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IDAHO DEPARTMENT OF

HEALTH & WELFARE

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

DEBRA RANSOM, R.N., R.H.I.T., Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
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CERTIFIED MAIL: 7007 3020 0001 4038 7495

October 12, 2011

Dr. Scott Magnusson, CEO
North Idaho Pain Center
2003 Lincoln Way Ste 310
Coeur D'Alene, ID 83814

RE: North Idaho Pain Center, Provider #13C0001058

Dear Dr. Magnusson:

Based on the survey completed at North Idaho Pain Center, on September 30, 2011, by our staff, we have determined North Idaho Pain Center is out of compliance with the Medicare ASC Conditions for Coverage of **Governing Body and Management (42 CFC 416.41); Surgical Services (42 CFC 416.42); Quality Assessment and Performance Improvement (42 CFC 416.43); Environment (42 CFR 416.44); Nursing Services (42 CFR 416.46); Medical Records (42 CFC 416.47); Pharmaceutical Services (42 CFC 416.48); Patient Rights (42 CFC 416.50); Infection Control (42 CFC 416.51); Patient Admission, Assessment, and Discharge (42 CFC 416.52).** 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 North Idaho Pain Center, to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567).

You have an opportunity to make corrections of those deficiencies, which led to the finding of non-compliance with the Conditions 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 November 15, 2011. 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 November 1, 2011.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **October 24, 2011**.

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

We urge you to begin correction immediately.

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

Sincerely,

SUSAN COSTA
Health Facility Surveyor
Non-Long Term Care

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

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

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

PRINTED: 10/11/2011
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
	13C0001058		09/30/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
NORTH IDAHO PAIN CENTER	2003 LINCOLN WAY STE 310 COEUR D'ALENE, ID 83814

(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 recertification survey of your Ambulatory Surgery Center. Surveyors conducting the recertification were: Susan Costa, RN, HFS, Team Leader Gary Guiles, RN, HFS Eric Mundell, REHS Acronyms used in this report include: ASC - Ambulatory Surgical Center CDC - Center for Disease Control cc - cubic centimeters CEO - Chief Executive Officer CNA - Certified Nursing Assistant CLIA - Clinical Laboratory Improvement Amendments CRNA - Certified Registered Nurse Anesthetist H&P - History and Physical IV - Intravenous mcg - microgram mg - milligram NaHCO3 - Sodium Bicarbonate NP - Nurse Practitioner POC - Point of Care RN - Registered Nurse QAPI - Quality Assessment and Performance Improvement UAP - Unlicensed Assistive Personnel Immediate Jeopardy was identified at Q-060 (Surgical Services) and the facility was notified on 9/26/11 at 9:40 AM and submitted an Immediate Plan on 9/26/11. The Immediate Jeopardy was abated on 9/27/11.	Q 000	RECEIVED OCT 31 2011 FACILITY STANDARDS	
Q 040	416.41 GOVERNING BODY AND	Q 040	Please refer to enclosed spreadsheet	

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

Scott Magnuson, MD — 27 OCT 2011

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

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Q 040	Continued From page 1 MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing,and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan. This CONDITION is not met as evidenced by: Based on staff interview and review of policies and administrative documents, it was determined the ASC failed to ensure the governing body assumed responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and the QAPI program. This resulted in a lack of guidance and oversight of the facility's staff and programs. Findings include: 1. No documentation was present to show the ASC's governing body had provided direction or guidance to the facility in the past year. No minutes of governing body meetings or other governing body activities were documented from 10/01/10 through 9/22/11. No documentation was present that the governing body had reviewed or approved any policies, meeting minutes, or reports in the past year. The CEO was interviewed on 9/27/11 beginning at 11:30 AM. He stated he was the governing	Q 040	Description of Governing Body amended in ASC Manual. Governing Body will meet annually and documentation of this meeting will be made. If need arises, Governing Body will meet more frequently than annually.	

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Q 040	Continued From page 2 body and confirmed there was no documentation of governing body activities. 2. Refer to Q042 as it relates to the failure of the ASC to ensure procedures for the transfer of patients to an acute care hospital were in place. 3. Refer to Q060 as it relates to the failure of the ASC to ensure systems related to patient safety during pre-procedural assessment, during procedures, during administration of sedation, during post procedural recovery and during discharge, were developed, implemented, and monitored necessary to ensure patient health and safety. 4. Refer to Q080 as it relates to the failure of the ASC to ensure a comprehensive, data driven QAPI program was developed, implemented and monitored. 5. Refer to Q100 as it relates to the failure of the ASC to ensure emergency equipment needed to ensure a safe environment was provided for patients receiving care at the facility. 6. Refer to Q140 as it relates to the failure of the ASC to provide nursing services in accordance with written policy and procedures. 7. Refer to Q160 as it relates to the failure of the ASC to ensure a complete, comprehensive, and accurate medical records system was in place. 8. Refer to Q180 as it relates to the failure of the ASC to ensure medications were prepared, administered and discarded in a safe and effective manner in accordance with acceptable	Q 040	Hospital Staff privelages for Dr. Magnuson is on file in Administrator's office. Transfer agreement with Kootenai Medical Center in place.	

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Q 040	Continued From page 3 standards of practice, and under the direction of a designated individual. 9. Refer to Q220 as it relates to the failure of the ASC to inform the patient or the patient's representative of the patient's rights, and that patient rights were protected and promoted. 10. Refer to Q240 as it relates to the failure of the ASC to ensure a comprehensive infection control program was developed, monitored and implemented. 11. Refer to Q260 as it relates to the failure of the ASC to ensure appropriate assessments were completed before and after procedures and that patients were discharged from the facility per physician orders. The cumulative effect of the lack of governing body involvement resulted in a lack of direction to staff and a lack of structure defining the ASC's processes.	Q 040		
Q 042	416.41(b) HOSPITALIZATION (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. (2) This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter. (3) The ASC must - (i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or	Q 042	* Refer to enclosed spread sheet Procedure revised and reviewed with staff. Copy of transfer agreement attached	10/12/11 MM 10/18/11 MM

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Q 042	Continued From page 4 (ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.	Q 042	Attached	7/23/10 MM
	This STANDARD is not met as evidenced by: Based on review of policies and procedures and staff interview, it was determined the facility failed to have a written procedure for transfer of patients to an acute care hospital. The failure to have a transfer process with an acute care facility had the potential to disrupt the coordination of patient care in the event of a medical emergency. Findings include: The ASC's policies and procedures were reviewed on 9/21/11. There was no evidence the ASC had procedures in place for the transfer of patients to an acute care facility. During an interview on 9/20/11 at 10:30 AM, the ASC RN stated the physician had privileges at the hospital. When asked for evidence of physician privileges, she was not able to provide documentation. The ASC did not have evidence of a transfer agreement with a hospital or written policies and procedure for the transfer of patients.		Copy of this in Administrator's Office.	7/23/10 MM
Q 060	416.42 SURGICAL SERVICES Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC	Q 060	Transfer agreement in place. Refer to enclosed Speadsheet	10/18/11 MM

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Q 060	Continued From page 5 This CONDITION is not met as evidenced by: Based on observation, review of policies and procedures, staff interview, and review of medical records, it was determined the facility failed to ensure systems were sufficiently developed and implemented for the administration of medications and emergency response. These systemic failures directly impacted 12 of 22 patients (#2, #4, #5, #7, #9 - #15 and #19) whose records were reviewed and had the potential to impact all patients receiving care at the facility. This resulted in patients being placed at risk for serious and immediate jeopardy from the potential to experience serious harm, impairment, or death as a result of unsafe practices. Findings include: 1. The ASC's medication administration and emergency response procedures were reviewed. The facility failed to ensure medication orders were given, medication were safely administered by qualified personnel, and that equipment and personnel were available to respond to patient emergencies. The cumulative effect of these failures placed patients at risk for serious harm, impairment or death as follows: a. The facility failed to ensure medications were ordered by the physician and in accordance with facility policy: An undated facility policy, "Care of the Patient Under Local Anesthesia," stated that all medications administered by the nurse must be written in the physician order sheet as a verbal order and signed by the physician after the	Q 060		

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Q 060	Continued From page 6 procedure. Medical records contained documentation of administration of IV medications by unidentified personnel without signed physician orders, as follows: - Patient #2's "Procedure Flowsheet," dated 8/04/11, included documentation Patient #2 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 4:26 PM. - Patient #4's "Procedure Flowsheet," dated 8/04/11, included documentation Patient #4 was administered Versed 2 mg IV at 2:03 PM. - Patient #5's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #5 was administered Versed 2 mg IV at 7:41 AM. - Patient #7's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #7 was administered Fentanyl 100 mcg IV and Versed 2 mg IV at 11:18 AM. - Patient #9's "Procedure Flowsheet," dated 9/08/11, included documentation Patient #9 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 4:18 PM. - Patient #10 received Versed 2 mg IV and Fentanyl 50 mcg IV on 8/16/11 at 10:08 AM, and Propofol 30 mg IV at 10:13 AM. - Patient #11's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #11 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 3:49 PM, and Propofol 100 mg at 4:04	Q 060		

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Q 060	Continued From page 7 PM. - Patient #12's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #12 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 11:02 AM, and Propofol 30 mg IV at 11:14 AM. - Patient #13's "Procedure Flowsheet," dated 8/11/11, included documentation Patient #13 was administered Propofol 100 mg IV at 11:44 AM. - Patient #14's "Procedure Flowsheet," dated 8/10/11, included documentation Patient #14 was administered Fentanyl 100 mcg IV and Versed 2 mg IV at 1:18 PM. - Patient #15's "Procedure Flowsheet," dated 8/31/11, included documentation Patient #15 was administered Versed 2 mg IV. - Patient #19's "Procedure Flowsheet," dated 5/31/11, included documentation Patient #19 was administered Versed 2 mg IV, Fentanyl 100 mcgs IV, and Propofol 100 mg IV. In an interview on 9/21/11 beginning at 10:45 AM, the RN reviewed the records and confirmed verbal orders had not been written or authenticated. The RN stated the format of the computer program the ASC used did not allow for order entry by the nursing staff. Without physician orders, it would not be possible to ensure patients received appropriate medications, resulting in the potential for patients experience serious adverse health outcomes.	Q 060		

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Q 060	Continued From page 8 b. The facility failed to ensure medications were administered by appropriately qualified staff: The facility's policy "Administration of Intravenous Conscious Sedation," not dated, did not state which staff were allowed to administer conscious sedation medications. Patient records documented patients had received anesthetic medication (Propofol), administered by the RN as follows: - Patient #13's medical record documented a 60 year old female who had a Lumbar Medial Branch nerve block on 8/11/11. The "Procedure Flowsheet," dated 8/11/11 at 11:20 AM, stated Patient #13 was given 100 mg of Propofol IV by the RN. The RN was interviewed on 9/21/11 at 2:30 PM. She confirmed she had administered Propofol to Patient #13. - Patient #12's medical record documented a 41 year old female who had a bilateral sacroiliac joint injection with local anesthetic and steroid on 8/16/11. The "Procedure Flowsheet," dated 8/16/11 at 11:02 AM, stated Patient #12 was given 30 mg of Propofol IV by the RN. The RN was interviewed on 9/21/11 at 2:30 PM. She confirmed she had administered Propofol to Patient #12. - Patient #10's medical record documented a 57 year old female who had radiofrequency ablation of the left lateral branch nerves serving the left sacroiliac joint. The "Procedure Flowsheet," dated 8/16/11 at 10:13 AM, stated Patient #10	Q 060		

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Q 060	Continued From page 9 was given 30 mg of Propofol IV by the RN. The RN was interviewed on 9/21/11 at 2:30 PM. She confirmed she had administered Propofol to Patient #10. - Patient #11's medical record documented a 47 year old male who had a lumbar sympathetic block on 8/16/11. The "Procedure Flowsheet," dated 8/16/11 but not timed, stated Patient #11 was given 30 mg of Propofol IV by the RN at 4:04 PM. The RN was interviewed on 9/21/11 beginning at 11:50 AM. She confirmed she had administered Propofol to Patient #11. - Patient #19's medical record documented a 46 year old female who had a bilateral sacroiliac joint injection with local anesthetic and steroid on 5/31/11. The "Procedure Flowsheet," dated 5/31/11 but not timed, stated Patient #19 was given 60 mg of Propofol IV by the RN at 10:15 AM. She was given another 40 mg of Propofol IV by the RN at 10:26 AM. The RN was interviewed on 9/21/11 beginning at 11:50 AM. She confirmed she had administered Propofol to Patient #19. Propofol information provided by the manufacturer, dated 8/05, stated "...for monitored anesthesia care (MAC) sedation, (Propofol) should be administered only by persons trained in the administration of general anesthesia...and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately	Q 060		

