

COPY



IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

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3232 Elder Street
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PHONE 208-334-6626
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July 25, 2011

Melisa Robinson, Administrator
Addison Surgery Center
191 Addison Avenue
Twin Falls, ID 83301

RE: Addison Surgery Center, Provider #13C0001018

Dear Ms. Robinson:

This is to advise you of the findings of the Medicare survey of Addison Surgery Center, which was conducted on July 20, 2011.

Enclosed is a Statement of Deficiencies/Plan of Correction Form CMS-2567, listing Medicare deficiencies. In the spaces provided on the right side of each sheet, please provide a Plan of Correction. It is important that your Plan of Correction address each deficiency in the following manner:

An acceptable plan of correction (PoC) contains the following elements:

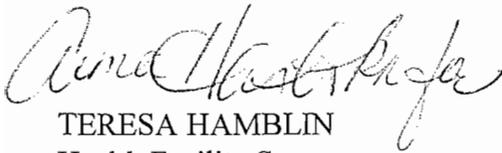
- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date 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 the Form CMS-2567.

Melisa Robinson, Administrator
July 25, 2011
Page 2 of 2

After you have completed your Plan of Correction, return the original to this office by **August 7, 2011**, and keep a copy for your records.

Thank you for the courtesies extended to us during our visit. If you have questions, please call this office at (208) 334-6626.

Sincerely,



TERESA HAMBLIN
Health Facility Surveyor
Non-Long Term Care



NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

TH/srm
Enclosures

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

PRINTED: 07/22/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001018	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/20/2011
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NAME OF PROVIDER OR SUPPLIER ADDISON SURGERY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 191 ADDISON AVENUE TWIN FALLS, ID 83301
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the recertification survey of your Ambulatory Surgical Center. The surveyors conducting the review were:</p> <p>Teresa Hamblin RN, MS, HFS, Team Lead Aimee Hastriter RN, BS, HFS Mark Grimes, Supervisor of Facility Fire Safety and Construction Program</p> <p>The following acronyms were used in this report:</p> <p>ASC - Ambulatory Surgical Center CRNA - Certified Registered Nurse Anesthetist DEA - Drug Enforcement Administration EKG - Electrocardiograph H&P - History and Physical MAC - Monitored Anesthesia Care PRE-OP - Preoperative QAPI - Quality Assurance Performance Improvement</p>	Q 000		
Q 041	<p>416.41(a) CONTRACT SERVICES</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on contract review, record review, staff interview, and review of information from the Idaho State Board of Pharmacy, and DEA, it was determined the ASC failed to ensure 2 of 2 contracted CRNA staff (A and B) had appropriate Idaho State Board of Pharmacy and DEA registrations for controlled substances to</p>	Q 041		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Melisa Robinson</i>	TITLE <i>RD, Manager</i>	(X6) DATE <i>8/4/11</i>
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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 041	<p>Continued From page 1</p> <p>independently administer controlled substances. This resulted in CRNAs administering controlled substances to patients without required pharmacy registration or physician oversight. Findings include:</p> <p>An "ANESTHESIA SERVICES AGREEMENT," dated 5/09/04, between the ASC and two CRNAs indicated the CRNAs were acting independently rather than as employees or agents of the ASC. The agreement stated the anesthesia providers would bill patients directly for anesthesia services, have "user privileges," carry their own malpractice insurance coverage, and not be employees. The agreement provided a "Declaration of Independent Contractor" status, assuring the ASC that the anesthesia providers had complied with all federal, state, and local laws regarding business permits, certificates and licenses that may have been required to carry out the work to be performed under the agreement</p> <p>During a review of credentialing and personnel files, there was no evidence of CRNAs registration with the Idaho State Board of Pharmacy or the DEA. During an interview on 7/12/11 at approximately 5:00 PM, the Administrator confirmed the CRNAs did not have pharmacy credentials. She stated it was her understanding they were not required.</p> <p>CRNA A was interviewed by telephone on 7/11/11 at 3:35 PM. She confirmed she was working independently, rather than under the supervision of ASC physician staff. She also confirmed she did not have licensure or registration with the Idaho State Board of Pharmacy or the DEA. She stated CRNAs were not required to have</p>	Q 041	<p>CRNA's contracted with</p> <p>Addison Surgery Center are currently in the process of obtaining a DEA and ID State Board of Pharmacy license. When DEA and Pharmacy license are obtained, CRNA's will be working independently as contracted and will be within their scope of practice. M. Robinson RN spoke with [REDACTED] at the State Board of Pharmacy on 8/2/11 at 0945 who confirmed that once paperwork is obtained by the State that registration will take approximately two weeks. M. Robinson RN will verify DEA and Pharmacy licenses when obtained and verify licenses yearly.</p>	9/15/11

