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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  
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**CERTIFIED MAIL: 7007 3020 0001 4038 9963**

September 5, 2012

Jennie Rawlings, Administrator  
PCS Endoscopy Suite  
500 S 11th Avenue, Suite 303  
Pocatello, ID 83201

RE: PCS Endoscopy Suite, Provider #13C0001041

Dear Ms. Rawlings:

Based on the survey completed at PCS Endoscopy Suite, on August 27, 2012, by our staff, we have determined PCS Endoscopy Suite is out of compliance with the Medicare ASC Condition for Coverage of **Governing Body and Management (42 CFR 416.41); Surgical Services (42 CFR 416.42); Quality Assessment & Performance Improvement (42 CFR 416.43); Nursing Services (42 CFR 416.46); Patient Rights (42 CFR 416.50) and Infection Control (42 CFR 416.51)**. To participate as a provider of services in the Medicare Program, a OR 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 PCS Endoscopy Suite, 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;

Jennie Rawlings, Administrator  
September 5, 2012  
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- 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 11, 2012. 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 1, 2012.**

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **September 17, 2012.**

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,

*Aimee Hastriter by  
I. M. Hara*

AIMEE HASTRITER  
Health Facility Surveyor  
Non-Long Term Care



NICOLE WISENOR  
Co-Supervisor  
Non-Long Term Care

AH/srm

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: 09/04/2012  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>13C0001041</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>08/27/2012</b>
NAME OF PROVIDER OR SUPPLIER  <b>PCS ENDOSCOPY SUITE</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>500 S 11TH AVENUE, SUITE 303 POCATELLO, ID 83201</b>	
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Q 000	<p><b>INITIAL COMMENTS</b></p> <p>The following deficiencies were cited during the recertification survey of your Ambulatory Surgical Center. The surveyors conducting the review were:</p> <p>Aimee Hastriter RN, BS, HFS, Team Leader Trish O'Hara RN, HFS</p> <p>The following acronyms were used in this report:</p> <p>ACLS - Advanced Cardiac Life Support ACG - American College of Gastroenterology AGA - American Gastroenterology Association APIC - Association for Professionals in Infection Control and Epidemiology AORN - Association of Perioperative Registered Nurses ASC - Ambulatory Surgical Center ASGE - American Society for Gastrointestinal Endoscopy CDC - Centers for Disease Control CMA - Certified Medical Assistant EGD - Esophagogastroduodenoscopy HIPAA - Health Insurance Portability and Accountability Act IDAPA - Idaho Administrative Procedures Act IV - Intravenous LPN - Licensed Practical Nurse mg - milligrams ml - milliliters O2 sats - Oxygen saturation level PCS - Primary Care Specialists RN - Registered Nurse QA - Quality Assurance QAPI - Quality Assurance Performance Improvement QI - Quality Improvement</p>	Q 000	<p><b>RECEIVED</b> SEP 19 2012 <b>FACILITY STANDARDS</b></p>	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *Quinn Rawlings* TITLE *ASC administrator* (X6) DATE *9/17/12*

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 SGNA - Society of Gastroenterology Nurses and Associates	Q 000			
Q 002	<p>Immediate Jeopardy was identified at Q242 (Infection Control) and the facility was notified on 8/22/12 at 4:30 PM. An Immediate Plan of Correction was submitted on 8/23/12. The Immediate Jeopardy was abated on 8/23/12.</p> <p>416.2 DEFINITIONS</p> <p>As used in this part: Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part. The ambulatory surgical center must comply with state licensure requirements.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, it was determined that the ASC failed to operate as a distinct entity, functioning only as an ASC during the days and times specifically allotted to the ASC. This failure directly impacted 1 of 1 patients (Patient #22) whose procedure was observed, and had the potential to impact all patients receiving services from the ASC. This failure resulted in the reception area, waiting room, and restrooms being utilized by patients being seen in both the ASC and the clinic during</p>	Q 002	Q002 - Definitions - ASC did not operate as a distinct entity - Effective 8/27/2012 ASC patients are directed to enter through the ASC entrance, check-in with the ASC staff, wait in and discharge through the designated ASC waiting area. Instructions will also be included in the patient paperwork given at consultation. Patients of the ASC and their families will no longer utilize any part of the main clinic, including areas of reception, waiting and restrooms. This will bring the ASC into compliance with operating as a distinct entity during the hours of operation, and will be monitored for compliance by the Director of Nurses (Erika Gunter, RN).	08-27-12	

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Q 002	<p>Continued From page 2</p> <p>ASC operating hours. Findings include:</p> <p>The ASC was located adjacent to the clinic and shared the reception area, waiting room, and restrooms. During the ASC's operating hours, the reception area, waiting room, and restrooms were utilized for patients seen in the ASC and for patients seen by the staff in the clinic before and between endoscopic procedures as follows:</p> <p>The CMA was interviewed on 8/21/12 at 9:00 AM. She explained that ASC patients checked in at the main desk in the office and were then moved to the ASC when it was time for their procedure. She stated that during the hours of ASC operation, non-ASC patients were seen by clinic staff in the clinic. She confirmed that on occasion, the physicians would see a patient in the office in between completing procedures in the ASC.</p> <p>During an interview on 8/21/12 at 9:30 AM, the Administrator confirmed the ASC's operating hours were Wednesday and Friday from 8:30 AM to 12:30 PM.</p> <p>According to the ASC schedule, one patient was scheduled for an endoscopy at 8:30 AM, Patient #22 was scheduled for a colonoscopy at 9:30 AM, and a third patient was scheduled for a colonoscopy at 10:30 AM. Patient #22's procedure, from check in to discharge assessment, was observed from 10:15 AM through 11:20 AM. Following Patient #22's procedure, the two surveyors proceeded back to the adjacent clinic. During the times the surveyors were in the clinic on 8/22/12, from 8:35 AM to 9:00 AM and from 11:20 AM to 12:30 PM,</p>	Q 002		
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Q 002	Continued From page 3 it was observed that numerous individuals, in addition to those patients scheduled for procedures at the ASC, checked in at the front desk to be seen by clinic staff.  The physician was interviewed on 8/27/12 at 12:30 PM. He confirmed that the pre-procedure waiting area and the check in desk were used for both the clinic and the ASC during the operating hours of the ASC. He also confirmed there were occasions when the physician (either he or his partner) would complete an office visit in the clinic in between performing procedures in the ASC.	Q 002			
Q 040	The facility failed to ensure that it functioned as a distinct entity during the ASC's hours of operation. <b>416.41 GOVERNING BODY AND MANAGEMENT</b>  The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.  This CONDITION is not met as evidenced by: Based on observation, staff interview, and review of policies, personnel files and administrative documents, it was determined the ASC failed to ensure the governing body assumed	Q 040	Q40 - Governing Body and Management - Governing Body must assume full legal responsibility for determining, implementing and monitoring policies governing the ASC's total operation. Effective immediately, ASC Governing Body will assume a more active role in developing and reviewing policies, ongoing staff training and program evaluation (IC, QAPI). Annual meetings with the Governing Body will be changed to quarterly meetings for the immediate year following the survey, to ensure ongoing compliance with any and all changes implemented as a result of the survey.	09.14.12	

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Q 040	<p>Continued From page 4</p> <p>responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. This resulted in a lack of guidance and oversight of the facility's staff and programs. Findings include:</p> <ol style="list-style-type: none"> <li>1. Refer to Q043 as it relates to the failure of the governing body to ensure a written disaster preparedness plan was maintained and coordinated with State and local authorities.</li> <li>2. Refer to Q060 Condition for Coverage: Surgical Services as it relates to the failure of the governing body to ensure procedures were conducted in a manner which minimized risks to patient health and safety.</li> <li>3. Refer to Q080 Condition for Coverage: Quality Assessment and Performance Improvement and associated standard level deficiencies as they relate to the failure of the governing body to ensure a comprehensive, data driven QAPI program was developed, implemented and monitored.</li> <li>4. Refer to Q103 as it relates to the failure of the governing body to ensure a comprehensive program was established to identify and report diseases to State authorities.</li> <li>5. Refer to Q140 Condition for Coverage: Nursing Services as it relates to the failure of the governing body to provide nursing services under the direction of an RN.</li> <li>6. Refer to Q162 as it relates to the failure of the governing body to ensure patients' medical records included comprehensive, accurate</li> </ol>	Q 040		
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Q 040	Continued From page 5 information.  7. Refer to Q181 as it relates to the failure of the governing body to ensure systems were developed, implemented and monitored in accordance with acceptable standards of practice.  8. Refer to Q184 as it relates to the failure of the governing body to ensure verbal orders were followed by a written order and signed by the prescribing physician.  9. Refer to Q220 Condition for Coverage: Patient Rights and associated standard level deficiencies as they relate to the governing body's failure to ensure the patient or the patient's representatives were informed of the patient's rights, and that patient rights were protected and promoted.  10. Refer to Q240 Condition for Coverage: Infection Control and associated standard level deficiencies as they relate to the governing body's failure to ensure a comprehensive infection control program was developed, monitored and implemented.  11. Refer to Q264 as it relates to the failure of the governing body to ensure patients' records included a comprehensive post-surgical assessment.  The cumulative effect of the lack of governing body involvement resulted in a lack of direction to staff and a lack of structure defining the ASC's processes.	Q 040			
Q 043	416.41(c) DISASTER PREPAREDNESS PLAN	Q 043			

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Q 043	<p>Continued From page 6</p> <p>(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.</p> <p>(2) The ASC coordinates the plan with State and local authorities, as appropriate.</p> <p>(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.</p> <p>This STANDARD is not met as evidenced by: Based on interview and administrative document review, it was determined the facility failed to ensure the governing body conducted an annual emergency preparedness drill and coordinate the written emergency preparedness plan with State and local authorities for all patients, staff and visitors. This resulted in the potential for the facility's inability to effectively deal with the care, health and safety of patients, staff and other individuals when a major disruptive event occurred. Findings include:</p> <p>On 8/27/12 at 12:30 PM, during the exit interview, the facility's emergency preparedness plan was requested. A follow up phone call was conducted on 8/30/12 at 10:45 AM. The Administrator confirmed that the facility did not have an emergency preparedness plan. She stated they had a fire drill plan and conducted fire drills on a quarterly basis, but they were unaware of the</p>	Q 043	<p>Q043 – Disaster Preparedness Plan – The ASC's Disaster Preparedness Plan was implemented on 9/10/12. The first drill is scheduled for 9/21/12. The Safety Officer (Erika Gunter, RN) and the Administrator (Jennie Rawlings) will carry out the Disaster Preparedness Plan.</p>	09.10.12
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Q 043	Continued From page 7 requirement for an annual emergency preparedness drill and the requirements for a hazard vulnerability analysis and coordination with State and local authorities.  The facility failed to ensure the emergency preparedness plan addressed all hazards, was coordinated with State and local authorities, and that an emergency preparedness drill was conducted at least annually to test the plan's effectiveness.	Q 043		
Q 060	416.42 SURGICAL SERVICES  Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC  This CONDITION is not met as evidenced by: Based on observation, review of policies and manufacturer's instructions, staff interview, and review of medical records, it was determined the facility failed to ensure the infection control program was sufficiently developed, implemented, and monitored to ensure procedures were performed in a safe manner. These systemic failures directly impacted 1 of 1 patients (Patient #22) whose procedure was observed, and had the potential to impact all patients receiving care at the facility. This resulted in patients being placed in immediate jeopardy and at risk to experience serious harm, impairment, or death as a result of unsafe practices. Findings include:  1. Refer to Q240 Condition for Coverage:	Q 060	Q060 – Surgical Services – An Infection Control Program will be developed as a part of the QAPI by 10/1/12. Erika Gunter, RN was appointed the new ASC Infection Control Officer and was registered on 9/14/12 for the following course: A Primer for Designated Infection Control Program Managers in Ambulatory Surgical Settings. She will complete this training by 10/1/12. The Infection Control Officer will oversee the program and will be responsible for staff training, ongoing monitoring and improvements. The Infection Control Program will ensure the ASC provides a sanitary environment for patient care at all times. The Program will provide a plan to prevent, identify, track and manage infections within the ASC.	10-01-12

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Q 060	Continued From page 8 Infection Control and associated standard level deficiencies as they relate to the facility's systemic failures as follows:  - The facility failed to ensure it provided a sanitary environment for patient care.  - The facility failed to ensure there was documentation of consideration, selection, and implementation of nationally recognized infection control guidelines used to maintain an ongoing program to prevent and control the risk of infections.  - The facility failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.  - The facility failed to ensure infection control was integrated in to the QAPI program.  - The facility failed to provide a plan of action to prevent, identify, and manage infections.  The cumulative effect of these deficient practices resulted in the facility's inability to ensure patients' procedures were performed in a safe manner, necessary to minimize infections and communicable diseases.	Q 060			
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			