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Q 060	Continued From page 10 available." According to the April 14, 2005 joint statement from the American Association for Nurse Anesthetists (AANA) and the American Society of Anesthesiologists (ASA), "propofol should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in the procedure." Propofol was administered to patients by unqualified staff. Without qualified personnel to administer and monitor the patient, the ASC could not ensure the risk of medication errors minimized and that adverse patient reaction to the drug were recognized and appropriately responded to. c. The facility failed to ensure single dose medications were administered appropriately: Propofol information provided by the manufacturer, dated 8/05, stated "...Diprivan (Propofol) is a single-use product." However, the ASC's "NARCOTIC COUNT," form with dates from 8/11/11 to 9/06/11 was reviewed. The form indicated Propofol was administered to three patients from one vial on 8/16/11. Review of the three patients' records documented Propofol had been administered as follows: - Patient #10's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #10 received Propofol 30 mg IV at 10:13 AM. - Patient #11's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #11 was	Q 060		

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Q 060	Continued From page 11 administered Propofol 100 mg at 4:04 PM. - Patient #12's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #12 was administered Propofol 30 mg IV at 11:14 AM. In an interview on 9/21/11 at 2:30 PM, the RN confirmed she had used the same vial of Propofol for Patients #10 - #12. The RN stated she was unaware that Propofol was a single use medication, and stated she thought it was a drug that could be used for up to six hours after being opened. d. The facility failed to equipment and personnel were available in the ASC to respond to medical emergencies: A tour of the ASC was conducted on 9/19/11 starting at 3:30 PM and ending at 4:20 PM. The ASC was located on the third floor of the hospital outpatient building. The ASC had an admitting/recovery area and two procedure rooms. The ASC did not have all required emergency emergency equipment including airways, a defibrillator, and mechanical ventilation equipment such as a breathing bag or a ventilator available within the ASC. The missing equipment was confirmed by the ASC's RN on 9/19/11 at 3:45 PM. The RN stated emergency equipment was in the form of a "Code Cart" that was provided by the hospital and shared by the hospital's Cardiac Rehabilitation Center. The hospital stored the Code Cart in a hallway outside of the ASC facility in an area that	Q 060		

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Q 060	Continued From page 12 separated the ASC and a Cardiac Rehabilitation Center. The RN stated in the event of an emergency, the staff would call the hospital and initiate the code response. The hospital would then provide a team of responders as well as the Code Cart. The RN stated the Code Cart and response team were part of the lease agreement with the hospital. However, a review of the undated and unsigned lease agreement did not include verbiage regarding the provision of emergency response by the hospital on behalf of the ASC. During an interview on 9/26/11 beginning at 3:00 PM, the Facility Administrator confirmed the absence of emergency response in the lease agreement by the hospital. The ASC's written "Emergency Procedures," undated, stated "Once the patient is stabilized he/she will be transported to [hospital name]." The policy did not specify responsibilities of ASC staff during the emergency or how staff were to respond if the hospital's crash cart and/or staff were not available. The facility failed to ensure all emergency equipment was readily available to ensure patients' emergency health care needs could be met. The cumulative effect of the ASC's lack of safe surgical practices resulted in a determination of Immediate Jeopardy to the health and safety of patients. The facility was notified on 9/26/11 at 9:40 AM.	Q 060		

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Q 060	Continued From page 13 The ASC responded with an Immediate Plan of Correction on 9/26/11. The plan included the following: -Verbal and written orders were developed to include admission orders, IV placement orders, medication orders, and discharge orders. - A written document by the Director/Physician stated Propofol would no longer be used in the ASC. The document stated if Propofol were to be used in the ASC, policies and procedures would be developed for its use and it would be administered by an anesthesiologist or CRNA. - A policy for single dose medications was developed. - Emergency equipment was obtained and placed in the procedural area, accessible to both procedure rooms. Observations, record review and staff interviews were conducted on 9/27/11 and it was determined at that time, the immediate jeopardy was abated.	Q 060		
Q 063	416.42(b) & (c) ADMINISTRATION OF ANESTHESIA b) Anesthetics must be administered by only: (1) A qualified anesthesiologist; or (2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases where a non-physician administers the anesthesia, unless	Q 063	Refer to enclosed spreadsheet	

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Q 063	Continued From page 14 exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist. (c) State Exemption (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission. This STANDARD is not met as evidenced by: Based on staff interview, review of medical records, ASC policies, and job descriptions, it was determined the ASC failed to ensure anesthetic medication (Propofol) was administered by appropriately qualified personnel for 5 of 12 patients (Patients #10 - #13 and #19)	Q 063		

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Q 063	Continued From page 15 who received intravenous conscious sedation during procedures. This resulted in increased risk of complications to patients from anesthesia. Findings include: 1. The facility's policy "Administration of Intravenous Conscious Sedation," not dated, did not state which staff were allowed to administer conscious sedation medications. Patient records documented patients had received anesthetic medication (Propofol), administered by the RN as follows: a. Patient #13's medical record documented a 60 year old female who had a Lumbar Medial Branch nerve block on 8/11/11. The "Procedure Flowsheet," dated 8/11/11 at 11:20 AM, stated Patient #13 was given 100 mg of Propofol IV by the RN. The RN was interviewed on 9/21/11 at 2:30 PM. She confirmed she had administered Propofol to Patient #13. b. Patient #12's medical record documented a 41 year old female who had a bilateral sacroiliac joint injection with local anesthetic and steroid on 8/16/11. The "Procedure Flowsheet," dated 8/16/11 at 11:02 AM, stated Patient #12 was given 30 mg of Propofol IV by the RN. The RN was interviewed on 9/21/11 at 2:30 PM. She confirmed she had administered Propofol to Patient #12. c. Patient #10's medical record documented a 57 year old female who had radiofrequency ablation of the left lateral branch nerves serving the left	Q 063		

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Q 063	Continued From page 16 sacroiliac joint. The "Procedure Flowsheet," dated 8/16/11 at 10:13 AM, stated Patient #10 was given 30 mg of Propofol IV by the RN. The RN was interviewed on 9/21/11 at 2:30 PM. She confirmed she had administered Propofol to Patient #10. d. Patient #11's medical record documented a 47 year old male who had a lumbar sympathetic block on 8/16/11. The "Procedure Flowsheet," dated 8/16/11 but not timed, stated Patient #11 was given 30 mg of Propofol IV by the RN at 4:04 PM. The RN was interviewed on 9/21/11 beginning at 11:50 AM. She confirmed she had administered Propofol to Patient #11. e. Patient #19's medical record documented a 46 year old female who had a bilateral sacroiliac joint injection with local anesthetic and steroid on 5/31/11. The "Procedure Flowsheet," dated 5/31/11 but not timed, stated Patient #19 was given 60 mg of Propofol IV by the RN at 10:15 AM. She was given another 40 mg of Propofol IV by the RN at 10:26 AM. The RN was interviewed on 9/21/11 beginning at 11:50 AM. She confirmed she had administered Propofol to Patient #19. Propofol information provided by the manufacturer, dated 8/05, stated "...for monitored anesthesia care (MAC) sedation, (Propofol) should be administered only by persons trained in the administration of general anesthesia..."	Q 063		

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Q 063	Continued From page 17 According to the April 14, 2005 joint statement from the American Association for Nurse Anesthetists (AANA) and the American Society of Anesthesiologists (ASA), "propofol should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in the procedure." The facility's RN was not qualified to administer Propofol. The ASC failed to ensure anesthetic medications were administered by qualified staff.	Q 063		
Q 080	416.43 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on staff interview and review of ASC policies, QAPI documents, and governing board meeting minutes, it was determined the facility failed to ensure a data driven QAPI program had been developed, implemented, and monitored. This resulted in the inability of the ASC to evaluate its processes and practices. Findings include: 1. Refer to Q081 as it relates to the failure of the ASC to ensure the scope of the QAPI program provided sufficient direction to staff to demonstrate measurable improvement in patient health outcomes. 2. Refer to Q082 as it relates to the failure of the ASC to ensure data, including adverse patient	Q 080		

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Q 080	Continued From page 18 events, was used to monitor the effectiveness and safety of its services. 3. Refer to Q083 as it relates to the failure of the ASC to conduct performance improvement projects. 4. Refer to Q084 as it relates to the failure of the ASC to ensure the governing body defined, monitored, and maintained the QAPI program. The cumulative effect of these negative facility practices prevented the ASC from utilizing information to improve its processes.	Q 080	Refer to enclosed spreadsheet	
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and	Q 081	Refer to enclosed Spreadsheet	

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Q 081	Continued From page 19 quality of care. This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to ensure the scope of the QAPI program provided sufficient direction to staff to demonstrate measurable improvement in patient health outcomes by using quality indicators. This resulted in performance measures that were insufficient to measure the quality of care provided to patients. Findings include: 1. The facility's policy "PERFORMANCE IMPROVEMENT...SCOPE OF ACTIVITIES," not dated, stated performance measures would be developed in the areas of assessment of patients, education of patients and family, management of information, leadership, infection control, utilization management, safety management, and risk management. The policy further stated "The monitoring and evaluation of the quality and appropriateness of patient care and clinical performance of all individuals with clinical privileges will be accomplished through...surgical and invasive procedure monitoring, medication usage evaluation, [and] medical record review." A plan to measure these areas, including quality indicators, had not been developed. The only QAPI activity that was documented in the past year consisted of patient satisfaction post cards that were given to patients to take home and fill out following their procedures. The questions on the cards were:	Q 081		

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Q 081	Continued From page 20 "1. Did you like the care you received at the North Idaho Pain Center? 2. Do you feel you received adequate pre-op and post-op instructions? 3. Were your questions answered during your follow up phone call? 4. Did you feel care was provided in a safe and pleasant environment?" The RN was interviewed on 9/20/11 beginning at 8:35 AM. She stated she coordinated the ASC's QAPI program. She stated there was no QAPI plan. She confirmed the items on the post card were the only items being measured. The ASC had not developed a plan to demonstrate measurable improvement in patient health outcomes.	Q 081		
Q 082	416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.	Q 082	Refer to enclosed Spreadsheet	

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Q 082	Continued From page 21 (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 medical records, ASC policies, and QAPI documents, it was determined the facility failed to ensure data, including adverse patient events, was used to monitor the effectiveness and safety of its services. This directly impacted the care of 2 of 2 patients (#17 and #19) who experienced adverse events during their treatment and had the potential to impact all patients receiving care at the facility. This resulted in the inability of the ASC to determine if services were being provided in a safe and effective manner. Findings include: 1. The facility's policy manual "Section V, PERFORMANCE IMPROVEMENT," not dated, did not specify how data would be gathered or used. The only data that had been collected between 10/01/10 and 9/22/11 was information received from the patient satisfaction post cards. The post cards asked 4 questions including: "1. Did you like the care you received at the North Idaho Pain Center? 2. Do you feel you received adequate pre-op and post-op instructions? 3. Were your questions answered during your follow up phone call? 4. Did you feel care was provided in a safe and pleasant environment?"	Q 082		

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Q 082	Continued From page 22 Raw data, including the number of patients who answered the questionnaire and the number of yes or no answers received, were noted by quarter. No objective data was documented. No analysis of the data was documented. The RN was interviewed on 9/20/11 beginning at 8:35 AM. She confirmed no objective data had been gathered or analyzed. 2. Medical records of 2 patients documented adverse events as follows: a. Patient #17's medical record documented an 87 year old female who presented for a lumbar epidural steroid injection on 9/06/11. The "Operative Report," dated 9/06/11 at 5:11 PM, stated "With injection of 1 cc of Omnipaque-240 patient complained of pain across her low back. Became very anxious. I decided to abort the procedure. She was returned to the recovery room. Skelaxin was given for presumed muscle spasm...[She] Was reassured that this would resolve in time." b. Patient #19's medical record documented a 46 year old female who had a bilateral sacroiliac joint injection on 5/31/11. A document titled "Physician Notes," dated 5/31/11 at 5:11 PM, stated Patient #19 became unresponsive and fell following her procedure. She was transported to a hospital emergency room. Incident reports had not been generated from these incidents. No record of the incidents being investigated or analyzed was present. No incident reports between 10/01/10 and 9/22/11	Q 082		

