COPY

IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

DEBRA RANSOM, R.N.,R.H.I.T., Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
Boise, ID 83720-0009
PHONE 208-334-6626
FAX 208-364-1888

CERTIFIED MAIL: 7000 1670 0011 3315 1743

September 19, 2014

Laurie Sothers, Administrator
Southwest Idaho Surgery Center
900 North Liberty Street, Suite 400
Boise, ID 83704

RE: Southwest Idaho Surgery Center, Provider #13C0001021

Dear Ms. Sothers:

Based on the survey completed at Southwest Idaho Surgery Center, on September 5, 2014, by our staff, we have determined Southwest Idaho Surgery Center is out of compliance with the Medicare ASC Conditions for Coverage of **Governing Body & Management (42 CFR 416.41), Quality Assessment & Performance (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 Southwest Idaho 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 for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of each form.

Such corrections must be achieved and compliance verified by this office, before October 20, 2014. 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 October 10, 2014.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **October 1, 2014**.

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 corrections immediately.

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

Sincerely,

GARY GUILES
Health Facility Surveyor
Non-Long Term Care

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

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

SOUTHWEST IDAHO
ENT
Surgery Center, Inc.

Eric T. Garner, M.D. • Arthur C. Jones III, M.D., F.A.C.S. • Peter J. Killian, M.D. • DelRay Maughan, M.D.
Ryan L. Van De Graaff, M.D. • Todd J. Rustad, M.D. • Matthew B. Schwarz, M.D.

September 30, 2014

Mr. Gary Guiles
Health Facility Surveyor
Idaho Department of Health & Welfare
P.O. Box 83720
Boise, ID 83720-0009

Re: Statement of Deficiencies/ Plan of Correction, Provider #13C0001021

Dear Mr. Guiles:

Please find enclosed the Statement of Deficiencies/Plan of Correction indicating our plan of correction for each of the deficiencies found during our recent survey.

If you require any additional information, please do not hesitate to contact me.

Sincerely,

Tracy L. McGeorge
Administrator
Southwest Idaho Surgery Center, Inc.

900 N. Liberty Street, Suite 450 • Boise, Idaho 83704
(208) 367-7431 • Fax (208) 367-7433

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001021	A. BUILDING _____ B. WING _____	09/05/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHWEST IDAHO SURGERY CENTER	900 NORTH LIBERTY STREET, SUITE 400 BOISE, ID 83704

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 000	INITIAL COMMENTS The following deficiencies were cited during the Medicare recertification survey of your surgical center from 9/02/14 to 9/05/14. Surveyors conducting the recertification were: Gary Guiles, RN, HFS, Team Leader Donald Sylvester, RN, HFS Cheri Samuels, RN, HFS Acronyms used in this report include: AAMI - Association of Advancement of Medical Instrumentation AORN - Association of Perioperative Registered Nurses APIC - Association for Professionals in Infection Control and Epidemiology ASC - Ambulatory Surgery Center CDC - Centers for Disease Control CMS - Center for Medicare and Medicaid Services CRNA - Certified Registered Nurse Anesthetist IC - Infection Control O2 - Oxygen OR - Operating Room OSHA - Occupational Safety and Health Administration QAPI - Quality Assessment Performance Improvement QAPIRM - Quality Assessment Performance Improvement Risk Management RN - Registered Nurse	Q 000		
Q 040	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining,	Q 040		

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OCT - 1 2014
FACILITY STANDARDS

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

Administrator | 9/30/14

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

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Q 040	Continued From page 1 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 interviews and review of medical records, policies, meeting minutes, and quality program documents, it was determined the ASC's Governing Body failed to ensure policies were monitored to ensure compliance. The Governing Body also failed to assume oversight and accountability for the ASC's QAPI program and IC program. The failure to enforce policies and provide oversight of programs directly impacted 1 of 20 patients (#5) whose records were reviewed and had the potential to impact all patients receiving care at the ASC. This resulted in the failure to protect patient rights and to provide direction to staff. Findings include: 1. Patient #5's medical record documented a 65 year old female who presented to the ASC on 9/10/13. A history and physical by the surgeon, dated 9/06/13, stated Patient #5 had left facial weakness from a prior surgery. The history and physical stated she was scheduled for left upper eyelid gold weight replacement, left canthoplasty (lifting the corner of the left eye), and left brow lift. The operative consent, dated 9/10/13 at 9:35 AM, stated Patient #5 consented to "left gold weight placement and a left endotine brow lift and left lower canthoplasty."	Q 040	See item #1 on attached Corrective Action Plan.	

