COPY

IDAHO DEPARTMENT OF HEALTH & WELFARE

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

DEBRA RANSOM, R.N.,R.H.I.T., Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, ID 83720-0009
PHONE 208-334-6626
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CERTIFIED MAIL: 70073020000140388607

September 11, 2013

Kylin Kovac, Owner
Idaho Foot Surgery Center
1540 Elk Creek Drive
Idaho Falls, ID 83404-8322

RE: Idaho Foot Surgery Center, Provider #13C0001008

Dear Dr. Kovac:

Based on the survey completed at Idaho Foot Surgery Center, on August 29, 2013, by our staff, we have determined Idaho Foot Surgery Center is out of compliance with the Medicare ASC Conditions for Coverage **Governing Body and Management (42 CFR 416.41), Surgical Services (42 CFR 416.42), Quality Assessment and Performance Improvement (42 CFR 416.43), Environment (42 CFR 416.44), Medical Staff (42 CFR 416.45), Nursing Services (42 CFR 416.46), Pharmaceutical Services (42 CFR 416.48), Patient Rights (42 CFR 416.50), and Infection Control (42 CFR 416.51).** To participate as a provider of services in the Medicare Program, 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 Idaho Foot Surgery 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.

<u>An acceptable Plan of Correction contains the following elements</u>:

- 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 October 13, 2013. 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 September 30, 2013.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **September 24, 2013**.

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.

If you have any questions regarding this letter or the enclosed reports, please contact me at (208) 334-6626.

Sincerely,

SUSAN COSTA
Health Facility Surveyor
Non-Long Term Care

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

SC/nw
Enclosures
ec: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Kate Mitchell, CMS Region X Office

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

PRINTED: 09/10/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED
	13C0001008		08/29/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IDAHO FOOT SURGERY CENTER	1540 ELK CREEK DRIVE IDAHO FALLS, ID 83404

(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 annual recertification survey conducted from 8/21/13 to 8/29/13. The survey was conducted by: Susan Costa, RN, HFS, Team Leader Don Sylvester, RN, HFS Common acronyms used in this report include: ACLS - Advanced Cardiac Life Support AORN - Association of Peri-Operative Registered Nurses APIC - Association for Professionals in Infection Control and Epidemiology ASC - Ambulatory Surgical Center BI - Biological Indicator BLS - Basic Life Support CDC - Centers for Disease Control CLIA - Clinical Laboratory Improvement Amendments CPR - Cardio Pulmonary Resuscitation CRNA - Certified Registered Nurse Anesthetist CST - Certified Surgical Technician DEA - Drug Enforcement Administration H&P - History and Physical HICPAC - Healthcare Infection Control Practices Advisory Committee Inj - Injection IV - Intravenous mcg - micrograms mg - milligrams ml - milliliter mm - millimeter OR - Operating Room OSHA - Occupational Safety Health	Q 000	RECEIVED OCT - 3 2013 FACILITY STANDARDS	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: Owner | (X6) DATE: 9/30/13

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 000	Continued From page 1 Administration POC - Point of Care QAPI - Quality Assurance Performance Improvement RN - Registered Nurse Note: Immediate Jeopardy was identified at Q-060 and the facility was notified on 8/21/13 at 5:00 PM. The facility submitted an Immediate Plan of Correction dated 8/21/13. Additional information was solicited on 8/22/13 and received on 8/22/13 at 5:00 PM. On site verification of the plan's implementation was completed on 8/22/13 at 5:15 PM and the Immediate Jeopardy was abated.	Q 000		
Q 040	416.41 GOVERNING BODY AND MANAGEMENT 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. This CONDITION is not met as evidenced by: Based on observation, staff interview, and review of medical records and ASC policies, it was determined the ASC failed to ensure the Governing Body developed, implemented, and monitored policies and programs necessary to ensure all patient needs were met. This resulted	Q 040		

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Q 040	Continued From page 2 in the inability of the facility to ensure quality health care services were provided in a safe manner. Findings include: 1. The physician owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated the facility had undergone a change of ownership in July of 2013. He stated no formal Governing Body meetings had been held since that time and he did not have meeting minutes from the previous physician owner which demonstrated Governing Body oversight of the ASC. 2. Refer to Q-043 as it relates to the Governing Body's failure to ensure annual emergency preparedness drills were conducted and that written emergency preparedness plans were developed and coordinated with State and local authorities. 3. Refer to Q-060 Condition for Coverage: Surgical Services as it relates to the Governing Body's failure to ensure safe surgical services were provided to patients. 4. Refer to Q-080 Condition for Coverage: Quality Assessment and Performance Improvement and related standard level deficiencies as they relate to the Governing Body's failure to ensure a QAPI program was developed, implemented and monitored to improve the quality of services and outcomes for patients. 5. Refer to Q-100 Condition for Coverage: Environment and related standard level deficiencies as they relate to the Governing Body's failure to ensure a safe environment was provided necessary to ensure patient health and safety.	Q 040	**Q 040 – Governing Body and Management:** The citation stated that our Governing Body failed to develop and oversee policy and procedures for several standards. The Governing Body oversees all operations of the ASC. However, in an effort to meet these standards thus improving our quality of care to patients, we are developing policies (from a sampling of policies we have discovered on the premises and other resources) and appropriate programs to monitor their implementation as well as creating minutes for each meeting held that will reference these practices. Governing Body, in conjunction with help from our consultant, has developed policies and procedures in order to provide quality health care in a safe environment for our patients. These policies, which will be outlined in subsequent sections of this plan of correction, include but are not limited to the following referenced conditions for coverage: Q043-Disaster Preparedness Plan, Q060-Surgical Services, Q080-Quality Assessment and Performance, Q100-Envionment, Q120-Medical Staff, Q140-Nursing Services, Q219-Patient Rights, Q240-Infection Control.	

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Q 040	Continued From page 3	Q 040		
	6. Refer to Q-120 Condition for Coverage: Medical Staff and related standard level deficiencies as they relate to the Governing Body's failure to ensure appropriately privileged and appraised medical staff were provided to patients.			
	7. Refer to Q-140 Condition for Coverage: Nursing Service and the related standard level deficiency as they relate to the Governing Body's failure to ensure nursing services were provided by qualified personnel and in accordance with accepted standards of practice.			
	8. Refer to Q-219 Condition for Coverage: Patient Rights and related standard level deficiencies as they relate to the Governing Body's failure to ensure patients or their representatives were informed of their rights.			
	9. Refer to Q-240 Condition for Coverage: Infection Control and related standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive infection control program was developed, implemented and monitored necessary to minimize infections and communicable diseases.			
	The cumulative effect of these systemic deficient practices resulted in the inability of the facility to furnish patient care in a manner which ensured patients' health and safety were protected and patient rights were upheld.			
Q 043	416.41(c) DISASTER PREPAREDNESS PLAN	Q 043		
	(1) The ASC must maintain a written disaster preparedness plan that provides for the			

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Q 043	Continued From page 4 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. (2) The ASC coordinates the plan with State and local authorities, as appropriate. (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. This STANDARD is not met as evidenced by: Based on interview and administrative document review, it was determined the facility failed to ensure the Governing Body developed an emergency preparedness plan that addressed all hazards, was coordinated with State and local authorities, and that an emergency preparedness drill was conducted at least annually to test the plan's effectiveness for all patients, staff and visitors. This resulted in the potential for the facility's inability to effectively deal with the care, health and safety of patients, staff and other individuals when a major disruptive event occurred. Findings include: On 8/22/13 at 11:00 AM, the facility's emergency preparedness plan was requested from the ASC's RN. The RN stated the facility did not have documentation of an annual emergency preparedness drill or a plan which addressed hazard vulnerability analysis and coordination with State and local authorities. This was confirmed by the ASC's physician owner on 8/22/13 at 2:00 PM.	Q 043	**Q 043 – Disaster Preparedness Plan:** The citation stated that there was no Disaster Plan at IFSC because at the time of survey we were not able to produce one. After a full review of existing IFSC policies however, we did find a 2010 Disaster Policy which has been revised and updated to satisfy the citation. It presently meets the requirements including the effort to coordinate with local and state disaster authorities and the implementation and evaluation of annual Disaster Drills. This policy can be seen on page one of the Emergency Preparedness Plan and was revised as of 9/302013 and will be effective immediately (See Appendix A). The practice administrator will act as the disaster coordinator and has already secured a letter from Bonneville County Emergency Management dated 9/4/2013 that states that they are aware of our desire and ability to help in a disaster situation and will reserve IFSC as an overflow site secondary to major area hospitals (See Appendix B). This letter is on file in the Fire/Disaster Manual. The emergency preparedness plan also provides for quarterly fire drills and annual disaster drills. The first Quarterly fire drill was held with IFSC staff on 9/19/2013 and a table top disaster drill was held on 9/26/2013 (See Appendix C). These drills will be recorded and evaluated for effectiveness and documented in the Fire/Disaster Preparedness Manual. This change will create a safer environment for patients.	

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Q 043	Continued From page 5 The facility failed to ensure an emergency preparedness plan that addressed all hazards was developed, coordinated with State and local authorities, and that an emergency preparedness drill was conducted at least annually to test the plan's effectiveness.	Q 043		
Q 060	416.42 SURGICAL SERVICES Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to develop, implement, and monitor systems to address medical emergencies for all patients receiving care at the facility. These systemic failures resulted in the inability of the facility to ensure patient safety and placed patients in serious and immediate jeopardy for the potential to experience serious harm, impairment, or death as a result of procedural complications. Findings include: 1. The facility's undated Code Blue policy stated "In the event of cardiac arrest, ACLS (Advanced Cardiac Life Support) protocol will be followed while awaiting patient transport to [hospital name] per ambulance." The protocol stated staff were to do the following: - Surgeon: Give order to call 911, record	Q 060	**Q 060- Surgical Services:** In regard to citations for Surgical Services, our present Code Blue policy was specific in regard to drill responsibilities; however the staff had not conducted code practices for training and did not know their responsibilities during a code. As of 9/30/2013 we have also revised our code blue responsibilities as outlined in our Cardiopulmonary Arrest (Code) policy (See Appendix D). A code practice for staff was performed on 9/19/2013, and each employee was educated on their responsibilities during a code. The training and all attendees were documented and filed in the in-service Binder (See Appendix E.) Code drills are to be performed at minimum on an annual basis per our updated disaster policy (See Appendix A). This change will create a safer environment for patients.	

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Q 060	Continued From page 6 medications/defibrillations on code blue record, and stay with patient and assist as needed. - Anesthesia: Verify rhythm, run code per ACLS protocol, manage airway/intubate, and give order to call 911 if necessary. - RN: Give ACLS medications per anesthesia order, start IV as needed, set up suction equipment, defibrillate per anesthesia order, ensure throughout that staff members are performing duties, that 911 has been called, and assist anesthesia as needed. - Scrub tech: Take crash cart to code blue location and chest compressions. However, the facility did not have the necessary medications, supplies, equipment or trained staff necessary to implement the policy, as follows: a. The facility's unsigned, undated Crash Cart policy stated "An inventory will be maintained with the cart. Any supplies used or outdated will be re-stocked as soon as possible following use/outdate and the seal [on the crash cart] replaced. This should be the responsibility of the RN with assistance of the anesthetist." The policy was not implemented, as follows: The Crash Cart policy listed medications which were required by the ASC for emergency purposes. The list included, but was not limited to, the following: - Atropine 1 mg (4) - 2% Lidocaine Inj 100 ml (1) - 1% Lidocaine Inj 50 ml (3)	Q 060	**Q 060 – Surgical Services (continued):** A. Crash Cart: In coordination with our anesthesia providers, the Crash Cart policy was revised, updated, and signed by the Medical Director on 9/21/2013(See Appendix F). Our new policy states that the crash cart will be inventoried each month ***by the RN on staff*** to prevent outdates and maintain proper inventory of emergency medications and emergency equipment. As noted, as of 8/28/2013 all expired medications were removed from the Crash Cart and new medications were immediately purchased to comply with our policy. This change will create a safer environment for patients.	

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Q 060	Continued From page 7 The policy stated the crash cart "will be opened monthly and checked for outdate [sic] medications and re-stocked as necessary." However, a tour of the facility was conducted on 8/21/13 at 9:00 AM. Medications identified in the Crash Cart policy were expired as follows: - 2% Lidocaine HCL 100 mg 20 mg/ml, with an expiration date of 07/2012. - 2% Lidocaine Inj 50 ml with an opened date of 6/28/13. Atropine was not found in the the facility's crash cart as stated in the crash cart policy. However, the anesthesia cart was also observed during the facility tour on 8/21/13 at 9:00 AM. The following expired medications were observed: - 4 boxes of Atropine Inj 1 mg, with an expiration date of 06/2013. - 2% Lidocaine Inj 20 mg/ml, with an expiration date of 07/2013. During an interview on 8/22/13 beginning at 11:10 AM, the RN confirmed the above drugs were expired and had not been discarded in a timely manner. The RN further stated she was unsure how many days were required to pass before an opened medication would need to be discarded. United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations, Second Edition, 6/01/08, states if a multidose vials has been opened or accessed the vial should be dated and discarded within 28 days unless the manufacturer specifies a different date for that opened vial. Additionally, the facility's Drug and Pharmaceutical Storage and Disposal policy dated 09/2010 stated	Q 060	**Q 060 – Surgical Services (Continued):** In regards to the use of multidose vials, we currently have medication administration policy, dated 9/21/2013 that supports the verbiage of the 28 day rule from USP 797; it is found in the medication guidelines section of the Nursing Manual, dated 9-2010 (See Appendix G). This policy states that all multidose vials will be labeled with an "Open Date" as well as a "Discard By Date", to avoid any confusion as to the meaning of the date on the bottle. As of 9/30/2013, we have performed training for staff on this policy so that no further compliance issues will arise, thus creating a safer environment for patients.	

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Q 060	Continued From page 8 "Multidose vials will be discarded on or before the 28th day after they are first accessed..." The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He confirmed the crash cart had expired and missing medications. He verified the ASC did not have other emergency medications in the facility. The facility failed to ensure the crash cart was stocked and maintained with emergency medications. b. The facility's unsigned, undated Crash Cart policy listed supplies which were required by the ASC for emergency purposes. The policy stated the "Airway drawer" was required to contain multiple items which included, but were not limited to, endotracheal tubes, sizes 5.5 to 8.0 (2 each size) and stylets. A tour of the facility was conducted on 8/21/13 at 9:00 AM. The following crash cart supplies were noted to be expired: - Endotracheal Tube 5.0 mm with an expiration date of 10/2010. - Endotracheal Tube 5.5 mm with an expiration date of 03/2009. - Endotracheal Tube 6.0 mm with an expiration date of 11/2010. - Endotracheal Tube 6.5 mm with an expiration date of 02/2011. - Endotracheal Tube 7.0 mm with an expiration date of 07/2011.	Q 060	**Q 060 – Surgical Services (Continued):** B. Crash Cart Airway Supplies: As noted in the citation some of our crash cart airway supplies were either expired or inconsistent with our stated Crash Cart Policy. As of 8/28/2013, all expired airway supplies were removed from the cart and discarded by the practice administrator and all supplies were inventoried and brought into consistency with our stated Crash Cart supply list and policy. In coordination with our anesthesia providers, we have written a new Crash Cart content list and policy (See appendix F). Our policy is that the crash cart will be inventoried each month ***by the RN on staff*** to prevent outdates and maintain proper inventory of emergency medications and emergency equipment. The Crash Cart policy was updated, dated and signed by the Medical Director by 9-21-2013.	