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Q 082	Continued From page 23 were documented. The RN was interviewed on 9/20/11 beginning at 8:35 AM. She confirmed no incident reports had been documented. She also stated no analysis of adverse events that had occurred at the ASC in the past year had been documented. The facility failed to ensure data, including adverse patient events, was used to monitor the effectiveness and safety of its services.	Q 082		
Q 083	416.43(d) PERFORMANCE IMPROVEMENT PROJECTS (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to conduct performance improvement projects. This resulted in the inability of the ASC to evaluate and improve its processes. Findings include: 1. The facility's policy manual "Section V, PERFORMANCE IMPROVEMENT," not dated, did not address performance improvement projects.	Q 083	Refer to enclosed spreadsheet	

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Q 083	Continued From page 24 No performance improvement projects were documented between 10/01/10 and 9/22/11. The RN was interviewed on 9/20/11 beginning at 8:35 AM. She confirmed no performance improvement projects had been developed or conducted in the past year. The ASC failed to develop and conduct performance improvement projects.	Q 083		
Q 084	416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies and meeting minutes, it was determined the governing body failed to ensure that the QAPI program was defined, implemented, and maintained. This resulted in the lack of direction to staff conducting the QAPI program. Findings include:	Q 084	Refer to enclosed spreadsheet	

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Q 084	Continued From page 25 1. The facility's policy manual "Section V, PERFORMANCE IMPROVEMENT 2. Quality Management and Improvement," not dated, stated the governing body required and supported the establishment and maintenance of an effective organization-wide quality management and improvement program. The governing body was charged with setting expectations, developing plans, and implementing procedures to assess and improve the quality of the organization's government, management, clinical and support processes. Further, the CEO's job description, not dated, stated he "Approves criteria for quality care; participates in Quality Management and Improvement to improve quality of care and appropriate utilization of services." Documentation that the governing body or CEO had fulfilled their duties in relation to quality could not be found. No meeting minutes documented any involvement in the QAPI program by the governing body or by the CEO. The CEO was interviewed on 9/27/11 beginning at 11:30 AM. He confirmed the lack of an organized QAPI program at the facility. He also confirmed there was no documentation of involvement or oversight of the QAPI program by himself or the governing body. The governing body failed to oversee the QAPI program.	Q 084		
Q 100	416.44 ENVIRONMENT The ASC must have a safe and sanitary environment, properly constructed, equipped, and	Q 100	Refer to enclosed spreadsheet Abated. Safety equipment readily available	9/27/11

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Q 100	Continued From page 26 maintained to protect the health and safety of patients. This CONDITION is not met as evidenced by: Based on observation, record review and interview, it was determined the facility failed to ensure a safe environment was provided and maintained for all patients receiving care at the facility. This resulted in a lack of appropriate environmental conditions, equipment, and personnel necessary to ensure patient health and safety. Findings include: 1. Refer to Q105 as it relates to the failure of the ASC to ensure all emergency equipment, necessary to ensure patients' emergency health care needs could be met, was readily available.	Q 100		
Q 105	416.44(c) EMERGENCY EQUIPMENT Emergency equipment available to the operating rooms must include at least the following: (1) Emergency call system. (2) Oxygen. (3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator. (4) Cardiac defibrillator. (5) Cardiac monitoring equipment. (6) Tracheostomy set. (7) Laryngoscopes and endotracheal tubes. (8) Suction equipment. (9) Emergency medical equipment and supplies specified by the medical staff. This STANDARD is not met as evidenced by: Based on observations, staff interviews and	Q 105	Abated. Safety equipment readily available.	9/27/11

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Q 105	Continued From page 27 review of the facility's lease agreement, it was determined the ASC failed to ensure all emergency medical equipment was maintained and readily available for all patients receiving care at the facility. This resulted in the potential for patients' health and safety to be compromised in the event of a medical emergency. Findings include: 1. A tour of the ASC was conducted on 9/19/11 starting at 3:30 PM and ending at 4:20 PM. The ASC was located on the third floor of the hospital outpatient building. The ASC had an admitting/recovery area and two procedure rooms. The ASC did not have all required emergency equipment including airways, a defibrillator, and mechanical ventilation equipment such as a breathing bag or a ventilator available within the ASC. The missing equipment was confirmed by the ASC's RN on 9/19/11 at 3:45 PM. The RN stated emergency equipment was in the form of a "Code Cart" that was provided by the hospital and shared by the hospital's Cardiac Rehabilitation Center. The hospital stored the Code Cart in a hallway outside of the ASC facility in an area that separated the ASC and a Cardiac Rehabilitation Center. The RN stated in the event of an emergency, the staff would call the hospital and initiate the code response. The hospital would then provide a team of responders as well as the Code Cart. The RN stated the Code Cart and response team were part of the lease agreement with the hospital.	Q 105		

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Q 105	Continued From page 28 However, a review of the undated and unsigned lease agreement did not include verbiage regarding the provision of emergency response by the hospital on behalf of the ASC. During an interview on 9/26/11 beginning at 3:00 PM, the Facility Administrator confirmed the absence of emergency response in the lease agreement by the hospital. The ASC's written "Emergency Procedures," undated, stated "Once the patient is stabilized he/she will be transported to [hospital name]." The policy did not specify responsibilities of ASC staff during the emergency or how staff were to respond if the hospital's crash cart and/or staff were not available. The facility failed to ensure all emergency equipment was readily available to ensure patients' emergency health care needs could be met.	Q 105		
Q 140	416.46 NURSING SERVICES 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, review of policies, and interviews it was determined the ASC failed to provide nursing services in accordance with written policy and procedures. This resulted in the lack of qualified personnel available to evaluate patients and provide emergency care. Findings include:	Q 140	Refer to enclosed spreadsheet	

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Q 140	Continued From page 29 1. Refer to Q141 as it relates to unqualified nursing personnel providing conscious sedation using Propofol, as well as delegation of tasks to unlicensed assistive personnel. The cumulative effect of these systemic practices resulted in increased risk of adverse events occurring and a decreased ability of the facility to recognize and respond to adverse events.	Q 140	Abated - Propofol no longer used in ASC as of 9/26/11	9/26/11
Q 141	416.46(a) ORGANIZATION AND STAFFING Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. This STANDARD is not met as evidenced by: Based on observation, review of policies, and staff interviews it was determined the facility failed to provide nursing services in accordance with written policy and procedures and delegated job responsibilities to Unlicensed Assistive Personnel. This deficiency directly impacted 7 of 22 patients (#10 - #13, and #19 - #21) whose records were reviewed. The lack of qualified personnel to administer propofol sedation and document monitoring of the patients while sedated, as well as the delegation of duties to UAP, had the potential to result in negative health outcomes to patients. Findings include: 1. During a review of personnel records and policy and procedures on 9/26/11 beginning at 3:30 PM, job descriptions for the RN, Medical Assistant, and CNA were not in the personnel	Q 141	Refer to enclosed spreadsheet P&P reviewed and revised. Detailed job descriptions formulated and given to each ASC nursing staff to read and acknowledge.	

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Q 141	Continued From page 30 records or the policy and procedures that were provided to the surveyors. During observation of procedures in the ASC on 9/27/11 between 8:00 AM, to 11:30 AM the CNA was observed to discontinue the IVs of two patients (Patients #20 and #21). In an interview with the RN on 9/27/11 at 11:30 AM, the RN confirmed the CNA discontinued the IVs and stated the Medical Assistant in the ASC, as well as the CNA, routinely discontinued IVs. The RN was unable to provide a job description for the UAPs who worked in the ASC. However, the Idaho Administrative Code, IDAPA 23.01.01, Rules of the Idaho Board of Nursing, 490.b.iii, UNLICENSED ASSISTIVE PERSONNEL (UAP) may not be delegated "...procedures involving acts that require nursing assessment or diagnosis, to include but are not limited to start, stop, or adjust any IV therapy." The ASC failed to delineate nursing procedures and interventions for UAP and did not ensure nursing procedures were performed by licensed nursing staff in accordance with State Board of Nursing Rules. 2. Refer to Q063 as it relates to the facility's failure to ensure anesthetic medication (Propofol) was administered by appropriately qualified personnel for Patients #10 - #13 and #19.	Q 141	Job descriptions for nursing staff have been clearly delineated in the Policy and Procedure manual. All nursing staff was given a copy of their job description to read. CNA nor MA discontinue IV's as of 9/30/11. Abated	10/19/11 MM 9/26/11 MM 9/26/11
Q 160	416.47 MEDICAL RECORDS The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.	Q 160	Refer to enclosed spreadsheet	

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Q 160	Continued From page 31	Q 160		
	This CONDITION is not met as evidenced by: Based on staff interview and review of medical records and facility policies, it was determined the ASC failed to ensure a complete, comprehensive, and accurate medical records system had been developed and implemented. This resulted in the potential for misinterpretation of information and had the potential to negatively impact the quality and safety of patient care. Findings include: 1. Refer to Q161 as it relates to the ASC's failure to ensure adequate patient record keeping systems were developed and maintained. 2. Refer to Q162 as it relates to the ASC's failure to ensure patient medical records were accurate and promptly completed. The cumulative effect of these negative systemic practices resulted in a lack of comprehensive, accurate patient information being maintained.			
Q 161	416.47(a) ORGANIZATION The ASC must develop and maintain a system for the proper collection, storage, and use of patient records. This STANDARD is not met as evidenced by: Based on staff interview and review of medical records and ASC policies, it was determined the ASC failed to ensure a system for the proper collection and use of patient records was developed and maintained for 19 of 22 patients (#1 - #19), whose records were reviewed. This resulted in a lack of documentation of the care	Q 161	Refer to enclosed spreadsheet.	

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Q 161	Continued From page 32 provided to patients. Findings include: 1. The facility's policy "PERFORMANCE IMPROVEMENT: 3. MEDICAL RECORDS" was not dated. The policy stated the medical record would contain the chief complaint or purpose of the visit, objective findings, diagnosis or impression, studies ordered, treatments administered, discharge and disposition, recommendations and instructions, and the signature of the practitioner. The policy did not mention admission or discharge information, consents, reports of procedures, progress notes for nursing or UAP, orders, or medications. The medical records for Patients #1 - #19, documented on the day of procedures, consisted of a consent signed by the patient, a "Procedure Flowsheet" and an "Operative Report." The medical records policies did not mention these forms or how staff would use them. Additionally, the procedure flowsheets for Patients #1 - #19 did not contain the name of the author or authors who completed the forms. The forms did not contain the time patients were admitted to the facility. The forms documented medications administered to patients during procedures, but did not state who administered the drugs. The RN reviewed the medical records with surveyors on 9/21/11 beginning at 11:50 AM. She confirmed the record content. The Administrator, interviewed on 10/3/11 at 9:40 AM, confirmed the policies were not complete. She stated in May 2007, the ASC had converted	Q 161		

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Q 161	Continued From page 33 from a paper medical record to an electronic medical record. She stated medical record policies were not updated at that time. Further, Patient #19's medical record documented a 46 year old female who had a bilateral sacroiliac joint injection on 5/31/11. A document titled "Physician Notes," dated 5/31/11 at 5:11 PM, stated it was an addendum to the operative report dated earlier that day. The addendum stated the physician completed Patient #19's procedure without difficulty, but following the procedure, Patient #19 became unresponsive and fell. The addendum stated staff from the hospital where the ASC was located came to the facility, provided treatment to Patient #19, and transported her to the emergency room. However, Patient #19's "Procedure Flowsheet," dated 5/31/11 but not timed or signed by the author, stated Patient #19 had discharge vital signs taken at 11:00 AM. The form did not document the incident. Patient #19's "Operative Report," dated 5/31/11 and electronically verified by the physician at 10:29 AM, documented following the procedure, "The patient was transported to the recovery area and was observed for possible medication reactions. There were none noted. The patient was discharged home in stable condition." Patient #19's medical record was not internally consistent. During the exit interview on 9/30/11 beginning at 9:05 AM, the RN stated following patient procedures, staff clicked a key and the computer	Q 161		

