IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

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

CERTIFIED MAIL: 7000 1670 0011 3315 1545

July 24, 2015

RECEIVED
AUG - 6 2015
FACILITY STANDARDS

Jennie Rawlings, Administrator
PCS Endoscopy Suite
110 Vista Drive
Pocatello, ID 83201-5824

RE: PCS Endoscopy Suite, Provider #13C0001041

Dear Ms. Rawlings:

Based on the survey completed at Pcs Endoscopy Suite, on July 10, 2015, by our staff, we have determined PCS Endoscopy Suite is out of compliance with the Medicare ASC Conditions for Coverage of Governing Body and Management (42 CFR 416.41), Quality Assessment and Performance (42 CFR 416.43), Nursing Services (42 CFR 416.46), Medical Records (42 CFR 416.47) and Infection Control (42 CFR 416.51). To participate as a provider of services in the Medicare Program, an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiencies, which caused these conditions to be unmet, substantially limit the capacity of 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.

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

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;

- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date for correction of each deficiency cited must be included;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the acceptable plan of correction; and
- The administrator's signature and the date signed on page 1 of each form.

Such corrections must be achieved and compliance verified by this office, before August 24, 2015. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than August 14, 2015.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **August 6, 2015**.

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, option 4.

Sincerely,

LAURA THOMPSON
Health Facility Surveyor
Non-Long Term Care

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

LT/pmt
Enclosures
ec: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Linda Harris, CMS Region X Office

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

PRINTED: 07/24/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED
	13C0001041		07/10/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
POS ENDOSCOPY SUITE	110 VISTA DRIVE POCATELLO, ID 83201

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 000	INITIAL COMMENTS The following deficiencies were cited during the Medicare recertification survey of your surgery center conducted from 7/6/15 to 7/10/15. Surveyors conducting the recertification were: Laura Thompson, RN, HFS, Team Leader Gary Gulles, RN, HFS Acronyms used in this report include: AAMI - Association for the Advancement of Medical Instrumentation AORN - Association of Perioperative Registered Nurses ASC - Ambulatory Surgical Center B/P - Blood Pressure bpm - beats per minute CDC - Centers for Disease Control and Prevention CMA - Certified Medical Assistant CMS - Centers for Medicare and Medicaid Services DON - Director of Nursing EMR - Electronic Medical Record GI - Gastro-Intestinal H&P - History and Physical Examination IV - Intravenous mg - milligrams O2 sat - oxygen saturation level OR - Operating Room PIP - Performance Improvement Project PPE - Personal Protective Equipment pt - patient QAPI - Quality Assessment Performance Improvement RN - Registered Nurse RR - Respiratory Rate	Q 000	RECEIVED AUG - 6 2015 FACILITY STANDARDS	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] MD | TITLE: GOVERNING BODY | (X6) DATE: 8/5/15

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

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Q 040	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing,and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan. This CONDITION is not met as evidenced by: Based on observation, staff interview, and review of policies, medical records, meeting minutes, and QAPI documents, it was determined the ASC's Governing Body failed to assume responsibility for determining, implementing, and monitoring policies and failing to oversee the QAPI program. The cumulative effect of these systematic failures resulted in a lack of clear processes to guide staff in the provision of care and to evaluate its services. The findings include: 1. The ASC had not developed policies to direct and document care and services. The ASC had not developed policies defining standards for post-procedure care. The ASC had not developed policies for the documentation of post-procedure care. The ASC had not developed policies for sterilization of surgical instruments. The ASC had not developed policies for surveillance for infections. The ASC had not developed a basic hand hygiene policy. The DON was interviewed on 7/08/15 beginning	Q 040	Q040 - The following policies were drafted and approved by the Governing Body. • Post Procedure Care policy drafted and approved 8/3/15. Effective 8/12/15. • Policy on Surveillance for Infections was drafted and approved 8/3/15. Effective 8/12/15. • Hand Hygiene policy drafted and approved 8/3/15. Effective 8/12/15. • Sterilization of Surgical Instruments (Autoclave Use). Policy drafted and approved 8/3/15. Effective 8/14/15. • Contract for use of Autoclave equipment drafted and approved 8/3/15.	

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Q 040	Continued From page 2 at 3:50 PM. She confirmed the lack of the above policies. The Governing Body failed to develop policies to direct care at the ASC. 2. During an interview on 7/08/15 beginning at 12:20 PM, the CMA was asked about sterilization of instruments used in the procedure suite. The CMA stated a steam autoclave was used for sterilization of instruments. She stated the autoclave was located in the clinic adjoining the ASC. The CMA accompanied the surveyor to the clinic where the steam autoclave was observed. When asked about the process for maintaining and monitoring the loads being sterilized the CMA stated she did not monitor the autoclave using mechanical indicators or keep a log to track the instruments in each load. She stated she was not responsible for maintaining or monitoring of the steam autoclave and stated a clinic employee, who was not an ASC employee, processed the surgical instruments. The clinic employee, who was responsible for maintenance of the autoclave, was interviewed at that time. When asked, the clinic employee stated she did not use a biological indicator for monitoring the autoclave. The clinic employee also stated she did not keep a log or monitor mechanical indicators. She further stated the instrument loads were not logged in order to track instruments in case of an identified infection or problem with the autoclave. The CDC website, accessed 7/15/15, stated "Sterilization procedures should be monitored	Q 040	Q040-In addition to the newly approved Contract for use, the ASC has created a Policy on Use of Autoclave for Sterilization of ASC instruments and supplies, approved 8/3/15, effective 8/14/15. This policy will inform staff on the guidelines to be followed when using the Autoclave. The ASC has also created and approved a log sheet to monitor each load. The ASC will include the use of Biologic Indicators with each load. The lot number of the BI will he include on the log form. A printer will be used to provide documentation that the appropriate temperature, psi and cycle length are reached with each load. Mikelle Mierra, will be primarily responsible for autoclaving surgical instruments. However, all staff was oriented to the new policy and log forms on 8/11/2015. Mikelle will notify the DON of any immediate problems or concerns regarding the Autoclave and/or its ability to successfully complete sterilization. The DON will collect log forms and printed documentation from the Autoclave monthly and include these forms with other tracking forms in the Infection Control Program. The forms will be reviewed for accuracy, and any problem areas identified will be addressed by the DON and brought to the QAPI committee for further review, evaluation or recommendations.	

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Q 040	Continued From page 3 through a combination of mechanical, chemical, and biological techniques designed to evaluate the sterilizing conditions and the procedure's effectiveness." The Perioperative Standards and Recommended Practices 2012, stated "Accurate and complete records are required for process verification and used in sterilizer malfunction analyses. Documentation establishes accountability." The guidelines further stated documentation should include the assigned lot number, contents of each load, and results of physical, chemical, and biological monitors. However, the ASC did not have a policy that addressed the sterilization of surgical instruments and a contract with the clinic to sterilize the surgical instruments could not be found in the ASC's records. The Physician Owner was interviewed on 7/09/15 beginning at 1:10 PM. He confirmed the ASC did not have a contract with the clinic or policies to direct the sterilization of surgical instruments. The Governing Body failed to enter into contracts and develop policies to direct the sterilization of surgical instruments. 3. Refer to Q80 Condition for Coverage: Quality Assessment and Performance Improvement and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a QAPI program was developed, implemented, and maintained. The ASC was previously cited at Q80 during a recertification survey dated 8/27/12. The Governing Body failed to ensure sustained compliance was achieved.	Q 040	Q40 - Governing Body will increase input and oversight to the Infection Control program through quarterly meetings. Minutes will reflect attendance and all other Governing Body input, recommendations, and involvement. The DON will be responsible for the day to day operations and activities of the Infection Control program, and providing documentation for the QAPI meetings. Documentation of meetings will be specific and include information regarding how many procedures were performed by month, how many patients were contacted following procedures to identify complication and/or infections, and how many surveys are being returned. Discussions held during the meetings will be documented, and further areas identified for initial assessment or ongoing assessment will also be documented. Documentation of meetings will be written by the DON. Administrator will be responsible for ensuring Governing Body attendance at all meetings. A collaboration with other local ASC Infection Control Officials will give PCS Procedure Suite objective input on ways to improve program oversight and ensure its sustainability. See Governing Body minutes from 8/3/15. Refer to Q80, Q140, Q160 and Q240. Full compliance is expected by 8/14/2015.	

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Q 040	Continued From page 4	Q 040		
	4. Refer to Q140 Condition for Coverage: Nursing Services as it relates to the Governing Body's failure to ensure nursing services were provided to meet patients' needs. The ASC was previously cited at Q140 during a recertification survey dated 8/27/12. The Governing Body failed to ensure sustained compliance was achieved.			
	5. Refer to Q160 Condition for Coverage: Medical Records as it relates to the Governing Body's failure to ensure nursing care was documented.			
	6. Refer to Q240 Condition for Coverage: Infection Control as it relates to the Governing Body's failure to define and oversee the infection control program. The ASC was previously cited at Q240 during a recertification survey dated 8/27/12. The Governing Body failed to ensure sustained compliance was achieved.			
	The cumulative effect of these systematic failures resulted in a lack of clear processes to guide staff in the provision of care and to evaluate its services.			
Q 080	416.43 QUALITY ASSESSMENT AND PERFORMANCE	Q 080		
	The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on staff interview and review of QAPI plans, meeting minutes, and QAPI documents, it was determined the ASC failed to ensure a comprehensive QAPI program was developed, implemented, and maintained. This impeded the ability of the ASC to evaluate its practices and			