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Q 040	Continued From page 2 A witness account on an "INCIDENT/ADVERSE EVENT REPORT FORM," dated 9/10/13, stated the staff member "was in OR providing lunch relief for CRNA. Noticed that surgeon was working on the right side. Surgical consent stated that procedure was to be on the left side (brow and eyelid). I confirmed this with [the] (circulating nurse). The procedure was stopped and the surgical side was correctly identified as the left side. Surgery was then directed to the left side." The form referred to the procedure performed on Patient #5 on 9/10/13. Two operative reports, both dated 9/10/13, were present in Patient #5's record. One operative report stated "A no charge procedure brow lift was performed." The report stated "The brow lift was performed on the right side. This was brow lift at no charge just to make her brows and forehead equal." No nursing or physician progress notes documented the brow lift was performed on the wrong side. The second operative report, dated 9/10/13, stated Patient #5 had "Left endoscopic brow lift and left gold weight placement in the upper lid." The report described the procedure. The only evidence of Patient #5's wrong side surgery in her medical record was a form titled "Quality Measures," not dated. It was a quality improvement form that was found in all patient records. It listed possible adverse events that could occur during procedures including "Patient Burn...Patient Fall...Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant...[and] Hospital Transfer/Admission." The box "Wrong Site, Wrong Side, Wrong Patient,	Q 040		

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Q 040	Continued From page 3 Wrong Procedure, Wrong Implant" was checked. No details were documented. No documentation was present in the medical record that Patient #5 was informed of the wrong side surgery. The RN who cared for Patient #5 pre-operatively was interviewed on 9/04/14 at 11:15 AM. She stated she was aware of Patient #5's wrong side surgery. She reviewed the record and confirmed no nursing or physician documentation describing the event was present. She also confirmed there was no documentation in the record stating Patient #5 had been informed of the wrong side surgery. Patient #5 was interviewed by phone on 9/03/14 at 9:20 AM. She was asked why surgery was performed on her right brow when her operative consent was for surgery on her left brow. She stated the physician told her surgery was done on her right brow at no charge in order to even up the two sides of her face. The policy "SYSTEM FOR NOTIFYING A PATIENT OF A SERIOUS ADVERSE INCIDENT," dated 11/10, stated the physician would inform patients and/or caregivers "...of any serious adverse incident." This policy was not followed. The physician, who was President of the Medical Staff and also one of the owners, was interviewed on 9/4/14 at 8:10 AM. He confirmed Patient #5's wrong side surgery case was discussed by the Governing Body. He stated he was not aware that the event had not been disclosed to Patient #5 as called for in the policy.	Q 040		

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Q 040	Continued From page 4 The Governing Body failed to ensure the policy regarding informing patients of adverse events was enforced. 2. Refer to Q80 as it refers to the failure of the Governing Body to ensure a QAPI program was developed, implemented and maintained. 3. Refer to Q240 as it refers to the failure of the Governing Body to ensure a comprehensive infection control program was developed, implemented and monitored. The cumulative effect of these omissions resulted in the inability of the ASC to enforce policies and maintain programs.	Q 040	See item #2 on attached Corrective Action plan.	
Q 080	416.43 QUALITY ASSESSMENT AND PERFORMANCE The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on staff interview and review of policies, meeting minutes, medical records, and quality program documents, it was determined the ASC failed to ensure a QAPI program was developed, implemented and maintained. This impeded the ability of the ASC to evaluate its practices and improve care. Findings include: 1. Refer to Q81 as it relates to the ASC's failure to ensure its quality program was defined and direction was provided to staff responsible for the program. 2. Refer to Q82 as it relates to the ASC's failure to ensure its quality program tracked adverse	Q 080	See items #1, #2 and #3 on attached corrective Action plan.	

