



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  
FAX 208-364-1888

**CERTIFIED MAIL: 7007 3020 0001 4038 8577**

July 8, 2013

Ron Kack, Administrator  
Sawtooth Surgery Center  
115 Falls Avenue West  
Twin Falls, ID 83303

COPY

RE: Sawtooth Surgery Center, Provider #13C0001003

Dear Mr. Kack:

Based on the survey completed at Sawtooth Surgery Center, on June 26, 2013, by our staff, we have determined Sawtooth Surgery Center is out of compliance with the Medicare ASC Conditions for Coverage of **Governing Body and Management (42 CFR 416.41)**, **Quality Assessment & Performance Improvement (42 CFR 416.43)** 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 these conditions to be unmet, substantially limit the capacity of Sawtooth 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.

An acceptable Plan of Correction contains the following elements:

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

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- 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 August 10, 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 August 1, 2013.**

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **July 21, 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,



GARY GUILLES  
Health Facility Surveyor  
Non-Long Term Care



NICOLE WISENOR  
Co-Supervisor  
Non-Long Term Care

GG/pt

Enclosures

cc: 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: 07/08/2013  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  13C0001003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  06/26/2013
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NAME OF PROVIDER OR SUPPLIER  SAWTOOTH SURGERY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 115 FALLS AVENUE WEST TWIN FALLS, ID 83303
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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 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the recertification survey of your Ambulatory Surgical Center on 6/18/13 through 6/26/13. The surveyors conducting the review were:</p> <p>Gary Guiles RN, HFS, Team Leader Don Sylvester RN, HFS Libby Doane RN, BSN, HFS</p> <p>The following acronyms were used in this report:</p> <p>APIC - Association for Professionals in Infection Control and Epidemiology ASC - Ambulatory Surgery Center BLS - Basic Life Support BP - Blood Pressure CDC - Centers for Disease Control and Prevention CRNA - Certified Registered Nurse Anesthetist CST - Certified Scrub Technician DVT - deep venous thrombosis (a blood clot in the legs) EGD - esophagogastroduodenoscopy H&amp;P - History and Physical IV - intravenous IVP - intravenous push MAC - Medical Advisory Committee MDV - Multidose Vial mcg - microgram mg - milligrams ml - milliliters MRSA - Methicillin Resistant Staph Aureus NS - Normal Saline OR - Operating Room OSHA - Occupational Safety and Health Administration PACU - Post Anesthesia Care Unit</p>	Q 000		

**RECEIVED**  
**JUL 22 2013**  
**FACILITY STANDARDS**

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *Deborah A. Johnson* TITLE *Administrator* (X6) DATE *7-19-2013*

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 PIP - performance improvement project pre-op - pre-operative post-op - post-operative QAPI - quality assessment/performance improvement QIC - Quality Improvement Committee RN - Registered Nurse EGD- Esophagogastroduodenoscopy	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 staff interview, and review of policies, QAPI documents, infection control documents, meeting minutes, personnel files, it was determined the ASC failed to ensure the governing body assumed responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body also failed to ensure BLS certifications were maintained for 2 of 7 staff members (Staff C and Staff D) whose personnel files were reviewed. These failures resulted in a lack of guidance to, and oversight of, the facility's staff and programs. Findings include:	Q 040	416.41 GOVERNING BODY AND MANAGEMENT PLAN OF CORRECTION The ASC's Governing Body will ensure that it assumes full legal responsibility for determining, implementing and monitoring policies governing the Center's total operation. The Center's Governing Body will ensure that it oversees and is accountable for the following: 1) Ensuring that BLS certifications are maintained for all required staff members. 2) Assign responsibilities to qualified staff members for management of both the Infection Control Program and the Quality Improvement Program. 3) Will assume responsibility for determining policies for nursing services. Policies and procedures for nursing services have been accepted by resolution and trained to the staff. 4) Disaster Preparedness Plan and the Disaster Preparedness Checklist has been updated and was approved by the Governing Body. 5) Will ensure that it oversees and is accountable for the Infection Control and the QAPI program. SYSTEMATIC CHANGES: The Governing Body has reviewed CMS Q 040 416.41 (Attachment A) and has attested to the understanding and responsibility to uphold recognized standards of practice for BLS certification of staff, delegate responsibilities for management of both the Infection Control Program and the Quality Improvement Program,	7/12/2013 7/11/2013 7/11/2013 7/11/2013	

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Q 040	<p>Continued From page 2</p> <p>1. The governing body failed to document delegation of authority to staff. Staff responsible for the infection control program had not been formally assigned those duties by the governing body. Staff responsible for the QAPI program had not been formally assigned those duties by the governing body. This led to confusion regarding who was responsible to develop and maintain those programs.</p> <p>The policy "Infection Control Monitoring," dated 1/01/09, stated "The Clinical Coordinator is designated as the Infection Control Officer."</p> <p>The RN who identified herself as the Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She stated she was not the Clinical Coordinator. She confirmed the former Infection Control Officer who had left in May of 2013 was not the Clinical Coordinator. She stated the ASC planned to offer a current employee, also not the Clinical Coordinator, the job of Infection Control Officer. She further stated there was no job description for Infection Control Officer.</p> <p>During the same interview, the identified Infection Control Officer answered questions about the QAPI program. She stated she was not the QAPI Coordinator. She stated no person was formally designated to be in charge of the QAPI program. She stated there was no job description for the QAPI Coordinator. She stated no records were kept noting how much time she spent working on QAPI and infection control or what those activities included.</p>	Q 040	<p>Continued from page 2</p> <p>determining policies and procedures for nursing services, ensuring that there is a disaster preparedness plan, and maintaining an infection control and QAPI program.</p> <p><b>RESPONSIBLE PARTY AND MONITORING:</b> The Chairman of the Governing Board will be responsible for ensuring that the Governing Body oversees and is accountable to uphold recognized standards of practice for BLS certification of staff, delegate responsibilities for management of both the Infection Control Program and the Quality Improvement Program, determining policies and procedures for nursing services, ensuring that there is a disaster preparedness plan, and maintaining an infection control and QAPI program. The Center Director will be responsible for ensuring that the facility upholds recognized standards of practice for BLS certification of staff. She or her designee will review all personnel files to determine need to update (Attachment B). Any employee who needs recertification will obtain no later than 7/12/2013. The Center Director will oversee and delegate responsibilities for the management of both the Infection Control Program and the Quality Improvement Program. With Governing Body oversight she will determine policies and procedures for nursing services, ensure there is a disaster preparedness plan, and maintain an infection control and QAPI program. The Center Director will additionally report on the above no less than quarterly to the QAPI Committee for review and recommendation to the Governing Body.</p>		

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Q 040	<p>Continued From page 3</p> <p>The Medical Director was interviewed on 6/26/13 beginning at 11:10 am. He confirmed staff had not been formally designated to manage the QAPI and infection control programs.</p> <p>The governing body did not delegate authority to staff.</p> <p>2. The governing body had not assumed responsibility for determining policies governing nursing services. Policies and procedures were reviewed. No nursing procedures or policies were documented which stated the standards nursing staff were to use as nursing procedures.</p> <p>The Medical Director was interviewed on 6/20/13 beginning at 1:25 PM. He stated the ASC had not adopted nursing procedures for staff to use. He stated the ASC had no approved documents that provided direction to nursing staff if they had questions about nursing procedures. He stated nurses should know how to perform procedures and if they did not he would replace them.</p> <p>The ASC did not identify nursing standards to be followed.</p> <p>3. The Governing Body failed to provide staff oversight for the completion of training and certification in BLS as evidenced by the following:</p> <p>a. On 6/20/13, beginning at 2:30 PM, a sample of seven personnel files were reviewed with the Clinical Director. It was noted that 2 of the 7 staff members did not have a current BLS certification as required in job descriptions, as follows:</p> <p>i. Staff C, a CST, was hired 4/06/07. The CST</p>	Q 040			

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Q 040	Continued From page 4 job description stated the CST must maintain "...current Basic Life Support certification according to American Heart Association standards." There was no evidence of a BLS certification for this staff member. The Clinical Director stated she did not think he had ever been certified in BLS.  ii. Staff D, an RN, was hired 10/09/00. The RN job description stated the RN must maintain "...current basic cardiac life support (BLS) certification and an advance cardiac life support certificate according to the American Heart Association." The BLS certification for this RN expired in 2009 and there was no documentation to indicate it had been renewed.  The ASC failed to ensure BLS certifications were current.  4. Refer to Q43 as it relates to failure of the facility to develop and maintain a disaster plan.  5. Refer to Q80 - Condition for Coverage for Quality Assessment and Performance Improvement and related standard level deficiencies as they relate to the failure of the ASC to develop and maintain a QAPI program.  6. Refer to Q240 - Condition for Coverage for Infection Control and related standard level deficiencies as they relate to the failure of the ASC to maintain an Infection Control program.	Q 040			
Q 043	416.41(c) DISASTER PREPAREDNESS PLAN  (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in	Q 043			

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Q 043	Continued From page 5 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 staff interview and record review the facility/governing body failed to ensure that a written disaster preparedness plan was in place to effectively deal with the care, health and safety of patients, staff and other individuals during a major disruptive event. This had the potential to negatively impact all patients, staff and visitors in the facility at the time of a such an event. Findings include:  When asked on June 20, 2013 at 2:30 PM, the Adminsitrator was unable to produce a disaster preparedness plan. During interview, the Administrator she stated that she did not know where the disaster preparedness plan was located.	Q 043	416.41(c) DISASTER PREPAREDNESS PLAN The ASC will maintain a written disaster preparedness plan that provides for the emergency care of patients, staff, and others in the facility in the event of fire, natural disaster, functional failure of equipment or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC. The disaster plan will be coordinated with state and local authorities as appropriate. PLAN OF CORRECTION: Disaster Preparedness Plan and the Disaster Preparedness Checklist (Attachment C) has been updated and was approved by the Governing Body. Center staff will be educated on the Plan and Policy. RESPONSIBLE PARTY AND MONITORING: The Center Director/designee is responsible for ensuring compliance with 416.41 Disaster Preparedness Plan requirements. The Center Director will be responsible for maintaining the Disaster Preparedness as changes are needed. Compliance to process will be monitored during the annual drills. Lessons learned and actions taken will be submitted at the regularly scheduled QAPI meetings for review with recommendations to the Governing Body for final review and approval.	7/11/2013	
Q 080	416.43 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT  The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program.	Q 080	416.43 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT PLAN OF CORRECTION: The Sawtooth Surgical Center will develop, implement and maintain an on-going, data-driven, quality assessment and performance improvement (QAPI) program.		