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Q 041	<p>Continued From page 2 pharmacy credentials.</p> <p>CRNA B was interviewed on 7/20/11 at 3:10 PM. He confirmed he was working independently and not under the supervision of ASC physician staff. He stated the physician staff did not know anything about anesthesia. He also stated he did not have pharmacy credentials and explained his professional organization did not require them.</p> <p>Surveyors received email correspondence, dated 7/14/11, from the Senior Compliance Officer with the Idaho State Board of Pharmacy. In the email, the Senior Compliance Officer stated that unless the CRNAs were acting as agents or employees of the practitioner they were required to obtain both a DEA registration and an Idaho Controlled Substance registration.</p> <p>In a letter, dated 5/25/11, the Executive Director of the Idaho State Board of Pharmacy referred to Idaho Code Section 37-2716 (a) Registration Requirements. It states: "Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, must obtain annually a registration issued by the board in accordance with its rules." He said the definition of "dispense" included prescribing and administering according to Idaho Code 37-2701(i). For exemption to the registration requirement, he referred to Idaho Code 37-2716. It states: "The following persons need not register and may lawfully possess controlled substances under this act: An agent or employee of any registered manufacturer, distributor, or dispenser, of any controlled</p>	Q 041			

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Q 041	Continued From page 3 substance if he is acting in the usual course of his business or employment." The letter further states that the Idaho Board of Pharmacy Rule 435 (IDAPA 27.01.01.435) required an applicant for a board of pharmacy controlled substance registration to hold a valid federal DEA registration. In a letter, dated 3/22/11, a representative of the DEA to the Idaho State Board of Pharmacy clearly stated that a CRNA could not independently administer, dispense, or prescribe controlled substances without being registered with the DEA. Versed (midazolam), a Schedule IV substance and Fentanyl, a Schedule II substance are examples of controlled substances that CRNA A and CRNA B selected and administered to patients in the ASC. Documentation in records indicated CRNA A administered Versed and/or Fentanyl to Patients #4, #5, #6, #7, #17, and #18. Documentation in records indicated CRNA B administered Versed and Fentanyl to Patients #1, #9, #11, #12, #13, #14, #15, #19, and #20.	Q 041			
Q 043	The ASC did not ensure appropriate pharmacy and DEA registration for CRNA staff. 416.41(c) DISASTER PREPAREDNESS PLAN (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.	Q 043			

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Q 043	<p>Continued From page 4</p> <p>(2) The ASC coordinates the plan with State and local authorities, as appropriate.</p> <p>(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, it was determined the facility failed to ensure the governing body conducted an annual emergency preparedness drill and coordinated the written emergency preparedness plan with State and local authorities for all patients, staff and visitors. This resulted in the potential for the facility's inability to effectively manage the care, health and safety of patients, staff and other individuals when a major disruptive event occurred. Findings include:</p> <p>The facility's emergency preparedness plan was reviewed. This plan did not include documentation of coordination with state and local authorities and there was no record of an emergency preparedness drill being conducted annually to test the plan's effectiveness. When asked about the plan, on 7/12/11 at approximately 3:30 PM, the facility Administrator acknowledged the lack of an annual drill and the lack of documentation of coordination with State and local authorities.</p> <p>The facility failed to ensure emergency preparedness was coordinated with State and local authorities and that an emergency preparedness drill was conducted at least</p>	Q 043	<p>██████████, Twin Falls County Department of Emergency Services Director was contacted on 8/2/11 about conducting annual drills with Addison Surgery Center. She responded and an initial meeting has been set up for 8/19/11 to commence preparations for drill. Drill worksheets will be provided and completed at each drill and documentation by local and state authorities will also be completed. Policy will be revised to include annual disaster drills. Administration is to be the contact for local and state services coordination.</p>	10/31/11	

