IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

TAMARA PRISOCK—ADMINISTRATOR
DIVISION OF LICENSING & CERTIFICATION
DEBBY RANSOM, R.N., R.H.I.T. – Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
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Boise, Idaho 83720-0009
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April 28, 2017

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

RE: Idaho Foot Surgery Center, Provider #13C0001008

Dear Dr. Kovac:

Based on the survey completed at Idaho Foot Surgery Center, on April 20, 2017, by our staff, we have determined Idaho Foot Surgery Center is out of compliance with the Medicare ASC Condition for Coverage of **Quality Assessment and Performance (42 CFR 416.43)**. To participate as a provider of services in the Medicare Program, an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

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

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

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 June 4, 2017. 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 May 25, 2017.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **May 9, 2017**.

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

We urge you to begin correction immediately.

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

Sincerely,

NICOLE WISENOR, Supervisor
Non-Long Term Care

NW/pmt
Enclosures

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

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001008	A. BUILDING _____ B. WING _____	04/20/2017

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IDAHO FOOT SURGERY CENTER	1540 ELK CREEK DRIVE IDAHO FALLS, ID 83404

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Q 000	INITIAL COMMENTS The following deficiencies were cited during the recertification survey of your Ambulatory Surgery Center conducted from 4/18/17 through 4/20/17. Surveyors conducting the recertification survey were: Gary Guiles, RN, HFS, Team Leader Trish O'Hara, RN, HFS Acronyms used in this report include: ASC - Ambulatory Surgery Center QAPI - Quality Assessment Performance Improvement	Q 000	RECEIVED MAY 17 2017 FACILITY STANDARDS	
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 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 record review and interview, it was determined the facility failed to provide documentation of an emergency preparedness	Q 043	416.41(c) DISASTER PREPAREDNESS PLAN IFSC's current Emergency Preparedness Plan will be amended to include: guidance of emergency care for our patients, staff, and other individuals within the facility, coordination of emergency services with local authorities, evaluation of risk by means of a hazard and vulnerability assessment, training of staff members and annual conduction of drills. A plan will be in place that identifies and provides for the prevention and mitigation for disasters.A hazard and vulnerability assessment has been completed for the highest risk disasters in the area that were previously identified by Bonneville County Emergency Management. Policies and procedures for each disaster will include plans for evacuation, tracking patients, documentation, transportation, and preparation for prevention in order to survive the potential disaster. The hazard	5/20/17

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Alicia Tye	Administrator	5/9/17

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 043	Continued From page 1 plan which outlined the facility roles in specific emergencies. Failure to provide an emergency plan which identifies and provides for the prevention, protection and mitigation for natural disasters or other hazards which may occur had the potential to hinder facility response and further expose the patients, staff and others to the risks associated with the event. Findings include: The facility's Disaster Preparedness Plan documentation was reviewed. The documentation did not include the following: - No Hazard Vulnerability analysis was conducted to identify site specific hazards or risks. - No information was provided regarding coordination or attempts to coordinate with local jurisdictional authorities, such as the County Disaster agencies, since 2013. - No information as to what specific activities were to be taken to eliminate or reduce the probability of an event was present. - The plan did not contain specific information regarding how the ASC was to meet the needs of the patients, staff and others in the absence of essential services. - The plan did not provide information related to actions taken for impending threats, or during and after an event necessary to address immediate and short term effects. - The plan did not identify activities to be implemented during and after an event to return the ASC to its usual state.	Q 043	Continued from page 1 and vulnerability assessment has been completed on May 5/5/17 (Appendix A). The coordination with local emergency management was conducted on 4/7/17 (Appendix B).The anticipated date for policy and procedures to be fully amended by is 5/15/17. The annual fire drill has been conducted on 4/20/17 (Appendix C). The Emergency Preparedness Plan will be evaluated annually and documented within governing body minutes. Supporting signatures will be documented within the Fire and Disaster Emergency Preparedness Manual as well. Governing Body will be responsible for complete oversight and approval of policy changes.	