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Q 080	Continued From page 5 Improve care. Findings include: 1. Refer to Q81 as it relates to the ASC's failure to ensure an ongoing comprehensive QAPI program capable of demonstrating measurable improvement in patient health outcomes and improve patient safety was developed and implemented. 2. Refer to Q82 as it relates to the ASC's failure to ensure data was analyzed and used to improve care. 3. Refer to Q83 as it relates to the ASC's failure to ensure PIPs were conducted. 4. Refer to Q84 as it relates to the Governing Body's failure to ensure the QAPI program was defined, implemented, and maintained. The cumulative effect of these systemic practices prevented the ASC from evaluating its practices in order to improve care.	Q 080	Q80-ASC has established a consulting relationship with Qualis Health to review and provide feedback on our current QAPI and Infection Control programs. Refer to Q81, Q82, Q83, and Q 84. Q81-Effective 8/14/15 and forward, QAPI meetings, which will be held quarterly, will include all activities being performed as well as conclusions drawn from activities. These items include: infection control, risk management, results of peer review, sentinel events and grievances, safety and disaster, patient satisfaction, staff education, pharmacy audits, medication errors, medical record audits, and incident reports. The DON will complete monthly tracking forms to track patient falls, patient burns, hospital transfer or admissions, wrong site, or infections. She will also track monthly medical record audits, pharmacy audits, medication reports, incident reports, adverse reaction reports and patient satisfaction reports. This information will be reviewed and any trends identified will be presented at the quarterly QAPI meeting. If an urgent trend is identified, it will be presented immediately to the Governing Body. Items such as risk management, peer review, safety and disaster, and staff education will not be tracked monthly, but will reviewed at least annually (or more often if the need arises). continued on next page...	
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services	Q 081		

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Q 081	Continued From page 6 furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care. This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI plans, meeting minutes and QAPI documents, it was determined the ASC failed to ensure an ongoing comprehensive QAPI program capable of demonstrating measurable improvement in patient health outcomes and improve patient safety was developed and implemented. This prevented the ASC from analyzing its processes in order to improve them. Findings include: 1. Minutes from 1 QAPI Committee meeting were documented between 7/01/14 and 7/09/15. The "QAPI Annual Review Meeting, November 13, 2014" minutes documented a discussion of incident reports including problems with a vital sign monitor, 1 fall, 1 log sheet not faxed to a laboratory, and a discrepancy on a narcotic tracking sheet. The minutes stated a nurse had been hired to work 1 day per week. The minutes discussed items on "Patient Survey Questionnaires" but did not include the dates of the questionnaires. No data was included regarding the questionnaires. The minutes stated	Q 081	Q81-Recommendations from the QAPI committee or Governing Body drawn from items presented and discussed at meetings will be included in meeting minutes. Goals, which must be measurable, will be identified and approved by the committee for the upcoming quarter. Goals may remain the same if they haven't been met, or new goals may be identified if new areas of concern are identified at the meeting. The DON, Erika Gunter will be responsible for analyzing data from all the above mentions item being monitored, including PIP projects, and present this information to the QAPI Committee. She will also be responsible for writing minutes of the QAPI and/or Infection Control Meetings, which will contain who all was in attendance, all data analyzed and discussed, any conclusions or recommendations drawn, and further evaluation or new goals will be set. The Administrator, Jennie Rawlings, will be responsible to ensure that the Governing Body and QAPI members are in attendance at meetings. The Governing Body will be responsible to attend all meetings, and provide oversight and direction to the committee. These changes will be implemented by 8/14/15.	

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Q 081	Continued From page 7 flu shots were provided to staff. The minutes stated "minimal charts" were being returned to staff for corrections. The minutes stated "No discrepancies in the pharmacy audit (incident report of incorrect log, not incorrect count), medication reports or adverse reaction reports." The actual audit report was not present. Finally, the minutes stated the ASC had no burns, hospital transfers, wrong site procedures, or "post procedure infections requiring treatment." The minutes did not document any data, quality indicators, conclusions, or recommendations. Additionally, 2 PIPs were documented in 2014. One was a colonoscopy preparation solution study, dated July 2014, and the other was a colonoscopy withdrawal time study, dated August 2014. However, the minutes did not include information regarding the PIPs conducted in 2014 or include documentation of a plan for the QAPI program for 2015. The Physician Owner was interviewed on 7/09/15 beginning at 1:10 PM. He confirmed the content of the minutes and stated there were no other meeting minutes in the past year that discussed the QAPI program. The ASC failed to document QAPI activities. 2. A "Quality Assessment and Performance Improvement" plan, dated "January 2015," stated the ASC had a QAPI Committee that met 1 time a year. The plan stated information would be gathered, reviewed, and disseminated to the Governing Body. The plan stated recommendations would be provided to the Governing Body. The plan stated the committee would review "identified issues and trends"	Q 081		

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Q 081	Continued From page 8 related to infection control, risk management, outside peer review, sentinel events, grievances, safety and disaster, patient satisfaction, staff education, pharmacy audits, medication error audits, and incident reports. The plan stated the committee would set priorities and determine criteria for problems, implement corrective actions, and evaluate PIPs. The plan stated the committee would review and revise the plan as needed. The QAPI plan stated the ASC would monitor quality measures mandated by CMS including falls, burns, hospital transfers, wrong site surgeries, and post procedure infections. This consisted of counting the number of events and notifying CMS of the numbers. The plan stated the ASC would conduct medical record audits but did not define the audits or state what they would be used for. The plan stated the ASC would conduct patient satisfaction surveys. The QAPI plan did not identify high risk, high volume, or problem prone areas for study. The plan did not mention any specific quality indicators or specific PIPs to be conducted in 2015. The QAPI plan did not state what data would be gathered or how that data would be used. The plan did not include any goals. The plan did not identify a system for causal analysis to investigate adverse events. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the content of the plan and stated a plan including specific data to be collected and how that data would be used to improve care had not been developed. The ASC failed to ensure a QAPI program	Q 081		

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Q 081	Continued From page 9 capable of demonstrating measurable improvement in patient health outcomes was developed and implemented.	Q 081	Q82- Refer to Q81 as it includes a description of how improvement will be made in the overall QAPI plan. The DON will monitor the monthly tracking forms (quality indicators) above mentioned at Q81, and identify trends to present at quarterly meetings. If there is a trend identified, the DON will investigate to determine what has happened, bow it is happening, and ways to prevent further occurrences. All data collected will be used to monitor the effectiveness and safety of services. Quarterly meetings will incorporate discussion to identify opportunities for improvement. Improved documentation at QAPI meetings will identify such information derived from the tracking sheets (made from quality indicators outlined in the QAPI plan) such as the percentage of charts being returned upon audit for completion, or the percentage of pharmacy errors, or the percentage of incident reports per month. Evaluation of data compared to past quarters will also be discussed. Action plans, including education or additional in-service, will be identified and approved at QAPI meetings to improve compliance with policies of tbe ASC. For example: staff responsible to call patients the evening of their procedure will ask for signs or symptoms of infection, including fever. If the patient reports infection, the DON will be notified and will investigate possible causes of infection, will report infection to physician for further guidance, and look for other similar cases continued on next page....	
Q 082	416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents, it was determined the ASC failed to ensure data was analyzed and used to improve care. This prevented the ASC from identifying ways to improve processes. Findings include: 1. Two PIPs were documented in 2014. One was a colonoscopy preparation solution study, dated July 2014, and the other was a colonoscopy	Q 082		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 082	Continued From page 10 withdrawal time study, dated August 2014. Both studies incorporated quality indicator data. Since the colonoscopy withdrawal time study, 11 months ago, the only data gathered was the counting of numbers of events. For example, a "PCS Procedure Suite Quality Indicators Required by CMS Tracking Sheet," dated 6/24/15, stated there were no falls, patient burns, transfers, etc. for May 2015. A "PCS Procedure Suite Quality Indicators Specific to PCS Procedure Suite," tracking sheet, dated 6/24/15, stated 1 medical record audit had been returned to staff for correction and a pharmacy audit found 1 outdated medication which was reordered. This form also documented select comments from patient satisfaction surveys such as 1 patient complained of having pain and swelling. No documentation was present that the data was analyzed or utilized to improve care. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She stated she collected the data once a month. She stated the medical record audits were used to determine if medical records were complete. She said if an item was missing the staff member was prompted to complete it. She stated pharmacy audits were used to identify errors in logs and missing or expired medications. She stated data from the tracking sheets was not analyzed and no recommendations for care had been made based on the data. She stated the last data analysis occurred with the colonoscopy withdrawal time study in August of 2014. She stated there was no documented plan to analyze data in 2015. She stated she was currently gathering data for a PIP but she said she could not find documentation of this.	Q 082	Q82- or common factors. The Infection will be included in both the Infection Control log and presented at the QAPI meeting for discussion. Staff may be re-oriented to infection control policies as needed, to prevent further episodes of infection within our ASC. Compliance is expected by 8/14/2015.	

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Q 082	Continued From page 11 The ASC failed to use data to monitor the quality of its care and to identify opportunities that could lead to improvements and changes in its patient care. 2. A "Benchmarking Study: Colonoscopy Withdrawal Time," dated August 2014, stated "The American College of Gastroenterology guidelines state that colonoscopy withdrawal times (measured from Cecum) should average at least 6 minutes..." The study stated colonoscopy withdrawal times were measured for 26 patients for each of 2 physicians. One physician's average withdrawal time was 8.2 minutes and the second physician's withdrawal time averaged 6.3 minutes. The study concluded the withdrawal times were adequate for both physicians. However, the data for the second physician showed the withdrawal time did not meet the standard for 27% of the procedures. The study's conclusion did not include this information. The Physician Owner was interviewed on 7/09/15 beginning at 1:10 PM. He stated he was not aware of the number of patients for whom the standard was not met. 3. The ASC's 2015 Infection Control Plan stated strict hand hygiene would be encouraged and enforced. The plan stated staff would follow CDC guidelines for hand hygiene and perform hand hygiene at every opportunity. The goal was for greater than 80% compliance with hand hygiene by staff. The plan stated if hand hygiene was not performed, an incident report would be written by the DON.	Q 082		