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Q 060	Continued From page 9 - Endotracheal Tube 7.5 mm with an expiration date of 06/2011. - Intubation Stylet 7.5 mm with an expiration date of 02/2009. - Intubation Stylet 5.0 mm with an expiration date of 12/2008. Additionally, the crash cart included the following supplies which were not identified in the facility's policy: - Tracheal Airway set, small adult, with an expiration date of 02/2011. - Tracheal Airway set, adult, with an expiration date of 01/2011. During an interview on 8/22/13 beginning at 11:10 AM, the RN confirmed the above emergency supplies were expired and had not been discarded in a timely manner. Further, an oxygen tank on a stand by the crash cart was noted to read 200 pounds (just above the red line which indicated empty). The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He confirmed the crash cart had expired emergency supplies. He verified that the ASC did not have other emergency supplies in the facility. The facility failed to ensure emergency supplies were maintained. c. The facility's unsigned, undated Crash Cart	Q 060		

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Q 060	Continued From page 10 policy stated "The defibrillator will be checked prior to the beginning of each surgery day." A tour of the facility was conducted on 8/21/13 starting at 9:00 AM. During the tour, the facility's defibrillator was observed. At that time, it was noted the inspection sticker on the defibrillator had expired in July of 2013. The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He confirmed the inspection sticker on the defibrillator had expired in July of 2013. He verified that the ASC did not have another emergency defibrillator in the facility. The facility failed to ensure emergency medical equipment was maintained. d. The facility's 10/27/97 "Nursing Organizational Plan" stated "Individual files will be kept on each nursing staff member." The policy stated nursing personnel files would include, but were not limited to, the following: - Credentialing: evidence of current licensure or certification in the State of Idaho. - Current CPR certification records. - A record of continuing education activities. However, the facility's personnel files were reviewed. The files did not include current documentation, as follows: - Physician A, whose credential records indicated reappointment and privilege review was dated 7/15/10, which was due for reappointment 7/2012. His CPR certification expired 3/2010. His records did not document continuing	Q 060	**Q 060 – Surgical Services (Continued):** C. Emergency Equipment Inspections and Logs: Per the citation, there were issues with maintenance of the crash cart and defibrillator. It was specifically cited that the defibrillator sticker had expired in July of 2013. A biomedical equipment inspector came on 8/22/2013 and found the defibrillator free of any malfunction. New defibrillator test logs for annual testing are implemented as of 8/22/13(See Appendix H). A weekly defibrillator testing log was also implemented as of 9/13/2013. This weekly testing is performed by the staff RN, and the log includes a dated, printed test strip for verification. (See Appendix I). Upon visiting with the biomedical inspector, we learned for small facilities such as ours, annual inspections are sufficient. This change will create a safer environment for patients.	

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Q 060	Continued From page 11 education, or current CPR. - CRNA B, whose appointment and privileges were dated 2/20/08, which was due for reappointment 2/2010. His ACLS certification expired 3/2009. His records did not document continuing education, or current ACLS. - CRNA C, whose reappointment and privileges were dated 1/10/11, which was due for reappointment 1/2013. His ACLS certification expired 10/2011. His records did not document continuing education, or current ACLS. - CRNA D, whose reappointment and privileges were dated 2/19/08, which was due for reappointment 2/2010. Her ACLS certification expired 11/2009. Her records did not document continuing education, or current ACLS. - During an interview on 8/22/13 at 9:30 AM, the ASC's consultant stated the facility's RN had been employed for approximately 2 years. The consultant could not produce a personnel record for the RN and was unable to verify current licensure, CPR, competencies, or inservice records for the RN. - During an interview on 8/22/13 at 9:30 AM, the ASC's consultant stated CST A had been employed for at least 2 years, but currently worked for the ASC as "on call" status only. The consultant could not produce a personnel record for CST A and was unable to verify current certification, CPR, competencies, or inservice records for CST A. - The consultant stated CST B had been employed for approximately 5 months. During	Q 060	**Q 060 – Surgical Services (Continued):** D. This section notes citations for deficiencies in medical staff credentialing and certification for multiple staff members. This deficiency was noted as one of the main conditions in the Immediate Jeopardy which was placed on the facility dated 8/21/2013. As evidenced by the abatement of the immediate jeopardy dated 8/22/2013, current staff credentials were obtained and present at the facility as of 8/22/2013.	

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Q 060	Continued From page 12 the interview on 8/22/13 at 9:30 AM, the consultant provided a personnel record for CST B. The competency forms and orientation forms were blank and CST B's CPR certification had expired 2/26/13. The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He stated the facility had undergone a change of ownership in July of 2013. He stated the ASC did not have documentation of current staff credentials including BLS/ACLS certifications or documentation that staff had been trained in the use of emergency equipment. He further stated that he had not received such documentation from the previous physician owner. The facility failed to ensure staff were trained to address the emergency medical needs of patients. The cumulative effect of the ASC's lack of safe surgical practices resulted in patients' being placed in immediate jeopardy for the potential to experience serious harm, impairment, or death as a result of procedural complications. Note: The facility was notified of the Immediate Jeopardy on 8/21/13 at 5:00 PM. The facility submitted an Immediate Plan of Correction, dated 8/21/13, which stated surgery scheduled for 8/22/13 would be canceled [the facility's next surgery was not scheduled until 8/29/13]. Additional systemic corrective measure included the following: - Staff credentials including licensure, DEA and Pharmacy licenses, privileges, BLS/ACLS certifications, job descriptions, competencies,	Q 060		

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Q 060	Continued From page 13 orientations, etc., would be compiled and available at the facility. - Equipment inspections, specifically the defibrillator, would be completed. - Expired medications would be removed and the anesthesia and crash carts would be stocked with appropriate medications. However, dates by which the corrections were to occur were not included in the plan. Additional information was solicited on 8/22/13 and received on 8/22/13 at 5:00 PM, which stated the following: - Current staff credentials had been obtained and were present at the facility as of 8/22/13. - The defibrillator had been inspected and found to be functioning according to standards as of 8/22/13. - The Crash Cart policy, including a list of drugs, was updated. All expired and outdated drugs were removed and disposed of. New drugs were purchased and stocked in accordance with current policy as of 8/22/13. The plan also noted that the drugs Atropine and 50% Dextrose had not been available at the pharmacy. However, the drugs would be obtained and available in the crash cart by 8/28/13. The plan further stated the Crash Cart policy would be further reviewed and updated to include Naloxone and Flumazenil. Those medications would then be purchased and included in the crash cart by 8/28/13. On site verification of the Plan's implementation was completed on 8/22/13 at 5:15 p.m. and the immediate Jeopardy was abated. Additional	Q 060		

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Q 060	Continued From page 14 observations were conducted at the facility on 8/28/13 at 2:00 PM and 8/29/13 at 7:30 AM prior to the surgery scheduled on 8/29/13. At that time, implementation of the Immediate Plan was verified and the Immediate Jeopardy abatement was confirmed.	Q 060		
Q 080	416.43 QUALITY ASSESSMENT AND PERFORMANCE 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 staff interview and review of facility policies, it was determined the ASC failed to develop and implement a QAPI program for all patients receiving services at the facility. This resulted in the inability of the ASC to evaluate performance and improve the quality of patient care. Findings include: 1. Refer to Q-081 as it relates to the lack of a QAPI program that measured, analyzed, and tracked quality indicators. 2. Refer to Q-082 as it relates to the lack of quality indicator data gathered by the ASC. 3. Refer to Q-083 as it relates to the failure of the ASC to developed and conduct performance improvement projects. 4. Refer to Q-084 as it relates to the failure of the Governing Body to oversee the QAPI program. The cumulative effect of these systematic failures resulted in the inability of the ASC to monitor programs and services.	Q 080	**Q 080 416.43- Quality Assessment and Performance:** Under previous ownership there had been a QAPI program implemented but there had been no QAPI activities of any kind undertaken since the first quarter of 2010. It is the intent of the new IFSC ownership to develop, implement and maintain an ongoing, data driven Quality assessment and performance improvement program. With the aid of our consultant we have completely re-written the IFSC QAPI manual as of 9/30/2013. Contained therein are procedures set forth to meet the following findings: Q081as it relates to establishing a QAPI program that measures, analyzes and tracks quality indicators, Q082 as it relates to a QAPI program that gathers appropriate quality indicator data, Q083 as it relates to developing and conducting of QAPI performance improvement projects, Q084 as it relates to Oversight of Governing body for the QAPI program. (See Appendix J)	

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Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (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 furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (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. This STANDARD is not met as evidenced by: Based on staff interview and review of facility policies and records, it was determined the ASC failed to ensure a QAPI program that measured, analyzed, and tracked quality indicators had been developed and implemented for all patients receiving services at the ASC. This resulted in the inability of the ASC to evaluate its processes necessary to improve the quality of patient care. Findings include:	Q 081	**Q081: 416.43(a)(1): Program Scope; Program Activities** Our newly adopted QAPI Program includes plans for future ongoing activities that demonstrate measureable improvement in patient safety. Specifically, the program goals are: "Our number one priority is to meet the needs of the patient. Each patient shall receive the highest quality of care that we can provide. It is the responsibility of the staff to be part of effectively evaluating and improving the quality and appropriateness of all aspects of patient care through QAPI activities and assessments; to understand and continuously improve the sequences and inter-dependencies among the processes of patient care; to provide safe, quality medical care to each patient..." The scope of the QAPI Program is "Patients, families, medical staff and staff members. Quality improvement activities that focus on the needs of patients and the aspects of care that are most important to the health, safety and satisfaction of patients served will be identified." Implementation of the Safe Surgery Checklist is one way that we can begin QAPI activities for all patients at the ASC. Implementation of these policies and procedures will ensure that tracking and monitoring activities are conducted in order t to provide a higher standard of patient care. (See Appendix J)	

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Q 081	Continued From page 16 The facility's policy manual, last approval dated 2009, did not include policies related to a quality improvement program. The physician owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated the facility had undergone a change of ownership in July of 2013. He stated the ASC had not developed a QAPI plan for monitoring purposes since that time. The previous owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated there had been no QAPI program activities since the first quarter of 2010. The ASC failed to ensure a QAPI program was developed, implemented and monitored.	Q 081		
Q 082	416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse	Q 082	**Q082- 416.43(b), 416(c)(2), 416.43(c)(3) Program Data; Program Activities** As of 9-19-2013, 2 QI studies were introduced to staff. They are currently being conducted and data collection is underway. The projects are: 1) Study of Patient Recovery Time and 2) Improving the Monitoring and Tracking of Controlled Substances. The second project was implemented as part of our QAPI activities in part due to citations by CMS. We commit to being thorough in tracking of controlled substances and realize the danger that not doing so could potentially impose upon patients. Our list of Quality Indicators will be a good resource for our QAPI studies and we will continue to add to it as pt needs evolve and change at IFSC. Our commitment to participation in QAPI activities will be evidenced by performance and projects conducted (1) each quarter. (See Appendix J.)	

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Q 082	Continued From page 17 patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on staff interview and review of facility records, it was determined the ASC failed to ensure quality indicator data had been incorporated as part of a QAPI program for all patients receiving care at the facility. This resulted in the inability of the ASC to make decisions about its programs and services which were based on relevant data. Findings include: Records demonstrating a QAPI program had been implemented and that quality indicator data had been tracked, monitored, and analyzed could not be found at the facility. The physician owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated the facility had undergone a change of ownership in July of 2013. He stated the ASC had not developed a QAPI plan for monitoring purposes since that time. The previous owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated there had been no QAPI program activities since the first quarter of 2010. The ASC failed to ensure quality indicator data was gathered and incorporated into a comprehensive QAPI program.	Q 082		
Q 083	416.43(d) PERFORMANCE IMPROVEMENT PROJECTS (1) The number and scope of distinct improvement projects conducted annually must	Q 083		

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Q 083	Continued From page 18 reflect the scope and complexity of the ASC's services and operations. (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 staff interview and review of facility records, it was determined the ASC failed to ensure performance improvement projects had been developed or conducted for all patients receiving care at the facility. This resulted in the inability of the ASC to evaluate specific processes and make improvements in patient care. Findings include: Records demonstrating that a quality improvement project had been developed, implemented, and monitored could not be found at the facility. The physician owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated the facility had undergone a change of ownership in July of 2013. He stated the ASC had not developed or conducted a performance improvement project since that time. The previous owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated there had been no performance improvement projects since the first quarter of 2010. The ASC failed to ensure performance improvement projects were conducted.	Q 083	**Q083- 416.43(d) Performance Improvement Projects** IFSC commits to participate in QAPI activities in efforts to increase patient health outcomes by implementing not only "after the fact" changes, but by incorporating changes before adverse events transpire. IFSC has processes in place for identifying and monitoring quality indicators as they relate to patient health begin. In the future, Governing Body and QI agendas will provide for reporting of QAPI studies which will be documented in the minutes. There will also be records of study/project chronology kept at the ASC. It will contain data collection, evaluations written in the accepted 10-step format, the outcomes of the study, and whether or not the performance goal was reached. The Quality Assurance and Performance Improvement Program will be evaluated by the committee annually for its effectiveness and changes will be made to accommodate the complexity of the ASC's operations.	