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Q 080	Continued From page 5 patient events and examined their causes. 3. Refer to Q83 as it relates to the ASC's failure to ensure distinct improvement projects were conducted. 4. Refer to Q84 as it relates to the Governing Body's failure to ensure the QAPI program was defined, implemented and maintained. The cumulative effect of these systematic failures resulted in the inability of the ASC's Governing Body to ensure programs and services were monitored.	Q 080		
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and	Q 081	See item #3 on attached Corrective Action plan.	

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Q 081	Continued From page 6 quality of care. This STANDARD is not met as evidenced by: Based on staff interviews, review of policies, review of meeting minutes and quality program documents, it was determined the ASC failed to ensure its quality program was defined and failed to ensure that direction was provided to staff responsible for the program. This prevented the ASC from analyzing its processes in order to improve patient care and patient safety. Findings include: The policy "AFFIRMATION OF RESPONSIBLE COMMITTEE," issued 11/10, stated "The Organization hereby constitutes and establishes the QAPI/Risk Management Committee as the Committee responsible for investigating and determining applicable standards of care required by state risk management laws and patient safety laws..." This policy described the QAPI program objectives, organization, scope and mechanisms for overseeing the effectiveness of monitoring, evaluation, improvement and problem solving activities. The policy stated "The Governing Body shall ensure that an effective linkage between QAPI ... is in place and is maintained within the organization." The policy "QUALITY ASSESSMENT/PERFORMANCE IMPROVEMENT RISK MANAGEMENT COMMITTEE," dated 11/10, stated a "QAPIRM Committee" would meet at least quarterly with the Medical Advisory Committee to discuss quality and safety issues. The policy stated the	Q 081		

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Q 081	Continued From page 7 committee would document a quarterly report. No QAPIRM Committee minutes or reports were documented between 9/01/13 and 9/04/14. No QAPI plan or program that defined the ASC's activities to demonstrate measurable improvement in patient health outcomes or improved safety were documented. The ASC's QAPI activities did not include distinct quality indicators to monitor. Also, the ASC did not have documentation to show high risk, high volume or problem prone areas had been identified in order to develop quality indicators. The RN responsible for the ASC's quality activities was interviewed on 9/02/14 beginning at 10:35 AM. She confirmed the QAPIRM Committee as outlined in polices had not met and there was no documentation of the Committee's activities. She also confirmed high risk, high volume, or problem prone areas had not been identified. The ASC failed to develop and define a QAPI program.	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	Q 082	See item # 3 on attached Corrective Action plan.	

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Q 082	Continued From page 8 improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on patient and staff interview and review of medical records, meeting minutes, and quality program documents, it was determined the ASC failed to ensure adverse patient events were examined for 1 of 1 patient (#5) who had a documented adverse event. The failure to analyze adverse patient events had the potential to impact all patients receiving care at the facility and resulted in the ASC's inability to take action to improve care and prevent future events being impeded. Findings include: A witness account on an "INCIDENT/ADVERSE EVENT REPORT FORM," dated 9/10/13, stated the staff member "was in OR providing lunch relief for CRNA. Noticed that surgeon was working on the right side. Surgical consent stated that procedure was to be on the left side (brow and eyelid). I confirmed this with [the] (circulating nurse). The procedure was stopped and the surgical side was correctly identified as the left side. Surgery was then directed to the left side." The form referred to the procedure performed on Patient #5 on 9/10/13.	Q 082		

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Q 082	Continued From page 9 The only evidence of Patient #5's wrong side surgery in her medical record was a form titled "Quality Measures," not dated. It was a quality improvement form that was found in all patient records. It listed possible adverse events that could occur during procedures including "Patient Burn...Patient Fall...Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant...[and] Hospital Transfer/Admission." The box "Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant" was checked. No details were documented. A causal analysis of the event and measures taken to prevent similar events from occurring in the future were not documented. Discussion of the event was not documented in Governing Body minutes and no QAPIRM Committee minutes or reports were documented between 9/01/13 and 9/04/14. The RN responsible for the ASC's quality activities was interviewed on 9/02/14 beginning at 10:35 AM. She stated she was not aware of any causal analysis or any action taken regarding the wrong side surgery event. The President of the Medical Staff was interviewed on 9/4/14 at 8:10 AM. He stated the wrong side surgery case was discussed in a medical staff meeting but was not documented. He confirmed a causal analysis of the incident was not conducted. The ASC failed to document, analyze, and implement improvement strategies to prevent adverse patient events.	Q 082		
Q 083	416.43(d) PERFORMANCE IMPROVEMENT	Q 083		