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Q 082	Continued From page 12 No data regarding hand hygiene was documented between 1/01/14 and 7/08/15. In addition, no incident reports related to hand hygiene were documented for the same time period. The DON was interviewed on 7/08/15 at 2:45 PM. She stated no data or incident reports related to hand hygiene were documented. The ASC failed to collect hand hygiene data.	Q 082	Q83-PIPs will be completed on a continuous basis, with a minimum of 2 identified and approved by the Governing Body for each upcoming year, at the annual meeting in November. Then, additional studies may be suggested and/or needs identified at quarterly QAPI meetings. The ASC intends to have a study in progress at all times. In a meeting held on 8/03/15, Two PIPs were approved by the Governing Body. These studies are to begin by 8/14/15 and include data from 2015. Data, Conclusions and Recommendations from these PIPs will be included in the QAPI minutes for 2015. -Colonoscopy was identified as a high volume procedure in the ASC. A follow up study from a AAAHC benchmarking study in 2013 showed PCS Procedure Suite recovery times to be higher than average. PIP #1 – Will collect and analyze recovery times in relation to amount of Versed received during procedure. -Hand Hygiene was identified as a high risk area for the ASC. PIP #2 – Will collect and analyze missed opportunities for hand hygiene in both staff and family members visiting the ASC. The DON, Erika Gunter, will be responsible to collect data for the PIP's, analyze data, and present data to the QAPI Committee at quarterly meetings. The Administrator, Jennie Rawlings, will be responsible to ensure attendance from all members at meetings. The Governing Body will attend all meetings, provide feedback and promote discussion from data provided, and provide oversight of the overall QAPI Committee.	
Q 083	416.43(d) PERFORMANCE IMPROVEMENT PROJECTS (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents, it was determined the ASC failed to ensure PIPs were conducted. This prevented the ASC from analyzing processes in depth. Findings include: 1. Two PIPs were documented in 2014. One was a colonoscopy preparation solution study, dated July 2014, and the other was a colonoscopy withdrawal time study, dated August 2014. Since the colonoscopy withdrawal time study, 11	Q 083		

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Q 083	Continued From page 13 months ago, no PIPs had been conducted. No documentation was present to show the ASC planned to conduct PIPs. A "Quality Assessment and Performance Improvement" plan, dated "January 2015," listed items included in the QAPI program for 2015. The plan did not include PIPs. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She stated she started a PIP but did not have documentation for this. She said no PIPs had been approved in writing by the ASC's QAPI Committee or by the Governing Body. The ASC failed to conduct PIPs.	Q 083		
Q 084	416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI plans and meeting minutes, it was determined the ASC's Governing Body failed to ensure the QAPI	Q 084		

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Q 084	Continued From page 14 program was defined, implemented, and maintained. This resulted in a lack of direction to staff responsible for the program. Findings include: 1. A "Quality Assessment and Performance Improvement" plan, dated "January 2015," did not mention any specific quality indicators or specific PIPs to be conducted in 2015. The QAPI plan did not state what data would be gathered or how that data would be used. The plan did not include any goals. In addition, the plan had not been approved by the Governing Body. The lack of direction to staff led to a lack of data. No data related to ASC practices, such as how staff cared for patients, was documented since August 2014. One QAPI Committee meeting was documented between 7/01/14 and 7/09/15. The Committee meeting was dated 11/13/14. The minutes did not identify quality indicators or include a discussion of data that had been gathered or would be gathered in the future. One set of Governing Body meeting minutes was documented between 1/01/14 and 7/09/15. The document was titled "Minutes of the Organizational Meeting of the Incorporators of PCS Endoscopy Suite, Inc. 2014." The minutes were not dated. The minutes stated "Quality Assurance Review." The review section stated the last equipment inspection was September 2014, there were no adverse medication reactions, and the pathology and drug disposal logs were approved. The review section also stated the crash cart was inspected, incident reports were reviewed and "Changes noted."	Q 084	Q84-QAPI 2015 The Governing Body will ensure the QAPI program is defined, implemented and maintained by attending quarterly meetings, providing feedback to data presented, promoting discussions from material presented at meeting, initiating new discussion if appropriate, and providing oversight to the overall program. Plan goals have been updated and approved by the Governing Body on 8/3/15, and included in the PIPs being conducted for 2015. They include: Improve and provide safe care, including discharging patients home within a reasonable amount of time following conscious sedation; and Improve overall compliance with overall hand hygiene that was found to be lacking in our facility, and to include all staff in the procedure suite as well as family and visitors in our efforts to prevent possible infections within our ASC. The DON will be responsible for initiating the PIP's, implementation, data collection, analyzation, and presentation to the QAPI committee meeting, and writing meeting minutes following the QAPI meetings. Minutes will include all in attendance, discussion items, items that are resolved or need further assessment, new items to be addressed, quality indicators to be addressed in future, future goals, and Governing Body approval. The minutes will be dated and then signed by all in attendance, including the Governing Body. The Administrator will be responsible to ensure attendance at meetings from all committee members, and the Governing Body will attend meetings, provide feedback, initiate discussion and communication and approve ongoing goals and plans. Compliance by 8/14/15.	

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Q 084	Continued From page 15 Finally, the review section stated fire drills and Patient Satisfaction Reports were approved. No discussion of the QAPI program, quality indicators, or the QAPI plan was documented. The Physician Owner was interviewed on 7/09/15 beginning at 1:10 PM. He confirmed the above 2 sets of minutes were the only documentation of administrative or Governing Body involvement in the ASC's QAPI program. He stated no documentation was present that the Governing Body provided direction or oversight to the QAPI program in the past year. He further stated the amount of time and resources used for the QAPI program were not tracked. The Governing Body failed to define, develop, and maintain the QAPI program.	Q 084		
Q 101	416.44(a)(1) PHYSICIAL ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to adhere to national guidelines and acceptable standards of professional practice related to procedure rooms and the reprocessing of endoscopes. This failure directly impacted 1 of 2 patients (#19) whose procedures were observed and had the potential to place all patients at risk for infection following their endoscopic procedures. Findings include:	Q 101		

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Q 101	Continued From page 16 1. A facility tour was conducted on 7/07/15 at 10:35 AM with the DON. The ASC had a waiting room, 1 procedure suite, 2 recovery rooms, a storage closet, and a restroom. When asked about the reprocessing of endoscopes, the DON stated endoscopes were reprocessed in the procedure suite. The procedure suite had a sink used for cleaning and rinsing the endoscopes and a basin filled with disinfectant covered by a countertop. The countertop covering the basin would be lifted to expose the basin for high level disinfection of the endoscopes, after the cleaning process was completed. An observation of Patient #19 was conducted beginning at 9:20 AM on 7/08/15. After the endoscope was removed the CMA began cleaning the endoscope in the sink, which was prefilled with enzymatic cleanser. The CMA was wearing a gown, gloves, and protective eyewear. Patient #19 was in the procedure suite with the DON. Neither the DON nor Patient #19 wore PPE. The CMA was continuing the cleaning process for the endoscope while the DON removed the IV from Patient #19's hand. Once Patient #19 was moved from the procedure suite to the recovery room the CMA finished the cleaning process and placed the endoscope into the basin filled with the disinfectant for high level disinfection. A policy "PCS Endoscopy Suite Procedure for Sterilization of Endoscopes," undated, did not include guidance about reprocessing taking place in the procedure suite and protection or safety of the patient related to the process.	Q 101	Q101-On 8/3/15, The Governing Body approved an update to the Procedure for Sterilization of Endoscopes, effective 8/12/15. This policy now reflects that scope reprocessing will take place inside the procedure suite. The patient within the procedure room will be transferred to the recovery room prior to the CMA/tech flushing ports/channels of the endoscope to protect and prevent the patient from infection. The CMA, Mikelle Mierra, and RN's Stevie Hunziker, Erika Gunter and Codie Robertson were oriented to the updated policy and were instructed that the patient must be in the recovery room prior to flushing the channels with syringes or brushes. The DON will monitor for compliance, as she works within the procedure suite and will witness if this procedure is not being followed. Full compliance is expected by 8/14/15.	

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Q 101	Continued From page 17 When asked on 7/08/15 at 1:30 PM, the DON stated the ASC followed AORN guidelines and manufacturer instructions for reprocessing their endoscopes. The 2012 Perioperative Standards and Recommended Practices by the AORN stated "Flexible endoscopes should be decontaminated in an area physically separated from locations where clean items are handled and patient care activities are performed." Additionally, an article by the Society of Gastroenterology Nurses and Associates, titled "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes," dated 2012, stated "Reprocessing of contaminated equipment must be done in an area designated and dedicated for this function. This must be a room separate from where endoscopic procedures are performed (AAMI, 2010)." The World Gastroenterology Organization/World Endoscopy Organization published global guidelines in 2011, titled "Endoscope disinfection-a resource-sensitive approach." The guidelines stated "Endoscopes should be disinfected in dedicated rooms by trained staff at the beginning and at the end of each patient list, as well as between patients." The ASC failed to follow professional standards of practice and guidelines for the reprocessing of endoscopes in a separate room away from patient care areas.	Q 101	Q101-Effective 8/3/15 the Governing Body approved for the ASC to follow CDC guidelines (2008) for reprocessing of endoscopes. These national guidelines do not include a requirement for room separation for scope reprocessing, allowing for a designated clean and dirty area in which the patient may still be present. The Governing Body feels these guidelines are better suited for our building design. The compliance date for this change is 8/3/15. The DON and Administrator will share responsibility for monitoring continued alignment with CDC guidelines.	
Q 140	416.46 NURSING SERVICES	Q 140		

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Q 140	Continued From page 18 The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met. This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the ASC failed to ensure nursing services at the facility were directed to meet the nursing needs of 13 of 13 patients (#2, #4 - #8, #10, #11, #13, #14, #17, #19, and #20) who underwent endoscopic procedures and whose records were reviewed. This resulted in a lack of post-procedure care and monitoring. Findings include: 1. The ASC's policy titled "POLICY ON MANAGEMENT OF ACUTE PAIN IN PATIENTS," undated, stated "It is important for all nursing staff to understand the normal discomforts that present during and post procedure, and to be aware of ways to minimize patient discomfort. Patients should be continually assessed for any signs or complaints of pain. This assessment should include a pain scale of 0-10, where 0 represents no pain and 10 represents immense pain. PCS Endoscopy Suite requires that any patients in the facility complaining of pain higher than 3 on the pain scale, be reported immediately, by the nurse, to the attending physician for a plan to manage that patient's pain." The records of 13 patients (#2, #4 - #8, #10, #11, #13, #14, #17, #19, and #20) who underwent endoscopic procedures were reviewed. Each patient record included a form titled "CONSCIOUS SEDATION FLOW SHEET" signed by the RN.	Q 140	Q140-On 8/3/15, the Governing Body approved a policy on Post Procedure Care, effective 8/12/15. This policy outlines care points and pain assessment, following AORN guidelines, to be performed and documented with all patients in recovery and prior to discharge. A recovery room flow sheet was also approved, and will now be used to document post procedure care until discharge. NOTE: Some ASC procedures do not require recovery room time, ie: those with only a local anesthetic; and as a result will not have post procedure care documented. The Governing Body also approved an update to PCS Policy on Management of Pain, effective 8/12/15, to reflect that only pain levels related to procedure will be managed. The Post Procedure Care flow sheet will be added to the chart audit form. Al charts are audited prior to being filed for accuracy. Any charts found to be lacking a pain assessment in either the RR or prior to DC will be brought to the DON following audit, and the DON will monitor and follow up with staff appropriately to ensure that this new policy is being followed and the new flow sheet is being used appropriately. All procedure room staff were oriented to the new policy and flow sheet on 8/11/15 at an in-service which began at 5:30 pm.	