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Q 084	416.43(e) GOVERNING BODY RESPONSIBILITIES 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. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. This STANDARD is not met as evidenced by: Based on staff interview and review of facility records, it was determined the ASC failed to ensure the Governing Body had developed and implemented a QAPI program for all patients receiving care at the facility. This resulted in the inability of the ASC to gather data to assess its services. Findings include: The policy manual, last review dated 2009, did not include QAPI policies. The physician owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated the facility had undergone a change of ownership in July of 2013. He stated no formal Governing Body meetings had been held since that time and a QAPI program had not been developed. The previous owner of the ASC was interviewed on 8/21/13 at 2:00 PM. He stated there had been no QAPI program activities since the first quarter	Q 084	**Q 084- 416.43(e) Governing Body Responsibilities** QAPI (Quality Assessment and Performance Improvement) Program: The Governing Body has written the policy in such a way that we will be monitoring our procedures for patient safety and quality of care quarterly at Governing Body and QI meetings. Our policy is to study a set of quality indicators that have been included in our QI Policy and Procedure Manual. These will be reviewed and revised as necessary. All reports of indicators studied and related incidents will be reported at Governing Body meetings for review quarterly and the process of completing studies will be evaluated in order to implement practices that will improve patient care. The Governing Body has assigned the Practice Administrator to head the QAPI Committee. She will enlist help from the ASC staff as needed for collection of data. The studies we are conducting presently are: 1) Study of Patient Recovery Time and 2) Improving the Monitoring and Tracking of Controlled Substances. These were introduced to staff at QI on 9-19-2013 and data collection began on 9/26/2013.	

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Q 084	Continued From page 20 of 2010. The ASC's Governing Body failed to ensure a quality improvement program was developed, implemented and monitored.	Q 084		
Q 100	416.44 ENVIRONMENT The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, it was determined the facility failed to ensure a safe and sanitary environment was provided and maintained for all patients receiving care at the facility. This resulted in a lack of appropriate environmental conditions, equipment, and personnel necessary to ensure patient health and safety. Findings include: 1. Refer to Q-105 as it relates to the facility's failure to ensure emergency equipment was appropriately maintained. 2. Refer to Q-106 as it relates to the facility's failure to ensure personnel were trained and available to address the emergency health care needs of patients. The cumulative effect of these systematic failures resulted in the inability of the ASC to ensure patients received routine and emergency care in a safe and effective manner.	Q 100	Q100 416.44 Environment: Idaho Foot Surgery Center has developed policies to ensure a safe and sanitary environment, properly constructed, equipped and maintained to protect the safety of patients. Please refer to Q105 and Q106 for further details.	
Q 105	416.44(c) EMERGENCY EQUIPMENT The ASC medical staff and governing body of the	Q 105		

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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
Q 105	Continued From page 21 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 observations, staff interviews, and record review, it was determined the ASC failed to ensure all emergency medical equipment was maintained for all patients receiving care at the facility. This resulted in the potential for patients' health and safety to be compromised in the event of a medical emergency. Findings include: 1. The facility's unsigned, undated Crash Cart policy stated "An inventory will be maintained with the cart. Any supplies used or outdated will be re-stocked as soon as possible following use/outdate and the seal [on the crash cart] replaced. This should be the responsibility of the RN with assistance of the anesthetist." The policy was not implemented, as follows: a. The Crash Cart policy listed medications which were required by the ASC for emergency purposes. The list included, but was not limited to, the following: - Atropine 1 mg (4) - 2% Lidocaine Inj 100 ml (1) - 1% Lidocaine Inj 50 ml (3) The policy stated the crash cart "will be opened	Q 105	**Q 105 416.44 (c) Emergency Equipment:** Crash Cart: The Governing Body, in coordination with our anesthesia providers, has overseen the revision of the Crash Cart policy to ensure that equipment and mediations are immediately available for emergency situations, appropriate to the patient population and maintained by appropriate personnel, thus creating a safer environment for patients. It was revised, updated, and signed by the Medical Director on 9/21/2013(See Appendix F). Our new policy states that the crash cart will be inventoried each month ***by the RN on staff*** to prevent outdates and maintain proper inventory of emergency medications and emergency equipment. As noted, as of 8/28/2013 all expired medications were removed from the Crash Cart and new medications were immediately purchased to comply with our policy. This change will create a safer environment for patients.	

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Q 105	Continued From page 22 monthly and checked for outdate [sic] medications and re-stocked as necessary." However, a tour of the facility was conducted on 8/21/13 at 9:00 AM. Medications identified in the Crash Cart policy were expired, as follows: - 2% Lidocaine HCL 100 mg 20 mg/ml, with an expiration date of 7/2012. - 2% Lidocaine Inj 50 ml with an opened date of 6/28/13. Atropine was not found in the the facility's crash cart as stated in the Crash Cart policy. However, the anesthesia cart was also observed during the facility tour on 8/21/13 at 9:00 AM. The following expired medications were observed: - 4 boxes of Atropine Inj 1 mg, with an expiration date of 6/2013. - 2% Lidocaine Inj 20 mg/ml, with an expiration date of 7/2013. During an interview on 8/22/13 beginning at 11:10 AM, the RN confirmed the above drugs were expired and had not been discarded in a timely manner. The RN further stated she was unsure how many days were required to pass before an opened medication would need to be discarded. United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations, Second Edition, 6/01/08, states if a multidose vials has been opened or accessed the vial should be dated and discarded within 28 days unless the manufacturer specifies a different date for that opened vial. Additionally, the facility's Drug and Pharmaceutical Storage and Disposal policy dated 9/2010 stated "Multidose vials will be discarded on or before the	Q 105	**Q 105 416.44 (c) Emergency Equipment (Continued):** In regards to the use of multidose vials, we currently have medication administration policy, dated 9/21/2013 that supports the verbiage of the 28 day rule from USP 797; it is found in the medication guidelines section of the Nursing Manual, dated 9-2010 (See Appendix G). This policy states that all multidose vials will be labeled with an "Open Date" as well as a "Discard By Date", to avoid any confusion as to the meaning of the date on the bottle. As of 9/30/2013, we have performed training for staff on this policy so that no further compliance issues will arise, thus creating a safer environment for patients.	

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Q 105	Continued From page 23 28th day after they are first accessed..." The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He confirmed the crash cart had expired and missing medications. He verified the ASC did not have other emergency medications in the facility. The facility failed to ensure the crash cart was stocked and maintained with emergency medications. b. The facility's unsigned, undated Crash Cart policy listed supplies which were required by the ASC for emergency purposes. The policy stated the "Airway drawer" was required to contain multiple items which included, but were not limited to, endotracheal tubes, sizes 5.5 to 8.0 (2 each size) and stylets. A tour of the facility was conducted on 8/21/13 at 9:00 AM. The following Crash Cart supplies were noted to be expired: - Endotracheal Tube 5.0 mm with an expiration date of 10/2010. - Endotracheal Tube 5.5 mm with an expiration date of 3/2009. - Endotracheal Tube 6.0 mm with an expiration date of 11/2010. - Endotracheal Tube 6.5 mm with an expiration date of 2/2011. - Endotracheal Tube 7.0 mm with an expiration date of 7/2011.	Q 105	**Q 105 416.44 (c) Emergency Equipment (Continued):** B. Crash Cart Airway Supplies: As noted in the citation some of our crash cart airway supplies were either expired or inconsistent with our stated Crash Cart Policy. As of 8/28/2013, all expired airway supplies were removed from the cart and discarded by the practice administrator and all supplies were inventoried and brought into consistency with our stated Crash Cart supply list and policy. In coordination with our anesthesia providers, we have written a new Crash Cart content list and policy (See appendix F). Our policy is that the crash cart will be inventoried each month ***by the RN on staff*** to prevent outdates and maintain proper inventory of emergency medications and emergency equipment. The Crash Cart policy was updated, dated and signed by the Medical Director by 9-21-2013.	

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Q 105	Continued From page 24 - Endotracheal Tube 7.5 mm with an expiration date of 6/2011. - Intubation Stylet 7.5 mm with an expiration date of 2/2009. - Intubation Stylet 5.0 mm with an expiration date of 12/2008. Additionally, the crash cart included the following supplies which were not identified in the facility's policy: - Tracheal Airway set, small adult, with an expiration date of 2/2011. - Tracheal Airway set, adult, with an expiration date of 1/2011. During an interview on 8/22/13 beginning at 11:10 AM, the RN confirmed the above emergency supplies expired and had not been discarded in a timely manner. Further, an oxygen tank on a stand by the crash cart was noted to read 200 pounds (just above the red line which indicated empty). The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He confirmed the crash cart had expired emergency supplies. He verified that the ASC did not have other emergency supplies in the facility. The facility failed to ensure emergency supplies were maintained. c. The facility's unsigned, undated Crash Cart policy stated "The defibrillator will be checked	Q 105		

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Q 105	Continued From page 25 prior to the beginning of each surgery day." A tour of the facility was conducted on 8/21/13 starting at 9:00 AM. During the tour, the facility's defibrillator was observed. At that time, it was noted the inspection sticker on the defibrillator had expired in July of 2013. The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He confirmed the inspection sticker on the defibrillator had expired in July of 2013. He verified that the ASC did not have another emergency defibrillator in the facility. The facility failed to ensure emergency medical equipment was maintained.	Q 105	**Q 105 416.44 (c) Emergency Equipment (Continued):** C. Emergency Equipment Inspections and Logs: Per the citation, there were issues with maintenance of the crash cart and defibrillator. It was specifically cited that the defibrillator sticker had expired in July of 2013. A biomedical equipment inspector came on 8/22/2013 and found the defibrillator free of any malfunction. New defibrillator test logs for annual testing are implemented as of 8/22/13(See Appendix H). A weekly defibrillator testing log was also implemented as of 9/13/2013. This weekly testing is performed by the staff RN, and the log includes a dated, printed test strip for verification. (See Appendix I). Upon visiting with the biomedical inspector, we learned for small facilities such as ours, annual inspections are sufficient. This change will create a safer environment for patients.	
Q 106	416.44(d) EMERGENCY PERSONNEL Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC. This STANDARD is not met as evidenced by: Based on review of facility records and staff interview, it was determined the ASC failed to ensure staff were trained and readily available to address the emergency medical needs for all patients receiving care at the facility. This resulted in the potential for patients' health and safety to be compromised in the event of a medical emergency. Findings include: 1. The facility's undated Code Blue Policy stated "In the event of cardiac arrest, ACLS (Advanced Cardiac Life Support) protocol will be followed	Q 106		

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Q 106	Continued From page 26 while awaiting patient transport to [hospital name] per ambulance." The protocol stated staff were to do the following: - Surgeon: Give order to call 911, record medications/defibrillations on code blue record, and stay with patient and assist as needed. - Anesthesia: Verify rhythm, run code per ACLS protocol, manage airway/intubate, and give order to call 911 if necessary. - RN: Give ACLS medications per anesthesia order, start IV as needed, set up suction equipment, defibrillate per anesthesia order, ensure throughout that staff members are performing duties, that 911 has been called, and assist anesthesia as needed. - Scrub tech: Take crash cart to code blue location and chest compressions. Additionally, the facility's 10/27/97 Nursing Organizational Plan stated "Individual files will be kept on each nursing staff member." The policy stated nursing personnel files would include, but were not limited to, the following: - Credentialing: evidence of current licensure or certification in the State of Idaho. - Current CPR certification records. - A record of continuing education activities. However, the facility's personnel files were reviewed. The files did not include documentation of current training to address the emergency medical needs of patients, as follows:	Q 106	**Q106 416.44(d) Emergency Personnel:** Per the citation, our policy stated that we re-credentialed practitioners every 2 years. Our current practice is to re-credential physicians and CRNAs every 3 years and we are changing our policy to state such. This is found in our medical staff bylaws which is currently being re-written and will be completed prior to 10/4/2013. Each medical staff member who qualifies for privileges will receive a letter stating such, with dates stating the period of privileging. The letter will be filed in his or her Credential file. All Medical Staff credential files were updated with current credentials for licensure, insurance, BLS/ACLS certification, job descriptions, peer review, etc. on 8-28-2013 when Immediate Jeopardy was abated. This ensures that patients of IFSC will have trained emergency personnel available at all times.	

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Q 106	Continued From page 27 a. Physician A: His CPR certification expired 3/2010. His records did not document continuing education or training, including training in the use of the facility's emergency medical equipment. b. CRNA B: His ACLS certification expired 3/2009. His records did not document continuing education or training, including training in the use of the facility's emergency medical equipment. c. CRNA C: His ACLS certification expired 10/2011. His records did not document continuing education or training, including training in the use of the facility's emergency medical equipment. d. CRNA D: Her ACLS certification expired 11/2009. Her records did not document continuing education or training, including training in the use of the facility's emergency medical equipment. e. During an interview on 8/22/13 at 9:30 AM, the ASC's consultant stated the RN and stated she had been employed for approximately 2 years. The consultant stated she could not produce a personnel record for the RN that included current licensure, CPR, competencies, or inservice records. f. During an interview on 8/22/13 at 9:30 AM, the consultant stated CST A had been employed for at least 2 years, but currently worked for the ASC as "on call" status only. The consultant stated she could not produce a personnel record for CST A that included current certification, CPR, competencies, or inservice records for CST A. g. During the interview on 8/22/13 at 9:30 AM, the	Q 106		

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Q 106	Continued From page 28 consultant stated CST B had been employed for approximately 5 months. The consultant provided a personnel record for CST B. However, the competency forms and orientation forms were blank and CST B's CPR certification had expired 2/26/13. The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He stated the facility had undergone a change of ownership in July of 2013. He stated the ASC did not have documentation of current staff credentials including BLS/ACLS certifications or documentation that staff had been trained in the use of emergency equipment. He further stated that he had not received such documentation from the previous physician owner. The facility failed to ensure staff were trained to address the emergency medical needs of patients.	Q 106		
Q 120	416.45 MEDICAL STAFF The medical staff of the ASC must be accountable to the governing body. This CONDITION is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure the Governing Body maintained responsibility for the medical staff. This resulted in the inability of the Governing Body to ensure medical staff members were responsible to provide care. Findings include: 1. Refer to Q-121 as it relates to the failure of the facility to ensure medical staff privileges were	Q 120	**Q120-123 Medical Staff:** Medical Staff issues had to do with citations for not having proper and current credentials for medical staff and that the process of Credentialing was current and ongoing. Our policy states that prior to privileging, medical staff will submit an application for privileges which will be evaluated and approved by the Governing Body. There were citations relating the absence of credentialing files for one physician and three CRNA's. This has been resolved as of 8/22/2013, as part of the immediate Jeopardy which was abated on the same date. Per the citation, our policy stated that we re-credentialed practitioners every 2 years. Our current practice is to re-credential physicians and CRNAs every 3 years and we are changing our policy to state such. This policy is contained in the Medical Staff bylaws which is currently being updated and will be completed by 10/4/2013. Each medical staff member who qualifies for privileges will receive a letter stating such, with dates stating the period of privileging. The letter will be filed in his or her Credential file.	

