all controlled substances in conformity with state and federal regulations. ACCOUNTABILITY...Controlled substances must

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 181 | Continued From page 21<br>be counted at the end of the day by two individuals licensed to handle controlled substances. Both individuals must sign the Controlled Substances log book thereby verifying that the count is correct."<br><br>During an observational tour of the facility on 4/11/18 at 12:35 pm a narcotic count was conducted. During the count, it was revealed that the facility counts narcotics once in the morning and once at the end of the day. The count sheet is only signed off by one licensed RN. There were, however, some dates that were signed by two people, but only one was licensed.<br><br>Interview of staff on 4/11/18 at 1:00 pm revealed the narcotic/controlled medications are not always counted by two licensed personnel.<br><br>All medication deemed to be in need of control by the facility must be administered, documented and counted accurately to ensure control of all scheduled drugs. The facility's system of record keeping should be able to readily identify loss or diversion of all controlled substances in a manner that would minimize the time frame between actual loss or diversion and the time of detection. Without properly securing and counting of narcotic/controlled medication, the facility cannot ensure the security of narcotics and prevent abuse and/or misuse of controlled substances.<br><br>This deficiency also applies to Federal tags: Q040 and Q180<br><br>Cross reference to State tags: 290, 300, 310, 1650, 2060, and 2070 | Q 181 | | |
| Q 240 | INFECTION CONTROL | Q 240 | | 5/25/18 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 240 | Continued From page 22 | Q 240 | | |

CFR(s): 416.51

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

This CONDITION is not met as evidenced by:
Based on review of the policy and procedure manual, review of staff credentialing and health files, and interview of staff, the administrator failed to maintain an infection control program, and TB (tuberculosis) testing/screening for staff in the Ambulatory Surgical Center (ASC).

The failure to maintain an infection control program and TB testing/screening placed the patients and staff at risk for infection.

The findings include:

1. Review of the policy and procedure manual, review of staff credentialing and health files, and interview of the administrator on 4/11/18 at 10:00 am revealed no documented evidence that staff completed annual infection control training and testing/screening for TB.

2. Review of staff credentialing and health files on 4/9/18 at 10:00 am revealed staff did not receive infection control training on an annual basis. Furthermore, staff did not have TB testing/screening completed.

This deficiency also applies to Federal tags: Q040 and Q242

Cross reference to State tags: 290, 300, 310, 570, 580, 620, and 1650

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 242 | Continued From page 23 | Q 242 | | |
| Q 242 | INFECTION CONTROL PROGRAM<br>CFR(s): 416.51(b)<br><br>The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the policy and procedure manual, review of staff credentialing files, and interview of staff, the administrator failed to ensure that measures to prevent infection were practiced at the facility. These measures included annual infection control training for eleven of eleven staff reviewed, and TB (tuberculosis) screening/testing for seven of eleven staff reviewed.<br><br>The failure to ensure that infection control measures were practiced at the facility placed the patients and staff at risk for infection.<br><br>The findings include:<br><br>1. Review of the policy and procedure manual on 4/12/18 at 1:45 pm revealed, "EDUCATION AND TRAINING...POLICY Personnel will be prepared for their responsibilities in the provision of ambulatory care through appropriate education, training programs and in-services. PROCEDURE..All facility personnel will receive annual update training that include, but are not limited to, general safety, hazardous material and | Q 242 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 242 | Continued From page 24<br>wastes, fire safety, emergency management, infection control, patient safety, HIPAA, and BCLS. Documentation of employee attendance is accomplished by using the sign-in sheep and kept on file in the training manual."<br><br>Review of eleven staff's credentialing files on 4/9/18 at 10:30 am revealed that staff had not received infection control training on an annual basis. The last recorded date of any infection control training was 3/21/15 for one staff member only. No additional documented evidence of any staff's annual infection control training was presented at the time of survey.<br><br>Interview of staff on 4/11/18 at 10:30 am revealed staff acknowledged staff had not received infection control training on an annual basis.<br><br>2. Based on review of staff credentialing and health files on 4/9/18 at 11:30 am revealed no documented evidence of staff ever receiving tuberculosis screening for seven of eleven staff reviewed.<br><br>Interview of staff on 4/11/18 at 10:00 am revealed staff acknowledged that there was no documentation to ensure all the staff had been screened for tuberculosis.<br><br>This deficiency also applies to federal tags: Q040 and Q240<br><br>Cross reference to State tags: 290, 300, 310, 570, 580, 620, and 1650 | Q 242 | | |
| Q 266 | DISCHARGE - ORDER<br>CFR(s): 416.52(c)(2) | Q 266 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______ B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 266 | Continued From page 25 | Q 266 | | |

[The ASC must -]
Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

This STANDARD is not met as evidenced by:
Based on review of policy and procedure manual, clinical record review and interview of staff, the administrator failed to ensure that a written discharge order signed by the physician who performed the surgery was completed for twenty of twenty patient records reviewed.

The failure of the physician who performed the surgery to write and sign a discharge order after a surgical procedure placed the patient at risk for injury due to an unsafe discharge.

Patients:#1, #2, #3, #4, #5, #6, #7, #8, #9, #10, #11, #12, #13, #14, #15, #16, #17, #18, #19, and #20.

The findings include:

Review of the policy and procedure manual on 4/11/18 at 1:15 pm revealed, "Discharge....The discharge order must be written by the operating physician."

Review of Patient: #1, #2, #3, #4, #5, #6, #7, #8, #9, #10, #11, #12, #13, #14, #15, #16, #17, #18, #19, and #20's clinical records on 4/11/18 starting at 9:00 am revealed no documented evidence that a discharge order was written and signed by the surgeon who performed the procedures.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 21C0001165 | A. BUILDING ______<br>B. WING ______ | 04/12/2018 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| GYNEMED SURGI CENTER | 17 FONTANA LANE SUITE 201-203<br>BALTIMORE, MD 21237 |

| (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) COMPLETION DATE |
|---|---|---|---|---|
| Q 266 | Continued From page 26<br>Interview of Staff on 4/11/18 at 12:45 pm revealed he/she acknowledged that a discharge order was not written and signed by the surgeon in the patient's clinical records.<br><br>This deficiency also applies to federal tags: Q040 and Q266<br><br>Cross reference to State tags: 290, 300, and 310 | Q 266 | | |