



IDAHO DEPARTMENT OF
HEALTH & WELFARE

BRAD LITTLE – Governor
DAVE JEPPESEN – Director

TAMARA PRISOCK—ADMINISTRATOR
DIVISION OF LICENSING & CERTIFICATION
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BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, Idaho 83720-0009
PHONE: (208) 334-6626
FAX: (208) 364-1888
E-mail: fsb@dhw.idaho.gov

February 20, 2019

Spencer Sessions, Administrator
Post Falls Ambulatory Surgical Center
602 North Calgary Court, Suite 203
Post Falls, ID 83854

RE: Post Falls Ambulatory Surgical Center, Provider #13C0001072

Dear Mr. Sessions:

Based on the survey completed at Post Falls Ambulatory Surgical Center, on February 11, 2019, by our staff, we have determined Post Falls Ambulatory Surgical Center is out of compliance with the Medicare ASC Conditions for Coverage of:

- **Governing Body and Management (42 CFR 416.41) and**
- **Quality Assessment and Performance (42 CFR 416.43 and**
- **Laboratory and Radiologic Services (42 CFR 416.49) and**
- **Patient Rights (42 CFR 416.50) and**
- **Infection Control (42 CFR 416.51)**

To participate as a provider of services in the Medicare Program, a OR an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiencies, which caused this condition to be unmet, substantially limit the capacity of Post Falls Ambulatory Surgical Center, to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567).

You have an opportunity to make corrections of those deficiencies, which led to the finding of non-compliance with the Condition for Coverage referenced above by submitting a written Credible Allegation of Compliance/Plan of Correction.

An acceptable Plan of Correction contains the following elements:

Spencer Sessions, Administrator
February 20, 2019
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- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of each form.

Such corrections must be achieved and compliance verified by this office, before March 28, 2019. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than March 18, 2019.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **March 5, 2019.**

Failure to correct the deficiencies and achieve compliance will result in our recommending that CMS terminate your approval to participate in the Medicare Program. If you fail to notify us, we will assume you have not corrected.

We urge you to begin correction immediately.

Thank you for the courtesies extended to us during the survey. If you have any questions, comments or concerns, please contact Dennis Kelly, RN or Nicole Wisenor, Co-Supervisors, Non-Long Term Care at (208) 334-6626, option 4.

Sincerely,



Dennis Kelly RN, Supervisor
Non-Long Term Care

DK/dk

ec: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Patrick Thrift, Survey & Certification Manager Region X
Julius Bunch, Certification & Enforcement Manager Region X

Post Falls 
AMBULATORY SURGICAL CENTER

March 4, 2019

RECEIVED
MAR 06 2019
FACILITY STANDARDS

VIA EXPRESS MAIL, OVERNIGHT

Dennis Kelly, RN
Idaho Department of Health and Welfare
3232 Elder Street
PO Box 83720
Boise, ID 83720

Re: Post Falls Ambulatory Surgical Center, Provider #13C0001072

Dear Mr. Kelly:

Enclosed please find the requested Plan of Correction based on the above-referenced survey completed on February 11, 2019 by your staff.

Rather than addressing each of the deficiencies listed on FORM CMS-2567 directly on the form you have provided, the Plan of Correction has been prepared as a separate document. However, the Plan of Correction references each deficiency as referenced on the FORM CMS-2567. In addition, Form CMS-2567, as enclosed, cross-references the page number each deficiency is referenced on the Plan of Correction.

Regarding the time frame you have referenced in your correspondence dated February 20, 2019, please note the following:

- Due to the limited scheduling provided by our surgery center and due to limited anesthesia support services available during the next four weeks, surgeries are scheduled ONLY on March 14, March 15, April 4 and April 5.
- The facility will be closed March 22 through March 31.

If you have questions regarding this Plan of Correction or dates available for follow-up visits, please contact me at 208.660.8814.

Sincerely,



Brad Barlow, DDS
Owner and Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 02/20/2019
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001072	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/11/2019
NAME OF PROVIDER OR SUPPLIER POST FALLS AMBULATORY SURGICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 602 NORTH CALGARY COURT, SUITE 203 POST FALLS, ID 83854	
(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 The following deficiencies were cited during the Medicare recertification survey of your facility conducted on 2/04/19 to 2/11/19. Surveyors conducting the recertification survey were: James Brown, RN, HFS - Team Leader Brian Osborn, RN, HFS Acronyms used in this report include: AC - Antecubital ASC - Ambulatory Surgery Center CDC - Centers for Disease Control and Prevention CQIP - Coordinated Quality Improvement Program DA - Dental Assistant ICC - Infection Control Coordinator IV - Intravenous PACU - Post Operative Care Unit QI - Quality Improvement RN - Registered Nurse	Q 000		
Q 040	GOVERNING BODY AND MANAGEMENT CFR(s): 416.41 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.	Q 040	See attached Plan of Correction, page 1.	

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MAR 06 2019
FACILITY STANDARDS

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *Paul VanDusen* TITLE: owner/director (X6) DATE: 3/4/19

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.

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Q 040	Continued From page 1 This CONDITION is not met as evidenced by: Based on facility quality document review, quality meeting minutes review, medical record review, contract review, Governing Body meeting minutes review, policy review, dosimetry radiation exposure report review, observation, manufacturer's instructions-for-use review, personnel file review, infection control document review, CDC infection control guidelines review, and staff interview, it was determined the Governing Body failed to provide sufficient monitoring and oversight that identified and resolved problems of a systematic and recurrent nature for all patients receiving services at the facility. This resulted in infection control, quality, radiology, and patient rights programs which were not sufficiently developed, implemented, and monitored to ensure patients' risk of infection was minimized, their care was provided in a safe and effective manner, and opportunities to improve patient care were maximized. Findings include: 1. Refer to Q 041 as it relates to the facility's failure to ensure oversight of contracted services. 2. Refer to Q 080 Condition for Coverage: Quality Assessment and Performance Improvement and associated standard level deficiencies as they relate to the Governing Body's failure to ensure the quality program was fully developed, implemented and maintained. 3. Refer to Q 200 Condition for Coverage: Laboratory and Radiology Services and associated standard level deficiencies as they relate to the Governing Body's failure to ensure Radiology Services were provided in a safe and effective manner.	Q 040	See attached Plan of Correction, page 1.		

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Q 040	Continued From page 2 4. Refer to Q 219 Condition for Coverage: Patient Rights and associated standard level deficiencies as they relate to the Governing Body's failure to ensure patients were informed of their rights and received care in a safe setting. 5. Refer to Q 240 Condition for Coverage: Infection Control and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive infection control program was developed, implemented, and monitored for all facility staff and patients receiving care at the facility. The cumulative effect of these systematic deficient practices impeded the facility's ability to evaluate services necessary to ensure appropriate patient care was being provided.	Q 040	See attached Plan of Correction, page 1.		
Q 041	CONTRACT SERVICES CFR(s): 416.41(a) When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. This STANDARD is not met as evidenced by: Based on a review of facility contracts, Governing Body meeting minutes, and staff interview, it was determined the facility failed to ensure oversight of contracted services. This resulted in a lack of appropriate contract development and monitoring of services provided to the facility. Findings include: A list of facility contracted services was requested on 2/05/19 and again on 2/07/19, but was not provided. A facility policy which governed	Q 041	See attached Plan of Correction, pages 1-2.		

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Q 041	Continued From page 3 contracted services was requested on 2/05/19 and again on 2/07/19, but was not provided. The 4 most recent Governing Body meeting minutes, dated 5/26/16, 10/20/17, 3/15/18, and 11/19/18, were reviewed. Four of the 4 meeting minutes did not include review or oversight of contracted services to ensure they were being provided in a safe and effective manner. It was unclear how the Governing Body provided oversight of contracted services. The facility physician owner, who was head of the facility's Governing Body, was interviewed on 2/07/19, beginning at 8:48 AM. He confirmed contracted services oversight was not documented. Additionally, the physician owner confirmed the facility did not have a current master list of contracted services or a policy which governed oversight of contracted services. The Governing Body failed to provide oversight of contracted services.	Q 041	See attached Plan of Correction, page 1-2.		
Q 080	QUALITY ASSESSMENT AND PERFORMANCE CFR(s): 416.43 The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on a review of facility quality documents, quality meeting minutes, medical records, and staff interview, it was determined the facility failed to ensure a comprehensive quality program was developed, implemented, and maintained. This impeded the ability of the facility to evaluate its practices and improve patient care. Findings include:	Q 080	See attached Plan of Correction, page 2.		

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Q 080	Continued From page 4 1. Refer to Q 081 as it relates to the facility's failure to ensure an ongoing quality program, that demonstrated measurable improvement in patient health outcomes, was developed and maintained. 2. Refer to Q 082 as it relates to the facility's failure to ensure performance improvement activities tracked and examined adverse patient events. 3. Refer to Q 083 as it relates to the facility's failure to ensure performance improvement projects were conducted. 4. Refer to Q 084 as it relates to the Governing Body's failure to maintain a quality program that addressed the facility's priorities, and specified data collection methods, frequency, and details. The cumulative effect of these systemic practices prevented the facility from evaluating its practices to improve patient care.	Q 080	See attached Plan of Correction, page 2.		
Q 081	PROGRAM SCOPE; PROGRAM ACTIVITIES CFR(s): 416.43(a), 416.43(c)(1) (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. (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	Q 081	See attached Plan of Correction, pages 2-3.		