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Q 140	Continued From page 19 The "CONSCIOUS SEDATION FLOW SHEET" documented the patients' pre-procedure and post-procedure vital signs, drug allergies, IV fluids, medications received, and admit and discharge times. The form did not include a place to document pain during or following the procedure. The 13 patient records reviewed did not include documentation of a pain assessment during or following their procedures. During an interview on 7/08/15 at 3:00 PM, the DON confirmed the flow sheet used by the nurses to document patient care from admission to discharge did not include a pain assessment. She confirmed there was no documentation of patients' pain levels in the 13 records reviewed. The DON was interviewed again on 7/08/15 beginning at 3:50 PM. She stated no documentation was present regarding the nursing care patients received during recovery or of their condition. She stated patients were attached to a monitor that automatically checked their vital signs at intervals whether staff was present or not. Other than the machine printouts, she stated recovery room care was not normally documented. She stated there was no policy that directed staff what to document while patients were in the recovery room. Patient records did not include additional documentation, completed by the RN, which demonstrated patients were provided with nursing care commensurate with their needs. Examples included, but were not limited to, the following: a. Patient #20 was a 71 year old male who had a colonoscopy on 7/08/15. His procedure was	Q 140		

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Q 140	Continued From page 20 observed by the surveyor. Following Patient #20's colonoscopy, he was taken to the recovery room at 9:00 AM. He was attached to a vital sign monitor. He stated his mouth was extremely dry. He asked for fluids from the nurse and/or the physician at 9:09 AM, 9:12 AM, and 9:15 AM. Each time he was told he would have to wait. He was not given fluids prior to leaving nor was he offered anything to moisten his mouth. Also, he complained of pain and cramping 2 times when the nurse was not present. When the nurse was present she did not ask him if he was uncomfortable and his pain was not addressed. Patient #20 was discharged at 9:31 AM. He was not given fluids and his pain was not assessed prior to discharge. Patient #20's "Conscious Sedation Flowsheet" stated "Time to [recovery room]: 9:03." At 9:30 AM when he was discharged, his record stated "Discharge Assessment: RR 16 B/P 106/70 Pulse 44 O2 Sats 93 Discharge Color Pink Level of Consciousness Alert & Oriented Level of Activity [up] to bathroom. Discharge Time 9:30." There was no documentation of care provided to Patient #20 or of his complaints or requests. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She stated post-procedure care for Patient #20 was not documented. She also stated the ASC had not developed policies to direct nursing staff providing post-procedure care or the documentation of such care. b. Patient #17 was a 64 year old female who had a colonoscopy at the ASC on 6/03/15. The "CONSCIOUS SEDATION FLOW SHEET,"	Q 140		

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Q 140	Continued From page 21 dated 6/03/15, stated Patient #17 was taken to the recovery room at 10:00 AM. The form stated she was discharged at 11:58 AM, 1 hour and 58 minutes later. A vital sign printout documented Patient #17's pulse rate dropped to 44 bpm at 11:21 and 11:22 AM and to 43 bpm at 11:33 and 11:34 AM. Patient #17's O2 sats were 84% and 89% at 11:21 and 11:22 AM and were 85% at 11:33 and 11:34 AM. Other vital signs were within normal limits. The Mayo Clinic website, queried on 7/13/15, stated normal oxygen saturation levels were from 95 - 100%. The site stated levels below 90% were considered low. Patient #17's condition was not documented during the recovery time. Patient #17's nursing care was not documented during the recovery time. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She stated no documentation was present regarding the nursing care Patient #17 received during recovery in the recovery room. c. Patient #2 was a 50 year old male who had a colonoscopy at the ASC on 1/28/15. The "CONSCIOUS SEDATION FLOW SHEET," dated 1/28/15, stated Patient #2 was taken to the recovery room at 10:55 AM. Patient #2's "Progress Notes" by the physician, dated 1/28/15, stated "The physical status of the patient was re-assessed after the procedure. Patient sat up and did well after the procedure, was given post-procedure handout, and went home with driver." The note was signed by the	Q 140		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PCS ENDOSCOPY SUITE	110 VISTA DRIVE POCATELLO, ID 83201

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 140	Continued From page 22 physician on 1/28/15 at 10:50 AM, 5 minutes before Patient #2 was taken to the recovery room. A printout of Patient #2's vital signs, dated 1/28/15, was contained in the medical record. The printout stated Patient #2's pulse was in the 70's at 11:02 and 11:07 AM. His heart rate dropped to 43 bpm at 11:20 AM. His pulse rebounded to 66 bpm at 11:22 AM then dropped to 41, 44, and 44 bpm at 11:31, 11:32, and 11:32 AM. Patient #2's O2 sats during this time were 97% at 10:42 AM, and dropped to 85%, 87%, 84%, 82%, 80%, and 89% at 11:02, 11:07, 11:17, 11:20, and 11:22, AM. Other vital signs were within normal limits. Patient #2's condition was not documented during the recovery time. Patient #2's nursing care was not documented during the recovery time. The Physician Owner of the ASC was interviewed on 7/09/15 beginning at 1:10 PM. He confirmed the lack of documentation describing Patient #2's condition and nursing care in the recovery room. d. The remaining records of endoscopic patients (#4 - #8, #10, #11, #13, #14, and #19) did not contain documentation of nursing assessments or nursing care provided from the time the patients were transferred to the recovery room to the time they were discharged. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed assessments and nursing care was not documented during the recovery phase of the patients' procedures. The ASC failed to provide nursing care to meet	Q 140		

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Q 140	Continued From page 23 patients' post-procedure needs.	Q 140		
Q 160	416.47 MEDICAL RECORDS The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. This CONDITION is not met as evidenced by: Based on staff interview and review of medical records, it was determined the ASC failed to ensure complete, comprehensive, and accurate medical records were maintained for 13 of 13 endoscopic patients (#2, #4 - #8, #10, #11, #13, #14, #17, #19, and #20) whose records were reviewed. This resulted in the inability of the ASC to verify the care provided to patients. Findings include: 1. Refer to Q162 as it relates to the failure of the ASC to ensure complete accurate medical records were maintained for each patient.	Q 160	Q160-The ASC will maintain complete, and accurate and comprehensive medical records. Physicians and staff were oriented at an in-service on 8/11/15 to updated policies and forms, including that all orders signed by the physician must include both a date and time. RN's noting physician orders must include a date, time and signature. Any reference from the physician regarding discharge from the facility should match the actual time of patient discharge. Patient care given in the Recovery Room will be documented on a new flow sheet specific to recovery room. These items will be monitored by chart audits to ensure the accuracy of records. All charts are audited after procedures, and prior to being filed. Any charts that do not include signatures, dates, times, recovery room care, and/or discharge will be brought to the DON. The DON will follow-up with all staff to ensure that policies are being followed (ie: signatures, dates and times, recovery room documentation) and will re-orient staff and physicians as needed. Staff are required to follow the direction of the DON. If the DON is having difficulty with physician's who are not signing, dating and timing orders, the Governing Body will he notified and asked for his assistance to obtain and then maintain compliance from physicians. The DON will follow up on chart audits, analyze data and present quarterly QAPI meetings to indicate overall compliance with new policies and accurate use of new forms. continued on next page...	
Q 162	416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions.	Q 162		

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Q 162	Continued From page 24 (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, it was determined the ASC failed to ensure complete, comprehensive, and accurate medical records were maintained for 13 of 13 endoscopic patients (#2, #4 - #8, #10, #11, #13, #14, #17, #19, and #20) whose records were reviewed. This resulted in the inability of the ASC to verify the care provided to patients. Findings include: 1. Patient records did not include comprehensive, accurate documentation. Examples included, but were not limited to, the following: a. Patient #2 was a 50 year old male who had a colonoscopy at the ASC on 1/28/15. A "Physician's Orders" form, dated 1/13/15, was present in Patient #2's medical record. The orders were noted by the nurse on 1/28/15. The date and time the orders were signed by the physician were not included on the form. The time the nurse noted the orders was not documented. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the above items were not dated and/or timed. The "CONSCIOUS SEDATION FLOW SHEET," dated 1/28/15, stated Patient #2 was taken to the recovery room at 10:55 AM. However, Patient #2's "Progress Notes" by the physician, dated	Q 162	Q160- The Administrator will be responsible to assist the DON as necessary with updating policies and maintain the Policy and Procedure Manual. The DON and Administrator will work together to generate new forms as necessary. The Governing Body will be presented with all information at QAPI meetings, and approve new forms, policies, and sign meeting minutes to indicate approval and oversight Full compliance is expected by 8/14/15. Refer to Q162, Q229 and Q263	