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Q 083	Continued From page 10 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, review of policies and quality program documents, it was determined the ASC failed to ensure distinct quality improvement projects were defined and conducted. This limited the ASC's opportunities to improve patient care and patient safety. Findings include: The ASC's "AFFIRMATION OF RESPONSIBLE COMMITTEE" policy, issued 11/10, and the "QUALITY ASSESSMENT/PERFORMANCE IMPROVEMENT RISK MANAGEMENT COMMITTEE" policy, dated 11/10, were reviewed. The policies did not include a definition for distinct quality improvement projects, they did not require the ASC to conduct such projects and no distinct quality improvement projects were documented between 9/01/13 and 9/04/14. The RN responsible for the ASC's quality activities was interviewed on 9/02/14 beginning at 10:35 AM. She confirmed the facility had not conducted a quality improvement project.	Q 083	See Item # 3 on the attached Corrective Action plan.	

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Q 083	Continued From page 11 The ASC failed to conduct distinct quality improvement projects.	Q 083		
Q 084	416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. This STANDARD is not met as evidenced by: Based on review of policies, Governing Body Meeting Minutes, personnel files and job descriptions and staff interviews, 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 to staff responsible for implementing the program. Findings include: The policy "AFFIRMATION OF RESPONSIBLE COMMITTEE," issued 11/10, stated "The Governing Body shall ensure that an effective linkage between QAPI ... is in place and is maintained within the organization." Four sets of Governing Body Meeting Minutes were documented between 9/01/13 and 9/04/14.	Q 084	See Item #1 on attached Corrective Action plan.	

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Q 084	Continued From page 12 The minutes were dated 5/19/14, 6/5/14, 7/24/14, and 8/14/14. None of the minutes included information related to QAPI activities or the review of QAPI data. The President of the Medical Staff, who was also one of the owners, was interviewed on 9/4/14 at 8:10 AM. He stated QAPI activities was not an agenda item for Governing Body meetings. He stated quality activities had been discussed in meetings but had not been documented. He stated a quality plan that defined the ASC's QAPI program had not been developed and approved by the Governing Body. Additionally, the "AFFIRMATION OF RESPONSIBLE COMMITTEE" policy stated "The Organization hereby constitutes and establishes the QAPI/Risk Management Committee as the Committee responsible for investigating and determining applicable standards of care required by state risk management laws and patient safety laws..." The personnel file for the RN responsible for the facility's QAPI program was reviewed. The RN's job description did not include information related to her QAPI responsibilities and training related to maintaining a QAPI program was not present. The RN was interviewed on 9/02/14 beginning at 10:35 AM. She stated she did not have a job description in relation to her duties with the QAPI program, she did not have any training specific to maintaining a QAPI program and she could not articulate the number of hours she spent performing QAPI related activities. The Governing Body failed to provided necessary	Q 084	See Item #4 on attached Corrective Action plan.	

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Q 084	Continued From page 13 oversight and monitoring to ensure the QAPI program was developed, implemented, and maintained by qualified staff.	Q 084		
Q 105	416.44(c) EMERGENCY EQUIPMENT The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC' s operating room. The equipment must meet the following requirements: (1) Be immediately available for use during emergency situations. (2) Be appropriate for the facility's patient population. (3) Be maintained by appropriate personnel. This STANDARD is not met as evidenced by: Based on observations, staff interviews, and record review, it was determined the ASC failed to ensure all emergency medical equipment was maintained for all patients receiving care at the facility. This resulted in the potential for patients' health and safety to be compromised in the event of a medical emergency. Findings include: 1. The facility's "Checking the Emergency Cart" policy, dated 11/10, stated,"the crash cart will be opened monthly and checked for outdate [sic] medications." However, a tour of the facility was conducted on 9/02/14 at 9:40 AM. Medications identified in the crash cart policy were expired, as follows: - 2 vials of Dopamine HCL 400 mg 40 mg/ml, with an expiration date of 12/1/13. - Phenytoin Sodium 100 mg/2ml, with an expiration date of 8/14.	Q 105	See Item #5 on attached Corrective Action plan.	