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Q 081	<p>Continued From page 5 furnished in the ASC.</p> <p>(c)(1) The ASC must set priorities for its performance improvement activities that -</p> <ul style="list-style-type: none"> (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care. <p>This STANDARD is not met as evidenced by: Based on review of facility quality documents, quality meeting minutes, and staff interview, it was determined the facility failed to develop and maintain an ongoing quality program, that demonstrated measurable improvement in patient health outcomes. This resulted in the inability of the facility to evaluate its processes of patient care. Findings include:</p> <p>The facility "COORDINATED QUALITY IMPROVEMENT PLAN," revised 1/30/19, was reviewed. The facility failed to follow their quality program. Examples include:</p> <ol style="list-style-type: none"> 1. The facility quality program stated "CQIP committee meetings are held quarterly..." CQIP meeting minutes for the last 4 quarters were requested, however, 2 were provided, dated 3/15/18 and 1/31/19. <p>The Nurse Manager was interviewed on 2/05/19, beginning at 10:01 AM. She confirmed the facility documented 1 CQIP meeting in 2018.</p>	Q 081	See attached Plan of Correction, pages 2-3.		

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Q 081	<p>Continued From page 6</p> <p>2. The facility quality program stated "The CQIP committee will address clinical, administrative, and cost-of-care performance issues and patient outcomes through collected data." Data addressing clinical, administrative, cost-of-care performance issues, and patient outcomes were requested for 2018, however, not provided.</p> <p>The Nurse Manager was interviewed on 2/05/19, beginning at 10:01 AM. She confirmed the facility did not have documented quality data for 2018.</p> <p>3. The facility quality program stated "The CQIP committee will set priorities for its performance improvement that focus on high risk, high volume prone [sic] areas as well as areas that effect [sic] health outcomes, patient safety, and quality of care." Facility quality indicators which focused on high risk, high volume, problem prone areas were requested, however, not provided.</p> <p>The Nurse Manager was interviewed on 2/05/19, beginning at 10:01 AM. She confirmed the facility did not have historical or current quality indicators documented. When asked for evidence the facility set priorities for its performance improvement, the Nurse Manager stated it was not documented.</p> <p>The facility's quality program was not ongoing, did not demonstrate measurable improvement in patient health outcomes, did not include quality indicators, and did not focus on high risk, high volume, problem prone areas.</p>	Q 081	See attached Plan of Correction, pages 2-3.		
Q 082	<p>PROGRAM DATA; PROGRAM ACTIVITIES CFR(s): 416.43(b), 416.43(c)(2), 416.43(c)(3)</p> <p>(b)(1) The program must incorporate quality</p>	Q 082	See attached Plan of Correction, page 3.		

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Q 082	<p>Continued From page 7</p> <p>indicator data, including patient care and other relevant data regarding services furnished in the ASC.</p> <p>(b)(2) The ASC must use the data collected to -</p> <p>(i) Monitor the effectiveness and safety of its services, and quality of its care.</p> <p>(ii) Identify opportunities that could lead to improvements and changes in its patient care.</p> <p>(c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.</p> <p>(c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.</p> <p>This STANDARD is not met as evidenced by: Based on a review facility quality documents, medical records, quality meeting minutes, and staff interview, it was determined the facility failed to ensure performance improvement activities tracked and examined adverse patient events for 1 of 1 patient (Patient #5) who experienced an adverse event and whose record was reviewed. This resulted in a failure to identify opportunities that could lead to improvements and changes in patient care. Findings include:</p> <p>The facility quality program stated "The CQIP committee will track any adverse reactions, examine cause, and implement improvements that will sustain over time." The facility failed to follow their quality program. One example includes:</p>	Q 082	See attached Plan of Correction, page 3.		

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Q 082	Continued From page 8 Patient #5 was a 2 year old male who was admitted on 11/29/18, for dentoalveolar structure surgery. His medical record included a "SAME DAY SURGERY PERI-OPERATIVE RECORD," dated 11/29/18, signed by an RN, which stated "Case discontinued...No IV access obtained [after] 6 attempts - pressure [illegible] on all sites: hands bil [bilateral], feet bil [bilateral], AC bil [bilateral]." The facility quality program stated "CQIP committee meetings are held quarterly..." The most recent CQIP meeting minutes, dated 1/31/19, were reviewed. The minutes from this meeting did not include documentation of patient adverse events, nor did it identify Patient #5's specific adverse event, examine its cause, or implement improvements based upon event analysis. The Nurse Manager was interviewed on 2/05/19, beginning at 10:01 AM. She confirmed Patient #5's canceled surgery qualified as an adverse event. The Nurse Manager confirmed Patient #5's adverse event was not documented as an adverse event and was not analyzed or investigated.	Q 082	See attached Plan of Correction, page 3.		
Q 083	PERFORMANCE IMPROVEMENT PROJECTS CFR(s): 416.43(d) (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.	Q 083	See attached Plan of Correction, pages 3-4.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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Q 083	Continued From page 9 (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 This STANDARD is not met as evidenced by: Based on a review of quality documents and staff interview, it was determined the facility failed to conduct performance improvement projects. This impeded the facility's ability to examine its processes in depth. Findings include: No performance improvement projects for 2018 or 2019 had been documented. It was unclear when the last time performance improvement projects were conducted. The Nurse Manager was interviewed on 2/05/19, beginning at 10:01 AM, and she confirmed no performance improvement projects had been conducted. The facility did not conduct performance improvement projects.	Q 083	See attached Plan of Correction, pages 3-4.		
Q 084	GOVERNING BODY RESPONSIBILITIES CFR(s): 416.43(e) The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details.	Q 084	See attached Plan of Correction, page 4.		

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Q 084	<p>Continued From page 10</p> <p>(4) Clearly establishes its expectations for safety.</p> <p>(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of facility quality documents and staff interview, it was determined the Governing Body failed to ensure the quality program was maintained, addressed the facility's priorities, and specified data collection methods, frequency, and details. This resulted in a lack of quality program oversight and direction to staff. Findings include:</p> <p>The facility "COORDINATED QUALITY IMPROVEMENT PROGRAM," revised 1/30/19, was reviewed. The quality program did not include the facility's quality priorities, data collection methods, frequency, or detail. It was unclear how the facility was collecting performance data, who was responsible for data collection, and what the facility's quality priorities were.</p> <p>The physician owner, who was head of the facility's Governing Body, was interviewed on 2/07/19, beginning at 8:48 AM, and the facility's quality program was reviewed in his presence. He stated he was ultimately responsible for maintaining the facility's quality program, setting its priorities, and specifying its data collection methods, frequency, and detail and confirmed execution of these responsibilities was not documented.</p> <p>The Governing Body failed to ensure the facility's</p>	Q 084	See attached Plan of Correction, page 4.		

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Q 084	Continued From page 11 quality program was maintained, addressed the facility's priorities, and specified data collection methods, frequency, and details.	Q 084	See attached Plan of Correction, page 4.		
Q 109	EMERGENCY EQUIPMENT CFR(s): 416.44(d) (d) Standard: Emergency equipment. The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements: (1) Be immediately available for use during emergency situations. (2) Be appropriate for the facility's patient population. (3) Be maintained by appropriate personnel. This STANDARD is not met as evidenced by: Based on a review of facility documents, policy review, and staff interview, it was determined the facility failed to maintain emergency medical equipment. This had the potential to compromise the health and safety of all patients seen in the facility. Findings include: The facility provided a policy titled "Emergency Equipment," dated 12/02/15, which stated: - "A registered nurse assigned to set up for surgery is responsible for ensuring that life saving equipment is checked at the start of every surgery day to ensure proper function prior to the start of first surgery."	Q 109	See attached Plan of Correction, page 4.		

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Q 109	Continued From page 12 When asked for a log of the emergency defibrillator check, the facility provided a form titled "CRITICAL EQUIPMENT LOG" which included a weekly check of the defibrillator. The log documented the defibrillator was checked from 12/14/18 to 2/09/19. There was no documentation the defibrillator was checked prior to 12/14/18. The Nurse Manager was interviewed on 2/08/19 beginning at 9:45 AM, and she confirmed there were no defibrillator checks documented prior to 12/14/18. The facility failed to ensure emergency equipment checks were being completed as required by the facility's policy.	Q 109	See attached Plan of Correction, page 4.		
Q 162	FORM AND CONTENT OF RECORD CFR(s): 416.47(b) The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration.	Q 162	See attached Plan of Correction, page 5.		

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Q 162	Continued From page 13 (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. This STANDARD is not met as evidenced by: Based on medical records review and staff interview, it was determined the facility failed to ensure medical records included properly executed informed patient consents for 10 of 10 patients (#'s 1 - 10) whose records were reviewed. This resulted in lack of documentation clarity and had the potential to impact patients' understanding of the course of patient care. Findings include: Patient #'s 1 - 10's medical records included a "CONSENT TO GENERAL ANESTHESIA & DENTAL TREATMENT," signed by the patients' legal guardians. The form included a section for the date the informed consent was signed, but not the time. It could not be determined if the patients' guardians signed the informed consents before or after the patients' surgical procedure. The Nurse Manger was interviewed on 2/05/19, beginning at 9:18 AM, and Patient #'s 1 - 10's medical records were reviewed in her presence. She confirmed it was unclear if patients' guardians signed the informed consents before or after the patients' surgical procedure. Patient #'s 1 - 10's informed consents were not properly executed.	Q 162	See attached Plan of Correction, page 5.		
Q 200	LABORATORY AND RADIOLOGIC SERVICES CFR(s): 416.49 This CONDITION is not met as evidenced by: Based on facility policy review, dosimetry	Q 200	See attached Plan of Correction, page 5.		