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Q 162	Continued From page 25 1/28/15, stated "The physical status of the patient was re-assessed after the procedure. Patient sat up and did well after the procedure, was given post-procedure handout, and went home with driver." The note was signed by the physician on 1/28/15 at 10:50 AM, 5 minutes before Patient #2 was taken to the recovery room. A printout of Patient #2's vital signs, dated 1/28/15, was contained in the medical record. The printout stated at Patient #2's pulse was in the 70's 11:02 and 11:07 AM. His heart rate dropped to 43 bpm at 11:20 AM. His pulse rebounded to 66 bpm at 11:22 AM then dropped to 41, 44, and 44 bpm at 11:31, 11:32, and 11:32 AM. Patient #2's O2 sats during this time were 97% at 10:42 AM, and dropped to 85%, 87%, 84%, 82%, 80%, and 89% at 11:02, 11:07, 11:17, 11:20, and 11:22, AM. Other vital signs were within normal limits. The Mayo Clinic website, queried on 7/13/15, stated normal oxygen saturation levels were from 95 - 100%. The site stated levels below 90% were considered low. Except for automated vital signs, Patient #2's condition was not documented during the recovery time. Patient #2's nursing care was not documented during the recovery time. The Physician Owner of the ASC was interviewed on 7/09/15 beginning at 1:10 PM. He confirmed Patient #2's recovery notes were written prior to him being taken to the recovery room. He confirmed the lack of documentation describing Patient #2's condition and staff efforts when Patient #2 was in the recovery room.	Q 162	Q162-As noted in Q160, the ASC will maintain complete, and accurate and comprehensive medical records. Physicians and staff were oriented at an in-service on 8/11/15 to updated policies and forms to address errors and omissions in current documentation. 1. Orders signed by the physician must include signature, date and time. RN's noting physician orders must include a signature, date and time. 2. Any reference from the physician regarding discharge from the facility should match the actual time of patient discharge. 3. Patient care given in the Recovery Room will be documented on a new flow sheet specific to recovery room. These CMA will be responsible for monitored daily chart entries. The RN will also monitor through chart audits to ensure compliance and accuracy of records. Any charts that do not include signatures, dates, times, recovery room care, and/or correct discharge time, that were not corrected before discharge, will be brought to the DON. The DON will be responsible for follow-up with staff to ensure that policies are being followed and will re-orient staff and physicians as needed. Staff are required to follow the direction of the DON. If the DON is having difficulty with physician's who are not signing, dating and timing orders, the Governing Body will be notified and asked for his assistance to obtain and then maintain compliance from physicians. The DON will analyze chart audit data and present quarterly QAPI meetings to indicate overall compliance with new policies and accurate use of new forms. The Administrator will be responsible to assist the DON as necessary with updating policies and maintain the Policy and Procedure Manual. The Governing Body will be presented with all information at QAPI meetings, and approve new forms, policies, and sign meeting minutes to indicate approval and oversight Full compliance is expected by 8/14/15.	

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Q 162	Continued From page 26 Patient #2's record did not reflect accurate, comprehensive information. b. Patient #6 was a 53 year old female who had a colonoscopy on 3/04/15. The "CONSCIOUS SEDATION FLOW SHEET," dated 3/04/15, stated Patient #6 was taken to the recovery room at 10:37 AM. It stated she was discharged at 11:30 AM, 53 minutes later. Except for automated vital signs, no nursing care was documented during this time. A "Physician's Orders" form, dated 2/09/15, was present in Patient #6's medical record. The orders were noted by the nurse on 3/04/15 at 9:50 AM. The date and time the orders were signed by the physician were not included on the form. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the above items were not dated and/or timed. c. Patient #8 was a 52 year old male who had a colonoscopy at the ASC on 3/04/15. The "CONSCIOUS SEDATION FLOW SHEET," dated 3/04/15, stated Patient #8 was taken to the recovery room at 11:15 AM. However, Patient #8's "Progress Notes" by the physician, dated 3/04/15, stated "The physical status of the patient was re-assessed after the procedure. Patient sat up and did well after the procedure, was given post-procedure handout, and went home with driver." The note was signed by the physician on 3/04/15 at 11:05 AM, 10 minutes before Patient #8 was taken to the recovery room.	Q 162		

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Q 162	Continued From page 27 The Physician Owner of the ASC was interviewed on 7/09/15 beginning at 1:10 PM. He confirmed Patient #8's recovery notes were written prior to him being taken to the recovery room. The "CONSCIOUS SEDATION FLOW SHEET," stated Patient #8 was taken to the recovery room at 11:15 AM. The form stated Patient #8 was discharged at 11:40 AM, 25 minutes later. Except for automated vital signs, no nursing care was documented during this time. A "Physician's Orders" form, dated 2/09/15, was present in Patient #8's medical record. The orders were noted by the nurse on 3/04/15 at 10:30 AM. The date and time the orders were signed by the physician were not included on the form. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the above items were not dated and/or timed. d. Patient #13 was a 69 year old male who had a colonoscopy on 7/03/15. The "CONSCIOUS SEDATION FLOW SHEET," dated 7/03/15, stated Patient #13 was taken to the recovery room at 10:17 AM. The form stated Patient #13 was discharged at 10:45 AM, 28 minutes later. Except for automated vital signs, no nursing care was documented during this time. A "Physician's Orders" form, dated 7/03/15, was present in Patient #13's medical record. The orders were noted by the nurse on 7/03/15 at 9:30 AM. The time the orders were signed by the physician was not included on the form.	Q 162		

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Q 162	Continued From page 28 The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the above items were not dated and/or timed. e. Patient #20 was a 71 year old male who had a colonoscopy on 7/08/15. Patient #20's "CONSCIOUS SEDATION FLOW SHEET" stated he was taken to the recovery room at 9:03 AM. The form stated he was discharged at 9:30 AM, 27 minutes later. Except for automated vital signs, no nursing care was documented during this time. A "Physician's Orders" form, dated 6/24/15, was present in Patient #20's medical record. The orders were noted by the nurse on 7/08/15 at 7:45 AM. The time and date the orders were signed by the physician was not included on the form. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the above items were not dated and/or timed. f. Patient #11 was a 51 year old male who had a colonoscopy on 6/19/15. The "CONSCIOUS SEDATION FLOW SHEET," dated 6/19/15, stated Patient #11 was taken to the recovery room at 10:45 AM. The form stated Patient #11 was discharged at 11:30 AM, 45 minutes later. Except for automated vital signs, no nursing care was documented during this time. A "Physician's Orders" form, dated 6/03/15, was present in Patient #11's medical record. The	Q 162		

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Q 162	Continued From page 29 orders were noted by the nurse on 6/19/15 at 9:50 AM. The time and date the orders were signed by the physician was not included on the form. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the above items were not dated and/or timed. g. Patient #17 was a 64 year old female who had a colonoscopy at the ASC on 6/03/15. A "Physician's Orders" form, dated 5/18/15, was present in Patient #13's medical record. The orders were noted by the nurse on 6/03/15 at 9:30 AM. The time the orders were signed by the physician was not included on the form. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the above items were not timed. The "CONSCIOUS SEDATION FLOW SHEET," dated 6/03/15, stated Patient #17 was taken to the recovery room at 10:00 AM. The form stated she was discharged at 11:58 AM, 1 hour and 58 minutes later. A vital sign printout documented Patient #17's pulse rate dropped to 44 bpm at 11:21 and 11:22 AM and to 43 bpm at 11:33 and 11:34 AM. Patient #17's O2 sats were 84% and 89% at 11:21 and 11:22 AM and were 85% at 11:33 and 11:34 AM. Other vital signs were within normal limits. Except for automated vital signs, Patient #17's condition was not documented during the recovery time. Patient #17's nursing care was documented during the recovery time.	Q 162		

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Q 162	Continued From page 30 Additionally, the records of the remaining patients who underwent endoscopic procedures (#4, #5, #7, #10, #14, and #19) did not include documentation of their condition or of post-procedure care provided. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She stated no documentation was present regarding the nursing care Patient #17 received during recovery or her condition in the recovery room. When asked about the records of Patients #4, #5, #7, #10, #14, and #19, the DON stated no documentation was present regarding the patients' condition or the nursing care the patients received during recovery. She stated patients were attached to a monitor that automatically checked their vital signs at intervals whether staff was present or not. Other than the machine printouts, she stated recovery room care was not normally documented. She stated there was no policy that directed staff what to document while patients were in the recovery room. The ASC failed to develop and implement a system to document post-procedure care, necessary to ensure complete, accurate medical records were maintained for each patient. 2. Refer to Q229 as it relates to the ASC's failure to ensure documentation of properly executed informed patient consent was present in each patient's record prior to their procedures. 3. Refer to Q263 as it relates to the ASC's failure to ensure patients' medical history and physical assessments were placed in their records prior to their procedures.	Q 162		

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Q 181	Continued From page 31	Q 181	Q181-Effective 8/3/15, ASC properly disposed of the Valium found on site. On 8/3/15, the Governing Body approved an update to Policy on Pharmaceuticals to reflect that any meds/drugs delivered without a printed expiration date are to be refused and returned to the supplier. ASC does not intend to continue use of Valium moving forward. Nursing staff has been re-oriented that, at the time the drug audits, two staff signatures are mandatory for all counts and disposals. The DON will be responsible for oversight and continue to monitor monthly audit forms, which include outdated medications being found in drawers, any adverse events, disposal logs, discrepancies in narcotic counts and double signatures of narcotic counts. The Crash Cart meds are monitored quarterly and outdated medications will be identified. These audits will be analyzed and presented at quarterly QAPI meetings. If compliance is found to be lacking by staff, such as double signature are not consistently being documented, staff will be re-oriented by the DON to ensure compliance. An in-service was provided on 8/11/15 which provided staff with all updated policies. This included the pharmaceutical policy, and safe injection policy. Compliance is expected by 8/12/15.	
Q 181	416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, policy review, record review, and staff interview, it was determined the ASC failed to adhere to acceptable standards of practice for medication administration. This had the potential to impact all patients receiving medications at the facility, and resulted in the potential for drug diversion and patients to receive expired medications. Findings include: 1. A policy, "PCS Endoscopy Suite Policy on Use and Accountability of Pharmaceuticals," undated, stated "All scheduled narcotics will be kept in a locked drawer. Labels will assure that they are properly identified with 1) the drug name 2) drug strength and 3) expiration date. This information should be readily visible to anyone working in the ASC." A tour of the facility was conducted on 7/07/15 beginning at 10:35 AM, with the DON accompanying surveyors. In the procedure room 2 locked drawers contained controlled substance medications used for moderate sedation of patients for procedures. One of the locked drawers contained unopened stock of controlled medications. This drawer contained Valium 10 mg pills in 2 blister packs. Neither of the packs included an expiration date for the Valium pills. The DON stated the pills came from the	Q 181		