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Q 043	Continued From page 5	Q 043		
Q 083	<p>416.43(d) PERFORMANCE IMPROVEMENT PROJECTS</p> <p>(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.</p> <p>(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</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to conduct performance improvement projects. This resulted in the inability of the ASC to measure the effectiveness of its services. Findings include:</p> <p>Neither the QAPI documents nor the undated "QUALITY ASSURANCE/PERFORMANCE IMPROVEMENT PLAN," contained information or data related to a performance improvement project.</p> <p>The Administrator was interviewed on 7/12/11 at 9:40 AM. She stated the ASC did not have a performance improvement project underway or planned for this year.</p> <p>The ASC failed to conduct performance improvement projects.</p>	Q 083	<p>Performance Improvement Project to be implemented on hand washing for 2011 and 2012. A yearly project will be initiated and a policy to support the projects will be written. Administration will implement the project and employees will participate. Periodic review of data collection will be overseen by administration and a description of the projects results will be reviewed by staff and Governing Body.</p>	7/11/11 for initiation. Project ongoing.
Q 162	416.47(b) FORM AND CONTENT OF RECORD	Q 162		

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Q 162	Continued From page 6 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: <ul style="list-style-type: none"> (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. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. This STANDARD is not met as evidenced by: Based on record review and staff interview it was determined the ASC failed to ensure medical records contained complete comprehensive information for 13 of 19 patients (#1, #4, #5, #6, #7, #8, #9, #11, #12, #13, #14, #15, and #20) whose medical records were reviewed. This resulted in a lack of clarity as to the course of medication administration during surgery and improperly executed consent. Findings include: 1. Documentation of medication administration by CRNAs during surgery was incomplete in patient records, as follows:	Q 162	CRNA's will attend education on documenting complete medication administration on records; i.e. "2 'mg'" Fentanyl instead of "2" Fentanyl. Chart audits will be modified to include monitoring of CRNA documentation. M. Robinson RN will complete the education with the CRNAs and monitor chart audits. Education will be provided to the CRNAs and pre-op nurse to review each consent for type of anesthesia, date, time, and signatures. Chart audits will be modified to include this information. M. Robinson RN will complete the education and monitor chart audits.	8/31/11	

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Q 162	<p>Continued From page 7</p> <p>a. Patient #1 was a 53 year old female had exploratory surgery for an inflamed ligament (capsulitis) on 12/28/10. The "ANESTHESIA RECORD," dated 12/29/10 at 8:45 AM, documented the CRNA administered "2" Versed and "2" Fentanyl. The unit measurements and route of the medications were not documented.</p> <p>b. Patient #4 was a 36 year old male who had corrective surgery on 2/16/11 for hammertoes. The "ANESTHESIA RECORD," dated 2/16/11 at 7:45 AM and 7:50 AM documented the CRNA administered "50" of Fentanyl. The unit of measurement and route for this medication was not documented.</p> <p>c. Patient #5 was a 39 year old male admitted to the ASC on 2/16/11 for removal of a bunion and correction of hammertoes on his right foot. The "ANESTHESIA RECORD," dated 2/16/11 at 11:25 AM documented the CRNA administered "50/50" of Fentanyl. The units of measurement and route of administration were not documented.</p> <p>d. Patient #7 was a 68 year old female admitted to the ASC on 2/16/11 for removal of a bunion on her right foot. The "ANESTHESIA RECORD," dated 2/16/11 at 9:45 AM, documented the CRNA administered "50/50" of Fentanyl. At 10:00 AM, the CRNA administered "30" of Toradol intramuscularly. The units of measurement for the Fentanyl and Toradol were not documented and the route of administration of the Fentanyl were not documented.</p> <p>e. Patient #8 was a 32 year old female who had surgical removal of a bunion on her right foot on 5/25/11. The "ANESTHESIA RECORD," dated</p>	Q 162			

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Q 162	<p>Continued From page 8</p> <p>5/25/11 at 9:30 AM, documented the CRNA administered "2" Versed and "1/1" Fentanyl. The unit measurements and route of the medications were not documented.</p> <p>f. Patient #9 was a 67 year old male admitted to the ASC on 3/09/11 for removal of an abnormal bony growth responsible for a chronic ulceration on his left foot. The "ANESTHESIA RECORD," dated 3/09/11 at 9:30 AM documented the CRNA administered "2" of Versed and "2" of Fentanyl. At 9:40 AM, the CRNA administered "12.5" of Ephedrine. The units of measurement and routes of administration for these medications were not documented.</p> <p>g. Patient #11 was a 53 year old male admitted to the ASC on 6/29/11 for correction of the hammertoes on his left foot. The "ANESTHESIA RECORD," dated 6/29/11 at 9:10 AM documented the CRNA administered "2" of Versed and "2" of Fentanyl. At 9:20 AM and 10:25 AM the CRNA administered "1" of Fentanyl. The units of measurement and routes of administration for these medications were not documented.</p> <p>h. Patient #12 was a 13 year old female admitted to the ASC on 5/25/11 for removal of a bunion on her right foot. The "ANESTHESIA RECORD," dated 5/25/11 at 7:40 AM documented the CRNA administered "1" of Versed and "1/2" of Fentanyl. At 7:45 AM the CRNA administered "1/2" of Fentanyl. The units of measurement and routes of administration for these medications were not documented.</p> <p>i. Patient #13 was a 14 year old male admitted to</p>	Q 162			