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Q 200	Continued From page 14 radiation exposure report review, observation, and staff interview, it was determined the facility failed to ensure comprehensive radiologic services were provided in a safe and effective manner. This resulted in lack of radiation exposure monitoring for staff and radiologic shielding inspection and maintenance for patients. Findings include: Refer to Q 203 as it relates to the facility's failure to ensure patient radiologic shielding was periodically inspected and radiation workers were checked for exposure. The cumulative effect of these systemic practices prevented the facility from evaluating its practices to improve patient care.	Q 200	See attached Plan of Correction, page 5.		
Q 203	RADIOLOGIC SERVICES CFR(s): 416.49(b)(1) [Radiologic services...] must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2) of this chapter. This STANDARD is not met as evidenced by: Based on facility policy review, dosimetry radiation exposure report review, observation, and staff interview, it was determined the facility failed to ensure patient radiologic shielding was periodically inspected and radiation workers were checked for exposure. This had the potential for increased radiation exposure for patients and staff. Findings include: Radiologic services were not provided in a safe and effective manner. Examples include:	Q 203	See attached Plan of Correction, page 5.		

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Q 203	<p>Continued From page 15</p> <p>1. A facility policy "Radiation Policy," revised 11/05/15, stated "A radiation badge will be worn by one staff personnel while in the ASC to ensure a minimal amount of exposure. Results of radiation exposure are kept by nursing manager." This policy was not followed.</p> <p>a. A tour of the facility was conducted in the presence of the Nurse Manager on 2/04/19, beginning at 9:03 AM. During the tour, a single dosimeter [equipment used to measure radiation exposure] was noted on the wall outside the operating room. When asked how many dosimeters were present in the facility for staff use, the Nurse Manager stated she was unsure. When asked how dosimeters were being tested for radiation exposure, the Nurse Manager stated she was unsure. When asked who was required to wear a dosimeter in the facility, the Nurse Manager stated she was unsure.</p> <p>b. Radiation exposure reports were requested, and 1 report from 11/20/17 to 11/27/17 was provided. Additional radiation exposure logs could not be located. It could not be determined how many dosimeters were being tested, by whom, and at what intervals.</p> <p>c. A surgical procedure was observed for Patient #10 on 2/08/19, beginning at 7:50 AM. During the procedure, radiation equipment was utilized, and x-ray films were taken. Staff present during the surgical procedure did not wear a dosimeter.</p> <p>The physician owner, who was head of the facility's Governing Body, was interviewed on 2/07/19, beginning at 8:48 AM. When asked how dosimeters were being tested for radiation exposure, the physician owner stated he was</p>	Q 203	See attached Plan of Correction, page 5.		

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Q 203	<p>Continued From page 16</p> <p>unsure. When asked who was required to wear a dosimeter in the facility, the physician owner stated only the DA. He confirmed the DA did not wear a dosimeter during Patient #10's surgical procedure. When asked why the DA did not wear the dosimeter located outside the operating room, the physician owner stated "that one is not ours." The physician owner stated he was unsure who the dosimeter belonged to.</p> <p>Staff were not monitored for radiation exposure.</p> <p>2. A tour of the facility was conducted in the presence of the Nurse Manager on 2/04/19, beginning at 9:03 AM. During the tour, 2 radiation shield [lead] aprons were noted in the operating room. One of the aprons had noticeable discoloration and wear to its collar, and it appeared to be soiled. When asked how many lead aprons and/or thyroid shields the facility utilized, the Nurse Manager stated she was unsure. When asked if a log was kept that documented maintenance and inspection of radiologic shielding, the Nurse Manager stated she was unsure.</p> <p>The physician owner, who was head of the facility's Governing Body, was interviewed on 2/07/19, beginning at 8:48 AM. When asked how many lead aprons and/or thyroid shields the facility utilized, the physician owner stated he was unsure. When asked if a log was kept with documented maintenance and inspection of radiologic shielding, the physician owner stated he was unsure. When asked who was responsible for radiologic services at the facility, they physician owner stated he was. He confirmed radiologic shielding inspection was not being performed.</p>	Q 203	See attached Plan of Correction, page 5.		

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Q 203	Continued From page 17	Q 203	See attached Plan of Correction, page 5.	
Q 219	<p>Radiologic shielding was not inspected.</p> <p>PATIENT RIGHTS CFR(s): 416.50</p> <p>Condition for Coverage - Patient Rights</p> <p>The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.</p> <p>This CONDITION is not met as evidenced by: Based on facility patient's rights information review, medical record review, observation, CDC infection control guidelines review, personnel file review, and staff interview, it was determined the facility failed to ensure patients had the right to receive care in a safe setting. Additionally, the facility failed to ensure patients were informed on how to submit a verbal or written complaint to the State Agency. This had the potential to impact safe patient care. Findings include:</p> <p>Refer to Q 221 as it relates to the facility's failure to ensure patient's rights information included all required information.</p> <p>Refer to Q 222 as it relates to the facility's failure to ensure the posted notice of rights included the address of a representative in the State Agency to whom patients could report complaints.</p> <p>Refer to Q 232 as it relates to the facility's failure</p>	Q 219	See attached Plan of Correction, page 6.	

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Q 219	Continued From page 18 to ensure facility and ancillary staff were provided oversight, trained, and competent to perform clinical duties.	Q 219	See attached Plan of Correction, page 6.		
Q 221	<p>The cumulative effect of these systematic practices resulted in a lack of information being provided to patients and the potential for patient rights to be violated.</p> <p>NOTICE OF RIGHTS CFR(s): 416.50(a)</p> <p>An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.</p> <p>This STANDARD is not met as evidenced by: Based on medical record review and staff interview, it was determined the facility failed to ensure patient's rights information included all required information for 10 of 10 patients (#'s 1 - 10) whose records were reviewed. This had the potential for patients to be uninformed about their rights prior to receiving care. Examples include:</p> <p>Patient #'s 1 - 10's medical records included a "PATIENTS RIGHTS" form signed by patients' guardians. The form did not include the correct web site for the Office of the Medicare Beneficiary Ombudsman and the correct State Agency's telephone number and address to which patients</p>	Q 221	See attached Plan of Correction, page 6.		

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Q 221	Continued From page 19 could report complaints. The Nurse Manager was interviewed on 2/05/19, beginning at 9:18 AM, and Patient #'s 1 - 10's medical records were reviewed in her presence. She confirmed the patient's rights form did not include all required information.	Q 221	See attached Plan of Correction, page 6.		
Q 222	Patient #'s 1 - 10's patient's rights information did not include all required information. NOTICE OF RIGHTS - POSTING CFR(s): 416.50(a)(1)(i) (1)[...] In addition, the ASC must - (i) Post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. This STANDARD is not met as evidenced by: Based on observation, patient's rights information review, and staff interview, it was determined the facility failed to ensure the posted notice of rights included the address of a representative in the State Agency to whom patients could report complaints. This had the potential to interfere with the ability of patients or their surrogates to file a complaint with the State Agency. Findings include: An observation of the facility's waiting room was conducted in the presence of the Surgery	Q 222	See attached Plan of Correction, page 6.		

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Q 222	Continued From page 20 Coordinator on 2/04/19, beginning at 9:03 AM. The facility had a posted notice of patient's rights, however, they did not include the correct address and telephone number of the State Agency to whom patients could report complaints. The Nurse Manager was interviewed on 2/04/19, beginning at 9:32 AM. She confirmed the posted notice of patient's rights did not include the correct address and telephone number of the State Agency. The facility's posted patient rights information did not include the correct address and telephone number of the State Agency.	Q 222	See attached Plan of Correction, page 6.		
Q 232	SAFETY CFR(s): 416.50(f)(2) [The patient has the right to -] (2) Receive care in a safe setting This STANDARD is not met as evidenced by: Based on CDC infection control guidelines review, observation, facility personnel file review, and staff interview, it was determined the facility failed to ensure facility and ancillary staff were trained and competent to perform clinical duties. These failures had the potential for poor clinical outcomes for all patients receiving care at the facility. Findings include: 1. Facility and ancillary staff did not have documented training or competencies to perform high level disinfection and sterilization of surgical equipment. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities 2008 stated:	Q 232	See attached Plan of Correction, pages 6-7.		

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Q 232	Continued From page 21 "Provide comprehensive and intensive training for all staff assigned to reprocess semicritical and critical medical/surgical instruments to ensure they understand the importance of reprocessing these instruments. To achieve and maintain competency, train each member of the staff that reprocesses semicritical and/or critical instruments as follows: - provide hands-on training according to the institutional policy for reprocessing critical and semicritical devices; - supervise all work until competency is documented for each reprocessing task; - conduct competency testing at beginning of employment and regularly thereafter (e.g., annually); - review the written reprocessing instructions regularly to ensure they comply with the scientific literature and the manufacturers' instructions." These guidelines were not followed. Examples include: a. The Nurse Manager was interviewed on 2/05/19, beginning at 10:48 AM. When asked what nationally recognized infection control guidelines guided the facility's disinfection and sterilization practices, the Nurse Manager stated "CDC guidelines." When asked who performed high level disinfection and sterilization of surgical equipment, she stated "each dentist has their own DA(s) who do the surgical equipment." When asked where the high level disinfection and sterilization of surgical equipment took place, the	Q 232	See attached Plan of Correction, pages 6-7.		

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Q 232	<p>Continued From page 22</p> <p>Nurse Manager stated "here at the facility." When asked if the DAs were facility or contracted employees, the Nurse Manager stated no. When asked if the DAs had facility personnel files or documented facility privileges approved by the Governing Body, the Nurse Manager stated no. When asked if the DAs had documented facility competencies and training in high level disinfection and sterilization of surgical equipment, the Nurse Manager stated yes, however, evaluations of the DA(s) were done by the associated clinic, not the facility. When asked if there was documented oversight of how the DAs performed high level disinfection and sterilization of surgical equipment, the Nurse Manager stated no.</p> <p>DAs were not documented as competent to perform high level disinfection and sterilization of surgical equipment.</p> <p>Refer to Q 241 as it relates to DAs' failure to follow surgical equipment pre-cleaning enzymatic manufacturer's instructions-for-use.</p> <p>b. High level disinfection and sterilization of surgical equipment by the Nurse Manager was observed on 2/08/19, beginning at 8:05 AM. The Nurse Manager was observed utilizing a Statim 2000 steam sterilizer for a surgical intubation blade.</p> <p>The Nurse Manager's personnel file was reviewed and did not include competencies or training related to use of the Statim 2000 steam sterilizer, high level disinfection of surgical equipment, or sterilization of surgical equipment. The Nurse Manager's job description was reviewed and did not include competencies or</p>	Q 232	See attached Plan of Correction, pages 6-7.		