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Q 105	Continued From page 14 During an interview on 9/02/14 beginning at 9:50 AM, an RN confirmed the above drugs were expired. The RN stated the medications were on order and were being tracked because of a shortage. However, after review of the RN's tracking log, one of the medications (Phenytoin Sodium), arrived at the ASC, but was not placed into the crash cart. The RN confirmed she did not know that the medication (Phenytoin Sodium) had arrived at the ASC, and she needed a better tracking system. She could not verify the medication (Dopamine) had not arrived at the ASC. The facility failed to ensure the crash cart was stocked and maintained with emergency medications. 2. The facility's "Checking the Emergency Cart" policy, dated 11/10, stated, "check the presence of, and workability of, suction and O2 equipment, cardiac press board, electric cords and alarms. Cardiac monitors-check at the beginning of each patient day for proper function and turned off at the end of the day. Portable suction units (battery back-up) - check at the beginning of each patient day for proper function and turn off at the end of the day. Portable O2 tanks - check at the beginning of each day." However, the most recent documented emergency equipment checklist was dated 8/18/14. During an interview on 9/02/14 beginning at 9:50 AM, an RN confirmed the above emergency equipment had been checked on 8/18/14. She also confirmed daily checks of the emergency	Q 105		

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Q 105	Continued From page 15 equipment were not being completed. The facility failed to ensure emergency equipment checks were being completed as required by the ASC's policy.	Q 105		
Q 225	416.50(d)(4),(5), & (6) SUBMISSION AND INVESTIGATION OF GRIEVANCES The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met: (1) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished. (3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed. This STANDARD is not met as evidenced by: Based on staff interview and review of policies and patient rights information, it was determined the ASC failed to ensure a procedure for documenting the existence, submission, investigation, and disposition of grievances had	Q 225	See item #6 on attached Corrective Action plan.	

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Q 225	Continued From page 16 been developed and implemented. This resulted in a lack of a clear system for patients to voice grievances and for staff to respond to those grievances. Findings include: The form "PATIENT RIGHTS AND RESPONSIBILITIES," not dated, was given to all patients prior to surgery. The form stated "The patient has the right to voice grievances and recommended changes in policies and services to the center's staff, the operator and the governing state agency without fear of reprisal." The form did not explain how patients could file a grievance with the ASC. A procedure directing staff how to handle a grievance, including the documentation of grievances, was not available and a grievance log was not available. RN A was interviewed on 9/04/14 at 12:00 noon. She stated the ASC did not have a policy and procedure for grievances. The ASC failed to ensure a policy regarding grievances was developed.	Q 225		
Q 240	416.51 INFECTION CONTROL The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented and monitored for staff and all patients receiving care	Q 240	See item #7 on attached Corrective Action plan.	

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Q 240	Continued From page 17 at the facility. This resulted in the inability of the facility to minimize infections and communicable diseases. Findings include: 1. Refer to Q242 as it relates to the ASC's failure to ensure an ongoing program to prevent, control, and investigate infections and communicable diseases was maintained.	Q 240		
Q 241	416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, interview and policy review, it was determined the facility failed to maintain a sanitary and functional environment for all patients receiving care at the facility. This resulted in the potential for infections to occur. Findings include: 1. The ASC's Policy and Procedure Manual for Infection Control, dated 12/12, included a section for housekeeping and infection control practices in the OR/Procedure room suite. The section stated "Nursing, OR and Housekeeping Personnel; cleaning shall be performed on a regular basis to reduce the amount of dust, organic debris and microbial load. Operating rooms shall be cleaned before and after each procedure and at the end of the day. Equipment coming into the sterile environment is thoroughly inspected and cleaned prior to entering this area. Nursing personnel are responsible for cleaning between cases and at the end of procedures.	Q 241	See item #8 on attached Corrective Action plan.	