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Q 080	Continued From page 6  This CONDITION is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to ensure an ongoing, data-driven QAPI program had been developed, implemented, and maintained. This resulted in the inability of the ASC to take a proactive approach to improving the quality and safety of the services it provides. Findings include:  1. Refer to Q081 as it relates to the failure of the ASC to define its QAPI program and ensure the program used quality indicators to measure, analyze, and track aspects of performance.  2. Refer to Q082 as it relates to the failure of the ASC to ensure its QAPI program incorporated quality indicator data and used that data to measure its performance.  3. Refer to Q083 as it relates to the failure of the ASC to ensure performance improvement projects were developed and conducted.  4. Refer to Q084 as it relates to the failure of the ASC to ensure the governing body defined, implemented and maintained a QAPI program.  The cumulative effect of these negative facility practices prevented the ASC from utilizing information to improve its processes.	Q 080	Continued from page 6  PLAN OF CORRECTION: The Center has established policies and procedures for the Quality Improvement Program (Attachment D). The Quality Improvement Plan was reviewed and approved on 7/11/2013. The QAPI plan includes measurement, analysis and tracking of quality indicators, adverse patient events, infection control program and other aspects of performance that includes care and services furnished at the Center. The QAPI plan includes utilization of infection control data, safety data, risk data, high risk/high volume and problem prone process data to monitor the effectiveness of its services and quality of its care. Performance Improvement indicators were approved (Attachment D) by the Governing Body for ongoing monitoring to include but not limited to: monitoring of post procedure infections, adverse patient events, hospital transfers, tissue review, procedural and anesthesia complications, employee exposures, adverse drug reactions, medication errors, and patient satisfaction. QI focus studies will be identified through data collection and review by the QAPI Committee. Quarterly meetings will be documented in a specific format (Attachment D) and be available to the Governing Body for review and action.  RESPONSIBLE PARTY AND MONITORING: The Center Director is responsible for maintaining an ongoing, data driven quality assessment and performance improvement program. The Center Director will ensure compliance with collection of approved PI indicators and for holding and documenting quarterly QAPI meetings to review collected data and make recommendations to the Governing Body for final approval.	7/11/2013	
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	Q 081			

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Q 081	<p>Continued From page 7</p> <p>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.</p> <p>(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.</p> <p>(c)(1) The ASC must set priorities for its performance improvement activities that -</p> <p>(i) Focus on high risk, high volume, and problem-prone areas.</p> <p>(ii) Consider incidence, prevalence, and severity of problems in those areas.</p> <p>(iii) Affect health outcomes, patient safety, and quality of care.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of policies, quality improvement documents, and meeting minutes, it was determined the ASC failed to define its QAPI program and failed to ensure the program used quality indicators to measure, analyze, and track aspects of performance. Also, the ASC failed to set priorities for its performance improvement activities. This prevented the ASC from evaluating its ability to provide quality care to patients. Findings include:</p> <p>1. The Policy "Quality Improvement/Risk Management Program," dated 1/01/09, defined</p>	Q 081	<p>416.43(a)(c)(1) PROGRAM SCOPE/PROGRAM ACTIVITIES</p> <p>PLAN OF CORRECTION: The Sawtooth Surgical Center will develop, implement and maintain an on-going, data-driven, quality assessment and performance improvement (QAPI) program.</p> <p>IMMEDIATE ACTION: Online policies and procedures for safe effective care to include the Quality Improvement Plan were approved by the Governing Body on 7/11/2013. Staff were in-serviced on updated policies. (Attachment D) The QAPI plan includes measurement, analysis and tracking of quality indicators, adverse patient events, infection control program and other aspects of performance that includes care and services furnished at the Center. The QAPI plan includes utilization of infection control data, safety data, risk data, high risk/high volume and problem prone process data to monitor the effectiveness of its services and quality of its care. Performance Improvement indicators for ongoing monitoring includes but is not limited to: monitoring of post operative infections, adverse patient events, hospital transfers, tissue review, procedural and anesthesia complications, employee exposures, adverse drug reactions, medication errors, and patient satisfaction. The quarterly QAPI minutes will be available to the Governing Body for review and action.</p> <p>SYSTEMIC CHANGES: 1) Based on initial findings by the Consultant Pharmacist where medications were administered without an order, the Quality Improvement Study Medication Administration/Physician Orders has been initiated. (Attachment D)</p>	7/11/2013	

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Q 081	<p>Continued From page 8</p> <p>the composition of the committee, stating "The QIC is comprised of the Medical Director, Administrator, Clinical Coordinator, Business Office Manager and invited guests." The policy did not specify QAPI activities. The policy did not address how quality indicators would be developed and implemented. The policy did not specify the committee's responsibilities for the QAPI program. The policy did not specify who was in charge of the committee. The policy did not specify who was responsible for developing quality indicators, gathering data, and monitoring the program.</p> <p>The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She stated no person was formally designated to be in charge of the QAPI program. She confirmed policies did not define the QAPI program structure including the lack of a description of the duties of staff in relation to QAPI.</p> <p>The ASC had not defined its QAPI program.</p> <p>2. The document "QAPI-RISK MANAGEMENT Annual Program Evaluation and Goals" for the year 2013, not dated, included "List Focus Studies Completed." The studies listed were "DVT stockings, Hand washing, Labeling on med vials and syringes, H&amp;Ps on charts." These included:</p> <p>a. The "DVT Program/Compression Stockings" study, dated October 2012, consisted of determining the number of DVTs that patients had experienced from 2008-2012. After obtaining this number, the ASC decided to utilize compression stockings for certain patients. The study stopped</p>	Q 081	<p>Continued from page 8</p> <p>2) The Clinical Director will attend the AAAHC Training session on "Achieving Accreditation" "Quality Improvement: Using the 10 Elements" and "Evaluation of QI Studies"</p> <p>3) Staff will be in-serviced on the QAPI Plan and all of the components: (Attachment D)</p> <ul style="list-style-type: none"> <li>-QAPI Important Aspects of Care</li> <li>-QAPI Outline</li> <li>-QAPI Focus Study</li> </ul> <p>RESPONSIBLE PARTY AND MONITORING: The Center Director is responsible for maintaining an ongoing, data driven quality assessment and performance improvement program. The Center Director will ensure compliance with collection of approved PI indicators and holding and documenting quarterly QAPI meetings to review collected data and make recommendations. The QAPI minutes will be reported to the Governing Body for review and approval.</p>	12/7/2013	

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Q 081	<p>Continued From page 9</p> <p>and there was no follow up, i.e. if stockings were being utilized appropriately, and no further data was gathered.</p> <p>b. No data was documented from the hand washing study.</p> <p>c. The "Medication Labeling Sept.-Dec." study, consisted of checking vials and syringes in 3 operating rooms on 9/26/12 and 12/03/12. The 9/26/12 review found only 43% compliance and the 12/03/12 review found 66% compliance. The study stopped at that point and there was no documented plan for further study.</p> <p>d. The "H&amp;P Study 2," dated May 2012 to November 2012, included a review of charts from March 2012 and November 2012. The number of charts missing H&amp;Ps were documented in March but not in November. The study document, not dated, stated "A restudy will be done during the first quarter 2013." No study from the first quarter of 2013 was documented.</p> <p>The Annual Program Evaluation and Goals for 2013 did not specify quality indicators or activities for 2013. The document stated the QAPI goals for 2013 were to "Reduce needle sticks" and "Adoption of AMSurg Policy and Procedure." The document did not state how this would be accomplished nor did it describe data to be gathered in relation to these goals.</p> <p>The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed the studies and the lack of specificity of the Annual Program Evaluation and Goals document. She confirmed no data had been gathered for the</p>	Q 081			

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Q 081	Continued From page 10 H&P study in 2013. She stated no data had been gathered for quality indicators in 2013.  The ASC did not develop a specific plan for its QAPI activities.  3. Three "QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT & PATIENT SAFETY QUARTERLY REPORT" meeting minutes were documented from 7/01/12 through 6/20/13. These were dated 10/17/12, 1/09/13, and 4/17/13. A list of priorities for the ASC's performance improvement activities that identified high risk, high volume, and problem-prone areas for study was not documented.  The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed priorities for the ASC's performance improvement activities were not documented.  The ASC did not develop a list of priorities for the ASC's performance improvement activities.	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	Q 082	416.43(b)(c)(2)(3) PROGRAM DATA/PROGRAM ACTIVITIES PLAN OF CORRECTION: The Sawtooth Surgical Center will develop, implement and maintain an on-going, data-driven, quality assessment and performance improvement (QAPI) program. IMMEDIATE ACTION: The Quality Improvement Plan was reviewed and approved by the Governing Body on 7/11/2013. The QAPI plan includes measurement, analysis and tracking of quality indicators, adverse patient events, infection control program and other aspects of performance that includes care and services furnished at the Center. The QAPI plan includes utilization of	7/11/2013	