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Q 232	<p>Continued From page 23</p> <p>training related to use of the Statim 2000 steam sterilizer, high level disinfection of surgical equipment, or sterilization of surgical equipment. It could not be determined how the facility deemed the Nurse Manager safe to perform this duty.</p> <p>The Nurse Manager was interviewed on 2/08/19, beginning at 10:15 AM. She confirmed she did not have documented training, competencies, or a job description regarding use of high level disinfection and sterilization of surgical equipment.</p> <p>The Nurse Manager was not documented as competent to perform high level disinfection and sterilization of surgical equipment.</p> <p>2. Three of 3 RN personnel files were reviewed. One RN's file documented a hire date of 7/17/18, 6 months prior to start of survey. The file included a "NURSING ORIENTATION" form, undated, and unsigned. The orientation form included 28 different competencies, ranging from location of emergency equipment, medication administration, patient evaluation, and infection control. This form was blank. It could not be determined if the facility had deemed the RN competent to perform patient care.</p> <p>A surgical procedure was observed for Patient #10 on 2/08/19, beginning at 7:50 AM. The aforementioned RN was assigned to Patient #10's pre and post surgical care. As of 2/08/19, the RN's clinical competency form was blank.</p> <p>The Nurse Manager was interviewed on 2/08/19, beginning at 10:15 AM. She confirmed the RN should have had completed competencies prior</p>	Q 232	See attached Plan of Correction, pages 6-7.		

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Q 232	Continued From page 24 to providing patient care.	Q 232	See attached Plan of Correction, pages 6-7.		
Q 240	<p>Facility nursing staff did not have documented competencies prior to providing patient care.</p> <p>INFECTION CONTROL CFR(s): 416.51</p> <p>The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.</p> <p>This CONDITION is not met as evidenced by: Based on observation, facility policy review, facility document review, manufacturers' instructions for use review, personnel file review, Infection Control document review, CDC infection control guidelines review, and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented, and monitored for all facility staff and patients receiving care at the facility. This resulted in the inability of the facility to minimize infections and communicable diseases. Findings include:</p> <ol style="list-style-type: none"> 1. Refer to Q 241 as it relates to the facility's failure to ensure a sanitary environment for patients receiving care at the facility. 2. Refer to Q 242 as it relates to the facilities failure to provide adequate infection control training to staff. 3. Refer to Q 245 as it relates to the facility's failure to ensure a comprehensive action plan to prevent, identify and manage infections within the facility was developed and implemented. 	Q 240	See attached Plan of Correction, page 7.		

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Q 240	Continued From page 25 The cumulative effect of these systemic deficient practices resulted in the inability of the facility to minimize patients' risk of infections and communicable diseases.	Q 240	See attached Plan of Correction, page 7.		
Q 241	SANITARY ENVIRONMENT CFR(s): 416.51(a) The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, manufacturer's instructions-for-use review, document review, and staff interview it was determined the facility failed to maintain a functional and sanitary environment for patients receiving care at the facility. This had the potential to impact all patients receiving services at the facility and placed patients at an increased risk for infections. Findings include: 1. A tour of the facility was conducted with the Nurse Manager on 2/04/19, beginning at 9:30 AM. The facility consisted of 1 bed in a pre-operative area, 1 bed in a PACU, 1 bed in an operating room, a peri-operative area, and an equipment reprocessing area. The facility failed to maintain a sanitary environment. Examples include: During the tour of the facility on 2/04/19, beginning at 9:30 AM with the Nurse Manager, the following observations were noted: a. The facility's sterilization room had the	Q 241	See attached Plan of Correction, pages 7-9.		

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Q 241	<p>Continued From page 26 following sanitation issues:</p> <p>i. All horizontal surfaces, on designated "clean" and "dirty" sides, were covered with dust and debris.</p> <p>ii. There was no built in barrier between the designated "clean" and "dirty" sides where reprocessing, sterilization, and handling of surgical equipment took place. Instead, a tabletop Midmark autoclave was placed midway on the longest counter with a taped sign "clean" to the left of the autoclave and a taped sign "dirty" to the right of the autoclave. There was dust and debris located behind and underneath the Midmark autoclave.</p> <p>iii. The sterilization room's sink was stained and had visible debris. Additionally, there was a drop of an unknown red fluid on the sink's outer rim.</p> <p>iv. The plastic around the doorframe was stained brown and appeared to be corroded and/or partially melted. Additionally, there were multiple visible cracks in the plastic. Gaps in the plastic housing, where plastic panels were seated and joined, had accumulation of visible debris.</p> <p>v. The Statim 2000 sterilizer had multiple areas where the factory paint had chipped off, exposing the metal housing underneath.</p> <p>The Nurse Manager confirmed the sanitation issues inside the sterilization room.</p> <p>b. One of 2 radiation lead shields was soiled with a stained and discolored collar.</p> <p>When asked how often the lead shields were</p>	Q 241	See attached Plan of Correction, pages 7-9.	

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Q 241	<p>Continued From page 27</p> <p>cleaned and disinfected she stated after every case. When asked for a log of the last time they were cleaned or disinfected she stated there was none.</p> <p>Refer to Q 203 as it relates to the lack of periodic inspection and maintenance of radiologic shielding.</p> <p>c. The mattress on the bed in the pre-operative area had 3 adhesive bandages covering a tear in the mattress.</p> <p>When asked how the torn area covered in adhesive bandages would be sanitized, the Nurse Manager confirmed the porous surface would not be able to be disinfected or sanitized effectively.</p> <p>d. There was a cloth bench noted in the PACU.</p> <p>The policy for disinfecting the cloth chairs was requested. The Nurse Manager stated there was no policy. When asked how the chairs were disinfected and how often, she stated she was unsure.</p> <p>e. The mattress on the bed in the operating room had an approximately 1 inch tear in the mattress.</p> <p>When asked how the torn area would be sanitized, the Nurse Manager stated the torn surface would not be able to be disinfected or sanitized effectively.</p> <p>f. The inflow register in the pre-operative area, had a visible build-up of dust and debris.</p> <p>The Nurse Manager confirmed the register needed to be cleaned.</p>	Q 241	See attached Plan of Correction, pages 7-9.		

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Q 241	Continued From page 28 g. There was a cloth fabric chair noted in the operating room with multiple stains on the seat cushion. The policy for disinfecting the cloth chairs was requested. The Nurse Manager stated there was no policy. When asked how the chairs were disinfected and how often, she stated she was unsure. The facility failed to ensure a sanitary environment. 2. Manufacturer's instructions-for-use for surgical instrumentation enzymatic solution and one-step disinfectant were not followed. Examples include: a. A tour of the facility sterilization room was conducted on 2/06/19, beginning at 8:23 AM. During the tour, multiple boxes of Maxizyme enzymatic tabs, used for pre-cleaning of surgical instruments prior to sterilization, were noted. Use of Maxizyme enzymatic tabs for pre-cleaning of surgical instruments prior to sterilization was observed in the presence of the DA on 2/08/19, beginning at 8:30 AM. The DA failed to follow Maxizyme enzymatic tabs manufacturer's instructions-for-use. Examples include: i. Pre-cleaning and sterilization of surgical equipment was observed following the first surgical case of the day on 2/08/19, beginning at 8:30 AM. Upon entering the sterilization room with the DA, the facility's ultrasonic cleaner was already open and had been previously filled with a blue liquid. When asked what the blue liquid was, the DA stated "the enzymatic." When asked if	Q 241	See attached Plan of Correction, pages 7-9.	

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Q 241	<p>Continued From page 29</p> <p>she had prepared the enzymatic tabs earlier that morning, the DA stated no. When asked who had mixed the enzymatic and at what time, the DA stated she did not know.</p> <p>Maxizyme enzymatic tabs manufacturer's instructions for use stated "If pre-mixing for later use, place two tablets in 4 liter container and fill with warm water. Store mixed solution in a covered container until ready to use."</p> <p>The Nurse Manager was interviewed on 2/08/19, beginning at 8:41 AM. When asked if she knew who had mixed the enzymatic being used in the sterilization room, she stated she was unsure. The Nurse Manager stated she thought it had been mixed the night before by a different DA. When asked if the DA documented following Maxizyme enzymatic tabs manufacturer's instructions-for-use, the Nurse Manager stated no.</p> <p>The DA failed to follow Maxizyme enzymatic tabs manufacturer's instructions for use.</p> <p>ii. The DA was observed to place the surgical equipment inside the enzymatic filled ultrasonic cleaner, close the lid, and start the pre-cleaning cycle. The DA set the timer for 10 minutes. When asked how long the ultrasonic cleaning cycle took in relation to the Maxizyme enzymatic tabs manufacturer's instructions-for-use, she stated "15 minutes." The DA then stated she was unsure and, after the initial 10 minute ultrasonic cycle ended, she restarted a new cycle with the same surgical equipment for an additional 15 minutes, a total pre-cleaning cycle of 25 minutes.</p> <p>Maxizyme enzymatic tabs manufacturer's</p>	Q 241	See attached Plan of Correction, pages 7-9.		