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Q 120	Continued From page 29 granted in accordance with recommendations from qualified personnel. 2. Refer to Q-122 as it relates to the failure of the facility to ensure medical staff privileges were reappraised. 3. Refer to Q-123 as it relates to the failure of the facility to ensure policies and procedures for the oversight and evaluation of non-physician practitioners were developed, implemented and monitored necessary to ensure appropriate patient care was provided. The cumulative effect of these deficient practices resulted in lack of practitioner accountability to the Governing Body.	Q 120		
Q 121	416.45(a) MEMBERSHIP AND CLINICAL PRIVILEGES Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure the medical staff had been appointed and granted privileges for 1 of 2 physicians (Physician B), practicing at the ASC. This resulted in the facility providing patient care by a physician who had not been reviewed for legal and professional qualifications. Findings include: 1. A policy titled Credentialing and Privileging of	Q 121		

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Q 121	Continued From page 30 Medical and Nursing Staff, dated 8/14/07, stated "Clinical privileges shall be granted only when the applicant meets all of the above requirements and is approved by the Governing Body." The facility's personnel files were reviewed. Physician B did not have a credential file on site. During an interview on 8/21/13 beginning at 2:00 PM, the physician owner stated he purchased the ASC in July of 2013 and had not completed a credentialing file for himself. The facility failed to ensure medical staff were credentialed and granted privileges.	Q 121		
Q 122	416.45(b) REAPPRAISALS Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure the Governing Body reappraised the privileges for 4 of 5 physicians and CRNAs (Physician A and CRNAs B - D,) who practiced at the ASC. This resulted in a lack of an evaluation to ensure medical staff privileges were appropriate for the facility. Findings include: 1. ARTICLE III and V of the ASC bylaws, undated, stated "Initial appointment shall be made by the Governing Body upon the recommendation of the Credentialing Committee	Q 122		

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Q 122	Continued From page 31 for a period of 2 years. Renewals of appointments shall also be for a term of 2 years." Credential files and reappraisals for privileges had not been maintained, as follows: a. Physician A, whose reappointment and privilege review was dated 7/15/10. b. CRNA B, whose reappointment and privilege review was dated 8/31/09. c. CRNA C, whose reappointment and privilege review was dated 1/10/11. d. CRNA D, whose reappointment and privilege review was dated 2/19/08. The physician owner and previous physician owner were interviewed on 8/21/13 at 2:00 PM. They confirmed the credentialing records had not been maintained and kept current. The previous physician owner stated the ASC's administrator had left in 2012 and she had been responsible for maintaining the records. The Governing Body failed to reappraise the privileges of the ASC's medical staff.	Q 122		
Q 123	416.45(c) OTHER PRACTITIONERS If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. This STANDARD is not met as evidenced by:	Q 123		

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Q 123	Continued From page 32 Based on record review and staff interview, it was determined the facility failed to ensure policies and procedures for the oversight and evaluation of 3 of 3 non-physician practitioners (CRNAs B - D) were developed, implemented and monitored. This resulted in the potential for patients to receive inadequate care. Findings include: 1. The facility's 10/27/97 Nursing Organizational Plan stated "Individual files will be kept on each nursing staff member." The policy stated nursing personnel files would include, but were not limited to, the following: - Credentialing: evidence of current licensure or certification in the State of Idaho. - Current CPR or ACLS certification records. - A record of continuing education activities. - Performance evaluations. Personnel files were reviewed. Documentation of oversight of the CRNAs could not be found, as follows: - CRNA B, whose appointment and privileges were dated 2/20/08, which was due for reappointment 2/2010. His ACLS certification expired 3/2009. His records did not document continuing education or performance evaluations. - CRNA C, whose reappointment and privileges were dated 1/10/11, which was due for reappointment 1/2013. His ACLS certification expired 10/2011. His records did not document continuing education or performance evaluations. - CRNA D, whose reappointment and privileges were dated 2/19/08, which was due for	Q 123		

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Q 123	Continued From page 33 reappointment 2/2010. Her ACLS certification expired 11/2009. Her records did not document continuing education or performance evaluations. When asked, on 8/21/13 at 2:00 PM, if the ASC had policies related to oversight and evaluation of CRNAs, the previous physician owner stated he did not know. He stated the practice had recently been sold, and he was not sure if policies and files were available and on site. The previous physician owner and current physician owner confirmed there was no documentation related to oversight and evaluation of the 3 CRNAs that provided anesthesia services for the ASC. The previous physician owner stated the administrator had left in November 2012, and the records for the CRNAs had not been maintained. The current physician owner stated he had not yet had time to review the credential files. The facility failed to ensure policies and procedures for the oversight and evaluation of non-physician practitioners were developed, implemented and monitored.	Q 123		
Q 140	416.46 NURSING SERVICES The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met. This CONDITION is not met as evidenced by: Based on record review and interview, it was determined the ASC failed to ensure nursing services at the facility were directed and staffed to meet the nursing needs of all patients receiving care at the facility. This resulted in the inability of the facility to ensure qualified personnel were	Q 140		

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Q 140	Continued From page 34 available to provide routine and emergency care in accordance with recognized standards of practice, thereby compromising patient health and safety. Findings include: 1. Refer to Q-141 as it relates to the facility's failure to ensure nursing responsibilities were clearly identified and to ensure appropriate nursing personnel were available to provide routine and emergency care to patients.	Q 140		
Q 141	416.46(a) ORGANIZATION AND STAFFING Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the facility failed to ensure qualified nursing personnel were available to provide routine and emergency care. This directly impacted 9 of 11 patients (#1 - #9) whose records were reviewed and had the potential to impact all patients receiving care at the facility. This resulted in the inability of the facility to ensure safe and effective nursing services were provided to patients. Findings include: 1. The facility's 10/27/97 Nursing Organizational Plan stated "Individual files will be kept on each nursing staff member." The policy stated nursing personnel files would include, but were not limited to, the following:	Q 141	**Q141 – Organization and Staffing:** In regard to the citation having to do with the RN's credential file where pieces of her file were missing; those have been collected and she has been oriented as to what her job entails. Per the 1997 policy referenced, we are to have current Credential files on all staff members. Under the conditions of the immediate jeopardy and as of 8/22/2013, all nursing and support staff had updated credential files with current state licensures, certifications etc. We now have current credential files on all ASC staff members that include job descriptions (laundry, medical records, housekeeping, etc), and orientations, BLS or ACLS certifications, etc. The job description for Nurse Manager was found in an early version of the facility's manuals and has since been deleted from the manual as we no longer have that position as part of our staff.	

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Q 141	Continued From page 35 - Credentialing: evidence of current licensure or certification in the State of Idaho. - Current CPR certification records. - A record of continuing education activities. The policy stated "Responsibilities and duties of all personnel shall be defined and outlined, and all personnel shall be evaluated based on these definitions of responsibilities." However, the facility's personnel files were reviewed. The files did not include documentation sufficient to ensure patient care responsibilities were appropriately delineated as follows: a. The facility's records included a job description for a perioperative RN and a separate job description for a nurse manager, who was also required to be an RN. When asked, during an interview on 8/22/13 at 9:30 AM, a consultant for the ASC stated the facility employed one RN. The consultant stated the RN had been employed for approximately 2 years. However, the consultant stated she could not produce a personnel record for the RN, including a signed job description or inservice records. The consultant further stated she was unable to verify current licensure, CPR, or competencies for the RN. Patients #1- #9's medical records documented they had procedures performed between 4/26/12 and 8/15/13. All 9 records documented the RN had participated in the procedures. The facility failed to ensure the RN's duties were clearly delineated and consistent with her	Q 141		

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Q 141	Continued From page 36 abilities. b. The facility's records included a job description for a scrub technician. When asked, during an interview on 8/22/13 at 9:30 AM, a consultant for the ASC stated the facility employed 2 CSTs. The consultant stated CST A had been employed for at least 2 years, but currently worked for the ASC as "on call" status only. The consultant stated she could not produce a personnel record for CST A, including a signed job description or inservice records. The consultant further stated she was unable to verify current certification, CPR, or competencies for CST A. The consultant stated CST B had been employed for approximately 6 months. CST B's personnel file was reviewed. The file did not include signed job description or inservice records and the CPR certification had expired 2/2013. When asked, during an interview on 8/22/13 at 9:30 AM, the consultant stated she was unable to verify current certification, CPR, or competencies for CST B. The facility failed to ensure the CSTs' duties were clearly delineated and consistent with their abilities. c. The facility's records did not include a contract or job description for CRNAs. The personnel files of 3 CRNAs were reviewed. The files were incomplete as follows: - CRNA B, whose appointment and privileges were dated 2/20/08, which was due for reappointment 2/2010. His ACLS certification had expired 3/2009. His records did not document continuing education or performance evaluations.	Q 141		

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Q 141	Continued From page 37 - CRNA C, whose reappointment and privileges were dated 1/10/11, which was due for reappointment 1/2013. His ACLS certification had expired 10/2011. His records did not document continuing education or performance evaluations. - CRNA D, whose reappointment and privileges were dated 2/19/08, which was due for reappointment 2/2010. Her ACLS certification had expired 11/2009. Her records did not document continuing education or performance evaluations. The facility failed to ensure the CRNAs' duties were clearly delineated and consistent with their abilities. d. During an interview on 8/22/13 at 9:30 AM, the consultant for the ASC stated a medical assistant worked at the facility. The consultant was not able to provide evidence the medical assistant had a personnel file and stated she was not aware the medical assistant worked on the ASC side of the practice. However, during an interview on 8/22/13 at 10:00 AM, the RN stated she would work with a medical assistant on the days when the ASC had more than 1 patient scheduled for procedures. She would designate patient care duties such as vital signs and monitoring of patients during the recovery phase to the medical assistant while she was in the OR with another patient. During a subsequent interview on 8/28/13 at 4:00 PM, the medical assistant stated she had trained "on the job," over the past 4 years she had been	Q 141		

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Q 141	Continued From page 38 employed. She stated her position had initially been as a receptionist for the clinic side of the practice. She stated her duties in the ASC had expanded to include monitoring of post operative patients, vital signs, and housekeeping duties. The medical assistant provided a personnel record she had completed on 8/27/13, and confirmed she had not taken CPR or had formal medical assistant training. The facility failed to ensure the medical assistant duties were clearly delineated and consistent with her abilities. The ASC failed to ensure that staff were qualified and trained for the duties necessary to ensure pre-operative, intra-operative, and post-operative services were provided in a safe manner.	Q 141	**Q141 Organization and Staffing (Continued):** D. In reference to the perioperative assistant position, the Governing Body has determined that it is in the patient's best interest to have a licensed RN fill any duties relating to pre and post operative care. In order to help ensure this goal, IFSC is in the process of hiring 1-2 more part time Registered Nurse staff members to fill peri-operative duties on days when surgical volume is too great for one RN to adequately attend to patient care pre-op and recovery duties. Governing body will continue to oversee that all credentialing licensures for these new RN staff members is current.	
A Q 162	416.47(b) FORM AND CONTENT OF RECORD 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	The Medical Records Policy (See Appendix K) was updated, modified, and accepted by Governing Body on 9/25/2013. It requires the following documents to be in the patient medical record: Demographic information; Photo ID; History and Physical; Advance Directive (if any); Informed Consent for procedure; Pre-op Forms: concerning the necessity, appropriateness, and risks of the proposed surgery, as well as discussion of treatment alternatives.; Pre-op tests (if any); Operative Report; Pathology Reports (if any); Perioperative Nursing Record; Anesthesia Consent; Pre- and Post- Anesthesia Evaluation; Intra-operative Anesthesia Record; Postoperative documentation of patient's status; Discharge Orders; Postoperative home care instructions; Patient Escort Agreement; Postoperative Follow-up Evaluation; Items Used Sheet; and a Patient Crayon. The policy also requires the records to be an accurate and	

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Q 162	Continued From page 39 (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. This STANDARD is not met as evidenced by: Based on review of medical records and policies, and staff interview it was determined the facility failed to ensure medical records were complete and accurate for 8 of 11 patients (#1 - #5 and #7-#9) whose records were reviewed. This failure resulted in a lack of complete comprehensive information being available in patient records. Findings include: 1. The Operating Room Policy, undated, stated the "...operating room record will be competed by the attending RN circulator..." The policy stated the surgery portion of the medical record would contain the patient's name, final diagnosis, procedure, times in and out of the OR, tourniquet record and nurses notes. The policy stated the recovery portion of the record would only contain recovery room vital signs. The discharge portion of the record would contain where the patient was discharged to, how the patient was discharged, who the patient was discharged with, whether the patient was alert and ambulatory, post operative appliances such as casts or crutches, signature and date of the nurse, "OK for Discharge" and date. Patient records were reviewed. The records did not demonstrate complete documentation, per facility policy, as follows: a. Patient #1 was a 56 year old female admitted to the ASC on 5/30/13 for tarsal tunnel decompression on her left foot. Her medical record was incomplete, as follows:	Q 162	legible completion of all documentation. The policy will allow us to have availability of complete comprehensive patient information. A Medical Records Clerk has been appointed as of August 28, 2013 to further ensure compliance to the Medical Record Policy. The O.R. Records Policy(See Appendix L) has been created and accepted by Governing Body as of 9/21/2013 to replace the Operating Room Policy. This new policy states that the RN on staff, anesthesia provider, and surgeon all are responsible for particular sections of the O.R. records. It also states that ultimately the Medical Records Clerk is responsible for final revision of records before filing the chart away.	

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Q 162	Continued From page 40 - An Anesthesia Record signed by the CRNA on 5/30/13, documented Patient #1 was administered a continuous infusion of Diprivan during her surgery, approximately 8:25 AM to 10:35 AM. There was no documentation to indicate the total amount of Diprivan Patient #1 received. The Anesthesia Record also documented Patient #1 had received IV fluids of lactated ringers throughout her time in the OR, approximately 8:15 AM to 10:49 AM. There was no documentation of the total amount of IV fluid Patient #1 had received. The CRNA was interviewed on 8/29/13 at 12:25 PM, and confirmed he had not documented the total amount of Diprivan he had administered to Patient #1 during her procedure. He confirmed the IV fluids had not been recorded on the form as well. - The Operative Report dated 5/30/13, documented Patient #1's foot was "prepped and draped in the usual aseptic technique." There was no documentation to indicate what type of prep was applied to Patient #1's foot. During an interview on 8/22/13 beginning at 1:00 PM, Physician A reviewed Patient #1's record and confirmed the prep solution had not been documented. He stated the facility used a Hibiclens prep for all patients. Patient #1's medical record contained incomplete documentation. b. Patient #2 was a 63 year old female admitted to the ASC on 3/28/13 for repair of a damaged	Q 162	In order to prevent improper documentation by staff, it is noted within the O.R Records Policy (See Appendix L) that "completing" is defined as legibly writing in the required blank spaces, adding up totals for medication amounts, recording accurate times, and signing in every required space. This will reinforce anesthesia provider's awareness of the requirement to add medication or fluid total amounts. Governing Body has accepted the use of a new Perioperative Nursing (See Appendix M). The specific type of prep used will now be documented in the Intra-Operative section to assist with proper dictation of the Operative Report.	