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Q 162	<p>Continued From page 9</p> <p>the ASC on 5/25/11 for a removal of a bunion on his left foot. The "ANESTHESIA RECORD," dated 5/25/11 at 11:20 AM documented the CRNA administered "1" of Versed. At 11:25 AM the CRNA administered "1" of Fentanyl. The units of measurement and routes of administration for these medications were not documented.</p> <p>j. Patient #14 was a 78 year old male admitted to the ASC on 4/20/11 for correction of hammertoes on his right foot. The "ANESTHESIA RECORD," dated 4/20/11 at 7:35 AM documented the CRNA administered "2" of Versed. At 7:45 AM the CRNA administered "40" of Xylocaine and "1/1" (each number was circled) of Fentanyl. At 9:05 AM the CRNA administered "1" of Fentanyl. The units of measurement and routes of administration for these medications were not documented.</p> <p>k. Patient #15 was a 63 year old female admitted to the ASC on 4/20/11 for removal of a bunion on her left foot. The "ANESTHESIA RECORD," dated 4/20/11 at 10:55 AM documented the CRNA administered "2" of Versed. At 11:00 AM the CRNA administered "40" of Xylocaine and "2" of Fentanyl. At 11:40 AM the CRNA administered "12.5" of Ephedrine. At 12:00 PM the CRNA administered "60" of Toradol intramuscularly. The units of measurement and for all of these medications was not documented. The routes of administration for these medications (except for the Toradol) were not documented.</p> <p>l. Patient #20 was a 68 year old female who had a neuroma (swollen inflamed nerve) surgically</p>	Q 162			

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Q 162	<p>Continued From page 10 excised on 3/09/11. The "ANESTHESIA RECORD," dated 3/09/11 at 7:25 AM, documented the CRNA administered "2" of Versed and "2" of Fentanyl. The unit of measurements or routes for these medications were not documented.</p> <p>During an interview on 7/12/11 between 4:35 and 5:00 PM, the Administrator reviewed patients' records referenced above. She confirmed the units of measurements and routes of administration for the medications were not clearly documented in medical records.</p> <p>The ASC did not ensure medication administration records were complete.</p> <p>2. Documentation of informed consent for anesthesia was incomplete in patient records, as follows:</p> <p>a. Patient #6 was a 44 year old female with a soft tissue mass excised on 5/04/11. The "ANESTHESIA CONSENT" was signed and timed by Patient #6. The consent did not include the date the consent was given. It also did not identify the type of anesthesia Patient #6 was consenting to, such as General Anesthesia, MAC, or local with sedation.</p> <p>During an interview on 7/12/11 at 5:00 PM, the Administrator stated the date, time, and type of anesthesia should have been on consent forms.</p> <p>b. Patient #7 was a 68 year old female admitted to the ASC on 2/16/11 for removal of a bunion on her right foot. Patient #7's "ANESTHESIA CONSENT" was not dated or timed. It was not</p>	Q 162			

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Q 162	Continued From page 11 clear when the consent was signed. The Administrator was interviewed on 7/12/11 at 4:35 PM. She reviewed Patient #7's medical record and confirmed the date and time the anesthesia consent was signed was not indicated. She stated she would have expected this information to be included on the consent. c. Patient #11 was a 53 year old male admitted to the ASC on 6/29/11 for correction of the hammertoes on his left foot. Patient #11's "ANESTHESIA CONSENT" was dated 6/29/11 but was not timed. It was not clear the consent had been signed prior to administration of any sedatives. The Administrator was interviewed on 7/12/11 at 4:35 PM. She confirmed the time the anesthesia consent was signed was not documented in Patient #11's medical record. The ASC did not ensure anesthesia consent forms were complete.	Q 162			
Q 181	416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to ensure that 1 of 1 multi-use vial observed during the tour of the ASC was discarded prior to the expiration date and	Q 181			