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Q 181	Continued From page 32 pharmacy without an expiration date. A request was made to view the controlled substance logs for January 2015 through July 2015. Each day the ASC was open and performed procedures, an Active Drug Count Form was filled out and signed by an RN. The ASC's Active Drug Count Forms were reviewed. For the 7 month period from January 2015 through July 8, 2015, the forms documented the beginning count for the day, any wasted doses, doses added from stock, the ending count for the day, and the signature of the staff who verified the count. The Active Drug Count Forms accounted for 58 days the ASC was open and performed procedures. On 21 of those days there was only 1 signature by an RN for verification of the controlled substance count and disposal of unused controlled medications. The forms did not include the Valium pills in the count. According to an article in the Gastrointestinal Endoscopy Journal "Guidelines for Safety in the Gastrointestinal Endoscopy Unit," Volume 79, Issue 3, 2014, the American Society for Gastrointestinal Endoscopy stated "Disposal of unused narcotics and other controlled drugs should be witnessed by 2 individuals and documented." The U.S. Food and Drug Administration website, accessed 7/14/15, stated using expired medication is risky and possibly harmful to your health. The U.S. Food and Drug Administration began requiring an expiration date on prescription and over-the counter medicines in the 1970's.	Q 181		

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Q 181	Continued From page 33 "Expiration dates on medical products are a critical part of determining if the product is safe to use and will work as intended." During an interview on 7/07/15 at 2:35 PM, the DON reviewed the process for documenting the controlled substance count. She stated she would count the medications in the morning prior to procedures beginning and would have the CMA witness waste of controlled medications. She confirmed this was not always documented. The DON further confirmed there was not a second signature by a staff member for each day the controlled substance count was completed. She stated she would dispose of the Valium pills. The ASC failed to adhere to their policy and acceptable standards of practice for controlled substance labeling, counts, and disposal.	Q 181		
Q 229	416.50(e)(1)(iii) EXERCISE OF RIGHTS - INFORMED CONSENT [(1) The patient has the right to the following:] (iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed. This STANDARD is not met as evidenced by: Based on policy review, record review, and staff interview, it was determined the ASC failed to ensure that patients were fully informed about procedures and the expected outcomes before they were performed for 14 of 20 patients (#2 - #8, #10, #11, #13, #14, #17, #19 and #20) whose records were reviewed. This resulted in the potential for a lack of information being provided to patients on which to base informed consent decisions. Findings include:	Q 229		

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Q 229	Continued From page 34 1. A policy "Patient Consents," undated, stated "It is the responsibility of the attending physician to provide the necessary information to the patient and family, obtain their informed consent, and document this in the patient's chart prior to the procedure or treatment." The policy further stated, it was the responsibility of the procedure assistant to verify the patient gave informed consent prior to the procedure and the appropriate documentation was in the patient's record prior to the procedure being performed. The ASC did not ensure informed consents for surgical procedures and anesthesia were properly executed, as follows: Patient #2 - #8, #10, #11, #13, #14, #17, #19 and #20's records were reviewed. The records included a surgical consent for their procedures which was signed by the patient and an ASC representative. All of the consent forms were dated on the same day of the patients' procedures. However, none of the consents documented times next to the signatures. During an interview on 7/09/15 at 10:45 AM, the DON reviewed the patient records. She confirmed there were no times next to the patient signatures to verify the patients received informed consent prior to their procedures. The ASC failed to ensure informed consent for procedures was documented in the patients records.	Q 229	Q229 The ASC revised the consent form to include patient date, signature and time. This form was approved by the Governing Body on 8/3/15. Receptionists will be responsible to obtain consent with signature, date and time upon patient arrival to ASC. The RN or CMA will be responsible to verify the consents are dated, signed and timed before placing them in the chart prior to the procedure being performed. This will be monitored by direct observation and chart review. Mikelle Mierra and Stevie Hunziker are currently performing chart audits. All charts are being audited for accuracy prior to being filed. Charts will be returned to the DON that do not have the consent signed with both and date and time. The DON will follow up and re-orient staff as necessary to ensure compliance. Full compliance is expected on 8-14-2015.	
Q 240	416.51 INFECTION CONTROL The ASC must maintain an infection control	Q 240		

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Q 240	Continued From page 35 program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, ASC policy review, and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented, and monitored for all facility staff and patients receiving care at the facility. This resulted in the inability of the facility to minimize infections and communicable diseases. Findings include: 1. Refer to Q241 as it relates to the ASC's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice. 2. Refer to Q242 as it relates to the ASC's failure to ensure an ongoing program to prevent, control, and investigate infections and communicable diseases was maintained. 3. Refer to Q244 as it relates to the ASC's failure to ensure infection control was addressed as an integral part of the ASC's QAPI program. The cumulative effect of these systemic deficient practices resulted in the inability of the facility to ensure patient risk of infections and communicable diseases was minimized.	Q 240	Q240-Infection Control Policy was drafted and approved by the Governing Body on 8/3/15. Refer to Q241, Q242, Q244.	
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.	Q 241		

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Q 241	Continued From page 36 This STANDARD is not met as evidenced by: Based on observation, policy review, record review and staff interview, it was determined the ASC failed to maintain a sanitary and functional environment for patients receiving care at the facility. This directly impacted 2 of 2 patients (#19 and #20) whose procedures were observed and had the potential to impact all patients receiving services at the ASC. This resulted in patients being placed at an increased risk for infections to occur. Findings include: 1. A policy "PCS Endoscopy Suite Policy on Surgical Attire," undated, stated "All persons who enter the semi-restricted areas of the PCS Endoscopy Suite should wear protective gowns intended for use within the suite." The policy also stated gowns should be changed between cases or more often if appropriate. An article in the Gastrointestinal Endoscopy Journal "Guidelines for Safety in the Gastrointestinal Endoscopy Unit", Volume 79, Issue 3, 2014, the American Society for Gastrointestinal Endoscopy stated "It is recommended that staff directly engaged in GI endoscopy or in processes in which splash or contamination could occur wear gloves, face and/or eye shields, and impervious gowns." a. An observation of Patient #19 was conducted beginning at 9:20 AM on 7/08/15. The DON ambulated Patient #19 into the procedure suite and remained in the suite during Patient #19's procedure. The DON did not put on a protective gown after entering the suite or during the procedure.	Q 241	Q241-Staff and Physicians were re-oriented to the current Surgical Attire policy and that gowns are required attire within the procedure room. The Surgical Attire policy was provided to all staff and physicians at in-service for review. Full compliance is expected as of 8/12/15. This will be monitored by direct observation. The responsibility for monitoring will be shared between all staff members. Non-compliance will be reported to DON. The DON will be responsible to over-see and re-orient as needed if it is reported to her that staff or physicians are failing to wear gowns within the procedure suite. Compliance is expected by 8/12/15.	

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Q 241	Continued From page 37 b. Patient #20 was a 71 year old male who had a colonoscopy on 7/08/15. His procedure was observed by the surveyor beginning at 8:04 AM. The DON ambulated Patient #20 into the procedure suite and remained in the suite during his procedure. The DON did not put on a protective gown after entering the suite or during the procedure. During an interview on 7/08/15 at 2:45 PM, the DON confirmed she did not wear a gown. The ASC failed to follow their policy or professionally accepted standards of practice for surgical attire in the procedure suite. 2. An undated policy "PCS Endoscopy Suite Practices for Environmental Cleaning," stated "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. When asked on 7/08/15 at 2:45 PM, the DON stated the cleansers used in the ASC were outlined in the Infection Control Plan. The ASC's 2015 Infection Control Plan stated the procedure and recovery rooms would be cleaned before the first procedure each day, and following each procedure. The plan stated guidelines from the AORN would be followed for environmental cleaning. Two cleansers were outlined in the Infection Control Plan and approved for use by the Governing Body. However, during observations on 7/08/15, 1 cleanser, Cavicide	Q 241	Q241-ASC Infection Control Plan does in fact reflect that both cleansers (CaviCide and Clorox Pro-Quat) are approved for use in the ASC. Either can be used at any time. Staff should always follow the manufacturers' instructions on contact time with surface.	

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Q 241	Continued From page 38 was used to clean the procedure suite after patients' procedures. When asked, on 7/08/15 at 10:30 AM, the DON stated the ASC had switched from the Clorox Pro Quaternary Cleanser to the Cavicide because of the required time for surface contact. She stated the Cavicide required 2 minutes for contact time versus 10 minutes with the Clorox. The DON confirmed this change was not updated in the Infection Control Plan. 3. When asked about infection prevention training on 7/08/15 at 2:45 PM, the DON stated employees were trained during orientation and annually thereafter. She stated she had recently completed an in-service for ASC staff regarding hand hygiene on 5/5/15. The DON stated training and in-services for infection prevention were the same for all staff members. She stated in-services for infection prevention were not provided for contracted staff, which included environmental services. Additionally, the contract between the ASC and the environmental services company stated "ASC cleaning will be held to hospital standards, utilizing appropriate grade cleaners and separate equipment from main office cleaning." The contract did not specify what type of disinfecting cleaners were used or what standards of cleaning would be followed. It was not specified how the ASC would be cleaned or how the procedure suite would be terminally cleaned at the end of each procedure day. An article in the Gastrointestinal Endoscopy Journal "Guidelines for Safety in the Gastrointestinal Endoscopy Unit," Volume 79,	Q 241	Q241-On 8/3/15 the Governing Body Approved a Policy on Terminal Cleaning, effective 8/12/15. The policy outlines the standards of cleaning to be followed (CDC); and that only approved ASC cleaners are to be used. A checklist is included in the policy to direct contracted staff on how the procedure suite is to be cleaned each night, and to allow ASC staff to evaluate the terminal cleaning. The policy includes a nursing staff observation/review to be performed first thing each procedure morning, to evaluate the level of cleaning being done each night. This evaluation will be used to continually assess our contracted staff performance, and to help identify any potential infection control issues related to environmental terminal cleaning. Each procedure morning, the ASC staff will look for visible signs that the terminal cleaning was not completed or was sub-standard. The ASC staff, which may be the RN or the CMA, will note on the checklist any concerns identified with the terminal cleaning and immediately report to the Administrator. When the terminal cleaning appears to be satisfactory, the ASC staff will complete checklist indicating such. These evaluations will he used to oversee the contracted staff's performance. Compliance is expected 8/12/15.	