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Q 082	<p>Continued From page 11</p> <p>track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.</p> <p>(c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of policies, quality improvement documents, and meeting minutes, it was determined the ASC failed to ensure its QAPI program incorporated quality indicator data and used that data to measure its performance. This prevented the ASC from objectively analyzing care provided to patients. Findings include:</p> <p>1. The Policy "Quality Improvement/Risk Management Program," dated 1/01/09, described the QIC, the MAC, and the governing board. The policy did not state how the ASC would incorporate quality indicator data into the QAPI program or how it would use that data to evaluate its services.</p> <p>The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed policies did not describe how data would be incorporated into the QAPI program.</p> <p>The ASC had not defined the use of data.</p> <p>2. The document "QAPI-RISK MANAGEMENT Annual Program Evaluation and Goals" for the year 2013, not dated, did not mention data or how</p>	Q 082	<p>Continued from page 11</p> <p>infection control data, safety data, risk data, high risk/high volume and problem prone process data to monitor the effectiveness of its services and quality of its care. Performance Improvement indicators for ongoing monitoring includes but is not limited to: monitoring of post operative infections, adverse patient events, hospital transfers, tissue review, procedural and anesthesia complications, employee exposures, adverse drug reactions, medication errors, and patient satisfaction. The QAPI minutes will be available to the Governing Body for review and action quarterly.</p> <p>SYSTEMIC CHANGES:</p> <p>1) The Center has reestablished the ongoing monitoring and analyzing of performance improvement indicators to collect data.</p> <p>2) The Center will review risk reports for trends to assist with identifying opportunities for process improvements.</p> <p>RESPONSIBLE PARTY AND MONITORING:</p> <p>The Center Director is responsible for maintaining an ongoing, data driven quality assessment and performance improvement program. The Center Director will ensure compliance with collection of approved PI indicators. She will ensure quarterly QAPI meetings occur to analyze collected data and make recommendations for focused studies as needed. The QAPI minutes will be reported to the Governing Body for review and approval on a quarterly basis.</p>	

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Q 082	<p>Continued From page 12 it would be gathered and utilized by the QAPI program for 2013.</p> <p>The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed the Program Evaluation and Goals did not include the use of data.</p> <p>The ASC did not develop a plan to incorporate quality indicator data into its QAPI activities.</p> <p>3. Three "QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT &amp; PATIENT SAFETY QUARTERLY REPORT" meeting minutes were documented from 7/01/12 through 6/20/13. These were dated 10/17/12, 1/09/13, and 4/17/13. None of these meeting minutes mentioned quality indicator data had been collected or analyzed. None of these meeting minutes described how data would be utilized in the future to evaluate patient care.</p> <p>The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed data was not discussed in QIC meeting minutes.</p> <p>The QIC did not provide for the use of data in the QAPI program.</p> <p>4. The only data that was present for 2013 was the number of surgery cancellations for the first quarter of 2013. This data was not gathered as part of a documented quality indicator or project.</p> <p>The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed the lack of data.</p>	Q 082			

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Q 082	Continued From page 13 The ASC had not gathered data upon which to assess, monitor, and improve the quality of patient care.	Q 082		
Q 083	416.43(d) PERFORMANCE IMPROVEMENT PROJECTS  (1) The number and scope of distinct improvement projects conducted annually must 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 policies, quality improvement documents, and meeting minutes, it was determined the ASC failed to ensure its QAPI program included distinct improvement projects. This impeded the ability of the ASC to evaluate care provided to patients. Findings include:  1. The Policy "Quality Improvement/Risk Management Program," dated 1/01/09, did not define performance improvement projects or state that they would be incorporated into the ASC's QAPI program.  The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed policies did not address PIPs or require that they be conducted.	Q 083	416.43(a)(c)(1) PERFORMANCE IMPROVEMENT PROJECTS PLAN OF CORRECTION: The Sawtooth Surgical Center will develop, implement and maintain an on-going, data-driven, quality assessment and performance improvement (QAPI) program. SYSTEMIC CHANGES: 1) The ASC Quality Collaboration ASC Data Collection Tool will continue to be submitted quarterly. 2) Routine monitors will be analyzed to identify trends and opportunity for improvement. QA focus studies will be developed based on analysis of data obtained. 3) The Center Director will attend the AAAHC Training sessions on "Achieving Accreditation", "Quality Improvement: Using the 10 Elements" and "Evaluation of QI Studies." RESPONSIBILITY AND MONITORING: The Center Director will oversee all aspects of the QAPI program. She will coordinate collection and reporting of data for analysis at the QAPI meetings. She will ensure QAPI meetings occur at least quarterly and minutes are recorded. The minutes will be made available to the Governing Body for review and final approval.	7/12/2013

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Q 083	Continued From page 14 The QAPI policy did not address PIPs.  2. The document "QAPI-RISK MANAGEMENT Annual Program Evaluation and Goals" for the year 2013, not dated, did not state PIPs had been conducted in 2012 or were planned for in 2013.  The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed PIPs were not documented in 2012 or 2013.  The ASC did not conduct PIPs nor did they plan to conduct them.  3. Three "QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT & PATIENT SAFETY QUARTERLY REPORT" meeting minutes were documented from 7/01/12 through 6/20/13. These were dated 10/17/12, 1/09/13, and 4/17/13. None of these meeting minutes mentioned PIPs were conducted or planned.  The Infection Control Officer was interviewed on 6/20/13 beginning at 1:20 PM. She confirmed PIPs were not discussed in QIC meeting minutes.	Q 083		
Q 084	The QIC did not develop or monitor PIPs. 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.	Q 084	416.43(e) GOVERNING BODY RESPONSIBILITIES PLAN OF CORRECTION: The Center's Governing Body will ensure that it oversees and is accountable for the QAPI program plan. SYSTEMIC CHANGES 1) The Governing Body will review and approve the QAPI plan and related policies at least annually. Quality Improvement Committee Minutes will be reviewed and final approval obtained during each of the quarterly Board Meetings.	

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Q 084	<p>Continued From page 15</p> <p>(4) Clearly establishes its expectations for safety.</p> <p>(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of meeting minutes, it was determined the ASC's governing body failed to ensure the QAPI program was defined, implemented, and maintained. This resulted in a lack of direction for the QAPI program. Findings include:</p> <p>1. Four "BOARD OF DIRECTORS" meeting minutes were documented between 7/01/12 and 6/20/13. These were dated 7/24/12, 9/27/12, 12/06/12, and 2/13/13. QAPI was not mentioned in the 7/24/12 minutes and the 9/27/12 minutes.</p> <p>* The 12/06/12 minutes stated the Infection Control Officer presented the QAPI report for the 2nd quarter of 2012. It stated "There were 0 issues reported to the Corporate Compliance Officer or noted on the report." The QAPI report was not present.</p> <p>* The 2/13/13 minutes stated "The existing organizational chart, Ancillary Services Contracts, current medical forms, center formulary, QAPI/Risk Program, Schedule A Form, credential files, and the Compliance Program were reviewed and approved." The minutes further stated the Infection Control Officer "...informed the Board the QAPI Committee met for the 4th quarter 2012. The minutes from that meeting are filed separately. There were 0 issues reported to the</p>	Q 084	<p>Continued from page 15</p> <p>2) The Governing Body will conduct quarterly meetings using the attached agenda (Attachment A). The meeting will discuss Quality Improvement including Medical Records/Utilization Review/Peer Review; Infection Review; Cancellation Log Reporting; Occurrence Analysis; Unplanned Transfers; Tissue/Pathology Summary; Patient Satisfaction; Safety Review; and Quality Improvement Studies. Data from appropriate Performance Improvement Indicators will be reviewed and analyzed</p> <p>RESPONSIBLE PARTY AND MONITORING: The Chairman of the Governing Board will be responsible for ensuring that the Governing Body oversees and is accountable for the quality assurance and performance improvement program, ensures facility policies and procedures are administered in a manner to provide quality health care in a safe environment. Board meeting minutes will reflect details of information reported and conclusions reached as well as recommended changes to make desired improvements. The Center Director will ensure staff assigned to perform QAPI and infection control responsibilities have appropriate training, specific job descriptions and adequate time to complete perform assignments. She will report on policy adherence and patient safety no less than quarterly to the QAPI Committee for communication to the Governing Body and more often if issues are identified.</p>	7/11/2013

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Q 084	Continued From page 16 Corporate Compliance Officer or noted on the report." The minutes referred to in the Board minutes stated getting histories and physical reports by physicians was getting better. Otherwise, no quality of care issues related to gathering data or quality indicators were identified.  No "BOARD OF DIRECTORS" meeting minutes questioned the lack of quality indicators, lack of data, or the lack of PIPs.  The Medical Director, a member of the Board, was interviewed on 6/24/13 beginning at 12:05 PM. He stated the Board of Directors discussed quality all of the time but he was not able to provide documentation regarding specific quality indicators or data collection or PIPs.  The Board of Directors did not monitor the QAPI activities at the ASC.  2. The governing body failed to define the QAPI program. Refer to Q81 as it relates to the lack of specific direction to staff to enable them to develop and implement the QAPI program.  3. The governing body failed to ensure staff gathered and analyzed data for the QAPI program. Refer to Q82 as it relates to the lack of data gathered and utilized by the QAPI program.  4. The governing body failed to ensure PIPs were conducted. Refer to Q83 as it relates to the lack of PIPs developed and implemented by the ASC.	Q 084			
Q 122	416.45(b) REAPPRAISALS	Q 122			

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Q 122	<p>Continued From page 17</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of medical records and credentials files, it was determined the ASC failed to ensure privileges were reappraised for 1 of 10 medical staff members (Staff A) whose credentials were reviewed. This impacted 1 of 20 (Patient #14) patients whose records were reviewed and resulted in the potential for practitioners' to perform procedures for which they were not qualified. Findings include:</p> <p>Patient #14's medical record documented a 46 year old female who had a Rhytidectomy (face lift) performed on 6/20/13 by Staff A.</p> <p>Staff A's credentials file was reviewed on 6/20/13. The file stated Staff A was reappointed to the medical staff on 10/01/10. His privilege list, dated 10/01/10, did not include privileges for Rhytidectomy.</p> <p>The Medical Director was interviewed on 6/20/13 beginning at 1:25 PM. He stated Staff A had performed several Rhytidectomy surgeries at the facility. He stated Staff A's privileges were reappraised at the time of reappointment but he acknowledged Staff A did not have privileges to perform Rhytidectomy.</p> <p>The ASC did not reappraise Staff A's privileges in</p>	Q 122	<p>416.45(b) REAPPRAISALS</p> <p>PLAN OF CORRECTION: Ongoing competency of the Medical Staff will be confirmed as outlined in the Medical Staff Bylaws by periodic reappraisal. Delineations of Privileges will accurately reflect granting of privileges for all procedures performed by the practitioner. Privileges granted be on the facilities's Approved Procedure List.</p> <p>SYSTEMIC CHANGES: The Center Director shall review the credentialing files and ensure that the physician's clinical privileges are complete and present in the file prior to the reappointment process. The privileges granted will accurately reflect all procedures performed by the practitioner. Privileges granted will be reflected on the facility Approved Procedures List.</p> <p>RESPONSIBLE PARTY/MONITORING: It is the responsibility of the Center Director to ensure that all credentialing is performed according to the Medical Staff Bylaws. She will ensure reappraisals are performed within specified time frames with the appropriate documentation. Completed credentialing files for physicians requiring reappraisal will be submitted to the Governing Body biannually for review and reappointment. She will verify the privileges granted are accurate and they appear on the Approved Procedure List. (Attachment E)</p>	7/11/2013	