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Q 162	Continued From page 41 flexor plate on her left foot. Her medical record was incomplete, as follows: - A Perioperative Nursing Record signed by the RN, contained a space labeled "OK for Discharge," which was left blank. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed that the space was for the physician to sign after the patient had been assessed in recovery and was cleared for discharge. He confirmed that due to the lack of signature, it was unclear if Patient #2 had been assessed prior to discharge from the ASC. - An Anesthesia Record signed by the CRNA on 3/28/13, documented Patient #2 was administered a continuous infusion of Diprivan during her surgery, approximately 8:20 AM to 10:45 AM. There is no documentation to indicate the total amount of Diprivan Patient #2 received. The Anesthesia Record also contained a section labeled Post Anesthesia Recovery Room, where the anesthesia provider was to document post anesthesia vital signs and circle the disposition of the patient, selecting from alert, awake, responsive, unresponsive, breathing deep/spontaneous, report to RN and IV infusing. The CRNA had not circled the disposition of Patient #2. It was unclear what Patient #2's disposition was after surgery. The CRNA was interviewed on 8/29/13 at 12:25 PM, and confirmed he had not completed the post anesthesia recovery document. - The Operative Report dated 3/28/13, listed the pre and post operative diagnosis, and provided details of pre-op and surgical procedures. The	Q 162	The Discharge Policy (See Appendix N) has been updated as of 9/21/2013. The policy has been changed to state that three signatures (from RN, anesthesia provider, and surgeon) are required after patient assessment and prior to the patients orders for discharge. By compliance to this policy, assessment prior to discharge of the patient will not be questionable. In order to prevent improper documentation by staff, it is noted within the O.R. Records Policy(See Appendix L) that "completing" is defined as legibly writing in the required blank spaces, adding up totals for medication amounts, recording accurate times, and signing in every required space. This will ensure all staff members writing in the O.R. records do so in all fields that require notation.	

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Q 162	Continued From page 42 Operative Report was not signed by the physician. In addition, the Operative Report documented Patient #2's foot was "prepped and draped in usual aseptic technique." There was no documentation to indicate what type of prep was applied to Patient #2's foot. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed he had not signed the Operative Report for Patient #2. He confirmed the prep solution had not been documented, and stated the facility used a Hibiclens prep for all patients. Patient #2's medical record contained incomplete documentation. c. Patient #3 was a 65 year old male admitted to the ASC on 3/21/13 for bunion surgery on his right foot. His medical record was incomplete, as follows: - A Perioperative Nursing Record signed by the RN, contained a space labeled "OK for Discharge," which was left blank. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed that the space was for the physician to sign after the patient had been assessed in recovery and was cleared for discharge. He confirmed that due to the lack of signature, it was unclear if Patient #3 had been assessed prior to discharge from the ASC. - An Anesthesia Record signed by the CRNA on 3/21/13, documented Patient #3 was administered a continuous infusion of Diprivan during his surgery, approximately 8:25 AM to 10:00 AM. There was no documentation to	Q 162	The Medical Records Policy (See Appendix K) states, "All reports, operative notes, and other patient information are reviewed and signed by the performing doctor and then incorporated into the record in a timely manner by the Medical Records Clerk." This modification will ensure operative reports are signed by Dr. Kovac before being filed into the patient record by the Medical Records Clerk.	

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Q 162	Continued From page 43 indicate the total amount of Diprivan Patient #3 received. The CRNA was interviewed on 8/29/13 at 12:25 PM, and confirmed he had not documented the total amount of Diprivan he had administered to Patient #3 during his procedure. - The Operative Report signed by the surgeon on 3/22/13 at 8:20 AM, documented Patient #3's foot was "prepped and draped in the usual aseptic technique." There was no documentation to indicate what type of prep was applied to Patient #5's foot. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed the prep solution had not been documented, and stated the facility used a Hibiclens prep for all patients. Patient #3's medical record contained incomplete documentation. d. Patient #9 was a 79 year old male admitted to the ASC on 4/26/12 for surgical correction of a mallet toe on his left foot. His medical record was incomplete, as follows: - An Anesthesia Record signed by the CRNA on 4/26/12, documented Patient #9 was administered a continuous infusion of Diprivan during his surgery, approximately 12:40 PM to 1:25 PM. There was no documentation to indicate the total amount of Diprivan Patient #9 received. The CRNA was interviewed on 8/29/13 at 12:25 PM, and confirmed he had not documented the total amount of Diprivan he had administered to	Q 162		

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Q 162	Continued From page 44 Patient #9 during his procedure. - The Operative Report signed by the surgeon on 5/1/12, documented Patient #9's foot was "prepped and draped in usual aseptic technique." There was no documentation to indicate what type of prep was applied to Patient #9's foot. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed the prep solution had not been documented, and stated the facility used a Hibiclens prep for all patients. Patient #9's medical record contained incomplete documentation. e. Patient #5 was a 59 year old female admitted to the ASC on 6/13/13 for bunion and hammertoe surgery on her right foot. Her medical record was incomplete, as follows: - The Operative Report dated 6/13/13, documented Patient #5's foot was "prepped and draped in the usual aseptic technique." There was no documentation to indicate what type of prep was applied to Patient #5's foot. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed the prep solution had not been documented, and stated the facility used a Hibiclens prep for all patients. Patient #5's medical record contained incomplete documentation. f. Patient #8 was a 51 year old male admitted to the ASC on 8/15/13 for bilateral plantar fasciotomy. His medical record was incomplete, as follows:	Q 162		

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Q 162	Continued From page 45 - The Perioperative Nursing Record signed by the RN, contained a section where the RN was to document the time the patient was discharged from the ASC. This section was left blank, causing a lack of clarity as to when Patient #8 was discharged. During an interview with Physician A on 8/22/13 at 1:00 PM, he reviewed Patient #8's record and confirmed the Perioperative Nursing Record indicating what time Patient #8 was discharged was not completed by the nurse. - The Operative Report dated 8/15/13, documented Patient #8's feet were "scrubbed, prepped and draped according to standard aseptic technique." There was no documentation to indicate what type of prep was applied to Patient #8's feet. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed the prep solution had not been documented, and stated the facility used a Hibiclens prep for all patients. Patient #8's record contained incomplete documentation. g. Patient #4 was a 54 year old female admitted to the ASC on 3/14/13 for repair of a hallux valgus deformity on her right foot. Her medical record was incomplete, as follows: - The Operative Report dated 3/14/13, documented Patient #4's foot was "prepped and draped in the usual aseptic technique." There was no documentation to indicate what type of prep was applied to Patient #4's foot.	Q 162		

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Q 162	Continued From page 46 During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed the prep solution had not been documented, and stated the facility used a Hibiclens prep for all patients. - An Anesthesia Record signed by the CRNA on 3/14/13, documented Patient #4 was administered a continuous infusion of Diprivan during his surgery, approximately 8:20 AM to 9:50 AM. There was no documentation to indicate the total amount of Diprivan Patient #4 received. The CRNA was interviewed on 8/29/13 at 12:25 PM, and confirmed he had not documented the total amount of Diprivan he administered to Patient #4 during her procedure. Patient #4's medical record contained incomplete documentation. h. Patient #7 was a 49 year old female admitted to the ASC on 7/11/13 for an excision of a soft tissue mass on her left ankle. Her medical record was incomplete, as follows: - The Operative Report dated 7/11/13, documented Patient #7's feet were "scrubbed, prepped and draped in the usual aseptic manner." There was no documentation to indicate what type of prep was applied to Patient #7's feet. During an interview with Physician A on 8/22/13 at 1:00 PM, he confirmed the prep solution had not been documented, and stated the facility used a Hibiclens prep for all patients. - The Pre-Anesthesia Evaluation contained a	Q 162		

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Q 162	Continued From page 47 section titled Post-Anesthesia Note. The CRNA documented Patient #7 had no anesthesia complications and was "doing well." The note was signed by the CRNA on 7/11/13 but was not timed. The CRNA was interviewed on 8/29/13 at 12:25 PM, and confirmed he had not documented the time of the post anesthesia note for Patient #7. The facility failed to ensure patients' medical records contained complete information.	Q 162		
Q 180	416.48 PHARMACEUTICAL SERVICES The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to ensure pharmaceutical services were provided under the direction of a specific, appropriately licensed healthcare professional for all patients receiving drugs and biologicals at the facility. This resulted in the lack of a comprehensive system necessary to ensure drugs and biologicals were stored, monitored and administered in a safe and effective manner. Findings include: 1. The physician owner of the ASC was interviewed on 8/21/13 at 10:30 AM. He stated the facility had undergone a change of ownership in July of 2013. He stated the facility had not	Q 180	**Q180: Pharmaceutical Services** As outlined throughout the Medication Administration policy (See Appendix G) the staff RN, under the oversight of the Medical Director, will oversee and he responsible for all drug storage, preparation, administration, and disposal. This will ensure continuity of all drugs including controlled substances. This will ensure a safe environment for all patients.	

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Q 180	Continued From page 48 designated an individual to be responsible for the ASC's pharmaceutical services. 2. Refer to Q-181 as it relates to the facility's failure to ensure policies and procedures were developed, implemented and monitored to ensure drugs and biologicals were stored, prepared, administered, and disposed of in accordance with acceptable standards of practice. The cumulative effect of these deficient practices resulted in the lack of a comprehensive system necessary to ensure drugs and biologicals were utilized in a safe and effective manner.	Q 180		
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, policy review, and staff interview, it was determined the facility failed to develop a comprehensive system necessary to ensure drugs and biologicals were stored, utilized, monitored and disposed in accordance with accepted standards of practice. This failure directly impacted 14 of 22 patients (Patients #1, #6 and #11 - #22) who received medication and had the potential to impact all patients receiving drugs and biologicals at the ASC. This resulted in the potential for patients to receive medications inappropriately. Findings include: 1. The Pharmaceutical Services policy, dated	Q 181	**Q181: Administration of Drugs** The policy referenced relating to management of drugs was dated 1997; we have a 2010 policy that was general in nature and have re-written those general drug policies to include specific safety measures that will result in a safer environment for patient services. In reference to the citation having to do with unsafe practices of drug storage, and monitoring, the Storage and Disposal of Medications Policy (See Appendix O) includes methods for checking drugs in, monitoring and disposing of outdated medications and improved methods of counting narcotics effectively to track use. Specifically, the Medical Director will be responsible for receiving drugs from the pharmacy and logging them. The citation refers to the marking of multi-dose vials as it states that our policy date 9-2010 states that we will make them with the date they are opened with a permanent marker. We have update our medication administration policy (See Appendix H) to support the verbiage of the 28 day rule from USP 797; it is found in the	

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Q 181	Continued From page 49 12/97, stated the RN was responsible for checking for outdated medication, ensuring all drugs are stored in a safe manner and disposing of outdated medications in a manner consistent with the requirements of the Idaho State Board of Pharmacy. A tour of the facility was conducted on 8/21/13 at 9:00 AM. Medications and biologicals were expired, as follows: a. The crash cart was unlocked and contained the following expired medications: - 50% Dextrose Inj 25 grams, with an expiration date of 10/2012. - 2% Lidocaine HCL 100 mg 20 mg/ml, with an expiration date of 7/2012. - 2% Lidocaine Inj 50 ml with an opened date of 6/28/13. - Ondansetron Inj 40 mg 20 mg/ml with an opened date of 6/28/13. b. The anesthesia cart was unlocked and contained the following expired medications: - 50% Dextrose 25 grams, with an expiration date of 5/2012. - 4 boxes of Atropine Inj 1 mg, with an expiration date of 6/2013. - 2% Lidocaine Inj 20 mg/ml, with an expiration date of 7/2013. - 4 vials of Pitressin 20 units/ml, with an expiration date of 5/2013. - 50% Dextrose 25 grams, with an expiration date of 7/2012. c. The narcotics cabinet contained 2 vials of Ketorolac 60 mg, with an expiration date of	Q 181	pharmaceutical section of the Nursing Manual, dated 9-2010. Our new policy states that multidose vials will be marked with both the opened date and the discard date, 28 days after opening, to avoid any confusion. In regard to drug security relating to the crash cart being locked, it is our policy to keep the crash cart and the anesthesia cart LOCKED except for the hours the surgery center is open for business. This will ensure secure storage of medication during off hours and allow for immediate access to them during hours of operation. All controlled substances will be stored in the double locked cabinet. In regard to counts, the RN will familiarize herself with the logs in order to perform and understand the counting process of narcotics. Additionally, single use vials of Fentanyl will NOT be used for more than one patient. This practice was updated in our Medication Administration Policy(See Appendix G) dated 9/21/2013.	