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Q 080	Continued From page 9  This CONDITION is not met as evidenced by: Based on staff interview and review of QAPI documents and governing board meeting minutes, it was determined the facility failed to ensure a data driven QAPI program had been developed, implemented, and maintained. This resulted in the inability of the ASC to evaluate its processes and practices. Findings include:  1. Refer to Q081 as it relates to the failure of the ASC to ensure the scope of the QAPI program provided sufficient direction to staff to demonstrate measurable improvement in patient health outcomes by using quality indicators.  2. Refer to Q082 as it relates to the failure of the ASC to ensure the QAPI program incorporated quality indicator data into the program.  3. Refer to Q084 as it relates to the failure of the Governing Body to ensure that the QAPI program was defined and implemented.  The cumulative effect of these negative facility practices prevented the ASC from evaluating its practices and processes.	Q 080	Q080 – QAPI – The current QI Policy will be replaced with a complete QAPI Program that will be implemented by the Governing Body prior to 10/1/12. This program will allow the ASC to demonstrate measurable improvement in health outcomes and utilize quality indicators to improve patient safety. The new QAPI Program will be approved by the Governing Body and implemented by the QAPI Officer (Erika Gunter, RN). The QAPI Program will initially include Pharmacy Inspections, Medical Record Audits, Medication Error Reports, Patient Satisfaction and Infection Control measures which include identifying and preventing infections, maintaining a sanitary environment, reporting communicable diseases to the proper authorities. Tracking sheets will be utilized to gather the information weekly. This information will be integrated and summarized annually to the Governing Board for guidance in determining areas for improvement as well as areas of optimal outcomes. The data driven information will be used to ensure that improvements are sustained over time.	10/01/12
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.	Q 081		

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Q 081	<p>Continued From page 10</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> <ul style="list-style-type: none"> <li>(i) Focus on high risk, high volume, and problem-prone areas.</li> <li>(ii) Consider incidence, prevalence, and severity of problems in those areas.</li> <li>(iii) Affect health outcomes, patient safety, and quality of care.</li> </ul> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of facility policies and QI meeting minutes, it was determined the ASC failed to ensure indicators for patient health outcomes, safety, and quality of care were tracked and analyzed in an ongoing program. This failure resulted in the facility's inability to determine potential areas for improving the care delivered to all patients receiving care at the ASC. Findings include:</p> <p>1. The "PCS Endoscopy Suite Quality Improvement Policy," undated, stated six processes would be measured. These processes included:</p> <ul style="list-style-type: none"> <li>a) Continuous QI studies</li> <li>b) Peer Review</li> <li>c) Quality controls for pathology services</li> <li>d) Quality controls for follow up and patient satisfaction</li> </ul>	Q 081			

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Q 081	<p>Continued From page 11</p> <p>e) Professional Evaluation f) Annual QI review</p> <p>There was no evidence how these processes would be measured, such as the collection and analysis of quality indicators for patient outcome and process of care.</p> <p>2. Review of the facility's annual Quality Assurance report for the year 2011 showed the following:</p> <p>a) Adverse Reaction Log; had a check mark indicating "None Noted."</p> <p>b) Incidents Documented; had a check mark indicating "None Noted."</p> <p>c) Med Errors Documented; had a check mark indicating "None Noted."</p> <p>d) Drug Disposal Log; had a check mark indicating "None Noted."</p> <p>e) Pathology Log; Three check marks indicated all specimens were logged out, all results were logged in, and all results were documented in patients' charts.</p> <p>f) Crash Cart Inspection was done annually and expired medication was ordered.</p> <p>g) Patient Satisfaction; Check marks indicated "Yes" for all patients surveyed by phone, all patients offered an alternative option to give feedback, all emergent/safety related feedback acted upon immediately, and all non-emergent feedback presented to the manager or medical</p>	Q 081		
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Q 081	<p>Continued From page 12 director for annual review.</p> <p>No information was present showing the ongoing collection, analysis, and monitoring of data that led to these annual summaries.</p> <p>Additionally, no information was present showing the collection, analysis, and monitoring of data relative to patient health outcomes, patient safety, quality of patient care, or infection control.</p> <p>In an interview on 8/22/12 at 10:00 AM, the facility Administrator stated she was not aware of any additional data collected to clarify the incidence, prevalence or severity of potential problems. She also stated the patient satisfaction results were not compiled, but were kept in individual patient records.</p> <p>3. The "PCS Endoscopy Suite Adverse Incident Policy," undated, defined an adverse incident as "an unexpected occurrence during a health care encounter involving patient death or serious physical or psychological injury or illness, including loss of limb or function, not related to the natural course of the patient's illness or underlying condition; any process variation for which recurrence carries significant chance of serious adverse outcome; or events such as breeches resulting in negative impact on a patient, even when death or loss of limb or function does not occur."</p> <p>The "PCS Patient Log Definitions," undated, defined the following as:</p> <p>Adverse reaction - "...a patient having a reaction to a medication given in the ASC, or from contact</p>	Q 081	<p>Q081/Q082/Q084 – Adverse Incident Policy – Effective 10/1/2012 the Director of Nurses (Erika Gunter, RN) will re-orient all ASC staff to the Adverse Incident Policy which includes situations of heavily sedated patients requiring rescue drugs (including Narcan and Romazicon). A misunderstanding of the policy definitions led to these drugs not being included on Adverse Reaction Logs previously. All rescue drugs will be tracked and monitored as a part of the ASC QAPI Program. This information will also be integrated and summarized annually to the Governing Board for guidance in determining what corrective actions, if any, are necessary.</p>	10-01-12
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Q 081	Continued From page 13 with any other item in the ASC."  Incident - "...patient injury or unexpected outcome during or as a result of their visit to the ASC."  When asked, in an interview on 8/21/12 at 1:00 PM, the facility Administrator stated there had been no incidents or adverse reactions over the past year.  When asked, in an interview on 8/21/12 at 3:30 PM, the staff RN stated there had been no incidents or adverse reactions over the past year.  Review of the facility's annual Quality Assurance Report for the year 2011 showed the Adverse Reaction Log had a check mark indicating "None Noted," and the Incidents Documented had a check mark indicating "None Noted."  However, review of medication logs from 7/27/11 - 8/8/12 showed six patients (Patients #21 and #23 - #27) required rescue medications due to decreased heart rate and oxygen saturation levels caused by oversedation.  The facility failed to maintain an ongoing QAPI program that measured, analyzed, and tracked infection control, adverse patient events, and quality of patient care.	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	Q 082	<i>refer to page 13 plan of correction</i>	<i>10-01-12</i>	

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Q 082	<p>Continued From page 14</p> <p>indicator data, including patient care and other relevant data regarding services furnished in the ASC.</p> <p>(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.</p> <p>(c)(2) Performance improvement activities must 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 record review, QAPI review and staff interview, it was determined the facility failed to ensure performance improvement activities tracked, examined the causes of adverse patient events, and implemented improvements for 6 of 6 patients (Patients #21 and #23 - #27) who required rescue drugs during their procedures at the ASC. Failure to analyze adverse events resulted in missed opportunities for the ASC to evaluate processes of care. Findings include:</p> <p>1. Patient #21 underwent a colonoscopy on 5/23/12. The anesthesia report stated, "due to oversedation and O2 sats dropping, patient was given reversal agents of Narcan 0.4 mg IV followed by Romazicon 0.1 mg IV."</p>	Q 082			

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Q 082	<p>Continued From page 15</p> <p>2. Patient #23 underwent a colonoscopy on 11/2/11. The anesthesia report stated rescue medication was given as, "Narcan 0.4 mg IV due to O2 sats &lt;90, &gt;80 for 1 minute."</p> <p>3. Patient #24 underwent a colonoscopy on 8/8/12. The anesthesia report stated, "due to decreased O2 x 2 minutes, Narcan 1.0 mg which resolved situation..."</p> <p>4. Patient #25 underwent a colonoscopy on 3/23/12. The anesthesia report stated, "Sats decreased to upper 70's during procedure therefore anesthesia reversed with Versed and Romazicon."</p> <p>5. Patient #26 underwent a colonoscopy on 9/7/11. The anesthesia report stated, "O2 sats dropped into the 50's during procedure and Romazicon and Narcan given with prompt return to normal."</p> <p>6. Patient #27 underwent an EGD on 7/27/11. The anesthesia report stated, "Versed reversed post procedure with Romazicon 0.01 mg IV."</p> <p>Review of the PCS Endoscopy Suite Log of Narcotics for Narcan and Romazicon confirmed the medications were given to Patients #21 and #23 - #27.</p> <p>The "PCS Patient Log Definitions," undated, defined the following as:</p> <p>Adverse reaction - "...a patient having a reaction to a medication given in the ASC, or from contact with any other item in the ASC."</p>	Q 082			

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Q 082	Continued From page 16  Incident - "...patient injury or unexpected outcome during or as a result of their visit to the ASC."  In an interview on 8/24/12 at 12:00 PM, the facility Medical Director confirmed the occurrences with Patients #21 and #23 - #27.  When asked in an interview on 8/21/12 at 9:30 AM, the facility Administrator stated there had been no incidents or adverse reactions over the past year.  When asked in an interview on 8/21/12 at 3:30 PM, the staff RN stated there had been no incidents or adverse reactions over the past year. She stated she did not qualify the need to administer reversal agents as an incident that required reporting.  The Quality Assurance Report, dated 2011 and presented at the 7/27/2012 Organizational Meeting, stated there were no Adverse Reactions or Incidents Documented during 2011.  The facility failed to record occurrences that, by facility definition, were adverse reactions/incidents. As a result of the lack of data collection, the facility missed an opportunity to improve the process of care.	Q 082			
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	Q 084	<i>refer to page 13 plan of correction</i>	<i>10-01-12</i>	

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Q 084	<p>Continued From page 17</p> <p>improvements are evaluated for effectiveness.</p> <p>(3) Specifies data collection methods, frequency, and details.</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 facility policies and QAPI documents, it was determined the ASC failed to ensure the governing body defined the QAPI program and failed to ensure staff were provided direction in their duties related to QAPI. The absence of governing body involvement resulted in a lack of guidance to staff and the inadequate development of the QAPI program. Findings include:</p> <p>The "PCS Endoscopy Suite Quality Improvement Policy," undated, had a section titled "Annual QA Review." It stated, "The Director of Nurses and the Administrator will oversee the QI program." The policy went on to state, "To achieve and maintain our goal of excellence, these standards will be enforced by the Administrator with the support of the Director of Nurses. These standards, and the corresponding documentation will be reviewed, in part with the Risk Management program and the Peer Review program by the Governing Board at least annually, more frequently when appropriate."</p> <p>This was the sole reference in the QI policy to the governing body's involvement with or responsibility for the facility's QAPI program.</p>	Q 084			

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Q 084	Continued From page 18  No other policies could be found referencing governing body responsibilities.  Additionally, a review of the facility's Organizational Meeting minutes for 2011 and 2012, showed attached Quality Assurance Reports were reviewed by the Medical Director, as confirmed by his signature.  In an interview on 8/22/12 at 2:00 PM, the Administrator provided a facility organizational chart showing the positions of Medical Director, governing body, and Board of Directors were fulfilled by the same person. She further stated one meeting, held annually, encompassed Board of Directors, governing body, and QAPI business.	Q 084		
Q 103	The governing body did not assume responsibility for all aspects of the facility's QAPI program. 416.44(a)(3) IDENTIFICATION, PREVENTION, AND MAINTENANCE  [The ASC must provide a functional and sanitary environment for the provision of surgical services.] The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.  This STANDARD is not met as evidenced by: Based on interview and review of infection control policies, it was determined the facility failed to establish a program for identifying infections and reporting communicable diseases identified to the proper authorities. This impacted	Q 103	Q103 – Identify and Report diseases to State authorities – Effective 10/1/12, the current ASC policy on reporting infections will be revised to include a protocol for identifying and preventing infections and reporting communicable diseases to proper authorities. All ASC staff will be oriented on ways to prevent infection within the ASC. These include proper hand hygiene, proper reprocessing of scopes, environmental cleaning between procedures. This action will serve to improve the ASC process of identifying, preventing and tracking infections. The Director of Nursing (Erika Gunter, RN) will monitor the new protocol to ensure compliance.	10-01-12