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Q 122	Continued From page 18	Q 122	416.47(b) FORM AND CONTENT OF RECORD		
Q 162	order to ensure he was granted privileges for all of the procedures he performed at the ASC. 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. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis.  This STANDARD is not met as evidenced by: Based on observation, 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 20 sample patients (#1, #4, #5, #8, #9, #11, #13, and #20) whose records were reviewed. This failure resulted in untimed physician orders and consents, lack of documentation related to allergies, and inaccurate documentation of events while being cared for at the facility. Findings include:	Q 162	PLAN OF CORRECTION: The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. SYSTEMIC CHANGES: 1) Documentation will be complete and accurate on all charts to adequately reflect care given. 2) Medication orders and signatures for patient assessments and consents will be dated and timed. 3) All preoperative orders will be documented and authenticated in the record. 4) Care provided will be per established policy 5) All records will contain patient identifying information. The following policies will be reviewed with all staff members and physicians (Attachment F): a) The Medical Record b) Medical Record Content-Order c) Medical Record Entries and Components d) Physician's Orders e) Documentation - Guidelines for Nursing Care f) Assessment - Post Operative Staff will be reminded of the importance of accurate charting and documentation. RESPONSIBLE PARTY AND MONITORING: It is the responsibility of the Center Director to ensure that the medical record for each patient is accurate, legible and promptly completed. The Center Director or designee will review 100% of all medical records for a period of three weeks beginning on 7/22/2013 for compliance with the documentation policies. If 100% compliance is not achieved, staff will be re-educated and the monitoring process will start over.	8/12/2013	

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Q 162	<p>Continued From page 19</p> <p>1. Patient #5 was a 59 year old female admitted to the ASC on 3/28/13 for an abdominoplasty, liposuction, a breast lift, and a thigh lift. Her medical record contained the following unclear documentation:</p> <p>A "Conscious Sedation Record," labeled page 3 and signed by the RN and surgeon, undated, documented that at 1:25 PM a size 32 nasal airway had been inserted due to Patient #5 snoring. The note did not document which nostril the airway had been placed in.</p> <p>A "Conscious Sedation Record," labeled page 4 and signed by the RN and surgeon, undated, documented that at 2:30 PM a size 34 nasal airway had been inserted into the left nostril. It was unclear as to whether this resulted in an airway in both nostrils or just a change in size from the first airway inserted at 1:25 PM.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed the documentation was unclear as to the course of Patient #5's treatment related to the nasal airways.</p> <p>Patient #5's medical record did not contain complete information regarding the course of her care while in surgery.</p> <p>2. Patient #8 was a 2 year old female admitted to the ASC on 6/12/13 for dental restoration. Her medical record contained the following unclear documentation:</p> <p>a. A "POST-OPERATIVE PROCEDURE</p>	Q 162	<p>Continued from page 19</p> <p>The results of all medical record audits will be tabulated and presented to the QAPI committee on a quarterly basis or review and recommendations. Recommendations will be presented to the Governing Body quarterly for review and approval.</p>	

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Q 162	<p>Continued From page 20</p> <p>NOTES," unsigned and undated, contained information pertaining to Patient #8's surgery, including pre-op and post-op diagnosis, blood loss and Patient #8's condition following the procedure. It was unclear who had written the procedure note and when it had been written.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed the procedure note lacked a signature and time. She also confirmed the physician had not written the information included on the procedure note. She stated that it was the practice of the ASC for the RN to complete the information on the "POST-OPERATIVE PROCEDURE NOTES." She stated the RN would discuss the information with the physician and the physician would sign the form later.</p> <p>b. An H&amp;P, electronically signed by a nurse practitioner on 6/04/13 at 11:21 AM, contained a stamp for the physician to sign indicating he had read the H&amp;P and there were no changes to Patient #8's condition. The stamp was not signed or dated. This lead to a lack of clarity as to whether the physician had examined Patient #8 prior to surgery.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed the physician had not signed the stamp on the H&amp;P. She confirmed this lead to a lack of clarity as to whether the physician had examined Patient #8 prior to surgery or not.</p> <p>Patient #8's record was incomplete.</p> <p>3. Patient #1 was a 45 year old female admitted</p>	Q 162		

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Q 162	<p>Continued From page 21 to the ASC on 5/09/13 for a revision of an abdominoplasty. Her medical record contained the following unclear documentation:</p> <p>An untitled form dated 5/09/13, documented the course of treatment for Patient #1 while in phase 1 recovery. This included vital signs, fluid intake, pain, activity, level of consciousness, and airway management. The form was not signed by a nurse.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed the form was unsigned. She confirmed this led to a lack of authentication as to the course of treatment in phase 1 recovery.</p> <p>Patient #1's course of treatment in the phase 1 recovery was not authenticated.</p> <p>4. Patient #9's medical record documented a 36 year-old female who had a surgical procedure on her sinuses on 5/29/13.</p> <p>Patient #9's medical record lacked clarity as follows:</p> <ul style="list-style-type: none"> <li>- A form, titled "ANESTHESIA QUESTIONNAIRE" was in Patient #9's record. The form did not contain identifying patient information including the patient name, medical record, or procedure. The form was not signed or dated by facility staff or the patient. The form was unclear as to who had completed the questionnaire, whether it was the patient or facility staff.</li> <li>-A form which included orders for pre-operative anesthesia and post anesthesia recovery was</li> </ul>	Q 162		

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Q 162	<p>Continued From page 22 signed and dated by the CRNA on 5/29/13 however, no time was included to indicate when the orders were written.</p> <p>During an interview on 6/20/13 at 7:45 AM, the Clinical Director reviewed Patient #9's record and confirmed the forms were incomplete.</p> <p>Documentation in Patient #9's record was not complete and accurate.</p> <p>5. Patient #4's medical record documented a 71 year-old male who had an EGD performed on 4/05/13, 4/26/13 and 5/24/13.</p> <p>Patient #4's medical records for each procedure lacked clarity as follows:</p> <ul style="list-style-type: none"> <li>-A form which included orders for pre-operative anesthesia and post anesthesia recovery for each of the three procedures were signed and dated by the CRNA but no time was included to indicate when the documents had been written.</li> <li>- An unnamed form documenting Patient #4's course of recovery did not document a blood pressure had been obtained before discharge on 4/02/13 and 4/26/13.</li> </ul> <p>In an interview on 6/20/13 at 7:45 AM, the Clinical Director reviewed Patient #4's record and confirmed the forms were incomplete and blood pressures had not been assessed prior to his discharge.</p> <p>The facility did not ensure documentation was complete and accurate.</p>	Q 162		

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Q 162	<p>Continued From page 23</p> <p>6. Patient #20's medical record documented a 25 year old male admitted to the ASC on 6/14/13 for left knee surgery under general anesthesia. His medical record contained the following unclear documentation:</p> <p>An untitled form, signed by the RN but untimed, documented the course of treatment for Patient #20 while in phase 1 recovery. This included vital signs, fluid intake, pain, activity, and level of consciousness. The form documented he was transferred to phase II recovery at 1:08 PM. The form documented Patient #20 received Fentanyl 50 mcg VP at 1:15 PM and 1:30 PM and Norco 20 mg po at 1:45 PM. The form stated Patient #20 was discharged home at 2:45 PM. No documentation was present that nursing staff checked vital signs or monitored Patient #20 between 1:08 PM and 2:45 PM.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 beginning at 9:00 AM. She reviewed Patient #20's medical record and confirmed the lack of documentation.</p> <p>Patient #20's medical record was incomplete.</p> <p>7. Patient #13's medical record documented a 58 year old male admitted to the ASC on 4/04/13 for a left inguinal hernia repair under general anesthesia. His medical record contained the following unclear documentation:</p> <p>- An untitled form, signed by the RN but untimed, documented the course of treatment for Patient #13 while in phase 1 recovery. This included vital signs, fluid intake, pain, activity, and level of</p>	Q 162			

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Q 162	<p>Continued From page 24</p> <p>consciousness. The form documented he was transferred to phase II recovery at 9:20 AM. The form stated Patient #13 was discharged home at 11:15 AM. No documentation was present that nursing staff checked Patient#13's vital signs after 9:20 AM, including checking them at the time of discharge.</p> <p>- Patient #13 had a H&amp;P documented on 3/22/13. No documentation was present the surgeon examined Patient #13 or reviewed the H&amp;P prior to surgery to ensure the H&amp;P was still current.</p> <p>- A "PRE-OP EVALUATION" and "Post-Op Note" were written by the anesthesiologist but were not timed.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 beginning at 9:00 AM. She confirmed the lack of documentation.</p> <p>Documentation in Patient #13's medical record regarding post-anesthesia recovery was incomplete.</p> <p>8. Patient #11's medical record documented a 38 year old female admitted to the ASC on 6/06/13 for bilateral breast reduction under general anesthesia. Her medical record contained the following unclear documentation:</p> <p>- An untitled form, signed by the RN but untimed, documented the course of treatment for Patient #11 while in phase 1 recovery. This included vital signs, fluid intake, pain, activity, and level of consciousness. The form documented he was transferred to phase II recovery at 4:40 PM. The form stated Patient #11 was discharged home at</p>	Q 162			