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Q 181	Continued From page 50 3/2013. d. The operative room storage cabinets contained the following expired medications and biologicals: - A open spray bottle of Ethyl Chloride with an expiration date of 1/2010. - An amber bottle with approximately 45 ml of fluid, labeled "Phenol." The label did not include a date. - One liter bag of Lactated Ringers IV solution, with an expiration date of 4/2012. - 6 boxes of Post-Op Surgical Kits which contained wound dressing ointment and wound wash solution with an expiration date of 1/2013. - 1 container of Duraprep Surgical solution with an expiration date of 1/2012. During an interview on 8/22/13 beginning at 11:10 AM, the RN confirmed the above drugs and biologicals were expired and had not been discarded in a timely manner. The RN further stated she was unsure how many days were required to pass before an opened medication would need to be discarded. United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations, Second Edition, 6/01/08, states if a multidose vials has been opened or accessed the vial should be dated and discarded within 28 days unless the manufacturer specifies a different date for that opened vial. Additionally, the facility's Drug and Pharmaceutical Storage and Disposal policy, dated 9/2010, stated "Multidose vials will be discarded on or before the 28th day after they are first accessed..." The facility failed to ensure drugs and biologicals	Q 181		

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Q 181	Continued From page 51 were monitored for expiration dates and disposed of in a timely manner. 2. The ASC's Drug and Pharmaceutical Storage and Disposal policy dated 9/2010 stated "The RN Circulator will check all medication storage areas on a monthly basis for...improper labels... Multidose vials will be marked, using a permanent marker, with the date they are opened." a. The cabinet in the instrument processing room contained the following: - One vial of Lidocaine 1% with Epinephrine 1:100,000 50 ml with approximately 10 ml remaining. The label did not include the date opened. b. The operative room storage cabinets contained a one liter bottle of 0.9% Sodium Chloride with approximately 850 ml remaining. The label stated "Neosporin added 8/15/13." The label did not include the date opened. During an interview on 8/22/13 beginning at 11:10 AM, the RN stated she was unsure how to label opened multi-dose medications. She stated she did not know if the expiration date should be written on the container, or if the opened date should be written on the container. The ASC did not ensure opened medications were labeled in accordance with facility policy. 3. The ASC's Drug and Pharmaceutical Storage and Disposal policy, dated 9/2010, was reviewed. The policy did not address drug security. A tour of the facility was conducted on 8/21/13 at	Q 181		

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Q 181	Continued From page 52 9:00 AM. Medications were not secured, as follows: a. The crash cart was located in the OR and was unlocked. The cart contained multiple medications, which included but were not limited to, the following: - 50% Dextrose Inj 25 grams. - 2% Lidocaine HCL 100 mg 20 mg/ml. - 2% Lidocaine Inj 50 ml. - Ondansetron Inj 40 mg 20 mg/ml. b. The anesthesia cart was located in the OR and was unlocked. The cart contained multiple medications, which included but were not limited to, the following: - 4 boxes of Atropine Inj 1 mg. - 2 boxes of Sodium Chloride 50 ml. - 4 vials of Pitressin 20 units/ml. Additionally, the unlocked anesthesia cart located in the OR contained 2 vials of Propofol 1%, 50 ml. c. The unlocked cabinet in the instrument processing room contained multiple medications, which included but were not limited to, the following: - Lidocaine 1% with Epinephrine 1:100,000 (50 ml vial with approximately 10 ml remaining). - A opened vial of Marcaine 0.5%. d. The medication refrigerator located in the reception area contained medications, which included, but were not limited to, the following:	Q 181		

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Q 181	Continued From page 53 -One box of Rocuronium 10 mg/ml. -One box of Succynicholine 200 mg. The physician owner of the ASC was interviewed on 8/21/13 at 3:00 PM. He confirmed the medications were unlocked and the medications, including the paralytic drugs, were not secured. The facility failed to secure medications. 4. The ASC's Drug and Pharmaceutical Storage and Disposal policy, dated 9/2010 stated "Controlled substances will be counted at the end of each surgical day by the Circulating Nurse and the Anesthesia Provider. Documentation of count will be signed by both persons in the Controlled Substance Log book." During a tour of the OR with the RN on 8/28/13 at approximately 11:40 AM, the narcotic storage was observed. A 500 mg/10 ml multidose vial of Ketamine was noted with an opened date 1/27/13 and last used 5/23/13. It was observed that 2.5 ml was accounted for on the controlled substance log book. It was observed RN withdrew 4.5 ml of the remaining Ketamine for a total of 7.0 mls. It was noted there were 3 mls unaccounted for on the controlled substance log book. The RN was present during the tour. She confirmed the Ketamine which was unaccounted for and the lack of documentation in the controlled substance log book. The facility failed to ensure proper documentation of a controlled substance. Additionally, during a tour of the OR with CST B on 8/27/13 at 2:20 PM, the Narcotic Reception	Q 181		

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Q 181	Continued From page 54 Verification Form was reviewed. Dates on the Narcotic Reception Verification Form did not match to the controlled substance log book for accountability. When asked, CST B stated "We just found the log." When asked how the facility had been tracking narcotic flow, CST B stated "they give the receipts to the accountant. The medical receptionist in the office receives the narcotic delivery and someone will put the narcotics away." CST B confirmed the facility had not maintained the tracking log. 5. The CDC single dose vial guidelines, dated 5/2/12, state "medications labeled as a single dose or a single use to be used for only one patient." During a tour of the OR with RN on 8/28/13 at approximately 11:40 AM, the controlled substance log book was observed. The logs for April, May, June and August 2013 were reviewed. The logs documented that during the 4 month period, 14 of 14 patients (Patients #1, #6 and #11 - #22) who received Fentanyl shared single dose vials of Fentanyl 50 mcg/ml. The RN was present during the tour, she confirmed the sharing of single dose vials of Fentanyl. During an interview on 8/29/13 at 12:30 PM, CRNA B, confirmed single dose Fentanyl was used for multiple patients. The facility failed to ensure single dose medication was used for only one patient.	Q 181		
Q 201	416.49(a) LABORATORY SERVICES	Q 201		

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			Q201: Lab Services	
Q 201	Continued From page 55 If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter. This STANDARD is not met as evidenced by: Based on review of facility policies and interview, it was determined the facility failed to ensure a CLIA waiver was obtained and procedures for point of care testing were developed for all patients receiving care at the facility. This had the potential to result in inaccurate test results. Findings include: The physician owner and previous physician owner were interviewed on 8/21/13 at 2:00 PM. Both physicians confirmed the facility performed point of care testing for pregnancy tests and blood glucose and did not have a CLIA waiver. The previous physician owner stated he was not sure who was responsible to insure that staff competencies and quality controls were performed for POC testing. The facility failed to maintain a CLIA waiver and ensure staff competencies for POC testing.	Q 201	The CLIA Waiver was applied for on August 25, 2013 by the Medial Director. The Idaho Certificate of Laboratory (See Appendix P) was received on August 29, 2013. After payment was made, the CLIA Waiver [redacted] was designated to the Idaho Foot Surgery Center and became valid as of August 29, 2013. The CLIA Waiver has been mailed out, but we continue to wait for it. With the CLIA Waiver validation number and date, we are able to perform any necessary POC testing to ensure adequate patient care is delivered to all surgical patients. The Idaho Foot Surgery Center requires only two types of point of care (POC) testing on individuals meeting the criteria for the tests. Governing Body delegated the development of policies for HCG and Blood Glucose testing to our consultant, Charlene Conilogue; The HCG Testing Policy and the Blood Glucose Testing Policy (See Appendix Q) were completed on September 25, 2013 and accepted to be in effect immediately by the Governing Body. The Perioperative RN and Perioperative Assistant are responsible for conducting these tests and therefore, have become familiarized with the policies on September 25, 2013. With these policies, proficiency testing may be conducted to provide accurate test results for improved patient care.	
Q 219	416.50 PATIENT RIGHTS Condition for Coverage - Patient Rights	Q 219		

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			Q219: Patient Rights	
Q 219	Continued From page 56 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. This CONDITION is not met as evidenced by: Based on observation, interview, review of ASC policies, and record review, it was determined the ASC failed to inform patients, or their representatives, of their rights and promote the exercise of such rights for all patients receiving care at the facility. This deficient practice resulted in the inability of the facility to ensure patients' rights were not violated. Findings include: 1. Refer to Q-220 as it relates to the facility's failure to ensure a written notice of rights was posted. 2. Refer to Q-224 as it relates to the facility's failure to ensure patients or their representatives were informed of the ASC's policies regarding advanced directives prior to their scheduled procedures. 3. Refer to Q-225 as it relates to the facility's failure to ensure a grievance procedure was developed, implemented and monitored.	Q 219	Our Civil Rights Manual was approved by Governing Body on 9-17-2013. Within it we have committed to Compliance with Title VI of the Civil Rights Act of 1964 and section 504 of the Rehabilitation Act of 1973. Compliance of the Civil Rights Manual by all IFSC staff members will enable improved promotion of rights and delivery of patient rights information to patients and their representatives. The following are policies that answer the listed deficiencies. (See Appendix R).	
Q 220	416.50 NOTICE - POSTING ... 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	Q 220		

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			Q220: Notice-Posting	
Q 220	Continued From page 57 treatment or by the patient's representative or surrogate, if applicable. This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to post written notice of rights for all patients receiving services at the facility. This failure resulted in a potential lack of rights information being available to patients and their representatives. Findings include: During a tour of the ASC on 8/21/13 at 9:15 AM, it was observed that no patient rights information was posted within the facility. The physician owner was interviewed on 8/21/13 at 2:00 PM. He confirmed that no patient rights information was posted within the ASC. The ASC failed to post written notice of rights.	Q 220	The IFSC Medical Director has framed and posted a written notice of the patient rights (See Appendix R) in the waiting room of the facility on August 27, 2013. The location is directly in front of the seating provided for patients and their families and/or representatives; In this way, there is greater likelihood of it being notice by patients to prevent depravation of their rights.	
Q 224	416.50(c)(1)(2)(3) ADVANCED DIRECTIVES The ASC must comply with the following requirements: (1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms. (2) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care. (3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.	Q 224	**Q224: Advanced Directives** The Idaho Foot Surgery Center has updated the Civil Rights Manual on 9/30/13 to include an Advance Directive Policy (See Appendix S) that ensures patients have a right to participate in their own care. An Advance Directive suspension form (See Appendix S) has also been created and approved by the Governing Body on 9/30/13 for the patient to sign at prior to surgery. This will enable patients to understand our policy of suspension of their DNR order while admitted at IFSC. It will also serve s proof of delivery to patient. It also allows an opportunity for patients to request and obtain further information regarding Advance Directives from our facility. We are able to provide an official state advance directive form per patient request.	

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Q 224	Continued From page 58 This STANDARD is not met as evidenced by: Based on policy review, record review, and staff interview, it was determined the ASC failed to provide patients or their representatives with information regarding advanced directives for all patients receiving services at the facility, including 11 of 11 patients (#1 - #11) whose records were reviewed. This resulted in patients not being fully informed of advance directive information prior to having procedures at the facility. Findings include: 1. The ASC's policy manual, last updated 9/2010, did not include a patient rights policy regarding advanced directives. Upon request, the ASC's medical receptionist provided a sample packet of information given to patients prior to their procedures. The sample packet did not include information regarding advanced directives. Additionally, the medical records for Patients #1 - #11 were reviewed. None of the medical records included information regarding advanced directives. When asked during an interview on 8/29/13 at 12:00 PM, the physician owner and previous physician owner stated there was no policy or information provided to patients regarding advance directives. The ASC failed to provide patients or their representatives with information regarding advanced directives prior to their procedures.	Q 224		
Q 225	416.50(d)(4),(5), & (6) SUBMISSION AND INVESTIGATION OF GRIEVANCES The ASC must establish a grievance procedure	Q 225		

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Q 225	Continued From page 59 for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met: (1) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished. (3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate 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 result of the grievance process and the date the grievance process was completed. This STANDARD is not met as evidenced by: Based on review of patient rights information, policy review, record review and staff interview, it was determined the ASC failed to fully develop and implement a grievance process for all patients receiving services at the facility, including 11 of 11 patients (#1 - #11) whose records were reviewed. This resulted in potential failure to identify, investigate, and respond to patient grievances appropriately. Findings include: 1. The facility's undated Patient Rights pamphlet stated the ASC "has a process for addressing any complaints or problems you may have while you are a patient here. Please feel free to contact our Quality Resource Manager...or ask for a form to	Q 225	**~~Q225: Submission of and Investigation of~~ Grievances** Patient Rights and Responsibilities/Grievance Procedures: A new brochure containing patient rights is in the process of being updated with current information and is to be implemented for use by on October 4, 2013 Pt rights policies have been written and added to our Civil Rights Manual. It includes policies for offering information to patients regarding Advanced Directives and a detailed Grievance Procedure form (See Appendix T), including the process for evaluating grievances. Alicia Raya-Elizondo has been appointed the Civil Rights Officer.	

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Q 225	Continued From page 60 fill out. You may report your complaint without identifying yourself, if you wish. Each signed complaint will receive a telephone response within 7 days..." The pamphlet did not include information regarding how the ASC would investigate the grievance, or how the ASC would provide a written decision notice (including 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) to the person filing the grievance. Further, the ASC's policy manual, last updated 9/2010, did not include a patient rights policy regarding grievances. On 8/21/13 at 3:00 PM, the ASC's medical receptionist provided a sample packet of information given to patients in advance of their procedures. She stated patients did not get the pamphlet as they were on the counter in the reception area, and available for patients and family if they were interested. Medical records for Patients #1 - #11 were reviewed. The medical records and the sample packet of information did not contain information regarding grievances. During an interview on 8/22/13 beginning at 9:30 AM, the ASC consultant confirmed the facility did not have a process in which to investigate or respond to grievances from patients and family members. She confirmed the ASC did not have a Quality Resource Manager as was indicated on the pamphlet, and was not able to provide a form	Q 225		

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Q 225	Continued From page 61 for the person to complete. The ASC failed to ensure a grievance procedure was developed, implemented and monitored.	Q 225	**Q240: 416.51: Infection Control** Our Infection Manual was approved by Governing Body on 9-17-2013. In accordance with acceptable standards of practice, we have adopted policies and procedures for this manual from a pool of resources including but not limited to AORN, CDC, OSHA, APIC, AAAHC, and Idaho Dept of Health and Welfare. The following are policies that answer the listed deficiencies:	
Q 240	416.51 INFECTION CONTROL The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented and monitored for staff and all patients receiving care at the facility. This resulted in the inability of the facility to minimize infections and communicable diseases. Findings include: 1. Refer to Q-241 as it relates to the facility's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice. 2. Refer to Q-242 as it relates to the facility's failure to ensure an ongoing program to prevent, control, and investigate infections and communicable diseases was maintained. 3. Refer to Q-243 as it relates to the facility's failure to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control. 4. Refer to Q-244 as it relates to the facility's failure to ensure infection control was addressed	Q 240	1. Communicable Disease: Acute or Infectious Communicable Diseases Policy (See Appendix U) states that **"Persons with any acute communicable disease will not routinely be allowed in the O.R. or recovery room. This center will evaluate on a case-by-case basis how to manage the care for persons known to be in the actively transmissible stage of communicable disease. Employees with any acute communicable disease will not be allowed to care for patients."** Policy relating to this objective can be found throughout the Infection Manual. We will endeavor to implement these policies and procedures to improve patient outcomes and protect patient and employee health. 2. Functional and Sanitary Environment: The Environmental Cleaning Policy states that **"The IFSC will be maintained in a clean and sanitary manner."** All policy relating to this objective can be found within this policy. It is the primary objective of IFSC to maintain a safe and sanitary environment in which to provide quality services to our patients. 3. Ongoing Program for Infections and Communicable Diseases: The Infection Control Program Policy	