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Q 181	Continued From page 12 stored in an area not accessible to patients. This had the potential to interfere with efficacy of the medication and promote diversion or loss. Findings include: The ASC was toured on 7/12/11 between 8:00 AM and 8:30 AM. The Administrator served as a tour guide. A bottle of Lidocaine was observed to be located on the counter of the pre-operative room, next to the chair where pre-operative patients sat. The bottle was marked as opened 03/11. The expiration date listed on the bottle was 7/01/11. At the time of the tour, the Administrator confirmed the expired medication and stated she did not realize it was not acceptable to leave the medication on the counter. The facility did not ensure an expired medication was removed from circulation and was kept secure.	Q 181	Drug expiration will be checked monthly and all medications that will expire within the coming month will be removed from circulation and reordered. At this time and before each operative day, a check will be performed by the manager and pre-op nurse that all medications are not accessible to patients. M Robinson RN to oversee expiration procedures.	8/15/11	
Q 202	416.49(b) RADIOLOGIC SERVICES (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients. This STANDARD is not met as evidenced by: Based on observation, staff interview, review of manufacturer's guidelines for safety precautions for radiation exposure of C-Arms, and review of state rules, it was determined the ASC failed to develop, implement and monitor procedures for radiation safety from C-Arm use. These failures had the potential to adversely impact health and	Q 202			

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Q 202	<p>Continued From page 13</p> <p>safety of all patients and personnel at the facility. Findings include:</p> <p>During a tour of the ASC on 7/12/11 between 8:00 AM and 8:30 AM, a C-Arm was observed. The Administrator was asked if staff and patients were shielded during C-Arm use and whether employees wore badges for monitoring of radiation exposure. She stated they did not use shields or wear badges because the radiation exposure was quite low. When asked, she confirmed the ASC did not have specific policies related to the C-Arm and protection from radiation. She stated the physician was the only person who operated the equipment and was credentialed to do so.</p> <p>Upon request, the Administrator provided the manual associated with the C-Arm. Under the section "Hazards," Radiation safety was addressed as follows: "WARNING: This system produces ionizing radiation and may be dangerous to patients and operators unless the safety and operating instructions provided in this manual are followed." It further stated "Although operating this system can result in low scatter radiation levels we recommend wearing protective X-ray clothing and using radiation safety precautions when operating the system."</p> <p>The Manager of the Laboratory Improvement & X-ray Certification Sections of the Idaho Bureau of Laboratories was interviewed by telephone on 7/15/11 at 9:25 AM. He stated when facilities used C-Arms, they were required to use shielding aprons and radiation monitoring badges unless the facility had been specifically exempted. In a follow-up email, dated 7/15/11, the Manager</p>	Q 202	<p>C-Arm shields have been obtained for staff and patient protection during C-Arm use. Registration of the C-Arm to be submitted to the Idaho Bureau of Laboratories and exemption to be requested for badge use. If exemption is denied, badges will be obtained. Policy and procedure to be approved by Governing Body.</p> <p><i>M. Robinson RN to oversee registration and exemption</i></p>	10/1/11	

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Q 202	Continued From page 14 stated that Addison's Surgery Center did not have radiation equipment registered with the Idaho Bureau of Laboratories and had not been exempted from requirements. He referred to the following IDAPA Radiation Control Rules that refer to radiation monitoring and personnel shielding: - IDAPA 16.02.27.120.02 Personnel monitoring - IDAPA 16.02.27.140.01 Records - IDAPA 16.02.27.203.01(i)(i)(ii) Administrative controls - IDAPA 16.02.27.205.09 Fluoroscopic x-ray systems He explained the ASC must monitor personnel by badges unless the ASC can prove no radiation exposure and had requested and been granted an exemption from the Idaho Bureau of Laboratories. In addition, the ASC must provide exposure protection to the personnel operating the device unless the ASC can prove no exposure and requests and is granted an exemption. The ASC had not been granted an exemption and did not develop policies and procedures for radiation safety, provide shielding from radiation exposure to employees and patients, or provide radiation monitoring.	Q 202			
Q 222	4166.50(a)(1)(i) NOTICE - POSTING In addition, the ASC must - Post the 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	Q 222			