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Q 162	Continued From page 25 6:15 PM. No documentation was present that nursing staff checked Patient #13's blood pressure after 4:40 PM, including checking it at the time of discharge.  - A "PRE-OP EVALUATION" and "Post-Op Note" were written by the anesthetist but were not timed.  The Clinical Director reviewed the record and was interviewed on 6/21/13 beginning at 9:00 AM. She reviewed Patient #11's medical record and confirmed the lack of documentation.  Documentation in Patient #11's medical record regarding post-anesthesia recovery was incomplete.	Q 162			
Q 181	416.48(a) ADMINISTRATION OF DRUGS  Drugs must be prepared and administered according to established policies and acceptable standards of practice.  This STANDARD is not met as evidenced by: Based on observation, staff interviews, and review of policies, it was determined the facility failed to ensure medication was stored, prepared and administered in accordance with acceptable standards of practice. This failure directly impacted 1 of 4 patients (Patient #18) whose surgeries were observed and had the potential to impact all patients receiving care after Patient #18. The ASC also failed to ensure medication orders were written according to acceptable standards of practice for 5 of 20 patients (#4, #5,	Q 181			

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Q 181	<p>Continued From page 26</p> <p>#8, #15, and #19) whose medical records were reviewed. Failure to adhere to acceptable standards of practice placed all patients who received medications at risk of adverse drug reactions. Findings are as follows:</p> <p>1. United States Pharmacopela (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations, Second Edition, 6/01/08, states if a multidose vial 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.</p> <p>The ASC policy, "Pharmaceuticals, Discarding," effective date 1/01/2009, stated that "Multi-dose vials are discarded when empty, when the manufacturer's expiration date had been reached, when opened and not labeled, visibly contaminated, or not stored according to manufacturer's recommendation..." The policy did not address the 28 day expiration period for open vials of medication, nor did it identify specific manufacturer expiration dates that were in use for open medications.</p> <p>Expired or unlabeled medications were observed in the ASC as follows:</p> <p>a. During a tour of the OR with the OR Director on 6/19/13 at approximately 10:00 AM, the narcotic storage was observed. A 10 mg multidose vial of Versed was noted with an IV tubing connection device placed in the hub. A vial of Ketamine was also noted with an IV tubing connection device placed in the hub. There were no labels on the vials to indicate when they had been opened.</p>	Q 181	<p>416.48(a) ADMINISTRATION OF DRUGS</p> <p>PLAN OF CORRECTION:</p> <p>The Center will ensure that drugs are prepared and administered according to established policies and acceptable standards of practice. The Center will ensure that all medications drawn up are clearly labeled with the drug name, dosage, date and initials of the person who prepared the medication. Medications will be disposed properly according to facility policy and regulations when expiration date is reached.</p> <p>SYSTEMIC CHANGES: (Attachment G)</p> <p>1) The Center will follow the policy that states any multi-dose vial will be dated for 28 day upon opening</p> <p>2) The Center will follow the policy that states any medication not given immediately will be properly labeled.</p> <p>3) The article "Syringe Labeling Made Simple," has been reviewed with all clinical Center staff</p> <p>4) The article "Syringe Swaps in the OR Still Harming Patients" has been reviewed with all clinical Center staff .</p> <p>5) The Article from APIC "Safe injection, infusion, and medication vial practices in Healthcare has been reviewed with all clinical staff.</p> <p>6) Center policy on Administration of Medication has been reviewed with all clinical Center Staff to ensure understanding of the policy.</p> <p>7) Single Use Medication - Center policy , Safe Injection Practices has been reviewed with all clinical Center Staff to ensure understanding of the requirements.</p> <p>8) Physician's Orders - All medications will be ordered by a physician or other qualified member of the medical staff acting within the scope of their practice, prior to the administration in the ASC.</p>	8/12/2013	

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Q 181	<p>Continued From page 27</p> <p>The OR Director, present during the tour, stated that the IV connection device allowed staff to access the medication via needless system. She stated the Versed and Ketamine were used to provide conscious sedation to patients and staff would draw from the vial and leave the rest for the next person. She confirmed that without labels, it was difficult to know when the vials had been opened and when the 28 day expiration date had been reached.</p> <p>b. On 6/19/13 at approximately 2:00 PM an inspection of the drug storage area in the PACU was conducted. A bottle of liquid Versed was noted with a label stating it had been opened 4/24/13. The RN present at the time of the observation confirmed the Versed was still in use, 56 days after opening.</p> <p>A bottle of liquid Oxycodone was noted with a label stating it was opened on 4/12/13. The RN present at the time of the observation confirmed the Oxycodone was still in use, 68 days after opening.</p> <p>A one pint bottle of hydrocodone elixir was noted with a label stating it had been opened 4/16/13. The RN present at the time of the observation confirmed the hydrocodone elixir was still in use, 64 days after opening.</p> <p>A bottle of liquid Tylenol was noted with a label from a pharmacy stating it had been prepared 7/12/12 and would expire 7/12/13. An RN present at the time of the observation confirmed the Tylenol was still in use.</p>	Q 181	<p>Continued from page 27</p> <p>All medication orders will be signed and dated prior to the administration of the medication.</p> <p>9) Recovery room forms will be completed to document course of treatment and medications administered as per documented doctor's orders. The clinical staff have been in-serviced on the ASC's policies on:</p> <ol style="list-style-type: none"> <li>1) Multiple Dose Medications-Shelf life after entry</li> <li>2) Multiple Dose Medication Expiration Table.</li> <li>3) Medication Administration.</li> <li>4) Doctor's Orders</li> <li>5) The Idaho Nurse Practice Act (Attachment B).</li> </ol> <p>RESPONSIBLE PARTY AND MONITORING: The Center Director is responsible for monitoring compliance.</p> <ol style="list-style-type: none"> <li>1) The Center Director or her designee will randomly monitor the multi-dose vial 28 day out date practices. They will monitor for multi-dose vials being used beyond 28 days each month for 3 months beginning 7/22/2013. If 100% compliance is achieved, periodic spot checks will occur to measure ongoing compliance. If 100% compliance is not achieved, re-education shall occur and the monitoring process will start over.</li> <li>2) The Center Director or her designee will randomly monitor the Center's syringe labeling for unlabeled and improperly labeled medications each month for 3 months beginning 7/22/2013. If 100% compliance is achieved, periodic spot checks will occur to ensure ongoing compliance. If 100% compliance is not achieved, re-education shall occur and the monitoring process will start over.</li> <li>3) The Center Director or her designee will randomly monitor the Center's use of single dose medications each month for 3 months beginning 7/22/2013. If 100% compliance is achieved, ongoing spot checks will occur to ensure ongoing compliance. If 100%</li> </ol>	8/12/2013

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Q 181	<p>Continued From page 28</p> <p>c. On 6/19/13 at 4:40 PM a vial of Humulin insulin was noted in the refrigerator of the PACU. A label on the vial indicated it had been opened in December of 2012. The charge nurse was present at this time and confirmed the vial should have been discarded 28 days after opening. She stated she could not recall the last time this insulin had been used. In addition, 5 unlabeled syringes containing a small amount of clear liquid were noted in the bottom of the refrigerator. The charge nurse stated she did not know what was in the syringes or why they had been left in the refrigerator.</p> <p>d. At 8:58 AM on 6/19/13, an inspection of the IV supply storage cart in the pre-op area was performed. An open 10 ml vial of normal saline was noted in one of the drawers. There was no label to indicate when the vial had been opened. In addition, there were 2 unlabeled syringes containing a clear liquid stored with the normal saline vial. The charge nurse was interviewed at the time and stated that the vial was currently in use by the nurses to provide numbing to the area where the IV line would be placed on the patients. She stated that sometimes nurses drew up the normal saline into small syringes and did not use them, at which time they are placed in the drawer. She stated that the 2 syringes found with the normal saline vial were drawn up by someone else and probably contained normal saline, though she confirmed it was difficult to know this without labels on the syringes.</p> <p>An unlabeled clear eye drop bottle containing clear liquid was noted in another drawer of the cart during the inspection. In an interview with the Clinical Director on 6/21/13 at 7:45 AM, she</p>	Q 181	<p>Continued from page 28</p> <p>compliance is not achieved, re-education shall occur and the monitoring process will start over.</p> <p>4). The Center Director or her designee will audit medical records for documentation of timing of physician's orders and signatures with dates by all practitioners as well as other entries related to care provided each month for 3 months beginning 7/22/2013. The results of all audits will be tabulated and presented to the QAPI Committee on a quarterly basis for review and recommendations. Recommendations will be presented to the Governing Body quarterly for review and approval.</p>

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Q 181	<p>Continued From page 29</p> <p>stated the clear liquid inside the bottle was a medication used for eye surgery patients. She confirmed it was unlabeled and therefore difficult to know what the medication was or when it had been opened.</p> <p>Medications in the ASC were unlabeled and/or expired, which had the potential to compromise the safety and effectiveness of the medications.</p> <p>2. During the observation of Patient #18's surgical procedure, a CRNA was observed drawing lidocaine from a vial labeled for single use at 11:15 AM on 6/19/13. He drew half of the contents of the vial into one syringe and the other half into a second syringe and labeled both syringes. He stated he planned to use one syringe for Patient #18 and save the second syringe for the next patient. He confirmed that the vial of lidocaine was labeled for single patient use and was not intended to be used on multiple patients.</p> <p>The Centers for Disease Control and Prevention's "Guidellne for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007" indicates safe injection practices include "Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use."</p> <p>The ASC did not ensure medications were prepared, stored and administered in accordance with accepted standards of practice.</p> <p>3. Patient #5 was a 59 year old female admitted to the ASC on 3/28/13 for an abdominoplasty, liposuction, a breast lift, and a thigh lift. Her</p>	Q 181		
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Q 181	<p>Continued From page 30</p> <p>medical record contained the following unclear documentation:</p> <p>An untitled form, signed by the RN but untimed, documented the course of treatment for Patient #5 while in phase 1 recovery. This included vital signs, fluid intake, pain, activity, level of consciousness, and airway management. The form also documented that Patient #5 had received a 2 ml of Romazicon, used to treat drowsiness caused by sedative medications, at 5:40 PM on 3/28/13. However, documentation on the form indicated that at 5:40 PM Patient #5 was "Awakening-responding to name and/or verbal commands." There was no order in the medical record for the Romazicon.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed there was no order for the Romazicon.</p> <p>Patient #5 received medication without an order.</p> <p>4. Patient #19 was a 27 year old male admitted to the ASC on 6/19/13 for surgery on his elbow. His medical record contained the following unclear documentation:</p> <p>a. An untitled form signed by the RN, untimed, documented Patient #19's course of treatment while in phase 2 recovery. This included vital signs, fluid intake, pain, activity and level of consciousness. The form also documented that Patient #19 had received a 10 mg Norco, a narcotic pain medication, for elbow pain at 4:30 PM. The medical record did not contain an order for the Norco.</p>	Q 181			