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Q 043	Continued From page 2 - The plan did not provide information or documentation of staff education or training on the components of emergency preparedness. - There was no documentation that an annual drill had been conducted. When asked, on 4/26/17 at 9:55 AM, the Administrator stated the documentation provided was the only Emergency Plan the facility had.	Q 043		
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 QAPI policies, meeting minutes, and QAPI documents, it was determined the ASC failed to ensure a comprehensive 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 an ongoing quality program that demonstrated measurable improvement in patient health outcomes was developed and maintained. 2. Refer to Q82 as it relates to the ASC's failure to ensure quality indicator data was used to monitor the effectiveness and safety of its services. 3. Refer to Q83 as it relates to the ASC's failure to ensure distinct quality improvement projects	Q 080	416.43 QUALITY ASSESSMENT AND PERFORMANCE The Quality Assessment and Performance Improvement Program has been reviewed and revised. It ensures a reliable, repeated process is undergone to sustain improved performance over time. The QAPI program will guide IFSC in the evaluation of our policies and practices in order to improve patient care and safety. Within this PoC are procedures set forth to meet the following findings: Q081as it relates to establishing a QAPI program that measures, analyses and tracks quality indicators, Q082 as it relates to a QAPI program that gathers appropriate quality indicator data, Q083 as it relates to developing and conducting of QAPI performance improvement projects, Q84 as it relates to oversight of governing body to the QAPI program. The QAPI program revision and updates have been completed as of 5/9/17. For each of the standards found deficient, an individual completion date has been provided for corrections. The QAPI program will be revised	5/8/17

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Q 080	Continued From page 3 were conducted. 4. Refer to Q84 as it relates to the Governing Body's failure to ensure a QAPI program was implemented and maintained. The cumulative effect of these systemic practices prevented the ASC from evaluating its practices in order to improve care.	Q 080	Continued from page 3 annually. This will be documented within the QAPI Manual. Governing body has approved the modifications of the program on 5/8/17 and will be responsible for completion of the annual revisions.	
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care.	Q 081	416.43(a), 416.43(c)(1)PROGRAM SCOPE; PROGRAM ACTIVITIES The QI/QAPI committee meetings have been scheduled to meet quarterly; exact anticipated dates have been assigned. The "QAPI Committee Member Responsibilities"policy has changed from requiring one study quarterly to two studies annually. Studies will be based on quality indicators and adverse events. Quarterly QI meetings will ensure ongoing and adequate attention is placed on our QAPI program and activities. They will continue to serve as a means to monitor our procedures for patient safety and quality of care. The reduction in the number of required studies will provide the committee an increased amount of time for the dedication of each study to ensure that positive outcomes are derived from each to improve the quality of patient care. QI meetings will be held on the anticipated scheduled dates and will be documented on the "IFSC QI Meeting Schedule" (Appendix D) and also by meeting minutes. The " QAPI Committee Member Responsibilities" policy has been updated to state that two studies will be initiated annually based on problem areas	5/8/17