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Q 103	<p>Continued From page 19</p> <p>all staff and patients cared for at the ASC. These failures had the potential to result in unidentified and unreported infections. Findings include:</p> <p>A policy, "PCS ENDOSCOPY SUITE PROTOCOL ON REPORTING INFECTIONS," undated, was reviewed. The policy did not indicate which diseases were reportable under State law. The policy did not indicate what steps were to be taken to assist staff in identifying potential infections related to care at the facility. The policy indicated that if an infection was reported, the entire procedure room where the incident occurred was to be re-cleaned and sterilized. The policy did not indicate what steps would be taken to determine the cause of the infection or actions to be taken if the infection was not related to environmental cross-contamination.</p> <p>The Administrator was interviewed on 8/24/12 at 9:30 AM. She confirmed the facility was not aware of which communicable diseases were reportable under State law. She stated the facility did not have a specific process to follow up with patients to identify infections potentially related to care at the ASC. She confirmed that the discharge instructions directed patients to contact the physician if they developed a temperature or had increased abdominal pain. She explained that often times the physician performing the procedure was also the patient's primary provider and would therefore likely follow up in the office with any concerns. She confirmed that the information was not tracked by the ASC.</p> <p>The facility failed to establish a program for identifying infections and reporting communicable diseases identified to the proper authorities.</p>	Q 103			

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Q 140	<p><b>416.46 NURSING SERVICES</b></p> <p>The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.</p> <p>This CONDITION is not met as evidenced by: Based on staff interview and review of the facility's organizational chart it was determined the facility failed to ensure nursing services were under the direction of an RN. This failure impacted all patients receiving care at the facility and created the potential for inadequate assessment and unaddressed patient needs. Findings include:</p> <p>In an interview on 8/22/12 at 2:00 PM, the Administrator provided a facility organizational chart showing the position of Director of Nursing Services was fulfilled by a staff member possessing a Licensed Practical Nursing license. She further confirmed the organizational chart to be accurate.</p> <p>The Rules of the Idaho Board of Nursing, IDAPA 23.01.01.460 stated, "Licensed practical nurses function in dependent roles. Licensed practical nurses, also referred to as LPNs, provide care at the delegation of a licensed professional nurse, licensed physician, or licensed dentist..."</p> <p>The Rules of the Idaho Board of Nursing, IDAPA 23.01.01.460.02.a also state LPNs "accept delegated assignments only as allowed by application of the decision-making model."</p> <p>The facility failed to provide appropriate nursing staff oversight.</p>	Q 140	<p>Q140 – Nursing Services to be directed by an RN – Effective 9/14/2012 the ASC Organizational Chart was revised to change the DON to an RN. This change was approved by the Governing Board and was given to Erika Gunter, RN. This change will serve to bring the ASC into compliance with Idaho Board of Nursing rules that require RN oversight of dependent roles.</p>	09.14.12	

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Q 162	<p>416.47(b) FORM AND CONTENT OF RECORD</p> <p>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:</p> <ul style="list-style-type: none"> <li>(1) Patient identification.</li> <li>(2) Significant medical history and results of physical examination.</li> <li>(3) Pre-operative diagnostic studies (entered before surgery), if performed.</li> <li>(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.</li> <li>(5) Any allergies and abnormal drug reactions.</li> <li>(6) Entries related to anesthesia administration.</li> <li>(7) Documentation of properly executed informed patient consent.</li> <li>(8) Discharge diagnosis.</li> </ul> <p>This STANDARD is not met as evidenced by: Based on review of medical records and facility policy, and staff interview, it was determined the facility failed to ensure complete and accurate documentation for 27 of 27 patients (Patients #1 - #27) whose medical records were reviewed. This failure resulted in missing documentation of vital signs, inaccurate documentation of vital signs, and difficulty determining accurate medication dosage administration. Findings include:</p> <p>1. The RN was interviewed on 8/21/12 at 2:30 PM. She stated she monitored vital signs throughout the procedure. She stated that the oxygen saturation level and pulse were monitored</p>	Q 162	<p>Q162 – Medical Records did not include comprehensive, accurate information – Patients charts were noted to have inaccurate date and time stamp on subsequent vital signs. Effective 8/21/12, during the survey, the vital signs monitor was recalibrated to correct the date and time. Procedures done after that were noted to show correct date and time stamps on all vital signs recorded. During QAPI medical records review, the DON will monitor that all charts include accurate vital signs and that they are documented in the medical record to ensure continued compliance.</p>	082712	

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Q 162	<p>Continued From page 22</p> <p>continuously and that the machine was programmed to take a blood pressure at specific intervals. She stated she set the machine to take a blood pressure at 1 minute, at 5 minutes, and then every 10 minutes throughout the procedure and recovery period. She stated that while still monitoring vital signs, she weaned the oxygen level. She stated most of the time patients were moved to the recovery room once they had significantly recovered from the procedure. She stated once the patient was moved to the recovery room and the curtain was closed to the room, they were monitored using a portable oxygen saturation level and pulse machine. She stated this information was not documented in the medical records.</p> <p>Patient #22's procedure was observed on 8/22/12. The procedure began at 10:31 AM and she was discharged at 11:47 AM. However, the Vital Signs Monitor strip in Patient #22's record was dated 8/21/12 and documented 15 vital sign entries starting at 1:59 PM through 2:56 PM. The Vital Signs Monitor strip did not accurately reflect the date or time of Patient #22's procedure.</p> <p>On 8/22/12 at 11:20 AM, the RN reviewed the strip of vital signs printed following Patient #22's procedure. She confirmed the date and times of the strip did not match the actual procedure date and time. She stated she was aware the machine was inaccurate but was not sure how to re-calibrate the machine to make the information on the Vital Signs Monitor strip accurate.</p> <p>Additionally, the medical records for Patients #1 - #21 and #23 - #27 were reviewed. The records did not include documentation of accurate vital</p>	Q 162			

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Q 162	<p>Continued From page 23 sign monitoring as follows:</p> <ul style="list-style-type: none"> <li>- Patient #1's record documented he was admitted for an EGD on 3/1/12. The start time of the procedure was 11:10 AM and the time of discharge was 12:10 PM. His Vital Signs Monitor strip, dated 2/29/12, documented 5 vital sign entries starting at 3:16 PM through 3:47 PM.</li> <li>- Patient #2's record documented she was admitted for a colonoscopy on 7/13/12. The start time of the procedure was 9:51 AM and the time of discharge was 11:45 AM. Her Vital Signs Monitor strip, dated 7/12/12, documented 6 vital sign entries starting at 1:25 PM through 2:07 PM.</li> <li>- Patient #3's record documented he was admitted for an EGD on 6/25/12. The start time of the procedure was 8:50 AM and the discharge time was 10:00 AM. His Vital Signs Monitor strip, dated 6/24/12, documented 8 vital sign entries starting at 10:58 AM through 11:40 AM.</li> <li>- Patient #4's record documented she was admitted for a colonoscopy on 5/23/12. The start time of the procedure was 9:05 AM and the time of discharge was 10:30 AM. Her Vital Signs Monitor strip, dated 5/22/12, documented 7 vital sign entries starting at 12:15 PM through 1:06 PM.</li> <li>- Patient #5's record documented she was admitted for a colonoscopy on 6/8/12. The start time of the procedure was 9:50 AM and the time of discharge was not listed. Her Vital Signs Monitor strip, dated 6/7/12, documented 7 vital sign entries starting at 3:09 PM through 2:01 PM.</li> </ul>	Q 162			

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Q 162	<p>Continued From page 24</p> <ul style="list-style-type: none"> <li>- Patient #6's record documented he was admitted for an EGD on 4/27/12. The start time of the procedure was 11:19 AM and the discharge time was 12:30 PM. His Vital Signs Monitor strip, dated 4/26/12, documented 14 vital sign entries starting at 2:42 PM through 3:04 PM.</li> <li>- Patient #7's record documented he was admitted for an EGD on 8/15/12. The start time of the procedure was 9:00 AM and the time of discharge was 10:30 AM. His Vital Signs Monitor strip, dated 8/14/12, documented 5 vital sign entries starting at 12:36 PM through 1:07 PM.</li> <li>- Patient #8's record documented she was admitted for an EGD on 2/29/12. The start time of the procedure was 8:55 AM and the time of discharge was 10:00 AM. Her Vital Signs Monitor strip, dated 2/28/12, documented 7 vital sign entries starting at 1:03 PM through 1:34 PM.</li> <li>- Patient #9's record documented he was admitted for a colonoscopy 5/2/12. The start time of the procedure was 10:38 AM and the time of discharge was 12:30 PM. His Vital Signs Monitor strip, dated 5/1/12, documented 18 vital sign entries starting at 1:59 PM through 2:34 PM.</li> <li>- Patient #10's record documented he was admitted for a colonoscopy on 5/4/12. The start time of the procedure was 9:30 AM and the time of discharge was 11:30 AM. His Vital Signs Monitor strip, dated 5/3/12, documented 5 vital sign entries starting at 12:53 PM through 1:24 PM.</li> <li>- Patient #11's record documented he was admitted for an EGD on 2/1/12. The start time of</li> </ul>	Q 162			

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Q 162	<p>Continued From page 25</p> <p>the procedure was 9:39 AM and the time of discharge was 11:00 AM. His Vital Signs Monitor strip, dated 1/31/12, documented 4 vital sign entries starting at 1:48 PM through 2:10 PM.</p> <p>- Patient #14's record documented she was admitted for a colonoscopy on 5/4/12. The start time of the procedure was 12:15 PM and the time of discharge was 2:30 PM. Her Vital Signs Monitor strip, dated 5/3/12, documented 8 vital sign entries starting at 3:46 PM. through 4:18 PM.</p> <p>- Patient #15's record documented he was admitted for an EGD on 4/11/12. The start time of the procedure was 12:30 PM and the time of discharge was 2:00 PM. His Vital Signs Monitor strip, dated 4/10/12, documented 10 vital sign entries starting at 3:14 PM through 4:15 PM.</p> <p>- Patient #16's record documented he was admitted for an EGD on 2/1/12. The start time of the procedure was 8:45 AM and the time of discharge was 10:20 AM. His Vital Signs Monitor strip, dated 1/31/12, documented 5 vital sign entries starting at 12:51 PM through 1:22 PM.</p> <p>- Patient #17's record documented he was admitted for an EGD on 4/4/12. The start time of the procedure was 11:55 AM and the time of discharge was 1:10 PM. His Vital Signs Monitor strip, dated 4/3/12, documented 12 vital sign entries starting at 2:10 PM through 3:41 PM.</p> <p>- Patient #18's record documented she was admitted for an EGD on 3/13/12. The start time of the procedure was 11:20 AM and the time of discharge was 12:30 PM. Her Vital Signs Monitor strip, dated 3/12/12, documented 8 vital sign</p>	Q 162			

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Q 162	<p>Continued From page 26 entries starting at 2:29 PM through 3:13 PM.</p> <p>- Patient #19's record documented he was admitted for a colonoscopy on 2/9/12. The start time of the procedure was 12:00 PM and the time of discharge was 1:00 PM. His Vital Signs Monitor strip, dated 2/8/12, documented 14 vital sign entries starting at 2:52 PM through 4:30 PM.</p> <p>- Patient #20's record documented he was admitted for an EGD on 2/2/12. The start time of the procedure was 12:10 PM and the time of discharge was 1:30 PM. His Vital Signs Monitor strip, dated 2/1/12, documented 5 vital sign entries starting at 4:14 PM through 4:46 PM.</p> <p>- Patient #21's record documented she was admitted for a colonoscopy on 5/23/12. The start time of the procedure was 10:45 AM and the time of discharge was 1:30 PM. Her Vital Signs Monitor strip, dated 5/22/12, documented 16 vital sign entries starting at 1:42 PM through 2:44 PM.</p> <p>The CMA reviewed the documentation regarding the inaccurate dates and times on the Vital Signs Monitor slip on 8/23/12 at 3:30 PM. She confirmed that the machine set to automatically obtain and record vital signs was calibrated incorrectly. She agreed that all of the sample medical records containing the Vital Signs Monitor slip, Patients #1 - #11, #14 - #21 and #23 - #27, did not contain accurate documentation of vital signs.</p> <p>-Patient #12's record documented he was admitted 3/16/12 for a colonoscopy. The start time of the procedure was 11:35 AM and the discharge time was 12:45 PM. During that time</p>	Q 162			

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Q 162	<p>Continued From page 27</p> <p>his vital signs were only documented once.</p> <p>-Patient #13's record documented he was admitted for an EGD and a colonoscopy on 4/25/12. The start time of the procedure was 12:03 PM and the discharge time was 12:37 PM. During that time his vital signs were only documented once.</p> <p>On 8/24/12 at 10:15 AM, the RN reviewed Patient #13's and #12's medical record. She explained that the set of vital signs documented in their records was obtained prior to the start of the procedure. She confirmed there was no documentation of vital signs obtained during the procedure or recovery period.</p> <p>The facility failed to ensure vital signs were documented and documented accurately.</p> <p>2. The facility's policy for "Reversal Agents," undated, stated Romazicon was to be given as a reversal agent for Versed/valium. Adults were to receive 0.2 mg over 15 seconds.</p> <p>However, the "PCS Endoscopy Suite Log of Narcotics" for Romazicon documented the strength of the medication was .01 mg/ml. The vials of Romazicon were examined with the RN on 8/24/12 at 11:50 AM. She confirmed the vials supplied showed actual drug strength as 0.1 mg/ml. She confirmed the log was not consistent with the vial strength. In addition, the medication actually administered was not consistent with facility policy, and the medication dosage on flowsheets did not match medication dosage on the narcotic log.</p>	Q 162			