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Q 222	Continued From page 15 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 and staff interview it was determined the ASC failed to ensure posted patient rights information included the name, address, and telephone number of a representative in the State agency to whom patients could report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. This resulted in the potential for patients and their representatives to not be fully informed of their rights. Findings include: The ASC was toured on 7/12/11 between 8:00 AM and 8:30 AM. The Administrator was the tour guide. Patient Rights information was observed to be posted in the waiting area. The information did not include contact information for the State agency to which patients could report complaints. It also did not include the Web site for the Office of the Medicare Beneficiary Ombudsman. The Administrator stated the information was on the handouts given to patients prior to surgery. She confirmed the information was not on the Patient Rights information posted in the ASC. The facility did not ensure written patient rights information was posted in the facility that included contact information for the State agency and the Web site for the Office of the Medicare Beneficiary Ombudsman.	Q 222	Multiple copies of Patients Rights to be placed in the waiting room for patient and family access. Ombudsman and State agency information to be placed in a picture frame on the wall for easy patient and family viewing. <i>M. Robinson RN to oversee.</i>	8/8/11	
Q 225	416.50(a)(3)(i), (v), (vi), (vii) SUBMISSION AND INVESTIGATION OF GRIEVANCES	Q 225			

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Q 225	Continued From page 16 (i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. (v) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished. (vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed. This STANDARD is not met as evidenced by: Based on staff interview and policy review, it was determined the ASC failed to ensure that a grievance procedure had been established for all patients receiving care at the ASC. This resulted in the potential for patient grievances not being adequately addressed. Findings include: The Administrator was interviewed on 7/12/11 at 9:20 AM. She confirmed there was not a formal procedure related to submission, investigation, and response to a grievance. She stated if the ASC received a grievance they would have the patient fill out a report which would be presented to the governing body. She stated after review by	Q 225	A grievance policy and procedure will be written and approved by the Governing Body to establish a procedure for patient and employee grievances. M Robinson RN to oversee writing and implementation of the policy.	9/15/11

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Q 225	Continued From page 17 the governing body the appropriate actions to respond to the grievance would be taken. She stated the time frame for review by the governing body would be dictated by the nature of the grievance.	Q 225			
Q 261	The ASC did not ensure a grievance procedures were established. 416.52(a)(1) ADMISSION ASSESSMENT Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the agency failed to ensure a comprehensive medical history and physical assessment was completed no more than 30 days before the date of the scheduled surgery and present in patient records prior to surgery for 3 of 19 patients (#1, #2, and #10) whose medical records were reviewed. This had the potential to limit access to relevant patient information and negatively impact patient safety during surgery. Findings include: 1. Patient #2 was a 66 year old male admitted to the ASC on 10/27/10 for amputation of the distal portion of a toe on his right foot. His medical record contained an undated, hand written, "HISTORY & PHYSICAL" form, signed by the	Q 261			

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Q 261	<p>Continued From page 18</p> <p>physician but not dated. Patient #2's medications and allergies were listed on the form and the physician documented a physical examination. A medical history was not included. The medical record also contained a patient questionnaire that indicated the information in the document was Patient #2's medical history as of 7/07/06, over 4 years prior to the surgery. Documentation on the form indicated Patient #2 had a history of diabetes, vascular disease, poor circulation, and high blood pressure. The form indicated Patient #2 had previous surgeries on his carotid artery, aortic valve, and back.</p> <p>The Administrator was interviewed on 7/12/11 at 4:35 PM. She reviewed Patient #2's medical record and stated it did not appear that a comprehensive medical history and physical assessment had been completed within 30 days of the Patient #2's surgery.</p> <p>2. Patient #10 was a 13 year old female who had painful hardware surgically removed from her right foot on 6/29/11. A hand written "HISTORY AND PHYSICAL," dated 6/14/11, was present in Patient #10's record. It was incomplete as it did not address whether Patient #10 had any current or past medical problems.</p> <p>During an interview on 7/11/11 at 2:05 PM, the Administrator reviewed Patient #10's record and confirmed the history and physical appeared incomplete.</p> <p>3. Patient #1 was a 53 year old female had exploratory surgery for an inflamed ligament (capsulitis) on 12/28/10. A handwritten "HISTORY AND PHYSICAL," dated 12/28/10,</p>	Q 261			