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Q 161	Continued From page 34 entered some information automatically. She stated the electronic medical record would not allow staff to enter information on the flowsheet, such as complications experienced after the procedure. The ASC did not develop a medical record system that allowed staff to document complete information.	Q 161		
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. (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 record review, policy review, and staff interview it was determined the ASC failed to ensure medical records contained information relevant to the course of patient care for 22 of 22	Q 162	Refer to enclosed spreadsheet Policy and Procedure for medical records was reviewed and updated. Front staff, who is responsible for retrieving medical records, was given an itemized list of what should be included in the medical record. This list will remain at the front desk for quick reference.	10/19/11

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Q 162	Continued From page 35 patients (Patients #1 - #22) whose records were reviewed. This resulted in incomplete patient records and had the potential to interfere with quality and coordination of patient care. Findings include: 1. The medical records for Patients #1 - #22 were reviewed. All records were missing information as follows: - The times that Patients #1 - #22 arrived at the facility, were admitted to the ASC for pain procedures, and when procedures began and ended were not documented. - The names of nursing staff who provided care before, during, and after procedures for Patients #1 - #22 were not documented. 2. The facility's policy "Care of the Patient Under Local Anesthesia," undated, stated there should be documentation of intraoperative assessment every 5 minutes of heart rate, respiratory rate, pulse oximetry and blood pressure. It further stated there should be documentation every 15 minutes and as needed after the procedure. Vitals signs were not documented according to the frequency identified in agency policy, as follows and/or were untimed as follows: a. Patient #1's "Operative Report," dated 9/01/11, documented "ANESTHESIA: Local skin infiltration with IV sedation plus 2 mg IV Versed" and one set of untimed vital signs. There was no other documentation of vital signs in Patient #1's record and the "Procedure Flowsheet" was missing. b. Patient #3's "Operative Report,"dated 8/04/11, documented "ANESTHESIA: Local skin	Q 162		

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Q 162	Continued From page 36 infiltration." Patient #3's "Procedure Flowsheet," dated 8/04/11, contained documentation of Patient #3's discharge vital signs at 11:18 AM. There were no other documented vital signs in Patient #3's record. c. Patient #5's "Operative Report," dated 8/16/11, documented "ANESTHESIA: Local infiltration with IV sedation plus 2 mg IV Versed." Patient #5's "Procedure Flowsheet," dated 8/16/11, contained documentation of Patient #5's vital signs at 7:41 AM (at the time of IV medication administration) and at 8:22 AM (at discharge). There were 19 minutes between documented vital signs. d. Patient #7's "Operative Report," dated 8/16/11, documented "ANESTHESIA: Local skin infiltration with IV sedation plus 100 mcgs IV Fentanyl...and 2 mg IV Versed." Patient #7's "Procedure Flowsheet," dated 8/16/11, contained documentation of Patient #7's vital signs at 11:18 AM (the time of IV medication administration) and 11:55 PM (at discharge). There were 37 minutes between vital signs. e. Patient #8's "Operative Report," dated 8/23/11, documented "ANESTHESIA: Local skin infiltration" and one set of untimed vital signs. There was no other documentation of vital signs present in Patient #8's record and the "Procedure Flowsheet" was missing. f. Patient #11's "Operative Report," dated 8/16/11, documented "ANESTHESIA: Local skin infiltration." Patient #11's "Procedure Flowsheet," dated 8/16/11, contained documentation of Patient #11's vital signs at 3:49 PM and 4:04 PM (at the time of IV medication administration) and	Q 162		

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Q 162	Continued From page 37 4:30 PM (at discharge). There were 26 minutes between the second and third set of vital signs. g. Patient #14's "Operative Report," dated 8/10/11, documented "ANESTHESIA: Local skin infiltration." Patient #14's "Procedure Flowsheet," dated 8/10/11, contained documentation of administration of Fentanyl 100 mcgs IV and Versed 2 mg IV at 1:18 PM. It also documented Patient #14's vital signs at 1:18 PM (at the time of IV medication administration) and 2:17 PM (at discharge). There were 59 minutes between vital signs. h. Patient #15's "Operative Report," dated 8/31/11, documented "ANESTHESIA: 2% lidocaine" and one set of untimed vital signs. There was no other documentation of vital signs present in Patient #15's record and the "Procedure Flowsheet" was missing. i. Patient #16's "Operative Report," dated 8/31/11, documented "ANESTHESIA: local infiltration plus IV sedation" and one set of untimed vital signs. There was no other documentation of vital signs present in Patient #16's record and the "Procedure Flowsheet" was missing. j. Patient #17's "Operative Report," dated 9/06/11, documented "ANESTHESIA: Local skin infiltration." Patient #17 did not have a "Procedure Flowsheet," or documentation of vital signs or the time of Patient #17's discharge. k. Patient #12's "Operative Report," dated 8/16/11, documented "ANESTHESIA: Local skin infiltration." Patient #12's "Procedure Flowsheet," dated 8/16/11, contained documentation of	Q 162		

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Q 162	Continued From page 38 Patient #12's vital signs at 11:02 AM and 11:14 AM (at the time of IV medication administration). There was no indication when Patient #12 was transferred to recovery and no further vital signs until discharge vital signs were documented at 11:52 AM. There were 38 minutes between the second and third set of vital signs. l. Patient #2's "Operative Report," dated 8/04/11, documented "ANESTHESIA: 0.5% Bupivicaine and 80 mg Methylprednisolone." Patient #2's "Procedure Flowsheet," dated 8/04/11, contained documentation of vital signs at 4:27 PM. There was no indication when Patient #2 was transferred to recovery and no further vital signs until discharge vital signs were documented at 4:59 PM. There were 36 minutes between documented vital signs. m. Patient #4's "Operative Report," dated 8/04/11, documented "ANESTHESIA: local skin infiltration." Patient #2's "Procedure Flowsheet," dated 8/04/11, contained documentation of vital signs at 1:58 PM. There was no indication when Patient #4 was transferred to recovery and no further vital signs until discharge vital signs were documented at 2:40 PM. There were 37 minutes between documented vital signs. n. Patient #9's "Operative Report," dated 9/08/11, documented "ANESTHESIA: local skin infiltration." Patient #9's "Procedure Flowsheet," dated 9/08/11, contained documentation of vital signs at 3:23 PM. There was no indication when Patient #9 was transferred to recovery and no further vital signs until discharge vital signs were documented at 4:33 PM. There were 50 minutes between documented vital signs.	Q 162		

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Q 162	Continued From page 39 o. Patient #10's "Operative Report," dated 8/16/11, documented "ANESTHESIA: Local skin infiltration plus IV sedation." Patient #10's "Procedure Flowsheet," dated 8/16/11, contained documentation of Patient #10's vital signs at 10:09 AM and 10:13 AM. There was no indication when Patient #10 was transferred to recovery and no further vital signs until discharge vital signs were documented at 11:25 AM. There was an hour and 12 minutes between the second and third set of vital signs. p. Patient #18's "Operative Report," dated 9/08/11, documented "ANESTHESIA: Local skin infiltration with IV sedation plus 100 mcg IV Fentanyl and 2 mg IV Versed." Patient #18's "Procedure Flowsheet," dated 9/08/11, contained documentation of Patient #18's vital signs at 4:20 PM. There was no indication when Patient #18 was transferred to recovery and no further vital signs until discharge vital signs were documented at 4:39 PM. There were 19 minutes between documented vital signs. q. Patient #6's "Operative Report," dated 8/11/11, documented "ANESTHESIA: local skin infiltration." Patient #6's "Procedure Flowsheet," dated 8/11/11, did not contain documentation of procedural or recovery vital signs, but contained documentation of discharge vital signs of blood pressure and pulse at 9:51 AM. There was no indication when Patient #6 was transferred to recovery. r. Patient #13's "Operative Report," dated 8/11/11, documented "ANESTHESIA: Local skin infiltration." The "Narcotic Count" record	Q 162		

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Q 162	Continued From page 40 indicated Patient #13 had received Propofol 100 mg. However, Patient #13's medical record did not contain a "Procedure Flowsheet" with documentation of medications administered, vital signs, or the time Patient #13 was discharged. In an interview on 9/20/11 at 3:00 PM, the RN confirmed Patient #13 had received Propofol on 8/11/11 at 11:44 AM, and stated the individual who had discharged Patient #13 had not completed the documentation. As a result, the medication administration, vital signs and the time of discharge had not been recorded. In an interview on 9/20/11 at 3:00 PM, the RN reviewed the records and confirmed the vital signs had not been documented as per the ASC policy. The RN stated she was unable to document vital signs in accordance with the policy as patients were usually out of the procedure room and discharged within five minutes. The RN stated the patients were usually discharged within minutes of arrival to the post procedural recovery area and she was only able to document discharge vital signs. Vital signs for patients who had undergone procedures were not documented as per written policy. 3. Patient # 19's medical record documented a 46 year old female who had a bilateral sacroiliac joint injection on 5/31/11. An untitled history and physical, written by an NP, was dated 4/07/11. The history and physical documented a history of Patient #19's back pain but it did not document a more complete medical	Q 162		

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Q 162	Continued From page 41 history. The RN, interviewed on 9/22/11 beginning at 8:20 AM, and the physician, interviewed on 9/27/11 beginning at 11:30 AM, both stated Patient #19 had a history of seizures. This was not documented on the history and physical. Patient #19's "Procedure Flowsheet," dated 5/31/11 but not timed or signed by the author, stated Patient #19 was taken to the procedure room at 10:01 AM. The flowsheet did not state when the patient was admitted to the ASC nor did it document an assessment by a nurse. The flowsheet documented Patient #19's vital signs were stable but the vital signs were not documented prior to 10:01 AM. The flowsheet stated Patient #19 was given 2 mg of Versed and 100 mcg of Fentanyl for sedation at 10:01 AM. She was then given 60 mg of Propofol, an anesthetic, at 10:15 AM and another 40 mg of Propofol at 10:26 AM. All medications were given IV. The flowsheet stated "Discharge Vital Signs" were taken at 11:00 AM. It stated she received oxygen at 3 liters and had an IV in her right arm. Vital signs were documented from 10:01 AM through 11:00 AM. The flowsheet contained a statement which said "Patient assessed after medication given and found to be moderately sedated." This statement was not signed and no other assessment of Patient #19 was documented on the flowsheet. Nothing unusual about her condition was documented on the flowsheet. No orders for the above medications were documented. Patient # 19's "Operative Report," dated 5/31/11	Q 162		

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Q 162	Continued From page 42 and electronically verified by the physician at 10:29 AM, documented the procedure. The report did not document which medications were used for sedation/anesthesia. The report stated following the procedure, "The patient was transported to the recovery area and was observed for possible medication reactions. There were none noted. The patient was discharged home in stable condition." Nothing unusual was documented on the report. The "Operative Report" was not accurate and a fall was not documented. A document titled "Physician Notes," dated 5/31/11 at 5:11 PM, stated it was an addendum to the operative report dated earlier that day. The addendum stated the physician completed Patient # 19's procedure "...without difficulty. The patient awakened on the procedure table. I had left the room. The nurse, [Staff A, a medical Assistant] was in there with her. The patient sat up on the procedure table without difficulty. She then stood up and was able to tuck in her shirt and fasten her jeans and her belt unassisted. The nurse was then escorting her to the recovery area. She had her by the arm. They took one step and the patient had an apparent syncopal episode. She fell down towards the floor. The nurse tried to break her fall. She stated that the patient's buttocks area fell against the wall and the patient essentially slid down the wall to the floor...[Staff A] called for help. [The RN] and I responded. The patient was still passed out. Her pulse was slightly threaded when I arrived. She had spontaneous respirations. Initially she did not respond to a sternal rub. Her pulse became stronger rather quickly." Patient #19 awoke. The note stated emergency room personnel	Q 162		