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Q 162	<p>Continued From page 28</p> <p>The facility's policy for "Reversal Agents," undated, also stated Narcan was to be given as a reversal agent for narcotics. Adults were to receive 0.4 mg to 2 mg every 2 to 3 minutes as needed.</p> <p>However, the "PCS Endoscopy Suite Log of Narcotics" for Narcan stated the strength of the medication as .04 mg/ml. The vials of Narcan were examined with the RN on 8/24/12 at 11:50 AM. She confirmed the vials supplied showed actual drug strength as 0.4 mg/ml. She confirmed the log was not consistent with the vial strength. In addition, medication actually administered was not consistent with facility policy, and the medication dosage on flowsheets did not match medication dosage on the narcotic log. Discrepancies were documented as follows:</p> <p>a. The narcotic Log did not match the medical record for Patients #21 and #23 - #27 as follows:</p> <ul style="list-style-type: none"> <li>- Patient #21 underwent a colonoscopy on 5/23/12. Her conscious sedation flowsheet showed she received 0.1 mg of Romazicon. The narcotic log showed she received .01 mg of Romazicon.</li> <li>- Patient #23 underwent a colonoscopy on 11/2/11. Her conscious sedation flowsheet showed she received .4 mg of Narcan. The narcotic log showed she received .04 mg of Narcan.</li> <li>- Patient #24 underwent a colonoscopy on 8/8/12. Her conscious sedation sheet showed she received 1.0 mg of Narcan. The narcotic log showed she received .4 mg of Narcan.</li> </ul>	Q 162	<p>Q162 - Medical Records did not include comprehensive, accurate information - Reversal Agents were not given according to ASC policy. On 9/14/12 the ASC staff and physicians were provided an in-service on the current ASC policy for Reversal Agents stating that adults were to receive Flumazenil 0.2 mg over 15 seconds, and Naloxone HCL 0.4-2mg every 2-3 minutes as needed. The DON will monitor as a part of the ASC QAPI program that correct doses are both administered to patient and documented accurately in the medical record.</p>	09.14.12	

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Q 162	Continued From page 29  - Patient #25 underwent a colonoscopy on 3/23/12. Her conscious sedation flowsheet showed she received .1 mg of Romazicon. The narcotic log showed she received .01 mg of Romazicon.  - Patient #27 underwent an EGD on 7/27/11. Her conscious sedation flowsheet showed she did not receive reversal drugs. The narcotic log showed she received .01 mg of Romazicon.  b. The narcotic log medication strength did not match the vial strength for medication received by Patients #21 and #23 - #27 as follows:  - Patient #21 underwent a colonoscopy on 5/23/12. Her conscious sedation flowsheet showed she received 0.1 mg of Romazicon. The narcotic log showed medication strength as .01 mg/ml. The vials supplied showed medication strength as .1 mg/ml. Additionally, her conscious sedation flowsheet showed she received .4 mg of Narcan. The narcotic log showed the medication strength as .04 mg/ml. The vial supplied showed medication strength as .4 mg/ml.  - Patient #23 underwent a colonoscopy on 5/23/12. Her conscious sedation flowsheet showed she received .4 mg of Narcan. The narcotic log showed the medication strength as .04 mg/ml. The vial supplied showed medication strength as .4 mg/ml.  - Patient #24 underwent a colonoscopy on 8/8/12. Her conscious sedation sheet showed she received 1.0 mg of Narcan. The narcotic log showed the medication strength as .04 mg/ml.	Q 162			

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Q 162	<p>Continued From page 30</p> <p>The vial supplied showed medication strength as .4 mg/ml.</p> <p>- Patient #25 underwent a colonoscopy on 3/23/12. Her conscious sedation flowsheet showed she received .1 mg of Romazicon. The narcotic log showed medication strength as .01 mg/ml. The vials supplied showed medication strength as .1 mg/ml.</p> <p>- Patient #26 underwent a colonoscopy on 9/7/11. His conscious sedation flowsheet showed he received .01 mg of Romazicon. The narcotic log showed medication strength as .01 mg/ml. The vials supplied showed medication strength as .1 mg/ml. Additionally, his flowsheet showed he received .04 mg of Narcan. The narcotic log showed the medication strength as .04 mg/ml. The vial supplied showed medication strength as .4 mg/ml.</p> <p>- Patient #27 underwent an EGD on 7/27/11. Her anesthesia report showed she received .01 mg of Romazicon. The narcotic log showed medication strength as .01 mg/ml. The vials supplied showed medication strength as .1 mg/ml.</p> <p>c. Medications dosages received by Patients #21, #25, #26, and #27 did not match medication dosages stated in the facility's policy for reversal agents as follows:</p> <p>- Patient #21 underwent a colonoscopy on 5/23/12. Her conscious sedation flowsheet showed she received 0.1 mg of Romazicon. Facility policy stated adult dosage of Romazicon was .2 mg over 15 seconds.</p>	Q 162			

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NAME OF PROVIDER OR SUPPLIER  <b>PCS ENDOSCOPY SUITE</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>500 S 11TH AVENUE, SUITE 303 POCATELLO, ID 83201</b>		
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Q 162	Continued From page 31 - Patient #25 underwent a colonoscopy on 3/23/12. Her conscious sedation flowsheet showed she received .1 mg of Romazicon. Facility policy stated adult dosage of Romazicon was .2 mg over 15 seconds.  - Patient #26 underwent a colonoscopy on 9/7/11. His conscious sedation flowsheet showed he received .01 mg of Romazicon. Facility policy stated adult dosage of Romazicon was .2 mg over 15 seconds. Additionally, his flowsheet showed he received .04 mg of Narcan. Facility policy stated adult dosage of Narcan was 0.4 to 2 mg every 2 to 3 minutes as needed.  - Patient #27 underwent an EGD on 7/27/11. Her anesthesia report showed she received .01 mg of Romazicon. Facility policy stated adult dosage of Romazicon was .2 mg over 15 seconds.  The facility did not ensure medication administration was accurately recorded and followed facility policy.	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, review of the narcotic log book, and interview, it was determined the facility failed to ensure policies and procedures were developed and implemented to monitor medication movement through the ASC. This	Q 181			

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Q 181	<p>Continued From page 32</p> <p>failure had the potential to impact all patients cared for at the facility, and had the potential to result in diversion of narcotics and administration of expired medications. Findings include:</p> <p>1. The facility's policy, "PCS Endoscopy Suite Policy on Use and Accountability of Pharmaceuticals," undated, was reviewed. According to the policy, "Records will be kept of the receipt and disposition of all controlled substances used in the facility. These records should include a log of all narcotics used, the date, time, patient's name, amount given, and physician's or nurses [sic] name." The policy did not specify a process to minimize the time between loss or diversion of a narcotic before detection. The policy did not provide guidance on a system of tracking scheduled drugs in a readily retrievable manner to facilitate the reconciliation of receipt and disposition of the drugs. In addition, the policy did not include a process to systematically review and dispose of expired medications in the facility.</p> <p>According to the Code of Federal Regulations 1304.11.e.3.i, any facility dispensing controlled substances (such as narcotics) must maintain an exact count of each medication.</p> <p>The facility did not process medications in accordance with established policies and accepted standards of practice as follows:</p> <p>a. The ASC was toured with the RN on 8/21/12 at 1:45 PM. She reviewed her process for documenting the receipt and disposition of narcotic medications. She referred to a narcotic log book and explained that upon receipt of a</p>	Q 181	<p>Q181 – Administration of Drugs – ASC failed to ensure policies and procedures were developed and implemented to monitor medication movement through the ASC. Effective 10/1/12 all narcotics will be counted prior to and immediately following procedures on days that ASC is designated open. ASC policy on Use and Accountability of Pharmaceuticals will include two separate log forms, one for sealed stock narcotic items not currently being used, and a second for stock items brought forward to active use. All sealed narcotic stock items may be counted per box instead of per dose, until box is opened and/or seal is broken. When a sealed box is opened, it will be brought forward from stock supply to current ASC use and a new ASC Log of Narcotics form will be initiated for all doses in that box. Each of those doses will be logged by: date, patient name, and dosage. These counts will be completed and initialed by two licensed personnel of the ASC. In this way, the ASC will be able to track all doses of narcotics, and be able to identify quickly if any doses are missing or have been tampered with.</p>	10-01-12
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Q 181	<p>Continued From page 33</p> <p>shipment of medication she completed a "PCS Endoscopy Suite Log of Narcotics" form. She explained that at the top of each form she documented the medication and dosage. She explained each form contained 30 lines, representing 30 doses. In the event that she had less than 30 doses of medication, she explained she crossed out the lines so that only the true number of doses of medication were accounted for. She stated that each time a dose of medication was administered, she documented in the log the name of the patient, date of procedure, dose of medication administered, and who administered the medication. She stated she used one line for each dose. She explained that using this process she was able to track the receipt and disposition of medications. She stated she was concerned about the potential for diversion of medications as she had witnessed this during employment at another facility.</p> <p>The RN was again interviewed on 8/24/12 at 10:15 AM, regarding her current process of monitoring narcotic drugs. She confirmed she did not complete a total count of medications received and used but rather maintained a running log of the dosages of medication on hand and how many doses of medication were used. She confirmed that it would be difficult to identify diversion of medications in a timely manner.</p> <p>The facility failed to ensure policies were developed and processes were in place to readily reconcile narcotic medications.</p> <p>b. The ASC was toured on 8/21/12 at 1:45 PM with the RN. She reviewed the crash cart medications and noted the GlucaGen Hypokit 1</p>	Q 181	<p>Q181 – Administration of Drugs – Items in Crash Cart were noted to be expired. Effective 9/14/12 all staff were in-serviced on current protocol for ASC Crash Cart List. Per protocol, all medications will be inspected quarterly by the DON, and replaced prior to the expiration date. All outdated medications will be disposed of according to ASC policy. This action will serve to reinforce current protocol and ensure compliance.</p>	09.14.12
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Q 181	Continued From page 34 mg expired 1/2007. In addition, a vial of Narcan 0.4 mg/ml expired in 2/2011, and three 5 mg vials of Verapamil expired 4/2011. The RN explained that the medications would not have been used in an emergency situation anyway because the new ACLS protocols did not require the above medications.  In addition, three 250 ml bottles of sterile water, used for irrigation, were stored in a cabinet in the procedure room. The expiration date on the bottles was 10/2004. The RN explained that they no longer use sterile water from the bottles and therefore they would not have been used.	Q 181	Q181 – Administration of Drugs – Expired Sterile Water – ASC will be inspected quarterly by the DON for any outdated medications. This will be incorporated into the ASC QAPI Program. This action will ensure that no medications are accidentally used past their expiration date.	09.14.12	
Q 184	416.48(a)(3) VERBAL ORDERS  Orders given orally for drugs and biologicals must be followed by a written order signed by the prescribing physician.  This STANDARD is not met as evidenced by: Based on review of medical records and facility policy, observation, and staff interview it was determined that the facility failed to ensure verbal orders for conscious sedation were co-signed by the physician for 27 of 27 patients (Patients #1 - #27) whose medical records were reviewed. Failure to obtain a physician signature for verbal orders impeded the verification that drugs were administered per physician order. Findings include:	Q 184	Q184 – Verbal Orders – ASC failed to require written orders for conscious sedation be followed by a physician signature and med administration by the RN. Effective 9/14/12 ASC Conscious Sedation flow sheet has been updated to include a signature line for the physician to approve verbal orders given for conscious sedation. In addition, the form was also updated to include a signature line designating the medication was administered by the RN. The updated form has been approved by the Governing Body. The DON will audit this form as part of the QAPI Program Medical Record review to ensure 100% compliance by all physicians.	09.14.12	

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Q 184	<p>Continued From page 35</p> <p>The medical records for Patients #1 - #27 were reviewed. Each patient record contained a "CONSCIOUS SEDATION FLOW SHEET" which indicated the name, dosage, and route of a medication administered and the time of administration. There was no documentation to indicate who administered the medication. Each medical record contained a "PROGRESS NOTE," completed by the physician, containing documentation of the procedure and the total amount of medication administered during the procedure. However, none of the individual verbal orders given during procedures were cosigned by the physician. For example:</p> <p>Patient #22 was admitted to the facility on 8/22/12 for a colonoscopy. Her procedure was observed by two surveyors on 8/22/12 from 10:15 AM to 11:20 AM. During the procedure, the physician was observed to give verbal orders for sedative medications four times. The RN was observed to repeat the order to the physician and then administer the medication. The name of the medication, dose, route, and time of administration were observed to be documented on the "CONSCIOUS SEDATION FLOW SHEET." The "PROGRESS NOTE," signed and dated by the physician on 8/22/12 at 11:11 AM, indicated Patient #22 received a total of Demerol 150 mg IV and Versed 3 mg IV. However, the "CONSCIOUS SEDATION FLOW SHEET" contained documentation of medication administration as follows: 10:25 AM Versed 2 mg IV, 10:29 AM Demerol 100 mg IV, 10:36 AM Versed 1 mg IV, and 10:40 AM Demerol 50 mg IV. There was no documentation that the physician co-signed the verbal orders received by the RN during the procedure.</p>	Q 184			