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Q 261	Continued From page 19 was present in Patient #1's medical record. It was incomplete as it did not include a past medical history or family history. A prior dictated "HISTORY AND PHYSICAL, dated 2/10/06, over 4 years prior, was present in Patient #1's medical record and included this information, stating Patient #1 had a family history of arthritis, cancer, heart attack, and hypertension and a personal of headaches. During an interview on 7/20/11 at 3:50 PM, the Administrator reviewed Patient #1's record and confirmed there was not a comprehensive history and physical in the record that was less than 30 days old. The primary physician was interviewed on 7/20/11 at 3:30 PM. He stated he routinely performed and dictated comprehensive history and physical examinations within 30 days of surgery, usually the week prior to surgery. He stated if his dictated reports were not in the ASC records, they were probably in his office records. He stated the dictation may not have been done in time for surgery or the History and Physical did not get filed in the ASC record.	Q 261	History and Physicals will be expedited by the dictation firm to ensure that H&P is available for operative day. Education will be provided to office staff of the Dr.'s office to ensure that the surgery center receives the information in a timely manner. The Dr. will also receive education to complete the short form H&P the day of surgery after pre-surgical assessment is completed. A stamp will be placed on the H&P stating that "No changes in History and Physical" with a place for the physician to date and sign after reviewing the information with the patient during the pre-surgical assessment. Monitoring and education to be completed by M Robinson RN and monitored by chart auditing.		
Q 262	416.52(a)(2) PRE-SURGICAL ASSESSMENT Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical	Q 262		8/15/11	

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Q 262	<p>Continued From page 20</p> <p>record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview it was determined the ASC failed to ensure medical records contained documentation of a physical examination of patients or an assessment for changes in condition upon admission since patients most recent H&Ps. This impacted 10 of 19 patients (#2, #3, #5, #7, #8, #9, #10, #11, #14, and #15) whose records were reviewed and 1 of 1 patient (#16) whose procedure was observed. Failure to perform and/or document pre-surgical assessments had the potential to impact patient safety during and after surgery. Findings include:</p> <p>None of the following patient records included documentation of a pre-surgical physical assessments (such as listening to heart and lungs) or assessment of patients for changes in conditions since their most recently documented H&P:</p> <ul style="list-style-type: none"> - Patient #2 admitted to the ASC on 10/27/10 for amputation of the distal portion of a toe on his right foot. - Patient #3 admitted to the ASC on 12/03/10 for removal of a foreign body from her right foot. - Patient #5 admitted to the ASC on 2/16/11 for 	Q 262			

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Q 262	<p>Continued From page 21 removal of a bunion and correction of hammertoes on his right foot.</p> <ul style="list-style-type: none"> - Patient #7 admitted to the ASC on 2/16/11 for removal of a bunion on her right foot. - Patient #8 admitted to the ASC on 5/25/11 for surgical removal of a bunion on her right foot. - Patient #9 admitted to the ASC on 3/09/11 for removal of an abnormal bony growth responsible for a chronic ulceration on his left foot. - Patient #10 admitted to the ASC on 6/29/11 for removal of painful hardware to her right foot on 6/29/11. - Patient #11 admitted to the ASC on 6/29/11 for correction of the hammertoes on his left foot. - Patient #14 admitted to the ASC on 4/20/11 for correction of hammertoes on his right foot. - Patient #15 admitted to the ASC on 4/20/11 for removal of a bunion on her left foot. <p>The Administrator was interviewed on 7/11/11 at 3:00 PM. She stated the physician completed the comprehensive history and physical examination during an office visit, usually a week or less prior to the surgery date. She stated, the physician saw the patient immediately prior to surgery to answer questions, perform a physical examination, and review information, such as medications, allergies, and histories with patients prior to surgery. She stated she was not sure the physician documented the examination in patient records.</p>	Q 262			

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Q 262	Continued From page 22 The Administrator was interviewed again on 7/12/11 beginning at 4:35 PM. She reviewed the patients' records referenced above and confirmed there was no clear documentation of a physical examination prior to surgery. Additionally, during an observation of the physician on 7/20/11 at 11:55 AM with Patient #16 prior to surgery, the physician was observed to listen to Patient #16's heart and lungs and review medical information with her. He was not observed to ask Patient #16 if there had been any changes in her condition since the most recent history and physical examination. During an observation of a CRNA with Patient #16 during a pre-anesthesia assessment on 7/20/11 at 12:10 PM, the CRNA was observed to talk to Patient #16 and confirm medical history information. He was not observed to do any physical examination or ask the patient if she had any changes in condition since her most recent history and physical examination. The CRNA was interviewed on 7/20/11 at 3:00 PM. When asked if he generally performed a physical examination on patients prior to surgery, he stated he generally did not physically examine patients prior to surgery, except in rare circumstances such as when a patient with asthma reported having current symptoms. He stated the physician routinely examined patients prior to surgery. The physician was interviewed 7/20/11 at 3:30 PM. He stated he routinely examined patients immediately prior to surgery but did not always	Q 262			