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Q 181	<p>Continued From page 31</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed there was no order for the Norco. She stated that the nurses had been giving patients the medication that had been prescribed at discharge and receiving a verbal order from the doctor, but she confirmed this was not documented in the medical record.</p> <p>b. An untitled form containing "PRE-OPERATIVE ANESTHESIA ORDERS" and "POST ANESTHESIA ORDERS," included post-op medications, IV orders, and discharge orders, including criteria that must be met prior to discharge. The form was signed by the CRNA on 6/19/13 but was untimed. It was unclear as to when the post-op orders had been written.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed the orders lacked a time and this resulted in a lack of clarity as to when the orders were written.</p> <p>Patient #19's medical record contained incomplete medication orders.</p> <p>5. Patient #15 was a 16 year old male admitted to the ASC on 4/24/13 for removal of a left eyebrow mass and orchiectomy (removal of the testicles). His medical record contained the following unclear documentation:</p> <p>a. An untitled form containing "PRE-OPERATIVE ANESTHESIA ORDERS" and "POST ANESTHESIA ORDERS," included post-op medications, IV orders, and discharge orders, including criteria that must be met prior to</p>	Q 181			

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Q 181	<p>Continued From page 32</p> <p>discharge. The form was signed by the CRNA on 4/24/13 but was untimed. It was unclear as to when the post-op orders had been written.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed the orders lacked a time and this resulted in a lack of clarity as to when the orders were written.</p> <p>Patient #15's medical record contained incomplete medication orders.</p> <p>6. Patient #8 was a 2 year old female admitted to the ASC on 6/12/13 for dental restoration. Her medical record contained the following unclear documentation:</p> <p>a. An untitled form containing "PRE-OPERATIVE ANESTHESIA ORDERS" and "POST ANESTHESIA ORDERS," included post-op medications, IV orders, and discharge orders, including criteria that must be met prior to discharge. The form was signed by the CRNA on 6/12/13 but was untimed. It was unclear as to when the post-op orders had been written.</p> <p>The Clinical Director reviewed the record and was interviewed on 6/21/13 at 7:45 AM. She confirmed the orders lacked a time and this resulted in a lack of clarity as to when the orders were written.</p> <p>Patient #8's medical record contained incomplete medication orders.</p> <p>7. Patient #4's medical record documented a 71 year-old male who had an EGD performed on</p>	Q 181			

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Q 181	Continued From page 33 4/05/13, 4/26/13 and 5/24/13.  A form which included orders for pre-operative anesthesia and post anesthesia recovery for each of the three procedures were signed and dated by the CRNA but no time was included to indicate when the documents had been written. This form included orders for pre-operative and post-operative medications  In an interview on 6/20/13 at 7:45 AM, the Clinical Director reviewed Patient #4's record and confirmed the forms were incomplete.  Patient #4's medical record contained incomplete medication orders.	Q 181		
Q 202	416.49(b) RADIOLOGIC SERVICES  (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.  This STANDARD is not met as evidenced by: Based on staff interviews, observation, and review of radiology documentation, it was determined that the ASC failed to ensure policies and procedures were developed to ensure staff competencies and safety within radiological services. This had the potential to result in improper use of equipment and risk of over-exposure of radiation to staff. Findings include:  1. OSHA standard regulation 1910.1096(d)(2) states "Every employer shall supply appropriate	Q 202	416.49(b) RADIOLOGIC SERVICES PLAN OF CORRECTION: The Center will ensure that they have procedures in place to provide safe and effective delivery of Radiologic services protecting patients and staff from harm. SYSTEMIC CHANGES: 1) The Center will supply appropriate dosimeter film badges to serve as personnel monitoring equipment. The badges will be assigned to individual staff members. (Attachment 1). The Policy-Radiation Exposure - Monthly Monitoring and Protective Guidelines will be reviewed by the Center Director. 2) The Center Director will monitor the results of staff radiation exposure. Documentation will be appropriately reviewed and maintained. Exposure history will be posted per requirements. If limits are exceeded, established protocol will be followed. 3) Manuals on operating the C-arm will be available to staff for review along with policies and procedures to define scope of practice.	7/12/2013

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Q 202	<p>Continued From page 34 personnel monitoring equipment, such as film badges, chambers, pocket dosimeters, or film rings..."</p> <p>A tour of the OR was provided by the OR Director on 6/19/13 at 9:35 AM. During the tour a box of dosimeter badges was noted sitting on top of the C-Arm. (A C-Arm is a type of mobile x-ray system, a dosimeter badge is an instrument that measures the amount of radiation or X-rays absorbed in a given period). Two of the badges in the box listed names of physicians. The other badges were labeled "Nurse 1," "Scrub," and "C-Arm Operator." The OR Director stated that these badges are shared by staff and no one staff member has his/her own badge. She stated the Clinical Director "kept track" of the dosimeter readings.</p> <p>The Clinical Director was interviewed on 6/20/13 beginning at 2:30 PM. She confirmed that ASC staff did not have their own dosimeter badges. She stated the staff shared the unlabeled badges. She stated the dosimeter badges were submitted to a company to be analyzed quarterly. She stated she did not have a process to identify which staff remembers were wearing the badges at what times. She stated there was no ASC policy in relation to radiology services.</p> <p>The ASC did not have a process to monitor staff radiation exposure.</p> <p>2. In an interview on 6/20/13 beginning at 2:30 PM, the Clinical Director stated that a C-Arm representative had given an inservice to some staff on the operation of the "small C-Arm" on 8/03/2010. He had returned and given an</p>	Q 202	<p>Continued from page 34 RESPONSIBLE PARTY AND MONITORING: 1) It is the responsibility of the Center Director to ensure that dosimeter badges are monitored and documented for individual staff members and that all variations are addressed per protocol. 2) Provider staff running the C-arms will be assessed for competency through the credential process and assignment of Delineation of Privileges (DOP). Results of monitors and actions taken will be reported at the regularly scheduled QAPI meetings for review and reporting to the Governing Body.</p>		

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Q 202	Continued From page 35 inservice to some staff on the "large C-Arm" on 9/16/10. The Clinical Director produced a sign-in sheet from the inservices. There was no documentation to indicate what information was covered in the inservices. There was no testing of competencies to confirm the staff members knowledge of use of the C-Arm. In addition, there was no manual available to provide guidance to staff on the use of the C-Arm.  The Infection Control Officer, who had been present for the inservices, was interviewed on 6/21/13 at 10:00 AM. She stated that the same people who were trained on the C-Arms were the same people who were operating them at the current time, though she confirmed there was no documentation or surveillance related to this. She stated there had been no competency check on staff trained to use the C-Arms. She also stated that staff would just "train each other" on how to use the equipment, though there was no documentation present to qualify staff to do so.	Q 202			
Q 240	416.51 INFECTION CONTROL  The ASC did not ensure staff competency in the use of the C-Arm.  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 interview, observation, and review of policies and infection control documents, it was determined the ASC failed to ensure a comprehensive infection control program was developed, implemented and monitored. This resulted in the increased risk of infection to	Q 240	416.51 INFECTION CONTROL PLAN OF CORRECTION: The Center will maintain on ongoing infection control program to prevent, control and investigate infections and communicable diseases. The infection control and prevention program includes documentation the ASC has considered, selected and implemented nationally recognized infection control guidelines. Policy - Infection Control Program (Attachment H) IMMEDIATE ACTION: 1) All staff have been advised of the cleaning of the glucometer and all other equipment shall be based on following manufacturer's recommendations. Glucometer cleaning processes were reviewed with staff. (Attachment H)	7/11/2013	

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Q 240	Continued From page 36 patients. Findings include:  1. Refer to Q 242 as it relates to the lack of infection control policies and procedures.  2. Refer to Q 243 as it relates to the lack of professional staff to direct the infection control activities of the ASC.  3. Refer to Q 244 as it refers to the ASC's lack of integration of the infection control program into the QAPI program.  4. Refer to Q 245 as it relates to the incomplete surveillance plan for identifying infections.  The cumulative effect of these systemic omissions resulted in the inability of the ASC to ensure all reasonable steps had been taken to identify and prevent infections.	Q 240	2) The Center Director will ensure compliance with medication labeling requirements. 3) The Center will ensure that all patient care items are disinfected accordance to facility policy and in compliance with CDC Recommended Practices and manufacturer's recommendations. 4) Single dose or single use items will be used for only one patient. 5) Hand hygiene will be per established protocol		
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 observation, staff interview and review of policies and infection control documents, it was determined the ASC failed to ensure an infection control program was sufficiently implemented and monitored to ensure patient health and safety.	Q 242	RESPONSIBLE PARTY/MONITORING; The Center Director is responsible for adherence to the Infection Control Program. The Center Director will ensure compliance with the Infection Control policy and procedure. The Center Director is responsible for ensuring proper decontamination of the glucometer and other patient care equipment. The Center Director is responsible for monitoring compliance. The Center Director or her designee will monitor the practices of the staff and physicians. Results of all audits will be reported to the QAPI Committee quarterly with results and recommendations submitted to the Governing Body for review and reporting.		