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Q 081	Continued From page 4 This STANDARD is not met as evidenced by: Based on staff interview and review of policies and QAPI documents, it was determined the ASC failed to ensure an ongoing quality program that demonstrated measurable improvement in patient health outcomes was developed and maintained. This resulted in the inability of the ASC to evaluate its processes of care. Findings include: The policy "QAPI COMMITTEE MEMBER RESPONSIBILITIES," dated 8/17/15, stated the committee would meet quarterly to oversee the QAPI program. The policy further stated 1 QAPI study would be conducted each quarter. The last documented meeting of the QAPI Committee was dated 1/28/16, over 14 months prior to the survey. A current QAPI plan, including quality indicators, was not present. No patient care data from the QAPI program was documented between 2/01/16 and 4/18/17. The Administrator was interviewed on 4/19/17 beginning at 2:35 PM. She stated the QAPI Committee had not met since January 2016. She stated no patient care data had been gathered or analyzed since that time. She stated a current QAPI plan had not been developed.	Q 081	Continued from page 4 identified by quality indicators and adverse event reports. A QI meeting for the 2nd quarter was completed on 4/20/17. The next QI meeting for the 3rd quarter has been scheduled for 7/10/17. The "QAPI Committee Member Responsibilities" policy has been updated by the Administrator as of 5/6/17 (Appendix E). Documentation of actual meeting dates will be entered on the "IFSC QI Meeting Schedule" in order to monitor and track completion of meetings. IFSC's Indicator Log and Incident reports will be continue to be reviewed quarterly in order to identify issues requiring to be one of the two annual QAPI studies. Governing Body has established the anticipated QI meeting dates and the Administrator will ensure meetings are conducted on those dates. Governing Body has approved changes made by the Administrator to the " QAPI Committee Member Responsibilities" policy. QI/QAPI Committee will review the Indicator log and Incident Reports quarterly and from there assign two study topics annually.	
Q 082	The ASC did not have a current QAPI program. 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	Q 082	416.43(b), 416.43(c)(2),416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES Two QAPI studies have been chosen and data collection for them is currently under way. The revised list of quality indicators	5/8/17

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Q 082	Continued From page 5 relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents, it was determined the ASC failed to ensure quality indicator data was used to monitor the effectiveness and safety of its services. This resulted in a lack of feedback to persons responsible for running the agency. Findings include: A current QAPI plan, including specific quality indicators used to collect data, was not present. No patient care data from the QAPI program was documented between 2/01/16 and 4/18/17. The Administrator was interviewed on 4/19/17 beginning at 2:35 PM. She stated a current QAPI plan had not been developed. She stated no patient care data had been gathered or analyzed	Q 082	Continued from page 5 has served as a basis for topic selection. The studies we will continue to work on for the remainder of the year are "Tourniquet Times" and "Surgery Times". The gathering and analyzation of performance data will enable us to track and evaluate the effectiveness and safety of patient care, as it relates to tourniquet times and surgery times. Data collection tools have been created to track each patient's tourniquet and surgery times (Appendix F & G). QI/QAPI committee will analyze data and determine if there is sufficient data. If so, identification of areas that may need improvement will be completed. The QI/QAPI committee will initiate methods or implement changes to our policies and procedures in order to improve and prevent the identified problem areas. Data for the Tourniquet Time study has been retrospectively collected from surgeries performed between the dates of Jan. 2017 and May 2017. The data gathered will be analyzed at the QI meeting scheduled for 7/10/17. The data collection phase of our Surgery Times study is anticipated to end by 10/ 2/17 (end of 3rd quarter), due to our low case volume. In order to ensure the new changes/additions to policies and procedures is effective, quality indicators related to the addressed problem area will continue to be collected on an ongoing basis. The Administrator will be responsible for creating data collection tools and overseeing data collection. QI/QAPI committee will be responsible for analyzation of data.	

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Q 082	Continued From page 6 since January 2016. The ASC did not gather and analyze data.	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 QAPI documents, it was determined the ASC failed to ensure distinct quality improvement projects were conducted. This impeded the ASC's ability to examine its processes in depth. Findings include: No distinct quality improvement projects involving patient care were documented between 2/01/16 and 4/18/17. The Administrator was interviewed on 4/19/17 beginning at 2:35 PM. She stated no distinct quality improvement projects had been conducted since January 2016. The ASC did not conduct distinct quality improvement projects.	Q 083	416.43(d) PERFORMANCE IMPROVEMENT PROJECTS For each QAPI study, documentation will be completed with a "10 Step" write up (Appendix H). The form provides explanation of the following: purpose, goal, description of data, evidence of data collection, data analysis, comparison of actual to goal, corrective actions, re-measurement, additional corrective action, and communication of results. It provides a thorough description of the quality improvement project. Upon the initiation of a study, the purpose, goal, and description of data will be completed. Once data has been collected, the remaining steps will be completed. The "10 Step" for the Tourniquet Time study is anticipated to be fully completed with the first phase on 7/10/17 (after all data is collected). The "10 Step" for the Surgery Times Study is anticipated to be fully complete with the first phase by 1/8/18, upon completion of data collection. All forms will be kept in the QAPI Manual and checked off a master index within the Manual (Appendix I). Governing Body will be responsible for overseeing the quality improvement project and specifically having oversight of the QAPI coordinator and committee. The "10-Step" write ups are the responsibility of the QAPI coordinator. The QAPI committee is responsible for data collection. All staff members will be responsible for the implementation of	5/8/17
Q 084	416.43(e) GOVERNING BODY RESPONSIBILITIES	Q 084		