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Q 184	Continued From page 36  The facility's policy, "PCS Endoscopy Suite Policy on Use and Accountability of Pharmaceuticals," undated, was reviewed. According to the policy, "Oral medication orders must be documented and signed by the physician the day of the procedure."  The CMA was interviewed on 8/23/12 at 3:30 PM. She stated that the RN always administered the medications but occasionally she was the one who documented the name, dose, route, and time of administration. She confirmed that based on the format of the "CONSCIOUS SEDATION FLOW SHEET" it was not clear the medications were administered by the RN. She stated the physician typically included the total amount of medication used during the procedure in the "Progress Notes" completed after the procedure. She confirmed that individual verbal orders received by the RN during the procedure were not cosigned by the physician.  The RN was interviewed on 8/24/12 at 10:15 AM. She reviewed the "CONSCIOUS SEDATION FLOW SHEET" and confirmed that as a result of the current process, for Patients #1 - #27 the physician did not co-sign the individual verbal orders for medication administered during the procedure.  The facility failed to ensure that verbal orders directing the nurse to give separate doses of medication during the procedure were cosigned by the ordering physician.	Q 184			
Q 220	416.50 PATIENT RIGHTS  The ASC must inform the patient or the patient's	Q 220			

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Q 220	<p>Continued From page 37</p> <p>representative of the patient's rights, and must protect and promote the exercise of such rights.</p> <p>This CONDITION is not met as evidenced by: Based on staff interview, observation, review of patient rights information, ASC policies and medical records it was determined the ASC failed to provide patients or their representatives with complete information regarding their rights. This failure impacted all patients receiving care at the facility, and had the potential to interfere with patients' ability to make fully informed decisions for their care. Findings include:</p> <ol style="list-style-type: none"> <li>1. Refer to Q222 as it relates to the failure of the ASC to post a written notice of the complete list of patient rights, and to ensure patient rights information included the name, phone number, and address of the state representative in the event patients wished to report complaints.</li> <li>2. Refer to Q224 as it relates to the failure of the ASC to provide complete information regarding advance directives prior to the day of the procedure and document in the medical record whether an advance directive had been executed.</li> <li>3. Refer to Q225 as it relates to the failure of the ASC to establish a grievance procedure for documenting the existence, submission, investigation, and disposition of grievances, timeframes for review, provisions of a response, and necessity of providing patients with written notice of the grievance process.</li> </ol> <p>The cumulative effect of these systemic practices resulted in the inability of the facility to ensure</p>	Q 220	<p>Q220 – Patient Rights – ASC failed to post a written notice of the complete list of Patient Rights, including state representative contact information, Advanced Directives and a grievance procedure. Effective 9/14/2012 ASC has updated its Patient Rights to include:</p> <p>Q222 – A complete list of patient rights including the name, phone number and address of the state representative in the event patients wished to report complaints.</p> <p>Q224 – ASC developed a policy on Advance Directive so that information regarding Advanced Directives will be given to patients prior to the day of the procedure, and that the patient's decision will be document prominently in the medical record whether an advance directive has been executed.</p> <p>Q225 – A grievance procedure that directs patients to appropriate local, state and federal officials to file a complaint, when needed. In addition, the grievance procedure outlines a protocol for a written response to each patient, the steps to be taken to investigate the grievance, the name of an ASC contact person, and the date the grievance was completed.</p> <p>The required elements will be posted in visible patient areas of the ASC, including the waiting room and recovery rooms. This information will also be included in the pre-procedure packet given to the patient at the time of their consultation. This action will serve to ensure patient rights are communicated and upheld and will be tracked by the Administrator.</p>	09.14.12	

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Q 220	Continued From page 38	Q 220			
Q 222	patient rights were communicated and upheld. 4166.50(a)(1)(i) NOTICE - POSTING  In addition, the ASC must - Post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.  This STANDARD is not met as evidenced by: Based on observation, review of patient rights information, and staff interview, it was determined the facility failed to post a written notice of patient rights and failed to ensure the patient rights information included the name, phone number, and address of the state representative in the event patients wished to report complaints. These failures impacted all patients receiving care at the facility and had the potential to result in patients and their representatives not being fully informed of their rights. Findings include:  A tour of the facility was conducted with the Administrator on 8/21/12 at 9:30 AM. No written notice of patients' rights was posted in the facility. In an interview, following the facility tour, the facility Administrator said the facility had moved to a new location approximately one month ago and all materials had not yet been unpacked.  On 8/21/12 at 1:00 PM the facility Administrator provided a copy of the "PCS Endoscopy Suite,	Q 222	<i>refer to page 38 of plan of corrections</i>		

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Q 222	Continued From page 39 Inc. Patient Rights and Responsibilities." She stated this document was given to patients at the time of their consultation visit, several days prior to the procedure date.  Review of the document showed it did not provide patients with information about a grievance process including the name, phone number, and address of the state representative, or the web site for the Office of the Medicare Beneficiary Ombudsman, in the event patients wished to report complaints.  The facility failed to ensure the appropriate contact information for reporting a complaint was available to patients, and failed to ensure a written notice of patient rights was posted in the facility.	Q 222			
Q 224	416.50(a)(2) ADVANCE DIRECTIVES  The ASC must comply with the following requirements: (i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms. (ii) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care. (iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.	Q 224	<i>refer to page 38 of plan of corrections</i>		

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Q 224	<p>Continued From page 40</p> <p>This STANDARD is not met as evidenced by: Based on medical record review, patient information review, and staff interview it was determined the ASC failed to ensure: 1) forms for advance directives were offered and provided prior to the day of procedures, if requested; 2) patients were provided with information regarding rights to make informed decisions; and 3) documentation was present in the medical records indicating whether an advance directive had or had not been executed. This failure impacted 27 of 27 patients (Patients #1 - #27) whose records were reviewed, and had the potential to impact all patients receiving services from the ASC. As a result, patients were not informed of their rights and missed the opportunity to execute advance directives, if desired, and/or have them honored. Findings include:</p> <p>On 8/21/12 at 1:00 PM the facility Administrator provided surveyors with patient information provided to ASC patients. She confirmed the information was given to patients at the time of their consultation appointment, several days before their procedure. The packet included the following:</p> <ul style="list-style-type: none"> <li>- Patient Rights and Responsibilities</li> <li>- Explanation of Procedure</li> <li>- Preparation Instructions for the Procedure</li> <li>- Consent for Procedure</li> <li>- Billing Information</li> <li>- Release of Information Form</li> <li>- HIPAA Privacy Practices</li> </ul> <p>The packet of information provided to patients preoperatively did not contain education on</p>	Q 224			

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Q 224	Continued From page 41 Advance Directives, provision of Advance Directive forms, or facility policy related to honoring Advance Directives.  Review of medical records for Patients #1 - #27 showed Advance Directives were not present and there was no indication whether Patients #1 - #27 had an existing Advance Directive.  In an interview on 8/23/12 at 1:00 PM, the facility Administrator said the facility did not have a policy concerning Advance Directives and did not provide Advance Directive information to patients.  The facility failed to ensure patients were provided with information about Advance Directives preoperatively, did not indicate if an existing Advance Directive was present, and did not indicate whether or not it would be honored by the facility.	Q 224			
Q 225	416.50(a)(3)(i), (v), (vi), (vii) SUBMISSION AND INVESTIGATION OF GRIEVANCES  (i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. (v) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished. (vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person,	Q 225	<i>refer to page 38 of plan of corrections</i>		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  13C0001041	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  08/27/2012
NAME OF PROVIDER OR SUPPLIER  PCS ENDOSCOPY SUITE			STREET ADDRESS, CITY, STATE, ZIP CODE 500 S 11TH AVENUE, SUITE 303 POCATELLO, ID 83201		
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Q 225	<p>Continued From page 42</p> <p>the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, ASC policies, and patient rights information, it was determined the ASC failed to ensure a grievance procedure for documenting the existence, submission, investigation, and disposition of grievances to the ASC had been developed and implemented, and failed to inform patients of the grievance process. This failure directly impacted 27 of 27 patients (Patients #1 - #27) whose records were reviewed and all patients receiving care at the facility. This resulted in a lack of information being provided to patients explaining the grievance process. Findings include:</p> <p>1. Review of the facility's policy manual showed there was no policy relevant to the presence of a grievance procedure. The "PCS Endoscopy Suite, Inc. Patient Rights and Responsibilities" was reviewed. It did not contain information for patients regarding a grievance procedure.</p> <p>Additionally, the medical records for Patients #1 - #27 were reviewed. None of the records contained documentation informing patients of a process to file grievances with the ASC.</p> <p>In an interview on 8/23/12 at 1:00 PM, the facility Administrator confirmed there was no formal grievance procedure. She said patients had the</p>	Q 225			

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Q 225	Continued From page 43 opportunity to voice complaints during the post-op follow up. She explained this was a telephone call made to the patient, by the facility CMA, the evening of the procedure. The post-op follow up form had two areas, titled "Patient Concerns" and "Comments," where patients could voice a complaint. The Administrator said a complaint received in this manner would be forwarded on to the Director of Nursing or the facility Administrator.	Q 225			
Q 240	416.51 INFECTION CONTROL  The ASC failed to ensure a patient grievance process had been sufficiently developed and implemented, and therefore patients were not informed of a grievance process.  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, interview, review of policies, manufacturer's instructions, medical records, QA information, and personnel files it was determined the facility failed to maintain an infection control program that minimized the potential for spread of infections and communicable diseases. These systemic failures directly impacted 1 of 1 patients (Patient #22) whose procedure was observed, and had the potential to impact all patients receiving care at the facility. This resulted in patients being placed in immediate jeopardy and at risk to experience serious harm, impairment, or death as a result of unsafe practices. Findings include:  1. Refer to Q241 as it relates to the facility's	Q 240			

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Q 240	Continued From page 44 failure to provide a sanitary environment for patient care.  2. Refer to Q242 as it relates to the facility's failure to ensure the documentation of consideration, selection, and implementation of nationally recognized infection control guidelines. In addition, the facility failed to use the guidelines to maintain an ongoing program to prevent and control the risk of infections.  3. Refer to Q243 as it relates to the facility's failure to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.  4. Refer to Q244 as it relates to the facility's failure to integrate infection control into the QAPI program.  5. Refer to Q245 as it relates to the facility's failure to provide a plan of action to prevent, identify, and manage infections.  The cumulative effect of these systemic practices resulted in the inability of the facility to ensure the risks of infection and communicable diseases were minimized.	Q 240	Q240 – Infection Control – ASC failure to provide an Infection Control Program that minimized the potential for spread of infections and communicable diseases. Q241 – Sanitary Environment / Hand Hygiene was not completed in accordance with acceptable standards of practice. Effective 9/14/12, ASC policy on Isolation, which includes Standard Precautions (which applies to all patients receiving care) was reviewed with staff. Standard Precautions were not followed at the time of survey. This action will serve to ensure that Standard Precautions are followed at all times in the ASC and will ensure a sanitary environment. The DON will supervise hand hygiene and reinforce this practice as needed. Q241 – Sanitary Environment / Environmental Cleaning was not performed according to product label. Clorox Pro was the approved cleaner, which required the solution to remain wet for 10 minutes. In addition, the spray bottle being used was not labeled as Clorox Pro. During survey, the RN placed a label on the spray bottle. ASC staff was found to be inconsistent in how long the cleaner was left on surfaces. ASC staff was in-serviced on 9/14/12 to read all labels for manufacturer instructions for appropriate use. The ASC Governing Body has approved an additional hospital grade cleaner for daily use in the ASC, which requires a 3 minute standing time. The DON will incorporate this into the Infection Control portion of the ASC QAPI Program. These actions will ensure a sanitary environment for patient care.	09.14.12
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 review of	Q 241		09.14.12