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Q 241	<p>Continued From page 30</p> <p>instructions for use stated "Ultrasonically clean items for 10 minutes. Extended time in solution can promote rusting on some types of steel or carbides."</p> <p>The Nurse Manager was interviewed on 2/08/19, beginning at 10:15 AM. She confirmed the DA did not follow Maxizyme enzymatic tabs manufacturer's instructions for use.</p> <p>The DA failed to follow Maxizyme enzymatic tabs manufacturer's instructions for use.</p> <p>b. A facility policy "Sterilization and Disinfection Guidelines," dated 1/10/10, stated "An expiration date, determined according to manufacturer's written recommendations, should be marked on the container of the disinfectant solution currently in use." This policy was not followed.</p> <p>Virex II 256 manufacturer's instructions-for-use stated "This product may be used to fill and refill clean containers for dilution elsewhere within your facility. Make sure the small container has been cleaned, dried and properly labeled.</p> <p>A tour of the facility was conducted in the presence of the Nurse Manager on 2/04/19, beginning at 9:03 AM. During the tour, 4 secondary spray containers of Virex II 256 disinfectant were present in several clinical areas. The containers had various levels of fluid in them, but were not labeled with an expiration date. It could not be determined when the solution expired.</p> <p>The Nurse Manager was interviewed on 2/04/19, beginning at 9:32 AM. She stated she was the staff member who mixed the Virex II 256 per</p>	Q 241	See attached Plan of Correction, pages 7-9.		

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Q 241	<p>Continued From page 31</p> <p>manufacturer's instructions-for-use. The Nurse Manager confirmed the secondary spray containers in use did not have a labeled expiration date.</p> <p>The facility failed to follow Virex II 256 manufacturer's instructions-for-use.</p> <p>3. Cleaning of the facility's Midmark autoclave, Statim 2000 steam sterilizer, BioSonic UC300R ultrasonic, and disinfectant changing was not documented.</p> <p>a. A facility document "Autoclave Cleaning Log," undated, listed the cleaning dates for the Midmark M11 autoclave. There was no documented cleaning of the autoclave prior to 11/16/18. It was unclear if the autoclave had been cleaned, when, and by whom.</p> <p>b. A facility document "Autoclave Cleaning Log," undated, listed the cleaning dates for the Statim 2000 steam sterilizer. There was no documented cleaning of the sterilizer prior to 11/16/18. It was unclear if the sterilizer had been cleaned, when, and by whom.</p> <p>c. A facility document "ULTRASONIC CLEANER LOG," undated, listed the cleaning dates for the BioSonic UC300R ultrasonic cleaner, however, the form was blank. The facility was unable to provide cleaning records for the ultrasonic on any date. It was unclear if the ultrasonic had been cleaned, when, and by whom.</p> <p>d. A facility document "DOCUMENTATION OF CHANGING DISINFECTION," undated, listed the disinfectant changing dates for the ultrasonic enzymatic fluid, however, the form was blank.</p>	Q 241	See attached Plan of Correction, pages 7-9.		

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Q 241	Continued From page 32 The facility was unable to provide disinfectant changing records for the ultrasonic on any date. It was unclear if the disinfectant had been changed, when, and by whom.	Q 241	See attached Plan of Correction, pages 7-9.		
Q 242	The Nurse Manager was interviewed on 2/07/19, beginning at 8:48 AM. She confirmed the cleaning of facility disinfection and sterilization equipment was not documented. INFECTION CONTROL PROGRAM CFR(s): 416.51(b)	Q 242	See attached Plan of Correction, page 10.		
Q 245	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. This STANDARD is not met as evidenced by: Refer to Q 232 as it relates to training of facility and ancillary staff for high level disinfection and sterilization of surgical equipment. INFECTION CONTROL PROGRAM CFR(s): 416.51(b)(3)	Q 245	See attached Plan of Correction, page 10.		
	The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement. This STANDARD is not met as evidenced by:				

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Q 245	<p>Continued From page 33</p> <p>Based on staff interview, medical record review, and infection control documentation, it was determined the facility failed to ensure the infection control program established a written plan of action for identifying infections and monitored all patients of the facility. This directly affected 1 of 10 patients (Patient #6) whose records were reviewed and had the potential for patient infections to go unidentified. Findings include:</p> <p>1. Facility infection control data was requested on 2/05/19, at 10:00 AM. The data provided at that time was the facility's Infection Control Plan.</p> <p>The facility provided a document titled "Infection Control Plan," undated. The Infection Control Plan did not include a written plan on how the facility would identify infections for patients treated at the facility.</p> <p>The Nurse Manager was interviewed on 2/05/19, beginning at 10:30 AM. When asked how the facility identifies infections, she stated they do post-operative calls to the patients. She confirmed there was no documentation in the Infection Control Plan on how the facility would identify infections.</p> <p>The facility failed to ensure the Infection Control Program documented a plan of action for identifying infections.</p> <p>2. Patient #6 was a 4 year old male admitted on 8/03/18 for dental restorations. Patient #6's medical record was reviewed; it did not include a post operative call.</p> <p>The Nurse Manager was interviewed on 2/06/19,</p>	Q 245	See attached Plan of Correction, page 10.		

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Q 245	Continued From page 34 beginning at 9:30 AM. She stated her expectation was for post-op calls to be completed on 100% of patients who had a completed procedure. She confirmed Patient #6's medical record did not include a post operative call. The facility failed to ensure a documented plan of action for identifying, and managing infections for all patients had been maintained.	Q 245	See attached Plan of Correction, page 10.		

PLAN OF CORRECTION – POST FALLS AMBULATORY SURGERY CENTER - MARCH, 2019

ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	COMPLETION DATE
Q 040	GOVERNING BODY AND MANAGEMENT CFR(s): 416.41	03/14/2019
Q 040	CORRECTIVE ACTION: Governing Body meetings will be held within two weeks of organized QAPI meetings which will occur on a quarterly basis. Governing Body members will review all services provided by the facility including and not limited to patient care, infection control, quality of care programs, radiology services, contracted services, patient rights programs, and performance improvement programs, as discussed in meetings of QAPI as well as by review of logs and documentation provided to Governing Body by facility employees. Meeting agenda will be prepared in advance of the meeting upon receipt of meeting minutes received from QAPI meeting and supporting documentation. After the meeting, minutes will be typed (by a member of the Governing Body), submitted for Governing Body approval and distributed to members. Governing Body will also impress upon the facility employees the importance of communicating any issues pertaining to patient care, infection control, safety management or any other matter which may need immediate attention to the Governing Body immediately, not waiting for a QAPI meeting or Governing Body meeting to discuss.	03/14/2019
Q040	PROCESS OF IMPROVEMENT: Holding Governing Body meetings within two weeks of QAPI meetings will allow the Governing Body proper oversight, evaluation and monitoring of patient care, quality improvement, infection control, laboratory/radiology services, frequent monitoring of logs and documentation of projects, employee performance, contracted services, patient rights, administrative duties, credentialing and appointments, and safety management program ensuring proper resolution of problems and incidents, and maximizing efforts to improve patient care.	03/04/2019
Q 040	PROCESS FOR IMPLEMENTATION: Governing Body meetings will be added to the facility calendar by Surgery Center Coordinator no more than two weeks following each QAPI meeting (which have already been calendared). At least one member of the Governing Body will attend each QAPI meeting reviewing monitoring logs, performance improvement program progress, patient care concerns, adverse patient events, infection control procedures, laboratory and radiation services, safety program management, training of facility employees, contracted services and credentialing.	03/14/2019
Q 040	TRACKING/MONITORING: Agendas will be prepared for QAPI meetings by the Nurse Manager, minutes taken by a member of the QAPI, typed and distributed to the Governing Body as well as all members of the QAPI committee. A member of the Governing Body will prepare an agenda for all Governing Body meetings, take notes during the meetings and distribute the minutes to members of the Governing Body.	03/14/2019
Q 040	RESPONSIBLE PERSON(s): Governing Body	
Q 041	CONTRACTED SERVICES CFR(s): 416.41(a)	03/14/2019
Q 041	CORRECTIVE ACTION: Contracted services list to be completed and stored on the computer in the administration office. The list of contracted services will include contact information for vendors entering into contract and/or providing services to the facility. The list will include any and all services provided. Contracted services will be reviewed and supervised as needed and the contracted services list shall be updated quarterly (or as needed) at QAIP and Governing Body meetings to ensure services are provided to the facility in a safe and effective manner.	03/14/2019
Q 041	PROCESS OF IMPROVEMENT: Periodic evaluation of the contractors providing services to the facility, including supervision of maintenance, repairs and completion of contracted services will allow the Governing Body the ability to monitor services	03/04/2019