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Q 242	<p>Continued From page 37</p> <p>This directly impacted 2 of 4 (#18, #19) patients whose procedures were observed and had the potential to impact all patients receiving care at the ASC. The lack of sufficient infection control program development and implementation resulted in the potential for patients to experience increased exposure to infectious agents. Findings include:</p> <p>1. Infection control breaches were observed as follows:</p> <p>a. At 8:58 AM on 6/19/13, an inspection of the IV supply storage cart in the pre-op area was performed. The following was observed:</p> <p>i. An open 10 ml vial of NS was noted in one of the drawers. There was no label to indicate when the vial had been opened. In addition, there were 2 unlabeled syringes containing a clear liquid stored with the NS vial. The charge nurse was interviewed at this time and stated that the vial was currently in use by the nurses to provide numbing to the area where the IV line would be placed on the patients. She stated that sometimes nurses draw up the NS into the small syringes and would not use them, at which time they were placed in the drawer. She stated that the 2 syringes found with the NS vial were NS someone else had drawn up, though she confirmed it was difficult to know this without labels on the syringes.</p> <p>ii. An unlabeled clear eye drop bottle containing clear liquid was noted in another drawer of the cart during the inspection. In an interview with the Clinical Director on 6/21/13 at 7:45 AM, she stated the clear liquid inside the bottle was a</p>	Q 242	<p>416.51(b) INFECTION CONTROL PROGRAM PLAN OF CORRECTION:</p> <p>The Center will maintain an ongoing infection control program to prevent, control and investigate infections and communicable diseases. The infection control and prevention program includes documentation the ASC has considered, selected and implemented nationally recognized infection control guidelines.</p> <p>SYSTEMIC CHANGES:</p> <p>1) Medication Administration-All staff with responsibility for administering medication have been provided additional education on all aspects of medication administration to include labeling multi-dose vials, use of single dose medications, and the 28 day policy for opened vials. New employees will receive training on medication administration initially, as needed and annually thereafter.</p> <p>2) The procedure for obtaining blood for glucose analysis has been reviewed. Blood for glucose analysis will be obtained utilizing single use lancet devices. Staff were educated on the process change. (Attachment H)</p> <p>3) The hand hygiene policies and decontamination of patient care items was reviewed with each caregiver (Attachment H) with the expectation of 100% compliance. Staff involved in medication administration were educated in acceptable practice standards</p> <p>4) All caregivers at the center were in-serviced on hand hygiene policies. (Attachment H)</p> <p>5) Staff were in-serviced on the decontamination of patient care items. (Attachment H)</p> <p>RESPONSIBLE PARTY AND MONITORING: The Center Director is responsible for ensuring appropriate training, education, and</p>	6/28/2013	

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Q 242	<p>Continued From page 38</p> <p>medication used for eye surgery patients. She confirmed it was unlabeled and therefore difficult to know what the medication was or when it had been opened.</p> <p>iii. A fingerstick device, used to prick the skin and obtain drops of blood for glucose testing, was observed in one of the drawers of the cart with two glucometers. The device resembled a pen and allowed for a lancet to be inserted in the pen and removed after use. The charge nurse was present and was interviewed at approximately 9:00 AM on 6/19/13. She confirmed the device was used for all patients in the facility needing a blood glucose test, but that the lancets are changed after each use.</p> <p>In an interview on 6/19/13 at 12:45 PM, the Clinical Director confirmed that the fingerstick device had been used for more than one patient.</p> <p>The Centers for Disease Control and Prevention's "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens," updated 2/09/11, the CDC recommends that these types of fingerstick devices never be used for more than one patient. The devices are difficult to clean and disinfect and have been linked to hepatitis B outbreaks. The CDC recommends the devices only be used by an individual person for self monitoring of blood glucose.</p> <p>b. During the observation of Patient #18, a CRNA was observed drawing lidocaine from a vial labeled for single use at 11:15 AM on 6/19/13. He drew half of the contents of the vial into one syringe and the other half into a second syringe</p>	Q 242	<p>Continued from page 38</p> <p>competency of staff for medication administration and blood glucose monitoring. Monitoring of these processes will be based on observation, interviews with staff, surveillance of medication administration practices and blood glucose analysis. The Center Director or her designee will coordinate a minimum of ten unannounced hand hygiene observations per week and patient care item decontamination processes to include all aspects of the appropriate policies and all caregivers for the next three months. Variances will be addressed with the team and tracked in a blinded report for trending. Trended behavior will be addressed individually for causes. If needed, additional training will occur and if needed, disciplinary action will occur. The Center Director or her designee will monitor the hand hygiene, equipment decontamination, medication labeling and single use item compliance for 1 month beginning 7/22 /2013. If 100% compliance is achieved random audits will occur to ensure ongoing compliance. If 100% compliance is not noted, additional staff education will occur and monitors will be repeated until compliance goals are reached. Results of all audits will be reported to the QAPI Committee quarterly with recommendations submitted to the Governing Body for review and final approval.</p>		

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Q 242	<p>Continued From page 39</p> <p>and labeled both syringes. He stated he planned to use one syringe for Patient #18 and save the second syringe for the next patient. He confirmed that the vial of lidocaine was labeled for single patient use and was not intended to be used on multiple patients.</p> <p>Centers for Disease Control and Prevention's "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007" indicated safe injection practices include "Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use."</p> <p>c. On 6/19/13 at approximately 2:00 PM an inspection of the drug storage area in the PACU was conducted. A bottle of liquid Versed was noted with a label stating it had been opened 4/24/13. The RN present at the time of the observation confirmed the Versed was still in use, 56 days after opening.</p> <p>A bottle of liquid Oxycodone was noted with a label stating it was opened on 4/12/13. The RN present at the time of the observation confirmed the Oxycodone was still in use, 68 days after opening.</p> <p>A one pint bottle of hydrocodone elixir was noted with a label stating it had been opened 4/16/13. The RN present at the time of the observation confirmed the hydrocodone elixir was still in use, 64 days after opening.</p> <p>A bottle of liquid Tylenol was noted with a label from a pharmacy stating it had been prepared 7/12/12 and would expire 7/12/13. An RN</p>	Q 242			

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Q 242	<p>Continued From page 40</p> <p>present at the time of the observation confirmed the Tylenol was still in use.</p> <p>United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding - Sterile Preparations, Second Edition, 6/01/08, states if a MDV 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. Use of an opened vial beyond the expiration date could compromise the sterility of the medication.</p> <p>The ASC policy, "Pharmaceuticals, Discarding," effective date 1/01/2009 stated that "Multi-dose vials are discarded when empty, when the manufacturer's expiration date had been reached, when opened and not labeled, visibly contaminated, or not stored according to manufacturer's recommendation..." The policy did not address the 28 day expiration period for open vials of medication, nor did it identify specific manufacturer expiration dates that were in use for open medications.</p> <p>d. During a tour of the OR with the OR Director on 6/19/13 at approximately 10:00 AM, the narcotic storage was observed. A 10 mg MDV of Versed was noted with an IV tubing connection device placed in the hub. A vial of Ketamine was also noted with an IV tubing connection device placed in the hub. There were no labels on the vials to indicate when they had been opened.</p> <p>The OR Director stated that the IV connection device allowed staff to access the medication via needless system. She stated the Versed and Ketamine were used to provide conscious</p>	Q 242			

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Q 242	<p>Continued From page 41</p> <p>sedation to patients and staff would draw from the vial and leave the rest for the next person. She confirmed that without labels, it was difficult to know when the vials had been opened and when the 28 day expiration date had been reached.</p> <p>The United States Pharmacopeia General Chapter 79 states if a multidose vial 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.</p> <p>e. On 6/19/13 at 4:40 PM a vial of Humulin insulin was noted in the refrigerator of the PACU. A label on the vial indicated it had been opened in December of 2012. The charge nurse was present at this time and confirmed the vial should have been discarded 28 days after opening. She stated she could not recall the last time this insulin had been used.</p> <p>The United States Pharmacopeia General Chapter 79 states if a multidose vial 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.</p> <p>f. On 6/19/2013 at approximately 1:05 PM, an LPN was observed admitting Patient #19. The LPN entered the room and washed hands, gloved and started an IV. She then proceeded to retrieve Patient #19's medications and did not wash her hands after removing gloves. She administered an oral medication without washing hands. She checked the patency of the IV and had to remove it, she did not wash her hands for the procedure. She proceeded to restart the IV and did not wash her hands before gloving.</p>	Q 242			

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Q 242	<p>Continued From page 42</p> <p>She did not wash her hands after gloving and removing gloves while performing the procedures.</p> <p>The CDC "Guideline for Hand Hygiene in Health-Care Settings," published 10/25/2002, states hand hygiene should be performed before direct contact with patients, before invasive procedures such as inserting and removing IV lines, after contact with patients, and after removing gloves worn while providing patient care.</p> <p>During an interview with the Clinical Director on 6/21/2013 at approximately 8:30 AM, the observation events during the admission of Patient #19 were discussed. She confirmed the ASC did not have a policy on hand hygiene, but that staff were expected to follow CDC hand hygiene guidelines. She confirmed the LPN had not followed CDC hand hygiene infection control guidelines.</p> <p>g. The charge nurse was observed starting an IV site on Patient #18 on 6/19/13 at approximately 9:10 AM. She used a blue rubber tourniquet she had pulled from the IV supply cart in the hallway. She applied the tourniquet to Patient #18's lower leg in preparation to start an IV site in his foot. Once the IV site was placed, the tourniquet was removed and set on Patient 18's stretcher. As the charge nurse was leaving the room she picked up the tourniquet and placed it back in the drawer of the IV cart. She did not clean the tourniquet after use.</p> <p>The CDC "Guide to Infection Prevention for</p>	Q 242			