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Q 241	Continued From page 45 facility policies and manufacturer's instructions, it was determined the ASC failed to provide a sanitary environment for 1 of 1 patients (Patient #22) whose procedure was observed and had the potential to impact all patients cared for at the facility. This resulted in the inability of the facility to minimize the risk of infection and the transmission of communicable diseases. Findings include:  1. Patient #22 was admitted to the facility on 8/22/12 for a colonoscopy. Her care was observed from 10:15 AM through 11:20 AM. Hand hygiene was not completed in accordance with acceptable standards of practice during this time frame as follows:  a. On 8/22/12 at 11:08 AM, the CMA completed the process of cleaning and setting the colonoscope in the disinfectant to soak. She removed her gloves and set the timer for 20 minutes. She then donned new gloves and continued to clean additional equipment used during the procedure, such as the suction canister and tubing. At 11:11 AM, the CMA removed the gloves that had been used to clean and disinfect equipment and opened the cabinet door to dispose of the gloves in the biohazard container. She was then observed prepare a tissue sample for transport to the laboratory to be biopsied. She was observed to open a drawer to get the bag for the biopsy container. She opened another cabinet to obtain the box for mailing, and a second drawer to obtain a label for the box. She then opened the procedure room door and donned a new pair of gloves. Hand hygiene was not observed between glove changes or when moving from one task to another.	Q 241			

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Q 241	Continued From page 46  b. On 8/22/12 at 11:14 AM, the RN was observed wearing gloves at the end of the procedure. While wearing gloves, she opened the cabinet to biohazard container and dirty laundry, then opened the door to the large oxygen tank to unhook the nasal cannula used by Patient #22, then went to the vital sign machine to print the strip of vital signs to place in Patient #22's chart. There was no glove change or hand hygiene observed between tasks.  A "PCS Endoscopy Suite Policy on Isolation," undated, addressed standard precautions and hand washing. According to the policy, CDC guidelines would be followed. The policy indicated that the fundamental of standard precautions included hand washing between patient contacts and "after contact with blood, body fluid, secretions, excretions, and equipment or articles contaminated by them whether or not gloves are worn."  The CDC "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, was reviewed. According to the guidelines, hand washing is recommended when hands are visibly soiled. Otherwise a list of when hand hygiene, either hand washing or decontamination with an alcohol based hand sanitizer, is recommended included when hands are not visibly soiled, before direct contact with patients, after contact with patient's intact skin, when moving from a contaminated body site to clean body site, after contact with inanimate objects in the immediate vicinity of the patients, and after removing gloves.  Hand hygiene was not performed in accordance	Q 241		

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Q 241	<p>Continued From page 47</p> <p>with standards of practice to ensure a sanitary environment for patient care.</p> <p>2. Prior to observing Patient #22's care, the process of cleaning the room between procedures was observed, on 8/22/12 from 9:45 AM to 10:15 AM.</p> <p>On 8/22/12 at 9:45 AM, the CMA was observed to wet down surfaces, including all counter tops, the patient chair, IV pole, and bedside table with spray bottle. At this time, the RN produced a bottle of Clorox Pro Quaternary cleaner. She explained that this was the disinfectant in the bottle and confirmed that the bottled used by the CMA was not labeled correctly. The RN was asked how long the solution was supposed to remain on the surfaces before being wiped down. She replied that ASC staff typically waited 1-2 minutes before wiping down the surfaces. She then read the label of the Clorox Pro Quaternary solution and stated the directions indicate that surfaces were to remain wet for 10 minutes. She confirmed that the staff have not been using the disinfectant according to the directions. She and the CMA stated the process for cleaning the room between patient use would now include a 10 minute wait between wetting surfaces with the Clorox and wiping the surfaces dry.</p> <p>Note: During the observation, the CMA was observed to wipe down the surfaces at 9:58 AM, after the surfaces had remained wet for just over 10 minutes.</p> <p>The environmental surfaces of the procedure room were not disinfected according to manufacturer's label between procedures.</p>	Q 241			

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Q 241	Continued From page 48	Q 241			
Q 242	<p>The facility failed to ensure a sanitary environment was maintained for the provision of services.</p> <p><b>416.51(b) INFECTION CONTROL PROGRAM</b></p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and review of policies and medical records it was determined the facility failed to ensure the documentation of consideration, selection, and implementation of nationally recognized infection control guidelines. In addition, the facility failed to use the guidelines to maintain an ongoing program to prevent and control the risk of infections. These failures resulted in underdeveloped policies, errors in cleaning and disinfecting endoscopic equipment, and lack of program to monitor potential infections resulting from care in the ASC. These systemic failures directly impacted 1 of 1 patients (Patient #22) whose procedure was observed, and had the potential to impact all patients receiving care at the facility. This resulted in patients being placed in immediate jeopardy and at risk to experience serious harm, impairment, or death as a result of unsafe practices. Findings include:</p>	Q 242	<p>Q242 – Infection Control – 1.Immediate Jeopardy Status. During survey, ASC was placed in Immediate Jeopardy status for incorrect processes for cleaning and disinfecting endoscopic equipment, lack of staff training documentation, expired pre-soak solution, lack of monitoring and tracking of the Cidex Plus concentration, including not documenting each time the disinfectant is changed, as well as the temperature of the concentration. All of these items were addressed and corrected in the Plan of Corrections for Immediate Jeopardy, dated 8/23/12. The surveyors approved the Plan of Corrections (copy attached) and abated the Immediate Jeopardy status. In addition, the appropriate ratio of enzymatic cleaner to gallons of water, which is 1-2 oz cleaner per gallon of water, was reviewed with ASC staff. The DON will oversee and document training of nursing staff, in the future, to ensure continued compliance.</p>	08.23.12	

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Q 242	<p>Continued From page 49</p> <p>The facility failed to maintain an ongoing infection control program designed to prevent, control, and investigate infections are as follows:</p> <p>1. Incorrect processes for cleaning and disinfection endoscopic equipment include the following:</p> <p>a. The CMA was interviewed on 8/21/12 at 9:00 AM. She stated she received on-the-job training to clean the scopes. She stated she was trained by the LPN who had been cleaning the scopes before her and had subsequently retired.</p> <p>The CMA's personnel file was reviewed. It did not contain evidence of training regarding cleaning of the endoscopes. Her job description indicated her responsibilities included cleaning and sterilizing endoscopy equipment between procedures, according to policy. Her annual competency review, signed by the physician on 9/16/11, indicated she demonstrated proficiency in the knowledge of critical policies for aseptic technique, infection control, scrub procedures, and environmental cleaning. The Administrator was interviewed on 8/23/12 at 3:30 PM. She confirmed that the personnel file did not contain documentation of education or training provided to staff and she was not sure that any education or training was documented and filed elsewhere.</p> <p>The facility failed to ensure adequate training and documentation of training related to infection control.</p> <p>b. On 8/22/12 at 10:56 AM, the CMA was observed in her process of cleaning a colonoscope that had just been used during a</p>	Q 242			

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Q 242	<p>Continued From page 52</p> <p>On 8/22/12 at 3:47 PM, the CMA compared her process with the instructions for cleaning and disinfecting with those found in the manufacturer's manual. She confirmed that the manufacturer's instructions indicated the enzymatic detergent was to be rinsed from inside and outside of the scope, and the scope emptied of rinse water, prior to being disinfected. She stated she did not rinse the detergent from the scope prior to disinfection, but rather placed the scope (with detergent in the lumens) into the disinfectant.</p> <p>The facility failed to ensure the endoscopic equipment was rinsed of the enzymatic detergent prior to disinfection.</p> <p>d. The CMA was observed and interviewed on 8/22/12 at 10:04 AM. She stated the facility used Cidex to disinfect the endoscopy equipment. She stated she checked the concentration of disinfectant each day, prior to the first use, but did not keep a log of this monitoring. She explained when she activated the disinfectant she counted the expiration date 28 days after activation and placed a piece of tape with this expiration date on the cover over the disinfection bucket. The expiration date of the current disinfectant was noted to be 8/28/12. She stated she has never had to change the disinfectant prior to the 28 day expiration but did not keep a log of when the disinfectant was changed.</p> <p>On 8/22/12 at 10:56 AM, the CMA was asked to test the disinfectant concentration for the surveyor. She explained that she was unable to do so because the facility was out of the chemical</p>	Q 242			

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Q 242	<p>Continued From page 50</p> <p>procedure. She explained that she filled the sink with enough tap water to cover the scope. She stated she used two pumps of enzymatic detergent for endoscopes, and three pumps of enzymatic detergent for colonoscopes because it took more water to cover the colonoscope. She was not able to say how many gallons of water were used to cover the scopes.</p> <p>On 8/22/12 at 2:30 the enzymatic detergent used by the facility was reviewed. The enzymatic detergent was a product called Enzol. In the procedure room, under the sink, a one-gallon bottle of detergent was partially full and in use for cleaning instruments. In addition, there were three full one gallon bottles of detergent. The expiration date on all of the bottles was 10/2005. Instructions on the bottle included, "Use by expiration date on the immediate container." In addition, the instructions for the appropriate concentration of detergent were one ounce (or one pump) per gallon of water.</p> <p>On 8/22/12 at 3:47 PM, the CMA confirmed the enzymatic detergent was expired.</p> <p>On 8/23/12 at 2:45 PM, the CMA stated she had measured the exact amount of water needed to cover the colonoscope. She stated it took 6 gallons of water and confirmed that the concentration of detergent used to previously clean endoscopic equipment was incorrect.</p> <p>The facility failed to ensure enzymatic detergent was appropriately utilized for cleaning endoscopic equipment prior to high-level disinfection.</p> <p>c. On 8/22/12 at 10:56 AM, the CMA was</p>	Q 242		

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Q 242	<p>Continued From page 51</p> <p>observed in her process of cleaning a colonoscope that had just been used during a procedure. Once the colonoscope was externally cleaned, the CMA proceeded to use a scrub brush to clean all ports and lumens of the scope. She was observed to use a system with multiple tubes and a 30 ml syringe to flush enzymatic detergent through the scope six times. The scope was then transferred to the disinfectant bath. The scope was not observed to be rinsed, inside or outside, prior to being placed in the disinfectant. The CMA was then observed to use the 30 ml syringe to flush disinfectant through the colonoscope six times, potentially impairing the concentration of the disinfection with the expulsion of the detergent into the solution.</p> <p>On 8/22/12 at 2:30, the disinfectant used by the facility was reviewed. The product was Regimen Glutaraldehyde Plus. The instructions indicated, "Glutaraldehyde Plus is compatible with enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the Glutaraldehyde Plus by altering it's pH." The directions for use of the disinfectant included, "Blood and other body fluids must be thoroughly cleaned from surfaces, lumens, and other objects before application of the disinfectant or sterilant...For complete disinfection...thoroughly clean and rinse rough, dry objects before immersing in Glutaraldehyde Plus. Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment..."</p>	Q 242			