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Q 241	Continued From page 18 Nursing personnel are responsible for the terminal cleaning of equipment and for cleaning the interiors of cupboards and carts. Between procedure cleaning is performed and shall include visual inspection for cleanliness before equipment and supplies are brought into the room." During an observation of a surgery in OR 2 on 9/04/14 beginning at 10:30 AM, it was noted the portable x-ray view box had a build-up of dust on the horizontal and vertical surfaces. Dust and debris was also noted on the top of a cart which held a machine. During an interview on 9/04/14 beginning at 11:55 AM, the circulating RN confirmed dust and debris on the equipment in the OR room. She stated ASC staff were responsible for cleaning before equipment entering the room, after procedures and at the end of the day. The ASC failed to ensure cleaning was sufficiently completed and monitored necessary to maintain a sanitary environment. 2. During a tour of the ASC on 9/02/14 beginning at 9:05 AM, the "BIOHAZARD" room was observed. The room included two containers labeled "BIOHAZARD" with red bags as well as patient supplies, such as specimen containers, stored on a shelf. The RN escorting the surveyors on the tour confirmed the specimen containers were used for samples from patients, and taken into the OR when surgery was being conducted. The facility failed to ensure patient supplies were not stored in the same vicinity as biohazard	Q 241		

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Q 241	Continued From page 19 material.	Q 241		
Q 242	416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: Based on policy review and staff interview, it was determined the ASC failed to ensure an ongoing infection control program was maintained for staff and all patients receiving care at the facility. This resulted in the facility's inability to minimize patients' risks of infection. Findings include: 1. The ASC's "INFECTION PREVENTION PROGRAM AND COMMITTEE" policy, dated 7/13, stated the "Infection Prevention Program is the plan this organization shall implement for controlling infectious disease hazards and surgical site infections. The program is based upon guidelines established by the CDC, OSHA, CMS, APIC, AORN, AAMI, state licensing and accreditation agencies." However, there was no evidence the ASC had implemented an infection control program that reflected the use of the nationally recognized guidelines identified in the policy. The Infection Control RN was interviewed on 9/04/14 beginning at 8:30 AM. She confirmed the	Q 242	See item #7 on attached Corrective Action plan.	

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Q 242	Continued From page 20 ASC did not have an infection prevention program plan, with goals or tracking methods for the year 2014. The facility failed to ensure an ongoing infection control program based on nationally recognized standards was maintained. 2. Refer to Q241 as it relates to the ASC's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice. 3. Refer to Q244 as it relates to the facility's failure to ensure infection control was addressed as an integral part of the ASC's QAPI program.	Q 242		
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 staff interview and review of facility policies and records, it was determined the ASC failed to ensure the infection control program was incorporated into the facility QAPI program for all patients receiving services at the ASC. This resulted in the inability of the ASC to evaluate its infection control processes necessary for improving the quality of patient care. Findings include: The policy "QUALITY ASSESSMENT/PERFORMANCE	Q 244	See item #7 on attached Corrective Action plan.	

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Q 244	Continued From page 21 IMPROVEMENT RISK MANAGEMENT COMMITTEE," dated 11/10, which included a section for infection control, stated the purpose of the policy was to monitor and assess the quality of patient care, to enhance and assure staff development, to assess and evaluate criteria, and standard services offered. However, there was no evidence to indicate the infection control program had been incorporated into the QAPI program in accordance with the policy. The Infection Control RN was interviewed on 9/04/14 at 9:20 AM. She stated the infection control program was not incorporated in the QAPI program and that the ASC had not developed a 2014 QAPI plan for monitoring purposes. She confirmed there was no documentation of quality reports or that formal meetings had been held at any level within the organization to discuss quality issues, including infection control, for the year 2014 The ASC failed to ensure infection control was incorporated into the facility's QAPI program.	Q 244		

Southwest Idaho Surgery Center, Inc.
Corrective Action Plan - 2014

1) The Southwest Idaho Surgery Center, Inc.'s (ASC) governing body meets monthly. Minutes are taken and filed for each meeting. The Quality Assurance Performance Improvement (QAPI) and Infection Control (IC) data and information will be reviewed and discussed quarterly and included in the meeting minutes. The QAPI policy will be revised by Todd Rustad, MD (President) and Tracy McGeorge (Administrator) to reflect this. This will be completed by the Administrator by November 15, 2014.