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Q 162	Continued From page 43 responded to the ASC and Patient #19 was transported to the emergency room by gurney for evaluation. The note stated Patient #19 was discharged home from the emergency room later that day. Patient # 19's medical record documented a bilateral sacroiliac joint injection was again performed on 7/12/11. A history and physical was not documented after 4/07/11. The 7/12/11 record did not mention a history of seizures or of complications from the prior procedure on 5/31/11. Under the heading of "Neurologic Exam," the "Operative Report," dated 7/12/11 at 9:20 AM, stated "Level of consciousness was normal." No other neurologic examination was documented. The "Operative Report" stated Patient #19 received Versed and Fentanyl for this procedure without incident. The facility failed to ensure complete, accurate records were kept for Patients #1 - #22. 4. Refer to Q261 as it relates to the ASC's failure to ensure patient medical records included a comprehensive history and physical examinations within 30 days prior to the procedure.	Q 162		
Q 180	416.48 PHARMACEUTICAL SERVICES The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. This CONDITION is not met as evidenced by: Based on observation, staff interviews, review of	Q 180	Refer to enclosed spreadsheet	

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Q 180	Continued From page 44 medical records, facility policies and medication logs, it was determined the ASC failed to ensure medications were prepared, administered and discarded in a safe and effective manner in accordance with acceptable standards of practice, and under the direction of a designated individual. This resulted in an increased risk of medication errors. Findings include: 1. Refer to Q181 as it relates to the lack of policies and procedures to guide staff in the preparation, administration and discarding of medications. 2. Refer to Q184 as it relates to the lack of documented medication orders.	Q 180		
Q 181	416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, staff interview, review of medical records and ASC policies, it was determined the ASC failed to ensure medications were prepared, administered, tabled, and discarded consistent with acceptable standards of practice. This directly impacted 12 of 22 patients (#2, #4, #5, #7, #9 - #15 and #19) whose medical records were reviewed and had the potential to impact all patients receiving care at the facility. That failure resulted in medication administration without orders, medication administration by unqualified staff, the potential for patients to	Q 181	Refer to enclosed spreadsheet	

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Q 181	Continued From page 45 experience adverse drug reactions, and receive expired medications. Findings include: 1. An undated facility policy, "Care of the Patient Under Local Anesthesia," stated that all medications administered by the nurse must be written in the physician order sheet as a verbal order and signed by the physician after the procedure. Medical records contained documentation of administration of IV medications by unidentified personnel without documentation of either written or verbal physician orders, as follows: a. Patient #2's "Procedure Flowsheet," dated 8/04/11, included documentation Patient #2 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 4:26 PM. b. Patient #4's "Procedure Flowsheet," dated 8/04/11, included documentation Patient #4 was administered Versed 2 mg IV at 2:03 PM. c. Patient #5's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #5 was administered Versed 2 mg IV at 7:41 AM. d. Patient #7's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #7 was administered Fentanyl 100 mcg IV and Versed 2 mg IV at 11:18 AM. e. Patient #9's "Procedure Flowsheet," dated 9/08/11, included documentation Patient #9 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 4:18 PM.	Q 181		

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Q 181	Continued From page 46 f. Patient #10 received Versed 2 mg IV and Fentanyl 50 mcg IV on 8/16/11 at 10:08 AM, and Propofol 30 mg IV at 10:13 AM. g. Patient #11's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #11 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 3:49 PM, and Propofol 100 mg at 4:04 PM. h. Patient #12's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #12 was administered Versed 2 mg IV and Fentanyl 100 mcg IV at 11:02 AM, and Propofol 30 mg IV at 11:14 AM. i. Patient #13's "Procedure Flowsheet," dated 8/11/11, included documentation Patient #13 was administered Propofol 100 mg IV at 11:44 AM. j. Patient #14's "Procedure Flowsheet," dated 8/10/11, included documentation Patient #14 was administered Fentanyl 100 mcg IV and Versed 2 mg IV at 1:18 PM. k. Patient #15's "Procedure Flowsheet," dated 8/31/11, included documentation Patient #15 was administered Versed 2 mg IV. l. Patient #19's "Procedure Flowsheet," dated 5/31/11, included documentation Patient #19 was administered Versed 2 mg IV, Fentanyl 100 mcgs IV, and Propofol 100 mg IV. In an interview on 9/21/11 beginning at 10:45 AM, the RN reviewed the records and confirmed medications had been given without documentation of orders. The RN stated the	Q 181		

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Q 181	Continued From page 47 format of the computer program the ASC used did not allow for order entry by the nursing staff. The ASC failed to ensure the physician issued orders for all medications administered at the facility. 2. Propofol information provided by the manufacturer, dated 8/05, stated "...Diprivan (Propofol) is a single-use product." However, the ASC's "NARCOTIC COUNT," form with dates from 8/11/11 to 9/06/11 was reviewed. The form indicated Propofol was administered to three patients from one vial on 8/16/11. Review of the three patients' records documented Propofol had been administered as follows: - Patient #10's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #10 received Propofol 30 mg IV at 10:13 AM. - Patient #11's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #11 was administered Propofol 100 mg at 4:04 PM. - Patient #12's "Procedure Flowsheet," dated 8/16/11, included documentation Patient #12 was administered Propofol 30 mg IV at 11:14 AM. In an interview on 9/21/11 at 2:30 PM, the RN confirmed she had used the same vial of Propofol for Patients #10 - #12. The RN stated she was unaware that Propofol was a single use medication, and stated she thought it was a drug that could be used for up to six hours after being opened.	Q 181		

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Q 181	Continued From page 48 3. The Textbook of Basic Nursing, published by Wolters Klewer Health/Lippincott Williams and Wilkins in 2008, stated that all medications must be properly labeled with the patient's name, the medication name and dosage, and the medication expiration date. The facility failed to label pre-filled syringes and vials according to acceptable standards of practice as follows: a. During a tour of the ASC on 9/19/11 beginning at 3:30 PM, a 10 cc syringe prefilled by the manufacturer with a needless adapter was noted on the desk area of the ASC workstation. The syringe had "Single Use Only" printed on the side. A blue tape was affixed to the syringe which read "Saline." The date and time when the syringe had been opened and attached to the adapter, and patient name had not been included on the label. In an interview on 9/19/11 at 4:00 PM, the RN stated she had opened the syringe and attached it to the adapter on 9/08/11, which was eleven days prior. The RN stated she had prepared the syringe for the last patient of the day, who did not come in for his appointment. The RN confirmed the syringe was not labeled with the date and time as well as the patient name. She then discarded the syringe. b. During an observation of a procedure on 9/27/11 at 8:50 AM in Procedure Room 1, an open 50 ml vial of 1% Lidocaine, dated 9/27/11 at 7:00 AM, was noted on a metal stand with the patient procedure tray. The Lidocaine vial had "NaHCO3" written with a bold permanent marker over the label. The date and time the medication was added, as well as the concentration, was not	Q 181		

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Q 181	Continued From page 49 included on the Lidocaine vial. During an interview on 9/27/11 at 8:55 AM, the CNA picked up the vial of 1% Lidocaine and stated NaHCO3 was not actually in the vial, it was a mistake. The CNA stated the ASC would, at times, add NaHCO3 to the Lidocaine as a buffer so the medication would not sting when it was administered. The ASC failed to prepare drugs in accordance with acceptable standards of practice. 4. An ASC policy titled "Expired Drug Policy," undated, stated all drugs would be checked on the first of each month for expiration date, and the expired drugs would be returned to the pharmacist for replacement or disposal. During a tour of the ASC on 9/19/11 beginning at 3:30 PM, the following expired drugs and patient care supplies were noted: - 1 box of 50 Benzoin swabsticks, expired 6/2007 - 5 vials Ketorolac, 60 mg/2 ml, expired 4/2010 - 1 vial Bupivicaine 0.25% 30 ml, expired 9/07/11 - 1 box of 50 sterile fields, expired 3/2011 - 1 Catheter access port kit, expired 5/18/2011 - 1 box of 50 IV catheters, 16 gauge, 1.16 inch, expired 06/2011 - 2 vials of Diphenhydramine, expired 5/2011 - 2 vials of Zantac, expired 5/2011 - 1 vial of Vancomycin, expired 4/11 The RN that was present during the ASC tour confirmed the expired medications and supplies and removed them from patient care areas.	Q 181		

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Q 181	Continued From page 50 The ASC failed to ensure outdated medications and supplies were not available for patient use. 5. Refer to Q063 as it relates to the facility's failure to ensure anesthetic medication (Propofol) was administered by appropriately qualified personnel for Patients #10 - #13 and #19.	Q 181		
Q 220	416.50 PATIENT RIGHTS The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights. This CONDITION is not met as evidenced by: Based on observation, staff interview, review of ASC policies, and the facility's patient rights information, it was determined the facility failed to ensure the patients were informed of their rights and that patient rights of were protected and promoted. This resulted in the inability of the facility to ensure patient rights were not violated. Findings include: 1. Refer to Q221 as it relates to the failure of the ASC to ensure patients or their representatives were provided with information regarding their rights in advance of the date of their procedures. 2. Refer to Q222 as it relates to the failure of the ASC to ensure a comprehensive written notice of patient rights was posted in the facility. 3. Refer to Q223 as it relates to the failure of the ASC to ensure information regarding physician ownership was disclosed to patients. 4. Refer to Q224 as it relates to the failure of the	Q 220	Refer to enclosed spreadsheet Policy and procedure reviewed and updated. Pt. Rights and Responsibilities are displayed in the waiting room. Front desk will provide pt. with a verbal and written form of R & R upon scheduling a procedure for the first time. Included on the R & R is information regarding physician ownership	11/1/11 MM

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Q 220	Continued From page 51 ASC to ensure information concerning its policies on advance directives and, if requested, official State advance directive forms were provided to patients. 5. Refer to Q225 as it relates to the failure of the ASC to ensure a grievance procedure for documenting the existence, submission, investigation, and disposition of grievances to the ASC had been developed and implemented. 6. Refer to Q227 as it relates to the failure of the ASC to ensure patients had the right to exercise their rights without being subjected to discrimination or reprisal. 7. Refer to Q230 as it relates to the failure of the ASC to ensure patients had the right to have a legal representative exercise their rights if they were not competent to exercise their rights. 8. Refer to Q231 as it relates to the failure of the ASC to ensure patients had the right to personal privacy. 9. Refer to Q232 as it relates to the failure of the ASC to ensure patients had the right to receive care in a safe setting. 10. Refer to Q233 as it relates to the failure of the ASC to ensure patients had the right to be free from all forms of abuse or harassment. The cumulative effect of these negative facility practices prevented patients from fully exercising their rights.	Q 220		
Q 221	416.50(a)(1) NOTICE OF RIGHTS	Q 221	Refer to enclosed spreadsheet	

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Q 221	Continued From page 52 The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands. This STANDARD is not met as evidenced by: Based on observation, staff interview, and review of patient rights information and ASC policies, it was determined the ASC failed to ensure 22 of 22 patients (Patients #1 - #22) or their representatives were provided with information regarding their rights in advance of the date of their procedures. This resulted in a lack of information which patients could use to make informed decisions regarding their care. Findings include: 1. The facility's policy "Patient's Bill of Rights," not dated, listed 20 rights afforded to patients at the facility, which included but was not limited to, items such as the right to be free from discrimination, the right to receive information regarding their condition, the right to refuse treatment, the right to change physicians, and the right to express grievances. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She stated she was not sure if patients were given a copy of their rights or not. She said she thought the rights were posted in the waiting room. The surveyor then walked to the waiting room and observed a list of rights and other information which was posted on the wall. These rights were different from the rights listed in the policy. The receptionist in the waiting room was	Q 221	Pt. Rts handout created for front staff to give pt. at time of scheduling their first procedure, staff has been trained	11/1/11 MM

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	13C0001058		09/30/2011

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Q 221	Continued From page 53 asked if patients were given a copy of their rights. She stated a copy of the rights was only given to patients if they requested them. She gave the surveyor a copy of the rights given to patients. This list contained 6 rights including: - The right "to have access and/or a copy of your health information." - The right "to receive an accounting of certain disclosures we have made of your health information." - The right "to request restrictions as to how your health information is used or disclosed." - The right "to request that we communicate with you in confidence." - The right "to request that we amend your health information." - The right "to receive notice of our privacy practices." Rights information given to patients and posted on the wall did not include: a. The name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. b. Physician financial interests or ownership in the ASC. c. Information concerning the facility's policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms. d. The right to make informed decisions regarding	Q 221		