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Q 242	<p>Continued From page 53</p> <p>indicator test strips. She confirmed that she had been unable to test the concentration of the disinfectant for about two weeks but had ordered the test strips and expected to receive them 8/23/12.</p> <p>The disinfectant used by the facility was Regimen Glutaraldehyde Plus, not Cidex. A label that was attached to the bottle of disinfectant was reviewed. According to these instructions, "Glutaraldehyde Plus can be reused for a period not to exceed 28 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based on monitoring described in Directions for Use. DO NOT rely solely on days in use. Efficacy of this product during its use-life must be verified by a 1.8% glutaraldehyde test indicator to determine that at least the minimum effective concentration (MEC) of 1.8: glutaraldehyde is present..." The directions for used recommended that the "Glutaraldehyde Plus be tested with a 1.8% glutaraldehyde test indicator prior to each usage. This is to ensure that the appropriate concentration of glutaraldehyde is present and to guard against a dilution which may lower the effectiveness of the solution below its MEC. The pH of the activated solution may also be periodically checked to verify that the solution is between 6.5 and 8.5"</p> <p>The facility failed to monitor and track the glutaraldehyde concentration to ensure the disinfectant remained at the appropriate level of concentration.</p> <p>e. On 8/22/12 at 3:47 PM, the CMA acknowledged that the facility did not have a</p>	Q 242		
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NAME OF PROVIDER OR SUPPLIER  PCS ENDOSCOPY SUITE	STREET ADDRESS, CITY, STATE, ZIP CODE 500 S 11TH AVENUE, SUITE 303 POCATELLO, ID 83201
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Q 242	<p>Continued From page 54</p> <p>method in place to monitor and track the temperature of the disinfectant to ensure the disinfectant was effective.</p> <p>The label on the bottle of disinfectant indicated, "Glutaraldehyde Plus is a high-level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days at 25 degrees centigrade..." The directions for use indicated, "During the usage of Glutaraldehyde Plus, as a high-level disinfectant and/or sterilant, it is recommended that a thermometer...be utilized to ensure that the optimum usage conditions are met."</p> <p>The facility failed to monitor and track the temperature of the disinfectant to ensure the maximum effect of the product was maintained.</p> <p>f. On 8/22/12 at 11:08 AM, the CMA was observed, after setting the colonoscope in the disinfectant to soak, to set the timer for 20 minutes.</p> <p>On 8/22/12 at 2:30 PM, the bottle of Glutaraldehyde Plus was examined. Instructions on the bottle indicated that instruments were to be soaked for a minimum of 90 minutes. The "INDICATIONS FOR USE" section of the written documentation attached to the bottled reiterated that, "Glutaraldehyde Plus is a high-level disinfectant when used or reused, according to Directions for Use, at full strength for a maximum of 28 days at 25 degrees centigrade with an immersion time of at least 90 minutes..."</p> <p>On 8/22/12 at 3:47 PM, the CMA confirmed that she soaked the instruments in the disinfectant for</p>	Q 242		
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Q 242	<p>Continued From page 55</p> <p>20 minutes. She stated often the scope was soaked several minutes longer than that, perhaps 30 to 35 minutes. She then reviewed the label on the bottle of Glutaraldehyde Plus. She confirmed there was a discrepancy between the process she had been trained to complete and the instructions on the bottle of disinfectant. She confirmed she had always let the instruments soak for 20 minutes as she was trained to do.</p> <p>The facility failed to ensure equipment was disinfected for the amount of time directed by the manufacturer of the product.</p> <p>g. Two surveyors intermittently observed patient care, including cleaning and disinfecting of endoscopy equipment, in the ASC on 8/22/12 from 8:30 AM through 11:20 AM. According to the ASC schedule one patient was scheduled for an endoscopy at 8:30 AM, Patient #22 was scheduled for a colonoscopy at 9:30 AM, and a third patient was scheduled for a colonoscopy at 10:30 AM. Patient #22's procedure, from check in to discharge assessment was observed from 10:15 AM through 11:20 AM.</p> <p>On 8/22/12 at 3:47 PM, the CMA confirmed the facility typically used only one endoscope and one colonoscope for procedures. She stated there was a "back up colonoscope" if it was needed. She confirmed all of the scopes had been processed as described in the steps above. She stated the colonoscope used for Patient #22 was used for the colonoscopy on the patient who was seen after Patient #22.</p> <p>The cumulative effect and serious nature of these practices had the potential to result in serious</p>	Q 242		
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Q 242	<p>Continued From page 56</p> <p>harm, impairment, or death. The facility was notified of the Immediate Jeopardy on 8/22/12 at 4:30 PM. The facility submitted and immediate plan of correction as follows:</p> <p>"Please accept this plan of correction for the items noted during our recent survey. By following this plan, we are confident that we will sustain compliance.</p> <p>Glutaraldehyde Solution - discrepancy between soaking time learned during training and recommended soaking time on product label. We have always followed the guidelines for Cidex Plus solution which allows for a 20 minute soak time. In switching to a generic glutaraldehyde solution it is now noted that the soaking time varies. Our plan is to immediately change back to Cidex Plus and continue with the 20 minute soak time, as noted on the Cidex Plus product use guide. A Soak Time Exception is also noted in a research paper published by the Society of Gastroenterology Nurses and Associates, Inc titled Guidelines for Use of High Level Disinfectants &amp; Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes, for (generic) Glutaraldehyde:</p> <p>"Soak Time Exception: SGNA in collaboration with the ASGE, AGA, the ACG and the APIC adopted the Multi-society Guideline for Reprocessing Flexible Gastrintestinal [sic] Endoscopes. This guideline, based on scientific data, supports the position that after meticulous manual cleaning, high level disinfection is achievable with a 20-minute exposure at 20 degrees C (room temperature) in a 2% glutaraldehyde solution ...This recommendation</p>	Q 242		
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Q 242	<p>Continued From page 57</p> <p>differs from the label claims ...because the current federal labeling regulation assumes no cleaning of the medical device prior to chemical exposure."</p> <p>"Enzymatic Detergent (pre-soak) - Current product in ASC was found to be expired. We will immediately replace that product with another enzymatic detergent and follow the specific use instructions for the replacement product."</p> <p>"Glutaraldehyde Test Strips - ASC has not kept a log of the level of MEC of the solution. Before each cleaning, test strips are used to verify the MEC of the glutaraldehyde solution. A log will now be kept to document the date and result of each test."</p> <p>On 8/23/12 at 2:45 PM, the facility's process for cleaning and disinfecting an endoscope was observed. The process was completed in accordance with the facility's plan of correction and the Immediate Jeopardy was abated on 8/23/12 at 3:30 PM.</p> <p>2. There was no documentation that the facility considered, selected, and implemented nationally recognized guidelines in the infection control program.</p> <p>The Administrator was interviewed on 8/24/12 at 9:30 AM. She stated that the ASC's accrediting organization recommended use of AORN guidelines and therefore most of the ASC's policies were AORN based. She confirmed there was no documentation that the ASC considered and then selected these specific guidelines for use in the infection control program.</p>	Q 242	<p>Q242 – Infection Control – ASC was found to be lacking documentation of Governing Body approval for the use of AORN guidelines for ASC policies. ASC Governing Body determined on 9/14/12, since the ASC Infection Control Program is to be revised prior to 10/1/12, to consider other nationally recognized guidelines for the basis of ASC policies. This recommendation will be made by DON as a result of the Infection Control training to be attended by DON prior to 10/1/12.</p>	10-01-12	

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Q 242	Continued From page 58  3. Policies related to infection control were not fully developed to guide staff in handling infection control issues as follows:  a. "PCS ENDOSCOPY SUITE PROTOCOL ON REPORTING INFECTIONS." The policy did not indicate what steps were to be taken to assist staff in identifying potential infections related to care at the facility. The policy indicated that if an infection was reported the entire procedure room where the incident occurred was to be re-cleaned and sterilized. The policy did not indicate what steps would be taken to determine the cause of the infection or actions to be taken if the infection was not related to environmental cross-contamination.  b. "PCS Endoscopy Suite Policy on Isolation." The policy indicated that "if a patient is in need of isolation procedure, they will not be admitted, treated, tested or undergo any procedure inside the PCS Endoscopy Suite." However, should the need present itself, the policy indicated CDC guidelines would be used based on the "Transmission Based Precautions." The policy indicated that the fundamentals of standard precautions included hand washing between patient contacts and "after contact with blood, body fluid, secretions, excretions, and equipment or articles contaminated by them whether or not gloves are worn." The policy did not contain an inclusive list of when hand hygiene was to be performed. The policy did not include instructions on the process for hand hygiene, either hand washing or sanitizing with alcohol based hand rub.	Q 242	Q242 – Infection Control – ASC policies not fully developed for IC. Refer to correction noted for Q103 which states 'Effective 10/1/12, current ASC policy on reporting infections will be revised to include a protocol for identifying and preventing infections.' This policy will also address steps to be taken to determine the cause of an infection, and actions to be taken if an infection is determined not to have been caused by environmental cross-contamination. Following the scheduled Infection Control training by RN (refer to Q060) additional ASC staff training will occur prior to 10/1/12 to ensure compliance.	10-01-12
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Q 242	<p>Continued From page 59</p> <p>The CDC "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, was reviewed. According to the guidelines, hand washing is recommended when hands are visibly soiled. Otherwise a list of when hand hygiene, either hand washing or decontamination with an alcohol based hand sanitizer, is recommended included when hands are not visibly soiled, before direct contact with patients, after contact with patient's intact skin, when moving from a contaminated body site to clean body site, after contact with inanimate objects in the immediate vicinity of the patients, and after removing gloves.</p> <p>c. "PCS ENDOSCOPY SUITE PRACTICES FOR ENVIRONMENTAL CLEANING." The policy indicated "the procedure room and all its contents, including IV pole, bed, lap tray, counter tops, equipment, and handles on all cupboards and doors are being cleaned with a facility approved disinfectant." The policy did not specify what this product was or the instructions for the product's use.</p> <p>d. "PCS Endoscopy Suite Policy on Cleaning and Processing Anesthesia Equipment." This policy indicated the "approved cleaner for use inside PCS Endoscopy Suite will be Cidex." The policy provided guidelines for cleaning and processing anesthesia equipment and instruments. However, the facility did not use anesthesia equipment as part of its services. The policy did indicate that gastrointestinal endoscopes were semicritical equipment and required chemical high-level disinfection. According to the policy, the "approved cleaner for use inside PCS Endoscopy Suite will be Cidex." This was not the product in use at the time of the survey.</p>	Q 242	<p>Q242 – Infection Control – ASC policies not fully developed for IC. ASC Policy on Isolation does not include a list of when hand washing is to be performed, nor did it include instructions on the process for hand washing or sanitizing with alcohol based hand rub. Effective 10/1/12, ASC policy on Isolation will be updated to include CDC approved steps on hand washing, use of alcohol based hand rubs, and when hand washing should occur.</p> <p>Q242 – Infection Control – ASC policies not fully developed for IC. ASC policy on Environmental Cleaning did not specify what this product was or the instructions for the product's use. On 9/14/12, ASC policy was updated to include the names of two approved products for cleaning the ASC, and requirements that staff follow manufacturer label for use instructions. ASC staff was inserviced on 9/14/12 to read all labels for manufacturer instructions for appropriate use. This action will ensure that ASC maintains fully developed policies in Infection Control and will be overseen by the Infection Control Officer (Erika Gunter, RN) and implemented into the QAPI program.</p> <p>Q242 – Infection Control – ASC policy indicated an approved cleaner for processing scopes was Cidex Plus, however during survey it was found that ASC was using another cleaner for processing scopes. Refer to Immediate Jeopardy Plan of Corrections, dated 8/23/12, where ASC immediately resumed the use of Cidex Plus, as per policy.</p>	<p>10-01-12</p> <p>09-14-12</p> <p>08-23-12</p>
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Q 242	Continued From page 60  e. "PCS Endoscopy Suite Procedure for Sterilization of Endoscopes." However, on 8/24/12 at 10:00 AM, the CMA presented a policy titled "CLEANING ENDOSCOPY." She stated this was the policy she referred to when cleaning endoscopes. This policy was also undated. The policy instructed staff to clean the scope inside and out with detergent and then evacuate the detergent from inside the lumens of the scope prior to placing the scope in the disinfectant. The policy did not indicate the scope was to be rinsed, and then the water removed from the lumens, prior to disinfecting. The policy directed staff to "Place scope in cidex and push solution through scope, leave in solution for at least 20 minutes."	Q 242	Q242 – Infection Control – ASC policy on Cleaning Endoscopy did not indicate a middle rinse step prior to disinfecting. On 9/14/12, ASC reviewed PCS Endoscopy Suite Procedure for Sterilization of Endoscopes and found policy to be correct. All ASC staff were inserviced on current policy on 9/14/12 to the correct procedure. A corrected check list titled Cleaning Endoscopy has been posted in the ASC to ensure compliance will all steps. This will be monitored by the Infection Control Officer (Erika Gunter, RN).	09-14-12
Q 243	416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION  The program is - Under the direction of a designated and qualified professional who has training in infection control.  This STANDARD is not met as evidenced by: Based on review of facility policies, personnel files and staff interview, it was determined the ASC failed to ensure the infection control program functioned under the direction of a	Q 243	Q243 – Infection Control – ASC failed to ensure that the Infection Control program was directed by a qualified professional who has training in infection control. Refer to Q060 which states: Erika Gunter, RN was appointed the new ASC Infection Control Officer and was registered on 9/14/12 for the following course: A Primer for Designated Infection Control Program Managers in Ambulatory Surgical Settings. She will complete this training by 10/1/12. A job description outlining the specific responsibilities of the Infection Control Officer will be developed. These actions will ensure ASC compliance in Infection Control.	10-01-12

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Q 243	<p>Continued From page 61</p> <p>qualified professional who had training in infection control. This impacted facility staff and all patients who received care at the facility. This prevented the ASC from utilizing the knowledge base of a trained professional to develop and monitor an infection control program. Findings include:</p> <p>1. On 8/21/12 at 1:45 PM, the RN and the CMA explained that an LPN, who had recently retired and was not available during the month of August, was the individual who had been responsible for infection control information prior to her retirement. The RN stated she believed the CMA was the person selected to run the infection control program. The CMA confirmed this belief and stated that upon the LPN's return from vacation she was to be trained on information necessary to complete this role.</p> <p>Personnel files were reviewed. The LPN's job description did not include any duties specific to directing an infection control program. Her personnel file did not include any documentation of training or education related to running an infection control program.</p> <p>Facility policies were reviewed. A job description outlining qualifications and responsibilities for the Infection Control Officer was not found.</p> <p>The Administrator was interviewed on 8/22/12 at 8:45 AM. She confirmed the Infection Control Officer position was in transition. She stated that the LPN, who was in charge of infection control, worked only intermittently in the ASC in July 2012 and was not available to work in the facility again until September 2012. The Administrator</p>	Q 243			

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Q 243	Continued From page 62 explained that the plan was to hire the LPN under contract to be in charge of the QAPI and Infection Control programs. The Administrator stated she believed the training and education that qualified the LPN as an Infection Control Officer was her long time experience as a nurse in the endoscopy environment. The Administrator stated that the plan was for the CMA to be in charge of infection control monitoring, etc., on a daily basis and the LPN would be responsible for pulling the data together for reports and review of policies.  The Administrator was again interviewed on 8/24/12 at 9:30 AM. She confirmed that she was unable to locate any documentation of infection control training or education for the LPN. She guessed that the LPN spent about 1-2 hours a month specifically dedicated to infection control activities. She stated the LPN spent time in the facility and as part of interacting with staff and patients would probably spend additional time evaluating infection control practices.  The Infection Control Officer was not available for interview.  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	Q 244			