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Q 241	Continued From page 39 Issue 3, 2014, the American Society for Gastrointestinal Endoscopy stated "The unit should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day." The ASC failed to ensure infection prevention training included contracted staff for environmental services.	Q 241	Q241-As a part of PCS Procedure Suite Infection Control Plan, contracted staff for environmental cleaning will provide documentation of annual Infection Prevention training. If this cannot be provided, PCS DON will provide this in-service for contracted staff. This in-service will document ongoing training and will be included with the Infection Control Plan tracking logs. Compliance is expected 8/12/15.	
Q 242	416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: Based on observation, policy review, and staff interview, it was determined the ASC failed to ensure nationally recognized infection control guidelines were considered, selected, and implemented to maintain an ongoing program to prevent and control the risk of infections. This directly impacted 2 of 2 patients (#19 and #20) whose procedures were observed and had the potential to impact all patients receiving services at the ASC. This failure resulted in underdeveloped policies and the lack of a program to monitor potential infections resulting from care in the ASC. Findings include: 1. The ASC's policy manual did not include a	Q 242		

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Q 242	Continued From page 40 policy related to an Infection Prevention Program. When asked on 7/08/15 at 2:45 PM, the DON confirmed there was not a policy for the Infection Control Program. 2. The ASC did not consistently demonstrate that nationally recognized infection control guidelines used to maintain an ongoing program to prevent and control the risk of infections had been considered, selected, and implemented, as follows: a. An undated policy,"PCS Endoscopy Suite Policy on Isolation" stated 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. The CDC "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, was reviewed. According to the guidelines, hand washing was recommended when hands were visibly soiled. Otherwise a list of when hand hygiene, either hand washing or decontamination	Q 242	Q242-Infection Control Policy was drafted and approved by the Governing Body on 8/3/15. This policy defines the guidelines that will be used to prevent and control infections. It also designated an Infection Control Officer for the ASC. Q242-On 8/3/15 the Governing Body approved a policy on Hand Hygiene, effective 8/12/15. This policy uses national guidelines (CDC) to identify when and how to perform hand hygiene, as well as when hand rubbing is an appropriate alternative to hand washing. All ASC staff and physician's attended an in-service on 8/11/15 and were provided a copy of the new Hand Hygiene Policy. Monitoring will include the implementation of a PIP specifically focused on hand hygiene. All staff will be involved in the PIP and required to complete direct observation of one another in an effort to increase overall awareness and compliance. The DON will be responsible to analyze all data collected within the PIP and report findings to the Governing Body and QAPI committee at the next scheduled QAPI/IC meeting. Discussion at that time will determine furtber action to be taken going forward. Compliance is expected 8/12/15.	

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Q 242	Continued From page 41 with an alcohol based hand sanitizer, was recommended included when hands were 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. When asked on 7/08/15 at 2:45 PM, the DON stated there was not a specific policy related to hand hygiene. She stated the CDC guidelines were outlined in the Infection Control Plan for staff to follow. The ASC's 2015 Infection Control Plan stated the CDC Guidelines for Hand Hygiene would be followed. According to the CDC website, accessed 7/13/15, "Healthcare providers should practice hand hygiene at key points in time to disrupt the transmission of microorganisms to patients including: before patient contact; after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn); before invasive procedures; and after removing gloves (wearing gloves is not enough to prevent the transmission of pathogens in healthcare settings)." However, the CDC guidelines were not consistently implemented, as follows: - Patient #20 was a 71 year old male who had a colonoscopy on 7/08/15. His procedure was observed by the surveyor. At 8:04 AM, the RN started an IV and then documented without performing hand hygiene. At approximately 8:15 AM, the RN administered IV medication without performing hand hygiene. At 8:21 AM, the RN administered IV medication without performing hand hygiene. At 8:51 AM, the RN discontinued	Q 242		

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Q 242	Continued From page 42 the IV and then repositioned the patient without performing hand hygiene. - An observation of Patient #19 was conducted beginning at 9:20 AM on 7/08/15. The DON assessed Patient #19 using a stethoscope to listen to her lungs in the procedure room. While listening to her lungs the DON placed her hand on Patient #19's shoulder. After assessing Patient #19, the DON put on disposable gloves and placed an IV in Patient #19's right hand. The DON removed her gloves and performed hand hygiene. She then connected the IV to tubing from a hanging bag of fluid. The DON then put on another pair of gloves and administered Patient #19's medications through the IV tubing. After, administering the medications the DON removed a pen from her pocket and documented in the paper medical record without removing her gloves. The DON did not perform hand hygiene following CDC guidelines during the observation. During an interview on 7/08/15 at 2:45 PM, the DON was asked when she would perform hand hygiene. She stated she would follow the guidelines from the CDC and clean her hands before and after contact with a patient and before and after wearing gloves. When asked about the observation of Patient #19's care, she stated she may have missed hand hygiene opportunities but was not aware of it. The ASC did not follow the hand hygiene guidelines outlined in the ASC's 2015 Infection Control Plan or recommendations from the CDC. b. A publication in the American Journal of Infection Control, 2010, Volume 38, contained an article titled "APIC (Association for Professionals	Q 242		

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Q 242	Continued From page 43 in Infection Control and Epidemiology) position paper: Safe injection, infusion, and medication vial practices in health care." The article documented APIC stated transmission of bloodborne viruses and bacteria to patients continued to occur due to improper and unsafe practices by health care professionals. The article stated prior to accessing IV ports and vial stoppers they should be disinfected by wiping and using friction with a sterile isopropyl alcohol, ethyl/ethanol alcohol, iodophor, or other approved antiseptic swab. An observation of Patient #19 was conducted beginning at 9:20 AM on 7/08/15. The DON wore gloves while starting the IV for Patient #19. After the IV catheter was inserted the DON removed her gloves and connected the IV catheter to tubing for IV fluid. She then put on another pair of gloves and picked up two syringes of medication out of the top drawer. The DON removed the cap from the first syringe and inserted the needle into the port on the IV tubing. After the first syringe of medication was administered, the DON then removed the cap from the second syringe and pierced the same port on the IV tubing with the needle. The DON did not clean the port of the IV tubing with an antiseptic prior to insertion of either medication during the observation. During an interview on 7/08/15 at 2:45 PM, the DON was asked about cleaning the IV port. She stated she normally would clean the port on the IV tubing with an alcohol wipe prior to inserting a needle. The ASC failed to follow professionally acceptable	Q 242	Q242-Effective 8/11/15, all ASC nursing staff were re-oriented on safe injection practices to reduce patient infections. The policy on safe injection practices was updated on 8/3/15 to include IV ports should be swabbed with alcohol prior to administering medications. A copy of the up-dated policy was provided to all staff. Direct observation of one another during procedures will be utilized to maintain compliance, or self-reporting of unsafe injection techniques may be reported. The DON will continue to monitor monthly audit forms which include safe injection/sharps, and report findings to QAPI committee and Governing Body at scheduled meetings. Compliance is expected 8/12/15.	

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Q 242	Continued From page 44 standards for safe injection practices, resulting in an increased risk of patient infections. c. When asked on 7/08/15 at 2:45 PM, the DON stated post procedure infections were monitored by patient responses to surveys and reporting by physicians. An undated policy,"PCS Endoscopy Suite Protocol on Reporting Infections," 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, nursing staff were to identify the type and location of the infection. However, it did not indicate how the infection would be identified. The policy further stated 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 it was determined the infection was not related to environmental cross-contamination. The ASC failed to ensure its protocol on reporting infections was sufficiently developed.	Q 242	Q242-On 8/3/2015 the Governing Body approved a revised policy on Reporting of Infections, effective 8/12/15. This policy now includes how to identify an infection, steps to be taken to determine the cause of an infection, and guidance on infections not caused by the ASC environment. This policy provides additional education and guidance to staff to improve compliance with identifying and reporting infections. Staff were oriented to this policy on 8/11/15. Copies of the policy were given to all staff. The DON will continue to monitor for infections and complete monthly audit forms. Infections will be identified by patient phone calls the evening of their procedure or morning after, follow-up visits with physicians following orthopedic procedures, and patient surveys (which now include a question regarding signs or symptoms of infection such as fever). If an infection is identified, the DON will initiate an investigation to determine the potential causes of infection, appropriate actions, will ensure adequate patient care is provided, and will notify Governing Body for further follow-up. The DON will look for additional infections and try to identify trends. All data collected will be analyzed by the DON and reported at QAPI/IC committee meetings, where further discussion will determine future actions. The Governing Body will sign all committee meeting minutes to indicate participation and oversight. Compliance is expected 8/12/15.	
Q 244	416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI [The program is -] An integral part of the ASC's quality assessment and performance improvement program This STANDARD is not met as evidenced by: Based on staff interview and review of facility	Q 244		

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Q 244	Continued From page 45 policies and records, it was determined the ASC failed to ensure the infection control program was incorporated into the facility QAPI program for all patients receiving services at the ASC. This resulted in the inability of the ASC to evaluate its infection control processes necessary for improving the quality of patient care. Findings include: 1. The ASC's 2015 Infection Control Plan documented 6 measures for outcome and process measurement. The 6 measures included: - Private entrance, waiting room, and bathroom - Hand hygiene - Environmental cleaning of procedure room and recovery rooms - Reprocessing of endoscopic equipment and surgical equipment - Safe injection and handling of sharps - Flu shots for all staff a. The Infection Control Plan did not include how data would be collected, measured, or analyzed other than by observation. Data related to the measures of private entrance, waiting room, and bathroom, environmental cleaning of procedure room and recovery rooms, reprocessing of endoscopic equipment and surgical equipment and safe injection and handling of sharps was not documented. When interviewed on 7/08/15 at 2:45 PM, the	Q 244		

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Q 244	Continued From page 46 DON confirmed the ASC did not have a policy defining an infection prevention program, plan, and goals or tracking methods for the facility. She stated she did not have specific data related to the measures identified in the Infection Control Plan. The DON stated she had handwritten notes related to the Infection Program in a binder, but she was unable to locate the binder. b. The plan did not include interventions or actions for implementing corrective and preventive measures that would result in improvement, as follows: - The Infection Control Plan stated strict hand hygiene will be encouraged and enforced. Staff were to follow CDC guidelines for hand hygiene and perform hand hygiene at every opportunity. The goal was for greater than 80% compliance with hand hygiene by staff. If hand hygiene was not performed, an incident report was written by the DON. Responsibility and monitoring for compliance was delegated to all staff members and if lapses were observed the Infection Control Plan stated the lapses "...should be pointed out by that staff member to increase compliance within the procedure room." There was no direction for implementing corrective measures or interventions to improve the process for hand hygiene documented in the Infection Control Plan. - The Infection Control Plan stated flu shots would be provided for staff and the goal was for all staff to be immunized. Upon request a list of current employees was received and listed 11 staff members, of which 3 were support staff and 3 were physicians. The plan stated the measure	Q 244	Q244-Infection Control Policy was drafted and approved by the Governing Body on 8/3/15. This policy defines the guidelines that will be used to prevent and control infections. It also designated an Infection Control Officer for the ASC.	