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Q 221	Continued From page 54 the patient's care. e. The right to exercise his or her rights without being subjected to discrimination or reprisal. f. The right to voice grievances regarding treatment or care that is (or fails to be) furnished. g. The right to be fully informed about a treatment or procedure and the expected outcome before it is performed. h. Information stating if a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf. If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law. i. The right to personal privacy. j. The right to receive care in a safe setting. k. The right to be free from all forms of abuse or harassment. The ASC had not developed a mechanism to fully inform patients of their rights. The medical records for Patients #1 - #22 were reviewed. None of the patient records contained documentation that they had received the required rights information.	Q 221		

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Q 221	Continued From page 55 The RN was interviewed on 9/27/11 beginning at 9:30 AM. She confirmed that none of the patient medical records contained notice of the required rights information.	Q 221		
Q 222	The ASC did not provide patients with a comprehensive written copy of their rights. 4166.50(a)(1)(i) NOTICE - POSTING In addition, the ASC must - Post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. This STANDARD is not met as evidenced by: Based on observation, staff interview, and review of posted information, it was determined the ASC failed to ensure a comprehensive written notice of patient rights was posted in the facility for all patients receiving care at the facility. This resulted in a lack of rights information available to all patients and/or their representatives. Findings include: 1. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She said she thought the rights were posted in the waiting room. The surveyor then walked to the waiting room and observed a list of rights and other information which was posted on the wall. The posted document in the lobby titled "Our Legal Duty." A section of the document was	Q 222	Refer to enclosed spreadsheet #1. Rights is posted prominently on the wall of the waiting room.	11/1/11 MM

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Q 222	Continued From page 56 labeled "Patient Rights." It contained 6 items having to do with accessing and protecting medical record information. The rights information posted on the wall did not include: a. The name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. b. Physician financial interests or ownership in the ASC. c. Information concerning the facility's policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms. d. The right to make informed decisions regarding the patient's care. e. The right to exercise his or her rights without being subjected to discrimination or reprisal. f. The right to voice grievances regarding treatment or care that is (or fails to be) furnished. g. The right to be fully informed about a treatment or procedure and the expected outcome before it is performed. h. Information stating if a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person	Q 222		

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Q 222	Continued From page 57 appointed under State law to act on the patient's behalf. If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law. i. The right to personal privacy. j. The right to receive care in a safe setting. k. The right to be free from all forms of abuse or harassment. The RN was interviewed on 9/27/11 beginning at 9:30 AM. She confirmed a comprehensive list of rights was not posted in the ASC. The ASC failed to ensure comprehensive rights information was posted.	Q 222		
Q 223	416.50(a)(1)(ii) NOTICE - PHYSICIAN OWNERSHIP The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure. This STANDARD is not met as evidenced by: Based on staff interview and review of medical records and patient rights information, it was determined the ASC failed to ensure required information regarding physician ownership was disclosed to 22 of 22 patients (Patients #1 - #22) whose records were reviewed. This resulted in a	Q 223	Refer to enclosed spreadsheet Included on Pt. Rights and Responsibilities Handout	11/1/11 MM

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Q 223	Continued From page 58 lack of information which patients could use to make informed decisions. Findings include: 1. The Administrator was interviewed on 9/26/11 at 3:20 PM. She stated the physician was the sole owner of the ASC. However, the medical records of Patients #1 - #22 did not contained information which disclosed physician ownership of the ASC. The RN was interviewed on 9/27/11 beginning at 9:30 AM. She confirmed patients were not informed of physician ownership of the ASC. The ASC did not disclose physician ownership as required.	Q 223		
Q 224	416.50(a)(2) ADVANCE DIRECTIVES The ASC must comply with the following requirements: (i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms. (ii) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care. (iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive. This STANDARD is not met as evidenced by: Based on observation, staff interview and review	Q 224	Refer to enclosed spreadsheet P&P manual reviewed and revised. Staff trained on informing pt. of Advance Directives at time of scheduling procedure. This will be documented in a prominent place in the pt.'s EMR for the physician to see before the procedure begins.	11/1/11 MM

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Q 224	Continued From page 59 of medical records, ASC policies, and patient rights information, it was determined the ASC failed to ensure comprehensive rights information was provided to 22 of 22 patients (Patients #1 - #22) whose records were reviewed. This resulted in a lack of information being provided to patients and/or their representatives regarding care decisions and advance directives. The findings include: 1. Medical records for Patients #1 - #22 were reviewed. None of these records contained documentation regarding advance directives. Additionally, the policy "Patient's Bill of Rights," not dated, stated patients had a right to have advance directives. The policy stated patients with an advance directives "...must provide a copy to the facility and to their physician for their wishes to be made known and honored." The policy did not state patients would be provided with information regarding advance directives, whether the ASC would honor the advance directive, or how advanced directives would be documented in a prominent part of the patient's medical record. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She confirmed the policy was incomplete. During a subsequent interview on 9/29/11 beginning at 2:40 PM, the RN confirmed the medical records did not contain information regarding advance directives. 2. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She stated she was not sure if patients were given a copy of their rights or not. She said she thought the rights were posted in	Q 224	Added to Pt. Bill of Rights	11/1/11 MM

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Q 224	Continued From page 60 the waiting room. The surveyor then walked to the waiting room and observed a list of rights and other information which was posted on the wall. These rights were different from the rights listed in the policy. The receptionist in the waiting room was asked if patients were given a copy of their rights. She stated a copy of the rights was only given to patients if they requested them. The rights information given to patients and posted on the wall did not include the right to make informed decisions regarding the patient's care. Additionally, the medical records for Patients #1 - #22 were reviewed. None of these records contained documentation regarding their rights to make decisions regarding their care. The RN was interviewed on 9/27/11 beginning at 9:30 AM. She confirmed that none of the patient medical records contained notice of the required rights information. The ASC failed to ensure comprehensive rights information was provided to patients and/or their representatives.	Q 224		
Q 225	416.50(a)(3)(i), (v), (vi), (vii) SUBMISSION AND INVESTIGATION OF GRIEVANCES (i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. (v) The grievance process must specify timeframes for review of the grievance and the provisions of a response. (vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding	Q 225	Refer to enclosed spreadsheet Policy and Procedures reviewed and updated to address (i), (v), (vi), and (vii). A grievance log book has been established to document all complaints per policy.	10/19/11

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Q 225	Continued From page 61 treatment or care that is (or fails to be) furnished. (vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed. This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, ASC policies, and patient rights information, it was determined the ASC failed to ensure a grievance procedure for documenting the existence, submission, investigation, and disposition of grievances to the ASC had been developed and implemented for 22 of 22 patients (Patients #1 - #22), whose records were reviewed. This resulted in a lack of information being provided to patients explaining the grievance process. Findings include: 1. The policy "Patient's Bill of Rights," not dated, stated patients had a right to "express grievances...by filing a written complaint, by calling Hot Line or by contacting any staff member or the Administrator. Resolution will be achieved by the Administrator or Medical Director within 30 days." The policy did not state how patients would be informed of this right or how to file a grievance. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She stated she was not sure if patients were given a copy of their rights or not. She said	Q 225	Added to Pt. Bill of Rights	11/1/11 MM

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Q 225	Continued From page 62 she thought the rights were posted in the waiting room. The surveyor then walked to the waiting room and observed a list of rights and other information which was posted on the wall. These rights did not include the right to file a grievance or outline a process to file the grievance. The receptionist in the waiting room was asked if patients were given a copy of their rights. She stated a copy of the rights was only given to patients if they requested them. She gave the surveyor a copy of the rights given to patients. This list also did not contain the right to file a grievance or specify a grievance process. The medical records for Patients #1 - #22 were reviewed. None of the records contained documentation regarding informing patients of a process to file grievances with the ASC. The RN was interviewed on 9/29/11 beginning at 2:40 PM. She confirmed the medical records did not contain information regarding a grievance process. She further stated she was not aware of a process for patients to file grievances and patients were not informed of a grievance process at the ASC. The ASC failed to ensure a patient grievance process had been sufficiently developed and implemented.	Q 225		
Q 227	416.50(b)(1)(i) RESPECT - PROPERTY & PERSON The patient has the right to - Exercise his or her rights without being subjected to discrimination or reprisal.	Q 227	Refer to enclosed spreadsheet Included in Pt. Rights and Responsibilities	10/14/11 MM

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Q 227	Continued From page 63 This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, ASC policies, and patient rights information, it was determined the ASC failed to ensure patients were informed of their right to exercise their rights without being subjected to discrimination or reprisal for 22 of 22 patients (Patients #1 - #22) whose records were reviewed. This resulted in patients not being fully informed of their rights. Findings include: 1. The policy "Patient's Bill of Rights," not dated, stated patients would be treated without discrimination in general, but it did not address the need to avoid discrimination or reprisal as patients attempted to exercise their rights. Additionally, the medical records for Patients #1 - #22 were reviewed. None of these records contained documentation regarding informing patients of their right to be free from discrimination or reprisal. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She stated she was not sure if patients were given a copy of their rights or not. She said she thought the rights were posted in the waiting room. The surveyor then walked to the waiting room. The receptionist in the waiting room was asked if patients were given a copy of their rights. She stated a copy of the rights was only given to patients if they requested them. She gave the surveyor a copy of the rights given to patients. This copy of rights did not address discrimination of patients. The RN confirmed the rights list did not include anti-discriminatory or reprisal language. During a subsequent interview, on 9/29/11 beginning at 2:40 PM, the RN confirmed	Q 227		

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Q 227	Continued From page 64 the medical records did not contain information regarding discrimination and reprisal. The ASC had not developed a process to ensure patients were informed of their right to be free from discrimination and/or reprisal.	Q 227	Refer to enclosed spreadsheet	
Q 230	416.50(b)(2), 416.50(b)(3) EXERCISE OF RIGHTS BY OTHERS (2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf. (3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law. This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies, it was determined the ASC failed to ensure patients had the right to have a legal representative exercise their rights if they were not competent to exercise their rights. This resulted in the potential lack of representation and advocacy for all patients receiving care at the facility who were mentally incompetent. Findings include: 1. The policy "Patient's Bill of Rights," not dated, did not address the rights of patients who were mentally incompetent. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She confirmed ASC policies did not	Q 230	Included in Pt. R&R	10/19/11 MM

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Q 230	Continued From page 65 address the rights of mentally incompetent patients. The ASC had not developed a process to ensure mentally incompetent patients rights were protected.	Q 230		
Q 231	416.50(c)(1) PRIVACY The patient has the right to - Personal privacy This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, ASC policies, and patient rights information it was determined the ASC failed to ensure patients were informed of their right to personal privacy for 22 of 22 patients (Patients #1 - #22), whose records were reviewed. This resulted in the potential for the ASC to not provide privacy rights. Findings include: 1. The policy "Patient's Bill of Rights," not dated, did not address the rights of patients to personal privacy. Additionally, the medical records for Patients #1 - #22 were reviewed. None of these records contained documentation regarding patients being informed of their right to personal privacy. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She confirmed ASC policies did not address the rights of patients to personal privacy. During a subsequent interview, on 9/29/11 beginning at 2:40 PM, the RN confirmed the medical records did not contain information regarding patients' right to personal privacy.	Q 231	Refer to spreadsheet Included in Pt. Bd R.	10/19/11 MM

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Q 231	Continued From page 66 The ASC had not developed a process to ensure patients were informed of their rights to privacy.	Q 231	Refer to enclosed spreadsheet	
Q 232	416.50(c)(2) SAFETY [The patient has the right to -] Receive care in a safe setting This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, ASC policies, and patient rights information, it was determined the ASC failed to ensure patients were informed of their right to receive care in a safe setting for 22 of 22 patients (Patients #1 - #22) whose records were reviewed. This resulted in a lack of information provided to patients regarding their right to receive care in a safe setting. Findings include: 1. The policy "Patient's Bill of Rights," not dated, did not address the rights of patients to receive care in a safe setting. Additionally, the medical records for Patients #1 - #22 were reviewed. None of the records contained documentation regarding informing patients of their right to receive care in a safe setting. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She confirmed ASC policies did not address the rights of patients to receive care in a safe setting. During a subsequent interview, on 9/29/11 beginning at 2:40 PM, the RN confirmed the medical records did not contain information regarding patients' right to receive care in a safe setting. The ASC failed to ensure patients were informed of their right to receive care in a safe setting.	Q 232	Included in Pt. R&R	10/19/11 MM
Q 233	416.50(c)(3) SAFETY - ABUSE/HARASSEMENT	Q 233	Refer to enclosed spreadsheet Included in Pt. R&R	10/19/11