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Q 084	Continued From page 7 The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents, it was determined the ASC failed to ensure the Governing Body implemented and maintained the QAPI program. This resulted in a lack of direction to staff and a lack of oversight of the QAPI program. Findings include: No current plan for the QAPI program was present. No quality indicators had been approved by the Governing Body. No patient care data from the QAPI program was documented between 2/01/16 and 4/18/17. The Physician Owner of the ASC was interviewed on 4/20/17 beginning at 2:20 PM. He stated the QAPI program had not been active since January 2016. He stated the Governing Body had not addressed the program's lapse. The Governing Body failed to direct and oversee the QAPI program.	Q 084	Continued from page 7 changes/additions to policy and procedures that result from study corrective actions. The QAPI Coordinator will ensure the master index of studies is kept current. Q 084 - 416.43(e) GOVERNING BODY RESPONSIBILITIES Governing body will document quarterly review of the QAPI program within the meeting's agenda/minutes. The QAPI program will be provided with the required leadership and guidance of the Governing Body. Quality improvement projects will be directly overseen and evaluated for effectiveness. Governing Body will oversee implementation of changes required for improvement in patient care, environment, and safety. Governing Body will maintain quality improvement projects ongoing. A Governing Body Meeting has been completed on 5/8/17 (Appendix J). This meeting and all subsequent meetings will have record of QAPI Program discussion. Acknowledgment signatures will be provided for each meeting minutes. The Administrator will be responsible for the placement of the QAPI program on the meeting agenda. All Governing Body members will be responsible for providing their signature to indicate active participation and verification of content.	5/8/17

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Q 223	Continued From page 8	Q 223		
Q 223	416.50(b) NOTICE - PHYSICIAN OWNERSHIP The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing. This STANDARD is not met as evidenced by: Based on staff interview and review of medical records and patient rights information, it was determined the ASC failed to ensure required information regarding physician ownership was disclosed to 11 of 11 patients (Patients #1 - #11) whose records were reviewed. This resulted in a lack of information which patients could use to make informed decisions. Findings include: The Medical Director was interviewed on 4/18/17 at 2:00 PM. He stated he was the sole owner of the facility, having purchased it in 2013. The medical records of Patients #1 - #11 were reviewed and did not contain information that patients were informed of the physician's ownership of the ASC. On 4/19/17 at 10:00 AM, the Administrator provided a patient rights/information packet. She said the packet was provided to patients during their pre-op office visit. She confirmed the packet did not include information pertaining to the ownership of the facility. The ASC did not disclose a physician's financial interest in the facility.	Q 223	416.50(b) NOTICE - PHYSICIAN OWNERSHIP In order to prove the receipt of the "Patient Rights" Brochure, a signature will be obtained from the patient on the pre-operative forms (Appendix K). The "Patient Rights" Brochure provides written disclosure of the physician's ownership to the surgery center. Providing this material to patients will assist them in making informed decision about their care. Patients will receive the brochure and sign on their pre-op forms to indicate they have indeed received information regarding the physician's ownership of IFSC prior to their surgical date. The forms will begin to be used as of 5/5/17. Patient chart audits will be conducted quarterly and verification of the patient initials will be done at that time. The Administrator will be responsible for updating the pre-op form and completing the quarterly audits. The MA/CST will be responsible in obtaining patient acknowledgment.	5/5/17