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Q 244	<p>Continued From page 63</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of quality assurance documentation and meeting minutes, it was determined the facility failed to ensure the ASC's infection control program was integrated into a QAPI program. This impacted all patients receiving care at the facility. Failure to integrate the infection control program with QAPI had the potential to inhibit the ASC's ability in identifying infections and improving infection control practices at the ASC. Findings include:</p> <p>1. The facility's annual Quality Assurance report for the year 2011 was reviewed. No information was present showing the collection, analysis, and monitoring of data relative to infection control.</p> <p>The QI Officer, who was also the Infection Control Officer, was not available for interview.</p> <p>In an interview on 8/22/12 at 10:00 AM, the facility Administrator stated she was not aware of any additional data collected to clarify the incidence, prevalence or severity of potential problems.</p> <p>The Administrator was interviewed on 8/23/12 at 3:45 PM. She confirmed that all information related to infection control had been presented to the surveyors. She stated she was unaware of any additional information related to the collection of infection control quality indicators.</p> <p>The Administrator was again interviewed on 8/24/12 at 9:30 AM. She stated the facility did not have a specific process to follow up with patients to identify infections potentially related to care at the ASC. She confirmed that this information</p>	Q 244	<p>Q244/Q245 -- Infection Control -- ASC failed to show a specific process for identifying and preventing infections. Refer to Q060: An Infection Control Program will be developed as a part of the QAPI by 10/1/12. Erika Gunter, RN was appointed the new ASC Infection Control Officer and was registered on 9/14/12 for the following course: A Primer for Designated Infection Control Program Managers in Ambulatory Surgical Settings. She will complete this training by 10/1/12. The Infection Control Officer will oversee the program and will be responsible for staff training, ongoing monitoring and improvements. The Infection Control Program will ensure the ASC provides a sanitary environment for patient care at all times. The Program will provide a plan to prevent, identify, track and manage infections within the ASC.</p>	10-01-12

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Q 244	Continued From page 64 was not tracked by the ASC.	Q 244			
Q 245	<p>The ASC failed to ensure the ASC's infection control program was developed and integrated into a QAPI program.</p> <p><b>416.51(b)(3) INFECTION CONTROL PROGRAM - RESPONSIBILITIES</b></p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of facility policies and interview, it was determined the facility failed to provide a plan of action to prevent, identify, and manage infections. This impacted all patients cared for at the facility. This had the potential to interfere with the quality and coordination of infection prevention and control efforts. Findings include:</p> <p>On 8/23/12 at 3:45 PM, the Administrator stated that all of the documentation related to infection control was in the policy and procedure manual. She confirmed no other data was available.</p> <p>The facility's policy, "PCS ENDOSCOPY SUITE PROTOCOL ON REPORTING INFECTIONS," undated, was reviewed. The policy did not indicate what steps were to be taken to assist staff in identifying potential infections related to care at the facility. The policy indicated that if an infection was reported the entire procedure room where the incident occurred was to be re-cleaned</p>	Q 245			

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Q 245	Continued From page 65 and sterilized. The policy did not indicate what steps would be taken to determine the cause of the infection or actions to be taken if the infection was not related to environmental cross-contamination. Documentation of an approved comprehensive infection control plan of action was not found in the ASC's records.  The Administrator was interviewed on 8/24/12 at 9:30 AM. She stated the facility did not have a specific process to follow up with patients to identify infections potentially related to care at the ASC. She confirmed that the discharge instructions directed patients to contact the physician if they developed a temperature or had increased abdominal pain. She explained that often times the physician performing the procedure was also the patient's primary provider and would therefore likely follow up in the office with any concerns. She confirmed that this information was not tracked by the ASC.  The ASC failed to ensure a documented infection control plan was developed to prevent, identify, and manage infections.	Q 245		
Q 264	416.52(b) POST-SURGICAL ASSESSMENT  (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Post-surgical needs must be addressed and included in the discharge notes.	Q 264	Q264 – Post Surgical Assessment – ASC Conscious Sedation Flow Sheet did not include all of the elements required by ASC policy, and therefore patients were being discharged without a complete post surgical assessment. Effective 9/14/12, ASC flow sheet was updated to include: time O2 was discontinued, time patient was taken to recovery room; and discharge assessment to include level of consciousness, level of activity, patient color. This change will ensure that post procedural assessments are documented in the medical record accurately. The DON will audit all charts to ensure continued compliance with the updated form.	09.14.12

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Q 264	<p>Continued From page 66</p> <p>This STANDARD is not met as evidenced by: Based on review of medical records and facility policy and interview it was determined the facility failed to ensure patients' post-procedural assessments were documented in the medical record for 27 of 27 patients (Patients #1 - #27) whose records were reviewed. Failure to clearly document discharge assessments had the potential to impede determination of how the recovery process proceeded and prevent premature discharge. Findings include:</p> <p>1. The RN was interviewed on 8/21/12 at 2:30 PM. She stated the physician met with patients and their representatives prior to discharge. She confirmed the physician determined when the patient was ready to be discharged from the facility and signed the discharge order.</p> <p>The Administrator was interviewed on 8/22/12 at 8:45 AM. She stated the facility did not have a policy regarding discharge criteria. Rather, a patient's discharge was at the physician's discretion.</p> <p>However, the "PCS Endoscopy Suite Policy on Medical Records," undated, included elements to be documented related to the discharge evaluation. According to the policy, the discharge evaluation was to include level of activity, respirations, blood pressure, level of consciousness, and patient color.</p> <p>The medical records for Patients #1 - #27 were reviewed. The records included the following information regarding their discharge evaluations:</p>	Q 264		
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Q 264	Continued From page 67 - Patient #1's record documented his procedure was completed at 11:28 AM and he was discharged at 12:10 PM. The record documented "Pt [patient] awake responding well."  - Patient #2's record documented her procedure was completed at 10:25 AM and she was discharged at 11:45 AM. The record documented "Alert [and] Responding Appropriately."  - Patient #3's record documented his procedure was completed at 9:05 AM and he was discharged at 10:00 AM. The record documented "9:30 awake responding."  - Patient #4's record documented her procedure was completed at 9:25 AM and she was discharged at 10:30 AM. The record documented "09:40 pt. [patient] awake responding."  - Patient #5's record documented her procedure was completed at 10:10 AM. The time of discharge was not documented. The record documented "10:30 responding."  - Patient #6's record documented his procedures was completed at 11:30 AM and he was discharged at 12:30 PM. The record documented "alert [and] reactive."  - Patient #7's record documented his procedure was completed at 9:17 AM and he was discharged at 10:30 AM. The record documented "Alert [and] Reacting Appropriately."  - Patient #8's record documented her procedures was completed at 9:03 AM and she was discharged at 10:00 AM. The record documented	Q 264			

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Q 264	Continued From page 68 "alert and reactive."  - Patient #9's record documented his procedure was completed at 11:05 AM and he was discharged at 12:30 PM. The record documented "Alert [and] Responding Appropriately."  - Patient #10's record documented his procedure was completed at 9:55 AM and he was discharged at 11:30 AM. The record documented "Awake responding well 10:10."  - Patient 11's record documented his procedure was completed at 9:56 AM and he was discharged at 11:00 AM. The record documented "Alert [and] Reacting Appropriately."  - Patient 12's record documented his procedure was completed at 12:00 PM and he was discharged at 12:45 PM. The record documented "alert [and] responsive."  - Patient #13's record documented her procedure was completed at 12:37 PM and she was discharged at 1:15 PM. The record documented "alert [and] reactivity."  - Patient #14's record documented her procedure was completed at 1:00 PM and she was discharged at 2:30 PM. Next to "Patient alert and reactive" was handwritten "yes."  - Patient #15's record documented his procedure was completed at 12:45 PM and he was discharged at 2:00 PM. The record documented "Alert [and] Reacting Appropriately."  - Patient #16's record documented his procedure	Q 264			

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Q 264	<p>Continued From page 69</p> <p>was completed at 9:10 AM and he was discharged at 10:00 AM. The record documented "Pt [patient] awake responding."</p> <p>- Patient #17's record documented his procedure was completed at 12:10 PM and he was discharged at 1:10 PM. The form documented "Pt [patient] awake responding well."</p> <p>- Patient #18's record documented her procedure was completed at 11:35 AM and she was discharged at 12:30 PM. The record documented "Pt [patient] awake responding well."</p> <p>- Patient #19's record documented his procedure was completed at 12:15 PM and he was discharged at 1:00 PM. The record documented "12:25 pt [patient] responding well."</p> <p>- Patient #20's record documented his procedure was completed at 12:25 PM and he was discharged at 1:30 PM. The record documented "Pt [patient] awake responding."</p> <p>- Patient #21's record documented her procedure was completed at 11:10 AM and she was discharged at 1:30 PM. The record documented "12:00 pt [patient] responding well."</p> <p>- Patient #22's record documented her procedure was completed at 10:58 AM and she was discharged at 11:47 AM. The record documented "Alert [and] Reacting Appropriately."</p> <p>- Patient #23's record documented her procedure was completed at 11:25 AM and she was discharged at 12:30 PM. The record documented "11:30 pt [patient] awake - responding."</p>	Q 264			

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Q 264	<p>Continued From page 70</p> <ul style="list-style-type: none"> <li>- Patient #24's record documented her procedure was completed at 9:25 AM and she was discharged at 11:10 AM. The record documented "Alert [and] Reacting Appropriately."</li> <li>- Patient #25's record documented her procedure was completed at 9:30 PM and she was discharged at 10:45 AM. The record documented "alert [and] reactive."</li> <li>- Patient #26's record documented his procedure was completed at 11:28 AM and he was discharged at 1:30 PM. The record documented "Alert [and] Reacting Appropriately."</li> <li>- Patient #27's record documented her procedure was completed at 9:28 AM and she was discharged at 11:00 AM. The record documented "Alert [and] Reacting Appropriately."</li> </ul> <p>However, the records did not include additional information related to level of activity, respirations, blood pressure, level of consciousness, or patient color between the completion of the procedure and discharge. The records did not contain documentation to indicate when supplemental oxygen had been discontinued. The records did not contain information to clearly define when a patient was transferred from the procedure room to a recovery room or monitoring provided in the recovery room</p> <p>The CMA reviewed medical records on 8/23/12 at 3:30 PM. She confirmed that the machine used to monitor and document vital signs was not calibrated with the correct date and time until</p>	Q 264			

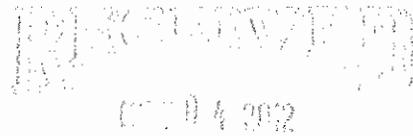
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Q 264	Continued From page 71 8/23/12. She acknowledged that because of the inaccurate calibration, it was difficult to correlate vital signs that were documented with the recovery phase of the procedure. She stated that the time supplemental oxygen was weaned or turned off was not documented, and neither was the time when the patient was moved from the procedure room to the recovery room. She agreed that for Patients #1 - #27, the documentation regarding post-procedural assessments was not complete.  The facility failed to ensure patients' post-procedural assessments were documented in the medical record.	Q 264			

PCS Endoscopy Suite

Addendum to Plan of Corrections dated 9/17/12



Q043 – Disaster Preparedness Plan – attached.

Faint stamp or watermark, possibly a date stamp, partially legible as 'OCT 04 2012'.

It was noted that local fire departments do not have any place for us within their community wide Disaster Preparedness Plan, but have reviewed our plan and assisted with setting up our first drill. *See attached email and drill documentation.*

Q080 – QAPI – as noted on page 4 of POC, the Governing Body meetings will be held quarterly for the first year following survey to ensure compliance with any and all changes implemented as a result of survey. If after one year, it is determined that it is necessary to continue quarterly meetings, the Governing Body will continue with that frequency. However, if it is determined that annual meetings will be adequate to oversee compliance, they may be changed back to annual at that time.

Q084 – POC referred to wrong section, should have been page 10 POC.

Q224 – Advance Directives – POC failed to reflect that this will be monitored by the DON to ensure all patients have been given information on Advance Directives prior to the procedure, and that their decision is documented in the patient chart. *See attached MR Audit Form.*

Q225 – Grievance Procedures – The ASC grievance procedure will be monitored by Administration to ensure that all grievances filed are handled with a thorough investigation and that all results are reported within the given time lines. The cumulative results will be reported to the QAPI Coordinator for inclusion in the ongoing QAPI program. For the immediate year following survey, the Governing Body meetings will be held quarterly, then annually after that. *See attached Grievance Report.*

Administrator Signature

Date