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Q 233	Continued From page 67 [The patient has the right to -] Be free from all forms of abuse or harassment This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, ASC policies, and patient rights information it was determined the ASC failed to ensure patients were informed of their right to be free from all forms of abuse or harassment for 22 of 22 patients (Patients #1 - #22) whose records were reviewed. This resulted in a lack of comprehensive information being provided to patients. Findings include: 1. The policy "Patient's Bill of Rights," not dated, did not address the rights of patients to be free from abuse or harassment. Additionally, the medical records for Patients #1 - #22 were reviewed. None of the records contained documentation regarding informing patients of their rights to be free from abuse and harassment. The RN was interviewed on 9/19/11 beginning at 3:10 PM. She confirmed ASC policies did not address the rights of patients to be free from abuse and harassment. During a subsequent interview, on 9/29/11 beginning at 2:40 PM, the RN confirmed the medical records did not contain information regarding patients' rights to be free from abuse and harassment. The ASC failed to ensure patients were fully informed of their rights.	Q 233		
Q 240	416.51 INFECTION CONTROL	Q 240	Refer to enclosed spreadsheet	

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Q 240	Continued From page 68 The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented and monitored for staff and all patients receiving care at the facility. This resulted in the inability of the facility to minimize infections and communicable diseases. The findings include: 1. Refer to Q241 as it relates to the ASC's failure to ensure patients were provided with a 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 infection program was maintained. 3. Refer to Q243 as it relates to the ASC's failure to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control. 4. Refer to Q244 as it relates to the ASC's failure to ensure the infection control program was integrated into the QAPI program.	Q 240		
Q 241	416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.	Q 241	Refer to enclosed spreadsheet	

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Q 241	Continued From page 69 This STANDARD is not met as evidenced by: Based on observation, review of facility policies and staff interview, it was determined the ASC failed to ensure facility policies and standards of practice related to infection control were followed. This directly impacted 2 of 2 patients (Patients #20 and #22) whose procedures were observed, and had the potential to impact all patients who received care at the ASC. This failure had the potential to result in the spread of infections among staff and patients. Findings include: 1. The CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, defines a biologic indicator as a device for monitoring the sterilization process. The device consists of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the sterilization process being monitored. Biologic indicators are intended to demonstrate whether conditions were adequate to achieve sterilization. The ASC's "Sterilization" policy, undated, indicated instruments would be placed in an enzymatic cleaner. The policy also stated a sterility indicator would be placed in each tray and a daily biological indicator test would be performed and documented. During an interview on 9/20/11 at 1:15 PM, the CNA described the cleaning process of the equipment utilized during procedures performed at the ASC. The CNA stated the instruments and trays would be placed in water to soak until there was time to process them. She stated she would then wipe down the tray and instruments with	Q 241		

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Q 241	Continued From page 70 alcohol, then wrap for processing. The wrapped tray would then be secured with a sterilization indicator tape and marked with the instrument size and date of processing. The CNA stated the ASC did not use biological indicators or maintain an autoclave record listing the items autoclaved, exposure time and temperature, and the date, time, and identification of the operator. She confirmed there was no process to determine which instrument was autoclaved when, or how to track which instruments were used on specific patients in the event sterilization was not achieved. The ASC failed to ensure staff followed standards of practice and maintained an autoclave log that included all necessary information. Without such documentation, the facility was unable to ensure each sterilizer cycle was monitored as it was occurring, the parameters to achieving sterility were met, and it inhibited the facility's ability to determine whether a recall of a particular lot or batch was needed. This resulted in the inability of the facility to ensure patients' exposure to infectious material was minimized. 2. The facility policy "Infection Control, Handwashing," undated, was reviewed. According to the policy, hands were to be decontaminated (with either hand washing or alcohol-based hand rub) in the following circumstances: - Before having direct contact with patients; - Before inserting an intravenous catheter; - After contact with patient's intact skin; - After contact with body fluids or excretions,	Q 241		

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Q 241	Continued From page 71 mucus membranes, non-intact skin, and wound dressing; - If moving from a contaminated body site to a clean body site during patient care; - After contact with inanimate objects in the immediate vicinity of the patient, and - After removing gloves. However, during observations conducted on 9/27/11 at 8:15 PM, it was noted Procedure Room #1 did not contain hand sanitizer. The RN was interviewed on 9/27/11 at 11:15 AM. She stated the procedure rooms did not contain hand sanitizer. Further, hand hygiene was not performed in accordance with facility policy and other infection control practices were not observed to be completed in accordance with accepted standards of practice as follows: a. Patient #20's care from admission to discharge was observed on 9/27/11 from 8:15 AM to 8:55 AM. Patient #20 had a lumbar epidural steroid injection. The following breaches in infection control were noted during the observation time frame: - During an observation on 9/27/11 beginning at 8:15 AM, the RN took Patient #20's temperature with a tympanic membrane scanner, discarded the disposable tip in the trash, and placed the thermometer back on the shelf without wiping it down. In an interview at 9:30 AM on 9/27/11, the RN confirmed she had not wiped down the thermometer and felt it was not necessary as the	Q 241		

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Q 241	Continued From page 72 tip of the instrument was disposable. - The RN providing care for Patient #20 was observed starting an intravenous line. She donned a pair of disposable gloves and applied the tourniquet to Patient #20's left arm. The RN removed the finger from her glove, exposing the forefinger. After swabbing the site, she palpated the vein with her un-gloved finger then punctured the skin with the catheter at the site where she palpated the vein. In an interview at 9:30 AM on 9/27/11, the RN confirmed she had palpated the site with her un-gloved finger. She stated it was okay, as she had reswabbed the site and did not believe she had broken aseptic technique. The RN did not ensure Patient #20's protection against the bacteria she may have introduced by touching the prepped area with her finger. - During Patient #20's procedure on 9/27/11, the physician was observed in the Procedure Room. He typed on the computer keyboard and then directly pulled on sterile gloves and performed the lumbar epidural steroid injection. He did not wash or sanitize his hands before applying the gloves. The physician was interviewed beginning at 11:30 AM on 9/27/11. He confirmed he did not wash his hands prior to performing the procedure. b. Patient #22's care from admission to discharge was observed on 9/27/11 from 10:22 AM to 10:53 AM. She was a 103 year old female who had a lumbar epidural steroid injection.	Q 241		

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Q 241	Continued From page 73 The physician was observed in the Procedure Room. He typed on the computer keyboard and then directly pulled on sterile gloves and performed the lumbar epidural steroid injection. He did not wash or sanitize his hands before applying the gloves. The physician was interviewed beginning at 11:30 AM on 9/27/11. He confirmed he did not wash his hands prior to performing the procedure. 3. On 9/27/11 at 10:55 AM, the CNA was observed cleaning the procedure room following a procedure. The CNA was observed to wipe down the counters and procedure table. The fluoroscopy equipment was not wiped down, although during the procedure it was noted to be touched by the CNA after touching the patient and other equipment. In an interview on 9/27/11 at 11:05 AM, the CNA confirmed she had not wiped down the fluoroscopy equipment during the cleaning between procedures. The ASC failed to implement facility policy and acceptable standards of practice related to infection control.	Q 241		
Q 242	416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the	Q 242	Refer to enclosed spreadsheet	

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Q 242	Continued From page 74 ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: Based on observation, staff interview and review of policies and infection control documents, it was determined the ASC failed to ensure an ongoing infection control program was maintained. This directly impacted 2 of 2 patients (Patients #20 and #21) whose procedures were observed and had the potential to impact all patients receiving care at the ASC. The lack of a defined program had the potential to prevent the ASC from identifying infections and maintaining a sanitary environment. Findings include: 1. The ASC's Administrator, who was also identified as the Infection Control Officer, was interviewed on 9/20/11 at 8:00 AM. She stated the ASC did not follow a nationally recognized infection control program. She stated she spent 2 hours a week working in infection control and there was not an infection control committee, meeting minutes, or documented infection control activities. On 9/27/11 at 8:45 AM, the physician was observed to take a drink from a container in the hallway. He then entered the procedure room, opened a sterile pack, put on gloves located in the pack, and proceeded to perform a lumbar epidural steroid injection for Patient #20. He did not wash his hands before opening the pack and performing the procedure. On 9/27/11 beginning at 10:35 AM, the physician	Q 242		

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Q 242	Continued From page 75 was observed to discuss the procedure to be done with Patient #21 and perform an examination which included leg strength, sensation, and then used the stethoscope to listen to her heart and lungs. The physician then went directly to the computer terminal without using hand sanitizer or washing his hands, and entered information on the computer. At 10:44 AM, the physician left the computer, stood up, and put on sterile gloves and proceeded with the lumbar epidural steroid injection for Patient #21. Following the procedure at approximately 11:20 AM, the physician was interviewed. He acknowledged he had not washed his hands before performing procedures on Patients #20 and #21. The Performance Improvement Infection Control plan, undated, stated "Hand Washing should be completed at the following times: - Before donning sterile gloves when inserting a central IV catheter - Before inserting indwelling urinary catheters, peripheral vascular catheters, or other invasive devices that do not requires [sic] a surgical procedure." The ASC's Performance Improvement, Infection Control plan was not implemented. Additionally, the Performance Improvement plan included infection control surveillance, which stated the ASC maintained an effective organizational wide program for the surveillance, prevention, and control of infection in which all patient care and patient care support services were included.	Q 242		

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Q 242	Continued From page 76 However, the ASC's policies did not include information regarding an infection control program which included, but were not limited to, the following: - Policies articulating the authority and circumstances under which the ASC screens its staff for infections likely to cause significant infectious disease or other risk to the exposed individual. - Policies articulating the authority and circumstances under which the ASC screens its staff for reportable diseases, as required under local, state, or federal public health authority. - Policies articulating when infected ASC staff are restricted from providing direct patient care or required to remain away from the facility entirely. - Policies describing the methods to evaluate staff exposed to patients with infections and communicable diseases. Additionally, review of the ASC's infection control documents showed minimal infection control surveillance activities in the summer of 2011. There was no current documentation of infection control surveillance found in the ASC's records. On 9/20/11, the Infection Control Officer was interviewed starting at 8:00 AM. She stated the ASC had not developed policies, procedures, and/or protocols for the infection control program. The ASC failed to define, develop, implement and maintain a comprehensive infection control	Q 242		

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Q 242	Continued From page 77 program.	Q 242		
Q 243	416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION The program is - Under the direction of a designated and qualified professional who has training in infection control. This STANDARD is not met as evidenced by: Based on record review and staff interviews, it was determined the ASC failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control for all staff and all patients receiving care at the facility. This prevented the ASC from utilizing the knowledge base of a trained professional to develop and monitor an infection control program. Findings include: 1. Facility records, including personnel records, were reviewed. A job description for the Infection Control Officer could not be found. The ASC's Infection Control Officer was interviewed on 9/20/11 starting at 8:00 AM. When asked, she could not describe her duties as the Infection Control Officer. She stated she had no experience in running an infection control program, she had no formal training in infection control and was not involved in any outside infection control groups. The ASC's Infection Control Officer stated she used a "Quarterly Post-Op Infection/Compliance Survey Tool," with which she obtained information from patients'	Q 243	Refer to enclosed Spread sheet	

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Q 243	Continued From page 78 post procedure as well as from the clinic side of the physician practice. She stated she did not participate in any meetings such as governing body or Quality Assurance meetings, and she had not provided training to staff. She further stated she did not know if the ASC had adopted nationally recognized infection control guidelines. The facility failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.	Q 243		
Q 244	416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI [The program is -] An integral part of the ASC's quality assessment and performance improvement program This STANDARD is not met as evidenced by: Based on staff interview and record review, it was determined the ASC failed to ensure the ASC's infection control program was integrated into a QAPI program for all patients receiving care at the facility. Failure to integrate the infection control program with QAPI had the potential to inhibit the ASC's ability in identifying infections and improving infection control practices at the ASC. Findings include: 1. No evidence of Quality meetings, including information related to infection control, could be found in the ASC's records. On 9/20/11, the Infection Control Officer was interviewed starting at 8:00 AM. She stated she had worked at the ASC for 5 years. She stated, during that time,	Q 244	Refer to enclosed spreadsheet	