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	provided to the facility and ensure services are provided in a safe and effective manner.	
Q 041	PROCESS FOR IMPLEMENTATION: Surgery Center Coordinator shall compile complete list of current vendors providing services (including contact information and services provided) to the facility to be presented to Governing Body for review and approval. Upon approval, Governing Body members will retain the list and an updated list will be kept on the computer in the administrative office. Surgery Center Coordinator will notify a member of the Governing Body if any contracted services are required, as well as when vendors provide services to ensure that the Governing Body may supervise services as needed.	03/14/2019
Q 041	TRACKING/MONITORING: Upon approval, Governing Body members will retain the list of contracted vendors. An updated list will be kept on the computer in the administrative office by the Surgery Center Coordinator.	03/14/2019
Q 041	RESPONSIBLE PERSON(S): Surgery Center Coordinator, Governing Body oversight	03/14/2019
Q 080	QUALITY ASSESSMENT AND PERFORMANCE CFR(s): 416.43	03/14/2019
Q 080	CORRECTIVE ACTION: Committee formerly known as CQIP committee will be renamed the Quality Assessment Performance Improvement (QAPI) committee and appropriate changes will be made to the plan coordinating and outlining the responsibilities of the QAPI committee. The revised plan will provide a comprehensive, detailed, quality improvement program and will focus on developing and maintaining a plan to evaluate, measure and track improvement in all facility activities, practices and projects. The plan will involve QAPI committee members in overseeing and reviewing patient health, adverse patient events, performance improvement projects, data collection methods, frequency and details, infection control, safety management, and patient care. The QAPI committee will report findings, measurements, activities and projects to the Governing Body for approval prior to the start of any project, during the process of the project, and provide documented results at the completion of any projects or activities.	03/14/2019
Q 080	PROCESS OF IMPROVEMENT: A functioning QAPI plan and committee will utilize ongoing, data driven assessments through daily, weekly, monthly, quarterly and annual logs and monitoring forms, implemented by the QAPI and Governing Body, which will result in an improved ability by the Governing Body to evaluate facility practices, resulting in improved patient care.	03/04/2019
Q 080	PROCESS FOR IMPLEMENTATION: At the first QAPI meeting each year, at least one quality improvement project will be discussed and chosen to implement during the year. The project will pertain to the unique scope of the facility, focusing on quality improvement.	02/20/2019
Q 080	TRACKING/MONITORING: Member of QAPI committee will create logs/documentation forms, oversee tracking of data and reporting of summarized results throughout the course of the program.	03/14/2019
Q 080	RESPONSIBLE PERSON(S): QAPI members, Governing Body oversight	
Q 081	PROGRAM SCOPE; PROGRAM ACTIVITIES CFR(s): 416.43(a), 416.43(c)(1)	
Q 081	CORRECTIVE ACTION: QAPI committee will discuss and, with Governing Body approval and oversight, approve an ongoing program to measure improvement in patient health outcomes, and implement data collection and monitoring of procedures to identify and reduce medical errors. Existing quality program will be updated to the following based on the results of the survey: "The QAPI committee will address clinical and administrative performance issues and patient outcomes through collected data."	03/14/2019
Q 081	PROCESS OF IMPROVEMENT: By consistently collecting data and identifying specific areas which may require improvement, as well as focusing ongoing attention on specific issues, patient care will improve and medical errors will be reduced.	03/04/2019

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Q 081	PROCESS FOR IMPLEMENTATION: Quality indicators, adverse patient events, infection control and other aspects of performance that include patient care and services will be measured, analyzed and tracked utilizing existing logs, daily, monthly, quarterly and yearly monitoring, prioritizing performance improvement on activities which may be high-risk, high-volume and/or problem-prone areas; consider incidence, prevalence and severity of problems in those areas; and affect health outcomes, patient safety, and quality of care.	03/14/2019
Q 081	TRACKING/MONITORING: <i>Adverse Events</i> forms are in use, and provided to physician/owner upon occurrence for review and investigated. Adverse events will also be reviewed at QAPI meetings for quality care improvement. Recently implemented <i>Post-Op Infections Statement</i> are now provided to each provider at the end of each month for reporting of post-operative infections for more accurate tracking and evaluation. Existing logs and monitoring forms will continue to be used to monitor and collect data. Data will be analyzed and presented to Governing Body at QAPI meetings for review and approval.	02/20/2019
Q 081	RESPONSIBLE PERSON(s): RNs, members of QAPI, Governing Body oversight	
Q 082	PROGRAM DATA; PROGRAM ACTIVITIES CFR(s): 416.43(b), 416.43(c)(2), 416.43(c)(3)	
Q 082	CORRECTIVE ACTION: Necessity of use of data collection vehicles in the form of monitoring forms and collection logs will be re-enforced with facility employees and required as part of employee job description. Facility employees will receive training regarding each data collection vehicle, its purpose and reason for requirement. Nurse Manager will oversee data collection, ensuring information is being tracked correctly, as assigned.	03/14/2019
Q 082	PROCESS OF IMPROVEMENT: Preventive strategies resulting from accurate data collection will allow the facility to target adverse patient events, ensure that all staff are familiar with strategies to prevent these events, and monitor the effectiveness and safety of its services and quality of its care and identify opportunities that could lead to improvements and changes in patient care.	03/04/2019
Q 082	PROCESS FOR IMPLEMENTATION: Facility employees will receive additional training by the Nurse Manager and Infection Control Coordinator regarding each monitoring form and tracking log required for all patient care and programs and will be notified that completion of this training as well as completion of these forms is required as a part of the job description for the position held within the facility.	03/14/2019
Q 082	TRACKING/MONITORING: Multiple existing forms & log tracking sheets such as: Handwashing Observation Log, Cleaning Observation Log, Crash Cart Daily Check Log, Lead Apron Inspection Log, Medication Check Form, Autoclaves Monthly Cleaning Log, Narcotic Count, etc.	02/28/2019
Q 082	RESPONSIBLE PERSON(s): RNs, Nurse Manager oversight, Governing Body oversight	
Q 083	PERFORMANCE IMPROVEMENT PROJECTS CFR(s): 416.43(d)	
Q 083	CORRECTIVE ACTION: On an annual basis during the first QAPI committee of each year, the committee will discuss and, with Governing Body approval and oversight, approve at least one improvement project which will reflect the scope and complexity of this facility's operation. The project chosen for the current year was proposed to the Governing Body and approved. The project shall measure improvement in patient health outcomes, and implement data collection and monitoring of procedures to identify and reduce medical errors.	02/20/2019
Q 083	PROCESS OF IMPROVEMENT: An annual project measuring improvement in patient health outcomes, and implementation of data collection and monitoring of procedures, shall identify and assist the Governing Body in identifying and reducing medical errors.	03/04/2019
Q 083	PROCESS FOR IMPLEMENTATION: During the first QAPI meeting of the year, typically in February, the QAPI and Governing Body will discuss and evaluate possible	03/14/2019

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	improvement programs which may be implemented for the year to document and evaluate current patient care practices, infection control procedures, safety procedures and/or patient rights procedures. Upon review, the QAPI and Governing Body will determine which project will be implemented and assigned to a QAPI member to begin and oversee, with Governing Body periodic review and approval.	
Q 083	TRACKING/MONITORING: Project plan will be written up by a member of the QAPI and approved by the Governing Body. Forms and tracking logs will be created, if necessary to collect data to be analyzed and evaluated prior to presenting summarized report to the QAPI and Governing Body.	03/14/2019
Q 083	RESPONSIBLE PERSON(s): QAPI member, Governing Body oversight	
Q 084 GOVERNING BODY RESPONSIBILITIES CFR(s): 416.43(e)		
Q 084	CORRECTIVE ACTION: Governing Body will update current QAPI program to ensure the program is defined, implemented, and maintained; addresses the facilities priorities, and all improvements are evaluated for effectiveness; specifies data collection methods, frequency, and details; clearly establishes expectations for safety; and allocates sufficient staff, time, systems and training to implement the program. The Governing Body will attend all QAPI meetings, and oversee QAPI projects, training and responsibilities assigned to QAPI members.	03/14/2019
Q 084	PROCESS OF IMPROVEMENT: Updating the Quality Assurance Performance Improvement program, which was formerly known as the Coordinated Quality Improvement Program, will allow the Governing Body to ensure the program is clearly defined, implemented and maintained, resulting in a higher quality program oversight and direction to facility employees.	03/04/2019
Q 084	PROCESS FOR IMPLEMENTATION: Governing Body member will revise the CQIP program and update to reflect the Quality Assurance Performance Improvement (QAPI) program to ensure the program is defined, implemented, and maintained; addresses the facilities priorities, and all improvements are evaluated for effectiveness; specifies data collection methods, frequency, and details; clearly establishes expectations for safety; and allocates sufficient staff, time, systems and training to implement the program.	03/14/2019
Q 084	TRACKING/MONITORING: Governing Body will attend all QAPI meetings, oversee programs as approved by Governing Body, periodically review program and committee to ensure procedures are being followed as dictated in the program.	03/14/2019
Q 084	RESPONSIBLE PERSON(s): Governing Body	
Q 109 EMERGENCY EQUIPMENT CFR(s): 416.44(d)		
Q 109	CORRECTIVE ACTION: Emergency equipment procedures have been set to ensure emergency equipment is available for immediate use during emergency situations, is appropriate for the facility's patient population, and is maintained by appropriate personnel.	12/14/2018
Q 109	PROCESS OF IMPROVEMENT: Evaluation of the emergency equipment on an daily, weekly and monthly basis ensures patients will receive proper emergency care, if needed, with equipment that has been evaluated and functions properly, resulting in safe patient care.	03/04/2019
Q 109	PROCESS FOR IMPLEMENTATION: The circulating RN has been assigned the responsibility of checking all life-saving equipment at the beginning of every surgery day to ensure proper function. RNs have been assigned specific daily duties as part of their job description and have been trained on those duties.	02/28/2019
Q 109	TRACKING/MONITORING: Crash Cart Daily Check log sheet, Emergency Equipment Log, Crash Cart/Braslow Bag Monthly Check are currently in use to track and monitor the suitability of use of the emergency equipment to ensure safe patient care.	02/28/2019
Q 109	RESPONSIBLE PERSON(s): RNs, Nurse Manager oversight, Governing Body oversight	