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Q 242	<p>Continued From page 43</p> <p>Outpatient Settings: Minimum Expectations for Safe Care," updated May 2011, states "Noncritical items (e.g., blood pressure cuffs) are those that may come in contact with intact skin but not mucous membranes and should undergo low- or intermediate-level disinfection depending on the nature and degree of contamination." The Clinical Director was interviewed on 6/21/13 at 7:45 AM. She stated that the tourniquets were used for multiple patients and were not cleaned between use.</p> <p>The ASC failed to identify infection control breaches.</p> <p>2. The Infection Control Officer was interviewed beginning at approximately 9:00 AM on 6/20/13 and was asked how the ASC ensured staff were following ASC policies related to infection control. She stated that in the past, surveillance had been done on hand hygiene but she had found the process to be ineffective and wanted to develop a new process, but had not yet done so. She confirmed there was no ASC policy related to hand hygiene but the ASC used CDC guidelines for hand hygiene practices. She confirmed it was difficult to ensure staff followed hand hygiene policy when there was no hand hygiene policy developed by the ASC. In addition, the Infection Control Officer confirmed there had been no other forms of staff surveillance related to infection control practices.</p> <p>The ASC did not have a process to ensure staff followed infection control practices.</p>	Q 242		
Q 243	<p>416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION</p> <p>The program is -</p>	Q 243		

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Q 243	<p>Continued From page 44</p> <p>Under the direction of a designated and qualified professional who has training in infection control.</p> <p>This STANDARD is not met as evidenced by: Based on review of facility records, personnel records, 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. This impacted staff and all patients receiving care at the facility and prevented the ASC from utilizing the knowledge base of a trained professional to develop and monitor an infection control program. Findings include:</p> <p>1. Facility records, including personnel records, were reviewed. A job description for the Infection Control Officer could not be found. Furthermore, there was no documentation to indicate who had been named Infection Control Officer.</p> <p>The Clinical Director and Infection Control Officer were interviewed together at approximately 9:00 AM on 6/20/13. The Infection Control Officer stated she had completed some web-based training in the past related to infection control but did not have documentation of this. She stated that the ASC had a membership to APIC and she utilized that for some training. She stated she spent approximately 8 hours a week dedicated to the infection control program. She stated she read articles related to infection control topics and discussed the articles in staff meetings, but there was no documentation of this.</p>	Q 243	<p>416.51(b)(1) INFECTION CONTROL PROGRAM-DIRECTION PLAN OF CORRECTION: The Center Governing Body will designate a qualified licensed professional who has training in infection control. This individual will direct the ASC's infection control program for all patients and the ASC staff at risk for ASC acquired infections. This individual will have specific responsibilities related to Infection Control in his/her job description. (Attachment H) SYSTEMIC CHANGES: 1) The Governing Body appointed the Infection Control Nurse during the 7/11/2013 Board Meeting. The newly appointed Infection Control Nurse will be an APIC member. 2) The Infection Control Nurse will maintain continuous education and training in Infection Control. RESPONSIBLE PARTY AND MONITORING: The Center Director is responsible for oversight of the Infection Control Nurse ensuring Infection Control education is provided to all staff and credentialed staff no less than annually. The Center Director will be responsible for monitoring the IC program ensuring reporting of IC activities to the QAPI Committee quarterly for upward reporting to the Governing Body.</p>	6/28/2013	6/28/2013

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Q 243	Continued From page 45 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		
Q 244	416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI  [The program is -] An integral part of the ASC's quality assessment and performance improvement program  This STANDARD is not met as evidenced by: Based on interview, review of infection control documentation and QAPI documentation, it was determined the facility failed to incorporate infection control into the QAPI program. This failure had the potential to impact all patients receiving care at the facility and inhibited the ASC's ability to identify infections and improve infection control practices. Findings include:  The "QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT & PATIENT SAFETY QUARTERLY REPORT" from 4/17/13 was reviewed. It contained documentation that the 2013 annual assessment of the infection control program had been completed. Results of the 2013 infection control assessment were not documented in the meeting minutes. In an interview with the Infection Control Officer on 6/26/13 at 11:00 AM, she stated that the infection control assessment for 2013 was the "QAPI/Risk Management Annual Program Evaluation and Goals."  The "QAPI/Risk Management Annual Program	Q 244	416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI PLAN OF CORRECTION: Infection Control will be an integral part of the QAPI program for the center. Data obtained will be analyzed and focus studies will be conducted to allow review and identify opportunity to improve current processes. SYSTEMIC CHANGES: The Center Director will ensure performance of ongoing monitors and data gathering to include data around monitors of Performance Improvement Indicators, Infection Control Surveillance, Risk Management trend analysis, focus study analysis and other items as required by policy or regulation. RESPONSIBILITY & MONITORING: The governing body will provide direction, approval and oversight for all processes. The Center Director will ensure required processes are performed and all staff with data retrieval responsibility report appropriately to the QAPI Committee. Meeting minutes will reflect analysis of the data and subsequent actions designed to improve the processes within the facility resulting in improved quality of services provided and ultimately patient outcomes.	7/18/2013

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Q 244	<p>Continued From page 46</p> <p>Evaluation and Goals" for 2013, signed by the Center Director and the QAPI Chairman on 1/09/13, documented QAPI established goals that had been achieved as reduced needles sticks and reduced infections. There was no documentation to indicate data related to these goals had been collected or analyzed to reach the determination that the goals had been achieved. The evaluation also documented studies had been completed on handwashing and labeling on medication vials and syringes. There was no documentation that data had been collected or analyzed in relation to these studies. In the section "Discuss trends in quality measures and corrective actions that were taken," the form documented IV antibiotic timing to within a 1 hour range of the incision time. There was no documentation presented at the time of the survey of data that had been collected or analyzed in relation to this identified quality measure. The evaluation also documented staff would complete quarterly education updates on hand washing and medication labeling. There was no documentation to indicate education had been provided or completed by staff on a quarterly basis.</p> <p>The Infection Control Officer was interviewed on 6/26/13 at 11:00 AM. She stated that the program evaluation only contained goals for 2013, not actual achievements. She confirmed no data had been collected and analyzed in relation to the goals for 2013. She stated data had been collected and reported to a national data bank in relation to IV antibiotic timing but confirmed she had not supplied this information to surveyors at the time of the survey. She confirmed that while the infection control program</p>	Q 244			

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Q 244	Continued From page 47 had been mentioned in the meeting minutes of the QAPI committee, measurement of data and quality indicators related to infection control had not been performed.	Q 244		
Q 245	The infection control program was not incorporated into the ASC's QAPI program. 416.51(b)(3) INFECTION CONTROL PROGRAM - RESPONSIBILITIES  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. The failure of the facility to implement a comprehensive infection control program placed all patients receiving services at the facility at risk of experiencing preventable infections. Findings include:  1. The ASC policy "Infection Control Monitoring," effective date 1/01/2009, stated each month physicians were provided with a list of patients and the procedure that was performed at the ASC. The physicians were to mark whether the patients had developed post-op infections. If an infection was reported, "an Infection Control Report From is sent to the physician and the Post	Q 245	416.51(b) INFECTION CONTROL PROGRAM PLAN OF CORRECTION: The Center will maintain on ongoing infection control program to prevent, control and investigate infections and communicable diseases. The infection control and prevention program includes 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. IMMEDIATE ACTION: The QAPI Plan and Infection Control Plan along with related policies were reviewed and approved by the Governing Body on 7/11/2013. The Infection Control Plan identifies and requires tracking measures related to infection control including at a minimum: a) Infection Control related incident reports b) Monthly physician review of patient procedure and documentation of any infections c) Track and trend all patient and employee infections d) Infection Control quality indicators e) Environment of Care f) Sterilization/Disinfection g) Hand Antisepsis	7/11/2013

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Q 245	<p>Continued From page 48</p> <p>form is implemented in order to consistently gather data on the factors surrounding the patient's experience, pre-existing health, co-morbidities and post-operative symptoms along with instruments sterilization, time of surgery, etc."</p> <p>The Infection Control Officer was interviewed on 6/20/13 at approximately 9:00 AM. She stated she no longer used the form that had been developed to document the investigation of a possible post-op infection. She stated she was in the process of developing a new form. She stated that the only possible infection that had been reported was a non-healing wound requiring an incision and drainage on 1/08/2013. There was no documentation that the data mentioned in the above policy had been gathered or reviewed. The only documentation provided of the investigation of the wound was a wound culture that was negative for bacterial growth. There was no investigation form present for this case. The Infection Control Officer stated that the investigation was closed as the cultures showed that there was no infection present. There was no documentation to indicate a resolution or an investigation of factors that contributed to the non-healing wound.</p> <p>The ASC did not have a process for thoroughly investigating post-op infections.</p> <p>2. The Infection Control Officer and the Clinical Director were interviewed beginning at approximately 9:00 AM on 6/20/13. The Infection Control Officer stated that the ASC had planned on performing surveillance of staff adherence to hand hygiene practices at some point but had not</p>	Q 245	<p>Continued from page 48</p> <p><b>RESPONSIBLE PARTY/MONITORING;</b> The Center Director will ensure compliance with the Infection Control Plan monitors and reporting. Results of all monitors including employee hand hygiene and follow up investigations of post-op infections will be reported to the QAPI Committee with recommendations submitted to the Governing Body for final review and approval at regularly scheduled meetings.</p>		

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FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  13C0001003	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  06/26/2013
NAME OF PROVIDER OR SUPPLIER  SAWTOOTH SURGERY CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 115 FALLS AVENUE WEST TWIN FALLS, ID 83303		
(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 245	<p>Continued From page 49</p> <p>developed a process for this. The Infection Control Officer stated there were no other types of surveillance activities documented or planned for the future.</p> <p>In addition, during this interview, the Infection Control Officer and Clinical Director were asked to provide surveyors with all policies and documentation related to infection control. Surveyors received three polices, "Infection Control Monitoring," "Infectious Waste -- Handling and Disposal," and "MRSA Precaution for Disease Control." There was no documentation of a plan for preventing, identifying or managing infections and for immediately implementing corrective and preventative measures that result in improvement.</p> <p>The ASC failed to develop sufficient policies related to infection control.</p>	Q 245			