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Q 240	Continued From page 62 as an integral part of the ASC's QAPI program. 5. Refer to Q-245 as it relates to the facility's failure to ensure the infection control program established a plan of action for preventing and identifying communicable diseases. The cumulative effect of these systemic deficient practices resulted in the inability of the facility to ensure patient risk of infections and communicable diseases was minimized.	Q 240	(See Appendix V) states our purpose "to reduce the number of healthcare associated infections (HAI's) and to take measures to prevent the transmission of infections and communicable diseases at Idaho Foot Surgery Center. The Idaho Foot Surgery Center will provide the highest quality of patient care, including a safe and effective system for the surveillance, prevention, and control of infections. A center-wide Infection Control Program is established to comply with the approved regulatory guidelines chosen by the Governing Body." More details relating to the specific mechanics of the Infection Control Program can be found within the policy. 4. Trained Infection Control Officer: Specific appointment of our Infection Control Officer was on 8/28/2013. The Infection Control Officer is acknowledged by signature on the last page (See Appendix W) of the Infection Control Manual. She is identified as Renee Tucker, RN. She has agreed to dedicate 15% of her time toward Infection Control activities and will complete Infection Control training by October 7, 2013. Having a trained professional oversee our program will ensure patient safety and satisfy requirements for ongoing oversight and implementation of our newly approved Infection Control Policies. 5. Infection Control as it relates to our QAPI program: Verbiage in our newly approved QAPI Manual (pgs 11, 12, 25, and 29) specify that Infection Control is an integral part of the QAPI program. At this point, while we have implemented strong and effective policies, we have no history for reporting and studying infections. However Infection Control is now	
Q 241	416.51(a) SANITARY ENVIRONMENT 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, interview, policy review and record review, it was determined the facility failed to maintain a sanitary and functional environment for all patients receiving care at the facility. This resulted in the potential for infections to occur and for expired supplies to be used. Findings include: 1. The ASC policy Infection Control Plan dated 9/2010, stated the ASC's infection control program was based on AORN Perioperative Standards and Recommended Practices. AORN's Perioperative Standards and Recommended Practices For Inpatient and Ambulatory Settings, 2012 Edition, Recommendation XVI, stated routine sterilizer efficacy monitoring should be done weekly and	Q 241		

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Q 241	Continued From page 63 preferably daily. "Each load containing an implantable device should be monitored with a BI and quarantined until the results of the BI testing are available and one BI Process Challenge Device should be run in three consecutive empty cycles for sterilizer qualification testing." However, the ASC's Sterilization Records policy, unsigned and undated, indicated testing would only be completed on a monthly basis. The policy stated "...At the first of the month, each month, a Castle Unispore Biological Sterility Monitor Test will be run for bacterial growth monitoring of autoclave effectiveness. The results of this test will be recorded on the attached annual sterilization log..." The ASC's policy was not sufficiently developed to include current AORN standards of practice. The ASC's Sterilization Log was reviewed. The last documented BI testing was 9/2010. There was no documentation to indicate biological testing had been completed at least weekly in accordance with AORN recommendations. CST B was interviewed on 8/22/13 at 10:00 AM. She identified herself as the main CST and in charge of sterile processing. She reviewed the Sterilization Log and confirmed there was no documentation to indicate biological sterility testing had been conducted in accordance with policy and accepted standards of practice. The Sterilizer Load Log and Sterilization Records policy were not sufficiently developed, implemented and monitored necessary to ensure appropriate biological indicator testing were being conducted in the ASC.	Q 241	permanent QI agenda item, and as such is something that will be reported quarterly to Governing Body and at QI per our policy. Our Infection Control Officer will participate with the Practice Administrator and Medical Director in auditing patient records and Idaho Foot Surgery Center practices in an effort to prevent and identify infections and communicable diseases. These activities will help us to maintain safety and excellence in patient care, and make us compliance with standards. **Q241: Sanitary Environment** 1.-3. Autoclave Monitoring Policies: We have implemented a new Infection Control Policy Manual as of 9-17-2013. This new manual has policies and procedures taken from a pool of resources including but not limited to AORN, CDC, OSHA, and IDHW. The version of AORN that we used was 2011, but upon researching the guidelines, they are the similar if not the same as the 2012 version and so our present policies meet the standards for CDC, as well. The Sterilization Performance Monitoring Policy (See Appendix X) of our manual speaks to the citations relating to the frequency of routine sterilization efficacy monitoring. On page 113, the policy specifically states that **"a biological indicator will be run each day the sterilizer is used and with each implant load. The implant will not be used until biologic indicator results verify sterilization."** All other specific details to the citations are located in the attached policies of this Infection Control Manual.	

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Q 241	Continued From page 64 2. AORN's Perioperative Standards and Recommended Practices For Inpatient and Ambulatory Settings, 2012 Edition, Recommendation XIV, stated sterilization records should be maintained for every sterilization cycle and include the assigned lot number, contents of each load, and results of physical, chemical and biological testing. The recommendation also stated "Accurate and complete records are required for process verification and used in sterilizer malfunction analyses. Documentation establishes accountability." The ASC's Sterilization Log contained spaces to document the description of the item being sterilized, the date and load number, the start and stop time of the sterilization cycle, the temperature, if a BI was performed with the load, and the initials of the operator running the cycle. The Sterilization Load Log documented a load on 8/06/13 containing four "3x3's" started at 8:26 AM. There was no documentation of cycle stop time, temperature, physical, chemical or biological indicators or initials of the person that removed the load and check the outcome of the indicators. The documentation did not clearly demonstrate whether the load of instruments had been properly sterilized. CST B was interviewed on 8/22/13 at 10:00 AM. She confirmed the lack of documentation and stated it was not clear whether the instruments had been sterilized properly. The facility failed to ensure complete documentation was kept on the Sterilization Load Log.	Q 241	In addition we have initiated use of a Biological Indicator log (See Appendix Y) as of 8/27/2013, that will allow us to track autoclave testing and accountability that includes logging of dates, load numbers, person running the load, start and stop time of cycle, use of BIs for each load, etc. This log will be filled out by the CST running the autoclave. We are currently looking into purchasing an after-market printer for our autoclave, in order to have more complete autoclave records. In regard to monitoring the autoclave, the following policy has now been added to our Infection Control Manual and can be found on pages in the Sterilization Performance Monitoring Policy (See Appendix X) **"Challenge of the steam sterilizer after installation, sterilization failure, repair, relocation, or major repairs will be conducted before the sterilizer is put into service... A biologic indicator will be done on 3 consecutive cycles for each cycle of the sterilizer..."** Ensuring safe sterilization practices will guarantee safer patient care that is consistent with our goal to provide excellent services. 4.Housekeeping: According to the Environmental Cleaning Policy (See Appendix Z) in our new Infection Control Manual, the housekeeping staff will be required to understand and follow manufacturer guidelines when using disinfectants and germicides. Policy that speaks specifically to training for housekeeping personnel states **"all housekeeping personnel will be responsible to the ASC Director or Infection Control Officer and will be trained regarding proper use of disinfectants and germicides...They are also required to be**	

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Q 241	Continued From page 65 3. The ASC's Sterilization Records policy, unsigned and undated, stated "...at the first of the month, each month, a castle unispore biological sterility monitor test will be ran for bacterial growth monitoring of autoclave effectiveness. The results of this test will be recorded on the attached annual sterilization log." The Association of Perioperative Registered Nurses (AORN) Recommendation XVI: Quality, Routine sterilizer efficacy monitoring should be done weekly, and preferably daily, as follows: -Each load containing an implantable device should be monitored with a biological indicator and quarantined until the results of the biological indicator testing are available. -One biological indicator process challenge device should be run in three consecutive empty cycles for sterilizer qualification testing. -If a steam sterilizer is intended to be used for multiple types of cycles (e.g., gravity displacement, dynamic air-removal, flash), each sterilization mode should be tested. The ASC failed to follow AORN guidelines and facility policies, as follows: - The most recent biological testing was 9/30/10, for control testing. There was no biological testing for 2011, 2012 and 2013. - The ASC's sterilizer load log did not include documentation of biological testing for 24 loads in 2012 and 37 loads in 2013. The sterilizer load log, dated 8/06/13, did not	Q 241	trained according to Idaho Foot Surgery Center's housekeeping policies and procedures." Other housekeeping guidelines and details are found within the Environmental Cleaning Policy. Employees with housekeeping responsibilities are also required to read, sign and date job descriptions upon training. The job descriptions are filed by the Practice Administrator in the employee credential file. Since current housekeeping staff have not been required to provide proper acknowledgment of job responsibility understanding, our goal is to provide adequate training and understanding of this role by October 17, 2013. By accomplishing this, we will prepare our staff to greater meet the needs of our patient population, by increasing the quality of care and protection of health for each individual patient. Laundry: The current Laundry Processing Policy (See Appendix AA) was not in compliance to any guidelines or standards within our resources; therefore, a new Laundry Policy (See Appendix AA), from our Infection Control Manual, is what we are to implement. Unfortunately, we are unable to fully implement this newly adopted policy that meets standards and recommendations. Governing Body will be making a decision by October 4, 2013, based on cost and availability, of which service to send laundry to. Once selected, IFSC will provide properly laundered linen for minimal risk of pathogen exposure to surgical patients. 5.Expired Supplies: On 8-21-2013, several supply items and solutions were noted to be expired and were consequently discarded. A new Handling of Sterile Supplies Policy (See Appendix BB) has been created and approved by Governing Body on 9/18/13. In regard to	

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Q 241	Continued From page 66 include documentation of cycle stop time, temperature, chemical color change, acceptable biologic indication, corrective action, and the initials of the operator checking the outcome. The sterilizer load log, dated 8/15/13, did not include documentation of chemical or color change, or the initials of the operator checking the outcome. CST B was interviewed on 8/22/13 at 10:00 AM. She confirmed the facility had no routine biological controls included or documented on the sterilization log. The ASC failed to ensure policy and monitoring for sterilization procedures were conducted. 4. During an interview on 8/28/13 beginning at 4:00 PM, the Medical Assistant stated she performed housekeeping duties such as terminal cleaning of the operating room and laundry for the ASC. a. The medical assistant stated she performed "Terminal Cleaning" of the operating room the evening before and at the end of the day of surgical procedures. She stated she would spray a disinfectant and wait approximately 15-20 seconds before wiping with a cloth. Upon review of the label of the cleaning product, the medical assistant verified the instructions specified "To DISINFECT, let stand for 1 MINUTE." The ASC did not ensure staff was trained related to cleaning of the operating room. The medical assistant stated she would separate patient care items such as patient gowns, pillow	Q 241	event-related sterility, it states, "**Event-related sterility packages containing sterile supplies wrapped in single-use or reusable materials are sterile until used or contaminated. Since some supplies have expiration dates and degrade over time, this document covers only those supplies for which the manufacturer or the distributor does not provide expiration dating in the form of labeling, instructions of use, or other statements. Facility packaged and sterilized items are also event related. They are sterile as long as they remain intact and in an environment of 30-60% humidity and temperatures between 62 degrees F and 70 degrees F, do not become moist or wet, and are not handled frequently or stuffed tightly in a storage container or dropped.**" In regard to manufacturer's sterile packaging, we will inventory cupboards and drawers containing supplies for expiration dates monthly and discard as needed. We will track items and their quantities wasted in order to make appropriate use of supplies that we order in the future. These procedures will ensure use of sterile supplies and injectables which translates to safer and more accountable record keeping as we conduct activities that relate to patient safety and greater quality of care.	

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Q 241	Continued From page 67 cases, sheets, blankets, towels, and staff scrubs by colors. She stated if an item contained blood stains, she would add bleach, otherwise she used an unscented laundry detergent bought from a local store for all the laundry. The medical assistant stated she used the "hot" cycle, and upon inspection, the washing machine was noted to be set on "hot/cold." She stated the machine only had an option for a hot wash and cold rinse. Upon request, a temperature of the water during the "hot" cycle was obtained, which read 110 degrees Fahrenheit. The medical assistant stated she did not know what the temperature should be for laundering patient care items with blood/body fluids. The CDC Guidelines for Environmental Infection Control in Health-Care Facilities, dated 2003, state "A temperature of at least 160 (degrees) F for a minimum of 25 minutes is commonly recommended for hot-water washing. The use of chlorine bleach assures an extra margin of safety." The ASC did not ensure staff was trained related to laundering of patient care items and staff scrubs. 5. A tour of the facility was conducted on 8/21/13 at 9:00 AM. Supplies were expired, as follows: a. The cabinet in the instrument processing room contained the following expired supplies: - Formalin Specimen Jars, (29 units) with an expiration date of 11/2012. - Bottle of Iodoform packing strip, with an expiration date of 3/2011.	Q 241		

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Q 241	Continued From page 68 - Box of biopsy punches, (19 units) with an expiration date of 12/2010. - Vicryl sutures, 2.0, (36 packs) with an expiration date of 7/2011. b. The operative room storage cabinets contained the following expired supplies: - 6 boxes of Post-Op Surgical Kits which included wound dressing, with an expiration date of 1/2013. During an interview on 8/22/13 beginning at 11:10 AM, the RN confirmed the above supplies expired and had not been discarded in a timely manner. The facility failed to ensure outdated supplies were removed.	Q 241		
Q 242	416.51(b) INFECTION CONTROL PROGRAM 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: Based on policy review and staff interview, it was determined the ASC failed to ensure an ongoing infection control program was maintained for staff and all patients receiving care at the facility. This resulted in the inability of the facility to prevent, control, and investigate infections and communicable diseases. Findings include:	Q 242	**Q242: Infection Control Program** 1. Evidence of Infection Control Program implementing recognized guidelines: On 9/17/2013, Governing Body met and approved a new Infection Control Program that adopted guidelines from AORN, CDC, OSHA, Idaho Dept. of Health and Welfare, AAAHC, and APIC. Infection Control is now a permanent agenda item on our QI agenda and at	

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Q 242	Continued From page 69 1. The ASC's Infection Control Plan, effective 9/2010, stated the infection control plan was based on guidelines from the CDC and HICPAC related to hand hygiene, disinfection and sterilization, environmental infection control, and management of occupational exposures. The policy also included APIC, OSHA, and AORN guidelines related to surveillance, occupational exposure, and perioperative standards of practice. However, there was no evidence the ASC had implemented an infection control program that reflected the use of the nationally recognized guidelines identified in the policy. The physician owner of the ASC was interviewed on 8/22/13 at 10:20 AM. He stated the facility had undergone a change of ownership in July of 2013. He stated the ASC did not have or follow a nationally recognized infection control program. He stated an Infection Control Officer had not been identified, the facility did not have an infection control committee, meeting minutes, or documentation of infection control activities. Additionally, the physician stated he did not have documentation from the previous physician owner which demonstrated infection control activities had occurred. The facility failed to ensure an ongoing infection control program based on nationally recognized standards was maintained.	Q 242	~~infections/complications will be reported and~~ evaluated at both Governing Body and QI for prevention. The evidence for this program will be evidenced in future minutes and studies and programs that detail reportable data and quantitative results; we conducted our first QI with this administration on 09/12/2013 and the minutes reflect that Infection Control was discussed at that meeting (See Appendix CC). The President of Governing Body who is the Medical Director/Physician Owner has assumed responsibility for implementation of the Infection Control Program and the QAPI Program. He will delegate responsibility for certain activities as he sees fit to the Practice Administrator and the Infection Control Officer.	
Q 243	416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION The program is - Under the direction of a designated and qualified professional who has training in infection	Q 243		