2) Incident/Adverse events, including peri- and post-operative complications, will be recorded on Incident/Adverse Event Report Forms. These forms will be available in the surgery center and outpatient clinic to facilitate identification of delayed adverse events and post-operative infections, etc. Clinical staff will be uniformly updated on the use of these forms by all surgery-center credentialed physicians by October 15, 2014. The surgery center staff has been working with these forms, but the form and its use will be reviewed at the November 3, 2014 staff meeting.

Incident/Adverse reports will be given to the ASC Manager (role currently being filled by Administrator) for complete investigation and root cause analysis when indicated. Once complete, the manager will provide the information to the President of the ACS for review. Adverse events will be reviewed quarterly by the Governing Body after investigation and if necessary, procedural changes will be implemented. Serious incidents will be escalated to the President immediately who may call a special meeting of the Governing Body. When patient notification is required, it will be handled by the surgeon involved and documented in the patient's chart. The manager will be responsible for reviewing the chart to confirm the patient has been notified and report to the Governing Board when this has not been completed. All events will be reviewed at quarterly meetings with consideration of further study when appropriate.

3) As previously noted, QAPI policy will be reviewed and revised. Currently, the ACS has 4 measurements it is tracking for 2014. They include:

- Patient Satisfaction through patient surveys
- Incident reports
- Chart Audits
- Study of on-time starts for surgeries

Studies were completed in 2013 and are enclosed. These will be reviewed and signed at the Governing Board meeting to be held on October 2, 2014.

At the October 2 meeting, new measures will be proposed for the 2015 year with attention to high risk, high volume on problem-prone areas. Data from the 2014 studies will be gathered and presented at the December meeting of the Governing Board. 2015 QAPI measures will be considered and finalized in the December meeting based on results of the 2014 findings and measurements proposed in October.

4) A revised job description will be created and reviewed with the staff RN (Lisa Peters) who is responsible for QAPI measurements by October 15. An online training program through Medline University will be completed by the RN by October 31. The staff RN will outline and review the elements of QAPI at an AC5 staff meeting in December with subsequent updates recorded in the minutes of these meetings. Dedicated time will be created for the RN to complete her QAPI responsibilities. This is estimated to be approximately 2 hours per week.

5) A log to indicate that the emergency cart is being inspected daily will be created by the Administrator by October 3, 2014. This log will be kept with the crash cart and once the page is full, filed by the surgery center manager. Expired medications have been removed from the cart as of September 29, 2014. Medications on the emergency cart will be reviewed monthly for expiration.

A new medication tracking system will be created by the Administrator by October 3, 2014. This system will indicate the date and amount of medication ordered, whether or not a medication is on backorder or if there is a shortage and a date the order is received.

6) A grievance policy will be drafted by the Administrator and submitted to the Governing Body for review and approval. This will be submitted to the Governing Body at the October 2 meeting. The policy will include timeframe for review and response of submitted grievances with a written response being sent to the patient within 14 days of receipt of the grievance. The ACS staff was educated about the difference between a complaint and a grievance at a staff meeting on September 26, 2014. The patient rights information that is distributed to a patient will be revised to include the name, address and phone number to file a grievance. Once the grievance process is approved by the Governing Body, the revised patient rights paperwork will be sent to print. The anticipated completion date is October 15, 2014.

7) Infection Control will be discussed at the October 2 Governing Board Meeting. Proposed measures for compliance and improvement will include post-operative surgical infections and hand hygiene. These measures will be incorporated with the QAPI program.

A revised job description will be created and reviewed with the staff RN (Carla Pladsen) who is responsible for Infection Control by October 15. An online training program through Association of perioperative Registered Nurses will be completed by the RN as well as the President of the ASC by October 31. The staff RN will outline and review the elements of IC at an ACS staff meeting in December with subsequent ongoing updates at least quarterly as new data is available. Dedicated time will be created for the RN to complete her IC responsibilities. This is estimated to be approximately 1 hour per week.

8) All ASC nurses were reminded about our cleaning procedures and policy at a staff meeting on September 26. Unannounced audits to ensure thorough cleaning will be completed monthly.

All patient supplies have been removed from the biohazard area as of September 26, 2014.