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001018	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 07/20/2011
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Q 262	Continued From page 23 document the examination. He stated he did not typically ask patients if there had been any changes in condition since their most recent comprehensive history and physical examination. He stated the comprehensive exams had usually been done just a week prior.	Q 262			
Q 264	The facility did not ensure patient records included documentation of pre-surgical physical examinations or assessment for changes in patients' conditions since completion of the most recently documented H&Ps. 416.52(b) POST-SURGICAL ASSESSMENT (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Post-surgical needs must be addressed and included in the discharge notes. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, it was determined the ASC failed to ensure post-surgical conditions were assessed and documented in accordance with ASC policy for 3 of 3 patients (#2, #3, and #10) who had procedures involving only local anesthesia. Failure to adequately assess a patient prior to discharge had the potential to result in premature discharge and subsequent negative patient outcomes. Findings include:	Q 264			

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Q 264	<p>Continued From page 24</p> <p>An undated ASC policy, "DISCHARGE" stated that prior to discharge, patients must, at a minimum, meet discharge criteria. The criteria included stable vital signs consistent with the patient's age and pre-surgical levels.</p> <p>Patient medical records did not include documentation to support the consistent implementation of the policy, as follows:</p> <p>a. Patient #10 was a 13 year old female who had removal of painful hardware to her right foot on 6/29/11. According to the "OPERATIVE NOTE," the surgery was completed using a local anesthetic. The "DAY SURGERY PATIENT'S CARE FORM," documented Patient #10's vital signs at admission. A second, untimed set of vital signs was documented on the same form. There were no vital signs timed after surgery, prior to discharge.</p> <p>During an interview on 7/11/11 at 12:15 PM, the Administrator stated it was the practice of ASC staff to take only one set of vital signs on patients who received local anesthesia only. At 2:05 PM on the same date, the Administrator stated vital signs were taken pre-operatively but not post-operatively for patients who received only local anesthesia.</p> <p>b. Patient #3 was a 44 year old female admitted to the ASC on 12/03/10 for removal of a foreign body from her right foot. The surgery was completed with local anesthetic and no sedation. An undated "DAY SURGERY PATIENT'S CARE FORM," was completed by the RN. The RN documented a set of vital signs taken at 7:45 AM, the documented time of admission. In the section</p>	Q 264	<p>Education for all RN's will be completed verifying that all patients, regardless of sedation, will have post-operative vital signs to assess readiness for discharge. Discharge policy will be modified to include this information. M Robinson RN to oversee education and monitoring of discharge notes.</p>	8/15/11	

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Q 264	<p>Continued From page 25</p> <p>of the form, titled "DISCHARGE SUMMARY" the RN indicated Patient #3 was discharged with stable vital signs. However, there was no documentation additional vital signs had been obtained after the surgery and prior to discharge.</p> <p>The Administrator was interviewed on 7/12/11 at 4:35 PM. She reviewed Patient #3's medical record and confirmed a set of vital signs was not obtained prior to discharge from the ASC.</p> <p>c. Patient #2 was a 66 year old male admitted to the ASC on 10/27/10 for amputation of the distal portion of a toe on his right foot. The surgery was completed with local anesthetic and no sedation. A "DAY SURGERY PATIENT'S CARE FORM," undated, was completed by the RN. The RN documented she obtained Patient #2's vital signs upon admission at 8:10 AM. The RN noted Patient #2's blood pressure was elevated and obtained a second set of vital signs with the blood pressure within the normal range. In the section of the form, titled "DISCHARGE SUMMARY" the RN indicated Patient #2 was discharged with stable vital signs. However, there was no documentation additional vital signs had been obtained after the surgery and prior to discharge.</p> <p>The Administrator was interviewed on 7/11/11 at 2:05 PM. She reviewed Patient #2's medical record and confirmed a set of vital signs was not obtained prior to discharge from the ASC. She stated it was not the facility's practice to routinely obtain post-surgical vital signs on patient's who only received local anesthetic. She stated vital signs after surgery would be obtained if the patient was having any complications.</p>	Q 264			

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Q 264	Continued From page 26 The facility did not ensure post-surgical vital signs were assessed prior to discharge for patients receiving local anesthetic only.	Q 264			