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Q 244	Continued From page 47 would be successful if 80% of staff were immunized against the flu. Minutes from 1 QAPI Committee meeting were documented between 7/01/14 and 7/09/15. The "QAPI Annual Review Meeting, November 13, 2014" minutes documented flu shots were provided to staff and of the 2 RN's employed by the ASC neither chose to receive the flu shot. Two other staff members received the immunization, the CMA and receptionist. However, the minutes did not document whether physicians were offered the immunization or if they had been immunized and there was no documentation related to how the measure could be improved. The QAPI Committee meeting minutes also stated the ASC had no "post procedure infections requiring treatment." No other information related to the Infection Control Program measure was documented in the minutes. The minutes did not document any data, conclusions, or recommendations for the Infection Control Program. The minutes did not document discussion of a plan for the Infection Control Program for 2015. The DON was interviewed on 7/08/15 at 2:45 PM. She stated she was responsible for the Infection Control Program. She confirmed she did not have documentation written on specific forms for observations that were performed or conducted for monitoring of processes outlined in the Infection Control Program. The DON stated she would conduct observations for compliance with the plan and had not found any problems over the last 12 months. She stated she had not needed to write any incident reports related to infection	Q 244	Q244- As referenced in Q40 - Governing Body will improve oversight to the Infection Control program via quarterly meetings that will be part of the QAPI meetings. The Governing Body will attend all quarterly meetings, and additional meetings as necessary. A collaboration with Qualis Health and other local ASC Infection Control Officials will give PCS Procedure Suite objective input on ways to better oversee the program and ensure its sustainability. Improved tracking is expected on flu shot compliance. The DON will encourage all staff, including physicians, to receive a flu shot this fall. The DON will document immunization status of all staff and physicians. A Hand Hygiene PIP is being implemented to improve compliance and monitoring with this portion of the Infection Control Plan. Implementation techniques (such as posters being posted in procedure area as reminder to wash hands, posters being placed in the waiting to encourage family and visitors to wash hands) and direct observation monitoring forms are being used from the CDC website, and are expected to be used by all staff. An in-service on 8/11/15 introduced the staff to this tracking/observation form, and staff were instructed that at least one procedure per week should be observed for Hand Hygiene opportunities. See Governing Body minutes from 8/3/15. The DON will be responsible to implement and track all data from the PIP, including direct observation forms, and report findings to the QAPI/IC committee and continued on next page...	

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Q 244	Continued From page 48 prevention problems in the last 12 months. The DON stated there was not a need to improve any processes because they have not identified any problems. The Physician Owner was interviewed on 7/09/15 beginning at 1:10 PM. He confirmed the content of the minutes and stated there were no other meeting minutes in the past year that discussed the QAPI program or the Infection Control Program. The ASC did not ensure an Infection Control Program was implemented to include a plan of action for preventing, identifying, actively surveying, and implementing corrective measures that would result in improvement. The ASC failed to ensure the QAPI program incorporated quantifiable infection control data, which was gathered, analyzed and used to minimize the risk of patient infections.	Q 244	Q244- Governing Body where further discussion and debate will determine future activity and action. Any infections identified or analyzed will also be included for discussion and debate at the QAPI/IC meetings. The Governing Body will dictate further direction for infections identified. Compliance is expected 8/12/15.	
Q 263	416.52(a)(3) ADMISSION ASSESSMENT - RECORD The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the ASC failed to ensure the patient's medical history and physical assessment were placed in their record prior to the procedure for 13 of 20 patients (#1 - #3, #6, #8, #9, #11 - #13, #16, #17, #18, and #20) whose records were reviewed. This had the potential to result in	Q 263		

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Q 263	Continued From page 49 negative outcomes or complications with procedural sedation. Findings include: 1. Patient #1 was a 54 year old female admitted on 1/22/15, for carpal tunnel release of her left hand. Patient #1's record included a Conscious Sedation Flow Sheet, dated 1/22/15. The flow sheet included a pre-operative assessment, intraoperative interventions and assessment, and post-operative assessment by the RN for Patient #1. The flow sheet was signed by the RN and surgeon. Additionally, the Conscious Sedation Flow Sheet included the procedure start and end times, as well as the discharge time from the facility. Patient #1's procedure was started at 1:26 PM. Patient #1 was discharged from the facility at 2:00 PM. However, the H&P included in the record was dated 1/22/15 at 2:01 PM. 2. Patient #3 was a 66 year old female admitted on 1/22/15, for tenotomy (tendon release) of her right hip. Patient #3's record included a Conscious Sedation Flow Sheet, dated 1/22/15. The flow sheet included a pre-operative assessment, intraoperative interventions and assessment, and post-operative assessment by the RN for Patient #3. The flow sheet was signed by the RN and surgeon. Additionally, the Conscious Sedation Flow Sheet included the procedure start and end times, as well as the discharge time from the facility. Patient #3's procedure was started at 3:17 PM. However, the H&P included in the record was dated 1/22/15 at 3:40 PM. 3. Patient #16 was a 29 year old female admitted	Q 263	Q263-Effective 8/3/15, ASC staff and physicians were re-oriented to the requirement of the patients' H&P being reviewed, dated, timed and physically placed into the patients' record prior to the surgical procedure beginning. Mikelle Mierra CMA is responsible to print H&P's prior to the procedure date and physically place in chart along with physician orders and advance directives. This will be monitored by the RN working in the procedure suite each day. If the H&P is not present at the beginning of the day, the RN will then print and place in chart. All staff were oriented on 8-11-2015 to this change in procedure. The DON will monitor for continued compliance, as she also works as a staff nurse in the ASC weekly and will be aware if H&P's are not present in chart. Compliance is expected 8/12/15.	

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Q 263	Continued From page 50 on 6/18/15, for tendon release of her right foot. Patient #16's record included a Conscious Sedation Flow Sheet, dated 6/18/15. The flow sheet included a pre-operative assessment, intraoperative interventions and assessment, and post-operative assessment by the RN for Patient #16. The flow sheet was signed by the RN and surgeon. Additionally, the Conscious Sedation Flow Sheet included the procedure start and end times, as well as the discharge time from the facility. Patient #16's procedure was started at 3:46 PM. However, the H&P included in her record was dated 6/18/15 at 4:05 PM. 4. Patient #18 was a 50 year old female admitted on 6/18/15, for tendon release of her right and left foot. Patient #18's record included a Conscious Sedation Flow Sheet, dated 6/18/15. The flow sheet included a pre-operative assessment, intraoperative interventions and assessment, and post-operative assessment by the RN for Patient #18. The flow sheet was signed by the RN and surgeon. Additionally, the Conscious Sedation Flow Sheet included the procedure start and end times, as well as the discharge time from the facility. Patient #18's procedure was started at 1:25 PM. However, the H&P included in her record was dated 6/18/15 at 2:32 PM. 5. Patient #9 was a 71 year old male who had tenotomy (surgical cutting of a tendon) performed on 3/19/15. The Conscious Sedation Flow Sheet stated his procedure started at 1:12 PM. Patient #9's H&P was dated 3/19/15 but was not timed. It referred to a physician progress note dated 3/19/15 at 1:40 PM, 38 minutes after the	Q 263		

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Q 263	Continued From page 51 procedure began. No documentation was present to show the H&P was in Patient #9's medical record prior to the procedure. 6. Patient #12 was a 40 year old female who had tenotomy performed on 5/21/15. The Conscious Sedation Flow Sheet stated her procedure started at 2:14 PM. Patient #12's H&P was dated 5/21/15 but was not timed. It referred to a physician progress note dated 5/21/15 at 2:49 PM, 35 minutes after the procedure began. No documentation was present to show the H&P was in Patient #12's medical record prior to the procedure. During an interview on 7/09/15 at 1:40 PM, the Physician Owner reviewed the patient records. He confirmed H&Ps were not printed out and placed in the patient record prior to the procedure. The Physician Owner stated the H&P was part of the EMR, as well as the operative report. He confirmed the time and date at the top of the H&P was when the EMR was opened and viewed by the surgeon. The Physician Owner stated his practice was to open the H&P on his laptop and view it while performing the pre-procedure assessment. He confirmed the times on the above H&Ps were after the start of the procedure. The patients' H&Ps were not placed in their records or viewed in the EMR prior to the their surgical procedures. Further, Patient #2, #6, #8, #11, #13, #17, and #20's records were reviewed. The records included H&Ps for their procedures. All of the H&Ps were dated on the same day of the patients' procedures. However, none of the	Q 263		

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Q 263	Continued From page 52 H&Ps documented times, to establish the H&Ps were completed prior to the patients' procedures. The DON was interviewed on 7/08/15 beginning at 3:50 PM. She confirmed the H&Ps were not timed. The ASC failed to ensure patients' medical H&Ps were placed in their record prior to their procedures.	Q 263		