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Q 162 FORM AND CONTENT OF RECORD CFR(s): 416.47(b)		
Q 162	CORRECTIVE ACTION: The consent form provided to patients/guardians shall include a request for entry of the "time" the document was signed by the patient/guardian and witnessed by a member of the facility staff.	03/14/2019
Q 162	PROCESS OF IMPROVEMENT: Providing a "time" entry on the Consent for General Anesthesia provides facility employees the ability to determine what time the consent was given and ensure that the consent was given at a reasonable time prior to the surgery, improving patient care and bringing the facility into regulatory compliance.	03/04/2019
Q 162	PROCESS FOR IMPLEMENTATION: Surgery Center Coordinator will add the "Time" blank on the forms prior to printing the patient chart and forms for completion, prior to surgery.	03/14/2019
Q 162	TRACKING/MONITORING: Periodic chart review by Surgery Center Coordinator and RNs will ensure time is entered on Consent for General Anesthesia forms prior to surgery.	03/14/2019
Q 162	RESPONSIBLE PERSON(S): Surgery Center Coordinator, Governing Body oversight	
Q 200 LABORATORY AND RADIOLOGIC SERVICES CFR(s): 416.49		
Q 200	CORRECTIVE ACTION: New policy has been implemented for Radiology Protection Equipment to ensure radiology protective equipment is inspected on a regular basis, is cleaned properly, adequately provides protection from radiation exposure and is cared for properly.	02/28/2019
Q 200	PROCESS OF IMPROVEMENT: Providing training to facility employees regarding correct procedures for inspecting radiology protection equipment and correct procedures for cleaning the equipment improves quality of patient care.	03/04/2019
Q 200	PROCESS FOR IMPLEMENTATION: Cleaning of radiation protection equipment occurs after each use, and again during the terminal cleaning process at the end of each surgery day. The equipment is also inspected each month as included in the RN monthly responsibilities. The RN will visually inspect each piece of equipment for wear and tear, as well as staining. The RN will be trained on proper storage, cleaning procedures and procedures for testing effectiveness of the radiology shield.	03/14/2019
Q 200	TRACKING/MONITORING: RNs will inspect radiology protection equipment on a monthly basis, and log inspection in appropriate log sheet.	03/14/2019
Q 200	RESPONSIBLE PERSON(S): RNs, Nurse Manager oversight, Governing Body oversight	
Q 203 RADIOLOGIC SERVICES CFR(s): 416.49(b)(1)		
Q 203	CORRECTIVE ACTION: Existing policy for Radiation Exposure has been reviewed and re-implemented. Dosimetry radiation badges have been ordered and have been introduced to RNs on staff. RNs have received instructions on how and when to wear the dosimetry radiation badge and the processing required to receive results of the measurements for radiation in the facility.	02/21/2019
Q 203	PROCESS OF IMPROVEMENT: Measurement of radiation exposure using radiation badges provides facility employees with the ability to evaluate the levels of radiation exposure in the facility, improves quality of patient care, and lowers risk of excessive radiation exposure.	03/04/2019
Q 203	PROCESS FOR IMPLEMENTATION: Dosimetry badges have been ordered, received and placed into use in the facility. A radiation badge will be worn by one facility employee while in the operating room to ensure a minimal amount of exposure. The badge will be sent to the appropriate agency for testing. Results of the radiation exposure are kept by the Nurse Manager.	02/21/2019
Q 203	TRACKING/MONITORING: Nurse Manager will wear the radiation badge while in the operating room, returned to the badge vendor on a monthly basis for evaluation and reporting. Nurse Manager will keep results on file for Governing Body periodic review.	02/21/2019
Q 203	RESPONSIBLE PERSON(S): Nurse Manager, Governing Body oversight	

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Q 219 PATIENT RIGHTS CFR(s): 416.50		
Q 219	CORRECTIVE ACTION: Patient Rights and Responsibilities have been posted in a conspicuous, visible area in the reception room. The Patient Rights and Responsibilities have also been updated to reflect all required information, including the address and phone number for the State Agencies to whom patients may report complaints.	02/20/2019
Q 219	PROCESS OF IMPROVEMENT: Posting the Patient Rights and Responsibilities in a visible place, likely to be seen by patients or by the patient’s representative improves patient care by protecting and promoting the exercise of the patient’s rights.	03/04/2019
Q 219	PROCESS FOR IMPLEMENTATION: Patient Rights and Responsibilities have been posted in the waiting area of the facility, and updated copies of the document will be given to all patients when scheduling a surgery appointment at their provider’s office, prior to arrival at the facility.	03/14/2019
Q 219	TRACKING/MONITORING: Printed forms will be distributed to provider offices to replace old forms previously used. Surgery Center Coordinator will follow up with provider offices to ensure use of proper forms.	03/14/2019
Q 219	RESPONSIBLE PERSON(s): Surgery Center Coordinator, Governing Body oversight	
Q 221 NOTICE OF RIGHTS CFR(s): 416.50(a)		
Q 221	CORRECTIVE ACTION: The facility’s Patient Rights and Responsibilities have been updated to reflect all required information, including the address and phone number for the State Agencies to whom patients may report complaints.	02/20/2019
Q 221	PROCESS OF IMPROVEMENT: Providing patients and their representatives with Patient Rights and Responsibilities protects patients and their representatives and promotes the exercise of the patient’s rights.	03/04/2019
Q 221	PROCESS FOR IMPLEMENTATION: Patient Rights and Responsibilities have been updated to include correct websites, agency name, addresses and phone numbers. The Patient Rights and Responsibilities will be given to all patients when scheduling a surgery appointment at their provider’s office, prior to arrival at the facility.	02/20/2019
Q 221	TRACKING/MONITORING: Printed forms will be distributed to provider offices to replace old forms previously used. Surgery Center Coordinator will follow up with provider offices to ensure use of proper forms.	03/14/2019
Q 221	RESPONSIBLE PERSON(s): Surgery Center Coordinator, Governing Body oversight	
Q 222 NOTICE OF RIGHTS – POSTING CFR(s): 416.50(a)(1)(i)		
Q 222	CORRECTIVE ACTION: The facility’s Patient Rights and Responsibilities have been updated to reflect all required information, including the address and phone number for the State Agencies to whom patients may report complaints.	02/20/2019
Q 222	PROCESS OF IMPROVEMENT: Providing patients and their representatives with Patient Rights and Responsibilities protects patients and their representatives and promotes the exercise of the patient’s rights.	03/04/2019
Q 222	PROCESS FOR IMPLEMENTATION: Patient Rights and Responsibilities have been updated to include correct websites, agency name, addresses and phone numbers. The Patient Rights and Responsibilities will be given to all patients when scheduling a surgery appointment at their provider’s office, prior to arrival at the facility.	02/20/2019
Q 222	TRACKING/MONITORING: Printed forms will be distributed to provider offices to replace old forms previously used. Surgery Center Coordinator will follow up with provider offices to ensure use of proper forms.	03/14/2019
Q 222	RESPONSIBLE PERSON(s): Surgery Center Coordinator, Governing Body oversight	
Q 232 SAFETY CFR(s): 416.50(f)(2)		
Q 232	CORRECTIVE ACTION: Organize and document annual training, new hire orientation, and specific-duty training for sterilization and disinfection of semi-critical equipment to be provided to all facility employees and ancillary personnel and ensure their understanding of the importance of reprocessing instruments for safe patient care.	02/28/2019

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Q 232	PROCESS OF IMPROVEMENT: Providing appropriate training and orientation to facility employees and ancillary personnel will provide comprehensive and intensive training for all staff assigned to reprocess semi-critical instruments to provide safe patient care and prevent and control infections and communicable diseases.	03/04/2019
Q 232	PROCESS FOR IMPLEMENTATION: Annual training completed. Competencies have been created for each sterilizing/disinfecting process and will be administered to all facility employees and ancillary personnel to ensure competency in successfully and accurately completing the processes required for safe patient care and infection control using ultrasonic cleaning and autoclave sterilizers for semi-critical instruments.	02/28/2019
Q 232	TRACKING/MONITORING: Training of facility employees and ancillary personnel to use daily, monthly sterilization logs to be kept when utilizing the sterilizing/disinfecting units. Annual training documents have been completed for those in attendance.	02/28/2019
Q 232	RESPONSIBLE PERSON(S): Nurse Manager, Governing Body oversight	
Q 240	INFECTION CONTROL CFR(s): 416.51	
Q 240	CORRECTIVE ACTION: Update, implement and monitor existing infection control program through training of facility employees and ancillary personnel with Governing Body oversight. Infection Control Coordinator will receive additional training to ensure proper documentation of infection control procedures, training and program necessities.	03/14/2019
Q 240	PROCESS OF IMPROVEMENT: Development, implementation and monitoring of a quality infection control program will provide the facility with the ability to minimize infections and communicable diseases.	03/04/2019
Q 240	PROCESS FOR IMPLEMENTATION: Governing Body will update existing infection control plan to include procedures which will ensure a sanitary environment for patients receiving care, provide adequate infection control training to staff and a comprehensive action plan to prevent, identify and manage infections within the facility. This will be accomplished through updating the contract of the janitorial company to include all areas of the facility including sterilization areas identified in Q 241; completion of annual training of all facility employees and ancillary personnel as identified in Q 242; and implementation of the updated action plan including training of all personnel associated with the facility and Infection Control Coordinator training.	03/14/2019
Q 240	TRACKING/MONITORING: ICC will oversee tracking and monitoring of all aspects of the infection control program utilizing tracking logs, monitoring forms, and scheduled periodic observation. ICC will then report findings to QAPI on a quarterly basis. The Governing Body will review findings on a quarterly basis as well. ICC will also be trained to notify ICC of any immediate concerns for resolution.	03/14/2019
Q 240	RESPONSIBLE PERSON(S): ICC, Governing Body oversight	03/14/2019
Q 241	SANITARY ENVIRONMENT CFR(s): 416.51 (a)	
Q 241	CORRECTIVE ACTION: 1. Include sterilization area in janitorial contract, to be terminal cleaned after every surgery day, including deep cleaning of cupboards, countertops and difficult-to-reach spaces on a monthly basis.	02/22/2019
Q 241	2. Clearly designate "Clean" and "Dirty" sides of sterilization area and provide additional training to ancillary personnel regarding process of sterilization to avoid contamination of sterilized instruments. Provide maintenance on existing sterilization equipment (i.e. Midmark autoclave, Statim autoclave and ultrasonic cleaner) including but not limited to, cleaning of inside and outside of equipment, order protective covering for sterilizers to assist in reducing wear and tear of the outside of the machine, training team on frequency of cleaning of equipment on a daily, weekly, monthly basis and documenting such cleaning.	02/28/2019