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			Q243: Infection Control Program Direction	
Q 243	Continued From page 70 control. This STANDARD is not met as evidenced by: Based on record review and staff interviews, it was determined the ASC failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control for all staff and all patients receiving care at the facility. This prevented the ASC from utilizing the knowledge base of a trained professional to develop and monitor an infection control program. Findings include: 1. The facility's records included a job description for an Infection Control Officer. However, the job description was not signed or dated. Additionally, the facility's personnel records were reviewed. Documentation which identified who the facility's Infection Control Officer was could not be found. The physician owner of the ASC was interviewed on 8/22/13 at 10:20 AM. He stated the facility had undergone a change of ownership in July of 2013. He stated an Infection Control Officer had not been identified. The facility failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.	Q 243	1. Job Description for Infection Control Officer (ICO): We appointed an Infection Control Officer (Renee Tucker, RN) on 8/29/2013 and she will be trained as of 10/07/2013 in order to maintain a high level of acuity of current regulations and recommendations as it relates to Infection Control. She has a job description (See Appendix DD) in her credential file that states her responsibilities as ICO and has been approved by the Medical Director.	
Q 244	416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI [The program is -] An integral part of the ASC's quality	Q 244		

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Q 244	Continued From page 71 assessment and performance improvement program This STANDARD is not met as evidenced by: Based on staff interview and review of facility policies and records, it was determined the ASC failed to ensure the infection control program was incorporated into the facility QAPI program for all patients receiving services at the ASC. This resulted in the inability of the ASC to evaluate its infection control processes necessary for improving the quality of patient care. The findings include: 1. The ASC's Infection Control Plan, effective 09/2010, stated the Infection Control Officer would "report surveillance findings and other (infection control) matters to the Quality Assurance Committee on a quarterly basis." There was no evidence to indicate the infection control program had been incorporated into the QAPI program in accordance with the policy. The physician owner of the ASC was interviewed on 8/22/13 at 10:20 AM. He confirmed the infection control program was not incorporated in the QAPI program. He stated the ASC had not developed a QAPI plan for monitoring purposes. He confirmed there was no documentation which demonstrated quality reports or formal meetings had been held at any level within the organization to discuss quality issues, including infection control. The ASC failed to ensure infection control was incorporated into the facility's QAPI program.	Q 244	**Q244: Infection Control Program QAPI** 1. No evidence to indicate the Infection Control Program had been incorporated into the QAPI Program: In both our QAPI and Infection Control Manual, there is verbiage that speaks to this evidence. In our QAPI manual, on page 11, it states that the **QAPI Program considers Quality Indicators including but not limited to infection control/prevention; equipment failure/breakage; respiratory complications; and sterile technique break** – all of which have to do with possible patient infection outcomes. These indicators will be monitored and reported via activities and studies that collect and evaluate quantitative data for reportable results that will directly and indirectly affect patient outcomes.	
Q 245	416.51(b)(3) INFECTION CONTROL PROGRAM	Q 245		

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Q 245	Continued From page 72 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: Based on observation, interview, review of policies, and infection control documentation, it was determined the facility failed to ensure the infection control program established a plan of action for preventing and identifying communicable diseases. This failure directly impacted 1 of 1 patient (Patient #9) who had a documented post-surgical infection and had the potential to impact all patients receiving care at the facility. This resulted in the potential for all patients to experiencing preventable infections. Findings include: The facility's policies were reviewed. Information related to reporting communicable diseases to the local health authority could be found. Additionally, the ASC's Infection Control-Surveillance Plan, effective date 9/2010, was reviewed. The plan stated all patients having surgery would be interviewed postoperatively to determine wound status. If an infection was identified, the patient record was to be reviewed for "extrinsic and intrinsic medical problems that would increase the patients potential for infection. These will be taken into account in determining the cause of the infection and to help identify any area for improvement of care." However, the policy was not implemented, as	Q 245	**Q245: Infection Control Program** In regard to patient charts that were incomplete or inadequately charted for information that impacted their health and welfare: The QAPI program that we have instated and do commit to follow will meet the requirements and standards for optimal patient care in regard to preventing infections and preventing communicable diseases. The plan includes recording of infections on an infection log that will be kept for all reported patient infections. The Infection Control Officer will review this information and be responsible for maintaining the infection log. More details in regard to the plan of action is outlined in the Infection Control Manual and has been approved by the Governing Body. It is our goal to put in place and follow the guidelines that have been recommended for optimal patient care by making QAPI a large part of our audits and protocols for improvement. For information in regard to content, see the Table of Contents for this manual (See Appendix EE) Per the citation, the facility had not been participating in Infection Control activities, nor did we have a trained qualified professional in infection control on staff. We have since appointed Renee Tucker, RN to be our Infection Control Officer. She is undergoing training from Excellentia and performing self study which will provide her with the necessary tools to head our Infection Control Program. She will be responsible for reading and providing necessary updates to the	

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Q 245	Continued From page 73 follows: Patient #9's medical record included a procedure note by the physician, dated 4/26/12, which stated Patient #9 had a surgical correction of Mallet toe on his left foot. A post operative visit on 5/09/12 documented Patient #9 had swelling and pain at the surgical site. A visit note on 5/16/12 documented Patient #9 had swelling and non-healing of the wound. The surgical area was debrided and Patient #9 was then referred to a wound clinic for further care. An entry in Patient #9's record on 5/22/12 documented culture results of the surgical wound indicated he had Methicillin Resistant Staphylococcus Aureus (MRSA). The physician documented he contacted Patient #9 to inform him that he (the physician) had ordered antibiotics and continued treatment at the wound clinic. Patient #9's record did not include documentation to indicate the record had been reviewed to determine the cause of the infection. The physician owner of the ASC was interviewed on 8/22/13 at 10:20 AM. He confirmed there was no documentation of infection control activities and the ASC did not follow an established plan for the identification of infections. During a subsequent interview on 8/22/13 beginning at 1:00 PM, the previous physician owner reviewed Patient #9's record and stated he had not conducted an investigation after receiving the positive culture for MRSA. He stated there was no working infection control program at the facility.	Q 245	Governing Body in regard to policy changes. She will also sit on the QAPI Committee and take an active part in research relating to pt care as it corresponds with Infection Control issues. According to our 2010 Infection Control policies, we stated that we had adopted AORN practices for ASCs. For future reference, we will take our guidance for our Infection Control Program from a pool of resources that include but are not limited to AORN, APIC, and the CDC. Our policy and procedure manual is being revised to reflect these practices and include latest updates regulations as they relate to our policies. In regard to sterilizing practices and use of biological testing, our autoclave policy is being reviewed and changes will be made per the pooled resources of AORN, APIC, and CDC. This will be completed by 9-30-2013.	

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Q 245	Continued From page 74 The facility did not ensure a program for identification, surveillance, and reporting of patient infections.	Q 245		
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 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. This STANDARD is not met as evidenced by: Based on record review, review of policies, and staff interview it was determined the facility failed to ensure assessments were completed prior to procedures and included in the medical records for 8 of 11 patients (#1 - #7 and #9) whose records were reviewed. This failure led to the potential for patients to receive inadequate care during their procedures. Findings included: 1. A policy titled Pre Surgical Assessment of Patient, dated and revised 9/2010, stated "...A presurgical assessment will be conducted by the surgeon and documented on the Medical Record prior to surgery." The policy was not implemented, as follows: a. Patient #1's medical record included a procedure note by the physician, dated 5/30/13,	Q 262	**Q262: Pre-Surgical Assessment** Adequate proof of a completed pre-surgical medical and physical assessment (by the surgeon on the day of surgery) has been implemented as of September 26, 2013. A sticker with verbiage of: **assessment completed & updated to confirm no changes since last H&P**, will be placed on the most recent medical history and physical assessment followed by a date, time and surgeon signature; if applicable. Otherwise, if changes have occurred, new documentation of those changes will be added to the patient medical record. As stated in our O.R. Records Policy (See Appendix L) **"The RN is responsible for complete documentation of the O.R. record"**. Therefore, the RN will be responsible to ensure that the surgeon has done the assessment and signed it, before the patient is taken to the O.R; the RN will serve as a monitor of compliance. The Pre-Surgical Assessment of Patient Policy has been updated and approved by Governing Body to include these specific changes; it has also been renamed as Pre-Operative Patient Assessment Policy (See Appendix FF). These changes will provide a higher level of patient care by preventing inadequate care or possible complications from undiscovered changes of patient health.	

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Q 262	Continued From page 75 which stated Patient #1 had a decompression of the deep peroneal nerve on her left foot and correction of hammertoe on the 5th toe of each foot. A form titled Pre Operative History and Physical, dated 5/28/13, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no further documentation of a pre-surgical assessment of Patient #1 by the physician on the day of the procedure. b. Patient #2's medical record included a procedure note by the physician, dated 3/28/13, which stated Patient #2 had a surgical repair of the damaged flexor plate on the bottom of her 2nd toe on her left foot. A form titled Pre Operative History and Physical, dated 3/25/13, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no further documentation of a pre-surgical assessment of Patient #2 by the physician on the day of the procedure. c. Patient #3's medical record included a procedure note by the physician, dated 3/21/13, which stated Patient #3 had a correction of the bunion deformity on his right foot. A form titled Pre Operative History and Physical, dated 3/13/13, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no further documentation of a pre-surgical assessment of Patient #3 by the physician on the day of the procedure. d. Patient #5's medical record included a procedure note by the physician, dated 6/13/13,	Q 262		

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Q 262	Continued From page 76 which stated Patient #5 had a surgical correction of her bunion deformity on her right foot, a surgical correction of hammertoe on her 2nd toe on her right foot, and a surgical removal of a neuroma between the 3rd and 4th toe of her right foot. A form titled Pre Operative History and Physical, dated 6/03/13, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no further documentation of a pre-surgical assessment of Patient #5 by the physician on the day of the procedure. e. Patient #9's medical record included a procedure note by the physician, dated 4/26/12, which stated Patient #9 had a surgical correction of Mallet toe on his left foot. A form titled Pre Operative History and Physical, dated 4/20/12, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no further documentation of a pre-surgical assessment of Patient #9 by the physician on the day of the procedure. f. Patient #6's medical record included a procedure note by the physician, dated 6/20/13, which stated Patient #6 had a surgical correction of plantar fascia right and left foot. A form titled Pre Operative History and Physical, dated 6/10/13, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no further documentation of a pre-surgical assessment of Patient #6 by the physician on the day of the procedure. g. Patient #4's medical record included a	Q 262		

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Q 262	Continued From page 77 procedure note by the physician, dated 3/14/13, which stated Patient #4 had a surgical correction of Modified Z-bunionectomy of her right foot. A form titled Pre Operative History and Physical, dated 3/11/13, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no further documentation of a pre-surgical assessment of Patient #4 by the physician on the day of the procedure. h. Patient #7's medical record included a procedure note by the physician, dated 7/17/13, which stated Patient #7 had a surgical correction of excision of left ankle soft tissue mass. A form titled Pre Operative History and Physical, undated, contained a stamped statement of "NO CHANGE SINCE LAST H&P," followed by a signature. There was no date or time by the signature. There was no date or time documented on a pre-surgical assessment of Patient #7 by the physician on the day of the procedure. The previous physician owner was interviewed on 8/22/13 at 1:00 PM. He reviewed the records and confirmed they did not include documentation of a pre-procedural assessment. He stated after the deficiency cited on the previous survey in 2010, he had started to use a stamp. The stamped "NO CHANGE SINCE LAST H&P" was followed by his signature and indicated he had performed an assessment of the patient prior to the procedure. He confirmed the stamp and signature did not include a date or time. The facility failed to ensure patient assessments were completed prior to procedures.	Q 262		

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Q 266	Continued From page 79 contained an area with a pre-printed statement "OK for Discharge." The section was blank. c. Patient #5's medical record included a procedure note by the physician, dated 6/13/13, which stated Patient #5 had a surgical correction of her bunion deformity on her right foot, a surgical correction of hammertoe on her 2nd toe on her right foot, and a surgical removal of a neuroma between the 3rd and 4th toe of her right foot. A form titled Perioperative Nursing Record, dated 6/13/13, contained an area with a pre-printed statement "OK for Discharge." The section was blank. d. Patient #6's medical record included a procedure note by the physician, dated 6/20/13, which stated Patient #6 had a surgical correction of her plantar fasicia to both feet. A form titled Perioperative Nursing Record, dated 6/20/13, contained an area with a pre-printed statement "OK for Discharge." The section was blank. During an interview on 8/22/13 beginning at 1:00 PM, the previous physician owner reviewed the patients' records and stated the section on the form was for his signature, which would have indicated an order for discharge. He stated the nurse should have secured his signature, and did not. He confirmed an order to discharge Patients #2, #3, #5, and #6 was not documented. The facility failed to ensure patients were discharged on the order of a physician.	Q 266		

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Q 266	Continued From page 78	Q 266		
Q 266	416.52(c)(2) DISCHARGE - ORDER	Q 266		
	[The ASC must -] Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy. This STANDARD is not met as evidenced by: Based on record review, review of policies, and staff interview it was determined the facility failed to ensure patients were discharged on the order of a physician for 4 of 11 patients (#2, #3, #5, and #6) whose records were reviewed. This resulted in patients being discharged without an evidence-based determination that they were medically stable. Findings include: 1. The policy Patient Care in Phase II Recovery, dated 9/2010, stated "Patients will be discharged only after approval by the surgeon." The policy was not implemented, as follows: a. Patient #2's medical record included a procedure note by the physician, dated 3/28/13, which stated Patient #2 had a surgical repair of the damaged flexor plate on the bottom to the 2nd toe on her left foot. A form titled "Perioperative Nursing Record," dated 3/28/13, contained an area with a pre-printed statement "OK for Discharge." The section was blank. b. Patient #3's medical record included a procedure note by the physician, dated 3/21/13, which stated Patient #3 had a correction of the bunion deformity on his right foot. A form titled Perioperative Nursing Record, dated 3/21/13,		**Q266: Discharge Order** The RN on staff is responsible for verification of the completed Discharge Orders as stated in the O.R. Records Policy (See Appendix L). In order to provide improved clarity of the surgical patient's stable condition prior to discharge, Governing Body modified the Perioperative Nursing Record (See Appendix M) and approved it for immediate use on September 27, 2013. The new form will improve patient care and eliminate concern for discharge of an unstable patient. It also requires a discharge signature from the RN, anesthesia provider, and surgeon. As stated in the O.R. Records Policy, "The RN on staff is responsible for completing the discharge section and must ensure that all three signatures (from the surgeon, anesthesia provider, and RN) are provided before patient is discharged and allowed to be taken home.	