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Q 241	3. Radiation protection equipment shall be cleaned after each use, during terminal clean after each surgery day, and will be cleaned of any stains on an as-needed basis as stated in Q 200, documented in appropriate tracking log.	02/28/2019
Q 241	4. Repair tears in mattresses in the pre-operatory area, operating room. Remove all cloth furniture and chairs from any patient care areas (i.e. operating room chairs, bench in PACU).	03/14/2019
Q 241	5. Post instructions for use for all sterilization equipment including enzymatic solution, provide additional training to all ancillary personnel regarding steps to correctly utilize the enzymatic tabs, ultrasonic cleaning equipment, proper documentation in tracking logs.	02/20/2019
Q 241	6. Establish procedure of marking and labeling appropriate containers (Virex) after mixing with the date mixed, expiration date according to manufacturer's recommendations, and initials of employee mixing the solution.	02/20/2019
Q 241	7. Provide additional training to facility employees and ancillary personnel on the proper cleaning and documentation of all facility sterilization equipment. Require cleaning and documentation of cleaning of facility sterilization equipment as part of job description of facility employees.	02/28/2019
Q 241	PROCESS OF IMPROVEMENT: Defining appropriate procedures and process for sanitation of facility and sterilization of surgical instruments will provide the facility with the ability to prevent and control infections and communicable diseases.	03/04/2019
Q 241	PROCESS FOR IMPLEMENTATION (item numbers refer to items referenced on deficiency Q 241, Form CMS-2567):	
Q 241	1.a)i. Include sterilization area in janitorial contract, to be terminal cleaned after every surgery day, including deep cleaning of cupboards, countertops and difficult-to-reach spaces on a monthly basis. ICC to evaluate and observe cleaning of all areas, documenting cleanliness utilizing existing and updated forms and tracking logs.	02/22/2019
Q 241	1.a)ii. Clearly designate "Clean" and "Dirty" sides of sterilization area and provide additional training to ancillary personnel regarding process of sterilization to avoid contamination of sterilized instruments. (Please see "Guidelines for Infection Control in Dental Health-Care Settings" of the CDC guidelines. A copy of the referenced section is attached as Appendix A. "DHCP should process all instruments in a designated central processing area to more easily control quality and ensure safety (24*). The central processing area should be divided into sections for 1) receiving, cleaning, and decontamination; 2) preparation and packaging; 3) sterilization; and 4) storage. Ideally, walls or partitions should separate the sections to control traffic flow and contain contaminants generated during processing. When physical separation of these sections cannot be achieved, adequate spatial separation might be satisfactory if the DHCP who process instruments are trained in work practices to prevent contamination of clean areas (248). Space should be adequate for the volume of work anticipated and the items to be stored (248).")	02/28/2019
Q 241	1.a)iii. Include sterilization room in janitorial contract, to be terminal cleaned after every surgery day, including deep cleaning of cupboards, countertops and difficult-to-reach spaces on a monthly basis. Provide additional training to facility and ancillary personnel including proper cleaning/use of sterilization equipment. ICC to evaluate and observe cleaning of all areas, documenting cleanliness utilizing existing and updated forms and tracking logs.	02/22/2019
Q 241	1.a)iv. Provide maintenance on existing sterilization equipment (i.e. Midmark autoclave, Statim autoclave and ultrasonic cleaner) including but not limited to, cleaning of inside and outside of equipment, order protective covering for sterilizers to assist in reducing wear and tear of the outside of the machine, training team on frequency of cleaning of equipment on a daily, weekly, monthly basis and	03/14/2019

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	documenting such cleaning. ICC coordinator to observe cleanliness of all areas and notify Governing Body of any issues which may arise such as tears in mattresses, specific employees not performing duties as trained, etc.	
Q 241	1.a)v. Provide maintenance on existing sterilization equipment including but not limited to, cleaning of inside and outside of equipment, order protective covering for sterilizers to assist in reducing wear and tear of the outside of the machine, training team on frequency of cleaning of equipment on a daily, weekly, monthly basis and documenting such cleaning. ICC coordinator to observe cleanliness of all areas and notify Governing Body of any issues which may arise such as tears in mattresses, specific employees not performing duties as trained, etc.	03/14/2019
Q 241	1.b) Radiation protection equipment shall be cleaned after each use, during terminal clean after each surgery day, and will be cleaned of any stains on an as-needed basis as stated in Q 200, documented in appropriate tracking log.	02/28/2019
Q 241	1.c) Repair tear in mattress in the pre-operative area. Contact repair company to evaluate and repair tears in mattresses to return mattresses to compliance for appropriate sanitation.	03/14/2019
Q 241	1.d) Remove all cloth furniture and chairs from any patient care areas (i.e. operating room chairs, bench in PACU).	03/05/2019
Q 241	1.e) Repair tear in mattress in the operating room. Contact repair company to evaluate and repair tears in mattresses to return mattresses to compliance for appropriate sanitation.	03/14/2019
Q 241	1.f) Include air flow vents, blinds, cupboard tops in janitorial contract, including difficult-to-reach spaces on a monthly basis. ICC to evaluate and observe cleaning of all areas, documenting cleanliness utilizing existing and updated forms and tracking logs.	03/02/2019
Q 241	1.g) Remove all cloth furniture and chairs from any patient care areas (i.e. operating room chairs, bench in PACU).	03/05/2019
Q 241	2.a)i. Enzymatic cleaning procedures have been posted, facility and ancillary personnel have been trained to use the posted instructions for preparing the enzymatic cleaner for pre-treatment of surgical instruments as outlined on manufacturer’s instructions and document preparation of enzymatic cleaner on appropriate log sheet posted on the wall near the enzymatic cleaner.	02/28/2019
Q 241	2.a)ii. Enzymatic cleaning procedures have been posted, facility and ancillary personnel have been trained to use the posted instructions for reference and process surgical instruments for only 10 minutes prior to sterilization.	02/28/2019
Q 241	2.b) Train facility employees on proper procedure of marking and labeling appropriate containers (Virex) after mixing with the date mixed, expiration date according to manufacturer’s recommendations, and initials of employee mixing the solution, following manufacturer’s instructions for use.	02/20/2019
Q 241	3. All tracking logs of all sterilization equipment have been posted, facility employees and ancillary personnel have been trained on the proper use of all sterilization equipment, manufacturer’s instructions and user manuals are posted and/or readily available for reference.	02/28/2019
Q 241	TRACKING/MONITORING: All monitoring forms and tracking logs are in place. Facility employees and ancillary personnel have been trained on the proper completion of the tracking vehicles. Nurse Manager and ICC will review forms for accuracy. Any concerns will be brought to the attention of the QAPI and Governing Body for investigation and resolution/evaluation for improvement.	02/28/2019
Q 241	RESPONSIBLE PERSON(S): Infection Control Coordinator, Governing Body oversight	02/28/2019

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Q 242 INFECTION CONTROL PROGRAM CFR(s): 416.51(b)		
Q 242	CORRECTIVE ACTION: Provide annual training, new hire orientation, and specific-duty training for sterilization and disinfection of semi-critical equipment to be provided to all facility employees and ancillary personnel and ensure their understanding of the importance of reprocessing instruments for safe patient care and infection control procedures.	02/28/2019
Q 242	PROCESS OF IMPROVEMENT: Providing appropriate training and orientation to facility employees and ancillary personnel will provide comprehensive and intensive training for all staff assigned to reprocess semi-critical instruments to provide safe patient care and prevent and control infections and communicable diseases.	03/04/2019
Q 242	PROCESS FOR IMPLEMENTATION: Annual training was provided to all facility employees and ancillary personnel, who have also been required to perform competency testing for infection control procedures prior to working in the facility. The Nurse Manager or ICC will evaluate the competency testing for each employee and ancillary personnel to ensure the ability to follow proper infection control protocol is followed.	02/28/2019
Q 242	TRACKING/MONITORING: Training of facility employees and ancillary personnel to use daily, monthly sterilization logs to be kept when utilizing the sterilizing/disinfecting units. Annual training documents have been completed for those in attendance.	02/28/2019
Q 242	RESPONSIBLE PERSON(S): Nurse Manager, ICC, Governing Body oversight	
Q 245 INFECTION CONTROL PROGRAM CFR(s): 416.51(b)(3)		
Q 245	CORRECTIVE ACTION: Prepare written plan of action for preventing, identifying and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.	03/14/2019
Q 245	PROCESS OF IMPROVEMENT: Establishing a written plan of action for identifying infections and monitoring all patients of the facility will provide the Governing Body, QAPI, ICC, Nurse Manager and all facility and ancillary personnel specific guidelines for preventing, identifying and managing infections and communicable diseases and immediately implementing corrective and preventive measures that result in improvement.	03/04/2019
Q 245	PROCESS FOR IMPLEMENTATION: Governing Body will prepare a written plan of action outlining the procedures for the facility to follow to identify infections for patients treated at the facility. The plan will include a newly-implemented form to be sent to each provider's office on a monthly basis, requesting verification of post-operative calls made to each patient/responsible party. Providers will be required to verify whether or not post-operative infections were noted by patient/responsible party. In addition, all providers will be required to complete and return post-operative call reports for each patient which will be included in the patient chart. Surgery Center Coordinator will follow up with each providers office to ensure receipt of a post-operative call form for each patient. Upon receipt of a form indicating any post-operative infection, the Surgery Center Coordinator will notify the ICC and Governing Body. The ICC and Governing Body will investigate and evaluate the policies and procedures in place which could have prevented the infection.	03/14/2019
Q 245	TRACKING/MONITORING: Post-operative call form will be required for each patient to be completed by provider. Newly implemented form will be sent to each provider's office on a monthly basis to request verification of post-operative calls.	03/14/2019
Q 245	RESPONSIBLE PERSON(S): ICC, Surgery Center Coordinator, Governing Body oversight	
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE		
	<i>Paul Mulder</i>	<i>owner/director</i>
		<i>3/4/19</i>