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Q 244	Continued From page 79 she had not attended a Quality meeting and she had not developed a quality project for the infection control program. The ASC failed to ensure the ASC's infection control program was developed and integrated into a QAPI program.	Q 244		
Q 245	416.51(b)(3) INFECTION CONTROL PROGRAM - RESPONSIBILITIES The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement. This STANDARD is not met as evidenced by: Based on staff interview and review of policies and infection control documents, it was determined the ASC failed to ensure it had documented a plan of action for preventing, identifying, and managing infections for all patients and staff at the ASC. This had the potential to interfere with the quality and coordination of infection prevention and control efforts. Findings include: Documentation of an approved comprehensive infection control plan of action could not be found in the ASC's records. On 9/20/11 at 8:00 AM, the Infection Control Officer stated the ASC did have an active infection control surveillance process, but did not have an approved and documented infection control plan. The ASC failed to ensure a documented infection	Q 245	Refer to enclosed Spreadsheet	

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Q 245	Continued From page 80 control plan was developed.	Q 245		
Q 260	416.52 PATIENT ADMISSION, ASSESSMENT AND DISCHARGE The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed. This CONDITION is not met as evidenced by: Based on observation, review of facility policies and medical records, and staff interview, it was determined the facility failed to ensure appropriate assessments were completed before and after the procedure, and that patients were discharged from the facility with physician orders. These failures had the potential to result in negative patient outcomes. Findings include: 1. Refer to Q261 as it relates to the ASC's failure to ensure a current and comprehensive H&P was performed prior to procedures. 2. Refer to Q263 as it relates to the ASC's failure to ensure H&Ps were placed in the patients' medical records prior to procedures. 3. Refer to Q264 as it relates to the ASC's failure to ensure patients were properly assessed prior to discharge. 4. Refer to Q266 as it relates to the ASC's failure to ensure patients were discharged per physician's orders.	Q 260	Refer to enclosed spreadsheet	
Q 261	416.52(a)(1) ADMISSION ASSESSMENT	Q 261	Refer to spreadsheet	

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	13C0001058		09/30/2011

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NORTH IDAHO PAIN CENTER	2003 LINCOLN WAY STE 310 COEUR D'ALENE, ID 83814

(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 261	Continued From page 81 Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy. This STANDARD is not met as evidenced by: Based on staff interview and review of records, the ASC failed to ensure comprehensive medical history and physical assessments were completed within 30 days of the date of the scheduled surgery for 15 of 22 patients (Patients #3 - #5 and #8 - #19) whose records were reviewed. This had the potential to compromise patient safety. Findings include: 1. Patient medical records were reviewed. The records did not included documentation of comprehensive H&Ps performed within 30 days prior to patient procedures as follows: - Patient #5 was a 67 year old female who had a pain procedure performed on 8/16/11. The comprehensive H&P was dated 7/13/11, 34 days prior to the date of the procedure. - Patient #9 was a 21 year old female who had a pain procedure on 9/08/11. The comprehensive H&P was dated 7/19/11, 51 days prior to the date of the procedure. - Patient #10 was a 57 year old female who had a pain procedure on 8/16/11. The comprehensive H&P was dated 7/07/11, 39 days prior to the date	Q 261		

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Q 261	Continued From page 82 of the procedure. - Patient #11 was a 44 year old male who had a pain procedure performed on 8/16/11. The H&P examination was conducted on 7/13/11, 34 days prior to the date of the procedure. Additionally, the H&P was not comprehensive. It did not include a cardiopulmonary examination. - Patient #13 was a 60 year old female who had a pain procedure on 8/11/11. The comprehensive H&P was dated 6/16/11, 55 days prior to the date of the procedure. - Patient #14 was a 59 year old female who had a pain procedure performed on 8/01/11. The H&P, performed on 7/01/11, was not comprehensive. It did not include a cardiopulmonary examination. - Patient #15 was a 50 year old female who had a pain procedure done on 8/03/11. The H&P, dated 7/06/11, was not comprehensive. It did not include a cardiopulmonary examination. - Patient #16 was an 80 year old male who had a pain procedure done on 8/03/11. The H&P, dated 6/02/11, was 61 days prior to the date of the procedure. Additionally, the H&P was not comprehensive. It did not include a cardiopulmonary examination. - Patient #17 was a 87 year old female who had a pain procedure on 9/06/11. The comprehensive H&P was dated 7/20/11, 53 days prior to the date of the procedure. - Patient #18 was a 52 year old female who had a	Q 261		

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Q 261	Continued From page 83 pain procedure on 9/08/11. The comprehensive H&P was dated 6/22/11, 78 days prior to the date of the procedure. - Patient #19's medical record documented a 46 year old female who had a bilateral sacroiliac joint injection on 5/31/11. An untitled H&P, written by a NP, was dated 4/07/11, 55 days prior to the procedure. A document titled "Physician Notes," dated 5/31/11 at 5:11 PM, stated following the procedure, Patient #19 became unresponsive and was transferred to a hospital emergency room for treatment. Patient #19 returned to the facility on 7/12/11 and had another bilateral sacroiliac joint injection. No H&P was documented between the 5/31/11 procedure and the 7/12/11 procedure. The RN was interviewed on 9/22/11 beginning at 8:20 AM. She confirmed the incident and confirmed the lack of H&Ps within 30 days prior to procedures. The ASC did not ensure a comprehensive H&P was performed less than 30 days before patient procedures were performed. 2. Refer to Q263 as it relates to the ASC's failure to ensure patients' history and physical examinations were placed in their medical records prior to surgery for Patients #3, #4, #8, and #12.	Q 261		
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.	Q 263	Refer to spreadsheet	

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Q 263	Continued From page 84 This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the ASC failed to ensure patients' history and physical examinations were placed in their medical records prior to surgery for 4 of 22 patients (#3, #4, #8 and #12) whose records were reviewed. This resulted in ASC staff not having access to medical information for review prior to proceeding with surgical procedures. It had the potential to compromise patient safety. Findings include: 1. Patient medical records were reviewed. The records did not included documentation of a comprehensive H&Ps being conducted prior to procedures being performed as follows: - Patient #3 was a 94 year old female who had a pain procedure on 8/04/11. There was no H&P present in Patient #3's record. - Patient #4 was a 47 year old female who had a pain procedure on 8/04/11. There was no H&P present in Patient #4's record. - Patient #8 was a 51 year old female who had a pain procedure performed on 8/02/11. There was no H&P present in Patient #8's record. - Patient #12 was a 41 year old female who had a pain procedure on 8/16/11. There was no H&P present in Patient #12's record. The RN was interviewed on 9/22/11 beginning at 8:20 AM. She confirmed the lack of H&Ps.	Q 263		

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Q 263	Continued From page 85 The ASC did not ensure a comprehensive History and Physical was placed in the patient's medical record before the procedure was performed.	Q 263		
Q 264	416.52(b) POST-SURGICAL ASSESSMENT (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Post-surgical needs must be addressed and included in the discharge notes. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, it was determined the ASC failed to ensure comprehensive post-surgical assessments by qualified practitioners were documented for 22 of 22 patients (Patients #1 - #22), whose records were reviewed. This resulted in the potential for patients to receive inadequate post-surgical care. Findings include: 1. An undated ASC policy, "Care of the Patient Under Local Anesthesia," stated pain assessments should be recorded on the post-operative record. It also stated patients were transferred to an appropriate area for recovery and monitored until patients were responsive to verbal or gentle physical stimulation or returned to pre-sedation levels of consciousness. Documentation of post-surgical assessments for	Q 264	Refer to spreadsheet	

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Q 264	Continued From page 86 Patients #1 - #22 did not identify whether a physician, registered nurse, or other qualified individual performed the assessments. None of the post-surgical assessments included documentation of pain levels, levels of consciousness or activity levels. Additionally, no evidence of post-surgical assessments could be found for Patients #1 and #8. In an interview on 9/20/11 at 3:00 PM, the RN reviewed the records of Patients #1 - #22, and confirmed pain assessments had not been performed. The RN stated "In general, this is a pain clinic, and patients are in pain." She further stated many patients do not obtain relief from pain until several days after the procedure had been performed. The ASC did not ensure comprehensive post-surgical assessments by qualified practitioners were conducted and documented.	Q 264		
Q 266	416.52(c)(2) DISCHARGE - ORDER [The ASC must -] Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the ASC failed to ensure patients had signed physician discharge orders for 22 of 22 patients (Patients #1 - #22) whose records were reviewed. This resulted in a lack of clarity as to whether patients had been appropriately	Q 266	Refer to spreadsheet	

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Q 266	Continued From page 87 evaluated and approved for discharge. Findings include: The medical records for Patients #1 - #22 were reviewed. None of the records included physician discharge orders. In an interview on 9/20/11 at 3:00 PM, the RN confirmed the records did not contain physician discharge orders. She stated the electronic medical record program was not set up to reflect either verbal physician orders or authentication of orders by the physician. In an interview on 9/26/11 at 6:30 PM, the Physician confirmed the software program was not set up to include order sets. However, the Physician stated he could develop standing orders which included patient discharge orders, and the written standing orders could be scanned in to the patient record. The ASC did not ensure each patient had written, signed, physician discharge orders.	Q 266		

North Idaho Pain Center, 27OCT2011

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q040	The description of the Governing Body has been amended in the ASC manual. GB will meet annually at a minimum, more frequently if necessary.	The GB will be meeting regularly and will exercise direct oversight of the ASCs programs.	The GB is named and the policy is in place.	Nov 1, 2011	Meetings are scheduled annually at a minimum. Date is in a tickler file. The GB will monitor QAPI on an ongoing basis and will meet to address any operational problems/variances that arise.	Scott Magnuson, MD
Q 042	Dr. Magnuson has admitting privileges to [redacted] A written transfer agreement has been made with [redacted]	Dr. Magnuson has had admitting privileges at [redacted] This has been in place since the opening of the ASC. This is on file in the administrators office.	This has been implemented.	Nov 1, 2011	Priveliging through [redacted] is every 2 years. The transfer agreement is renewable in 3 years (17OCT2014).	Michele Magnuson

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 060	Medications were always administered at the direction of the physician. A written orders sheet is in place for medication administration, IV placement, admission and discharge consistent with facility policy. Medications are administered by 2 Registered Nurses under physician direction. These nurses have had training in conscious sedation. This training is completed every 2 years. Evidence of this training is kept in administrators office. Propofol has been removed from the ASC and is no longer used. The ASC is maintaining appropriate emergency resuscitation equipment. We still are part of [redacted] emergency response system.	These changes will enable the ASC to be able to appropriately document correct procedure for medication administration during conscious sedation. The presence of emergency resuscitative equipment will ensure immediate access to this equipment in the event of an emergency.	These changes have been implemented.	Nov 1, 2011	These policies are reviewed at a minimum of every 2 years by the Governing Body. The GB is also responsible for verifying the registered nurse training in conscious sedation every 2 years. A policy and procedure is in place for monitoring for outdated medications on a regular basis.	Scott Magnuson, MD as the Governing Body

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 063	Propofol was removed from this facility.	No aesthetics will be given unless given by a qualified anesthesiologist or CRNA separate than the anesthesiologist performing the procedure.	All Propofol removed from the ASC. Ensured conscious sedation policy reflected appropriate medications for conscious sedation.	Nov 1, 2011	Policies are reviewed at least every 2 years.	Scott Magnuson, MD
Q 080	The ASC has set forth a data driven QAPI program. The Policies & Procedures have been updated to reflect this. The first QAPI project will start on 01Nov2011.	This will ensure that this ASC is consistently evaluating its processes to help ensure quality care.	A QAPI director has been set up. This person will report to the Governing Board on its progress and findings. This will be an ongoing program.	Started 11/1/2011. Completion of first project expected in approximatel y 3 months.	Through QAPI director and Governing Board.	Machel Barnhart, RN (QAPI) and Scott Magnuson, MD(Governing Board)

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 081	The ASC has set up a QAPI program. See response on Q 080.	The ASC will have an ongoing program to evaluate quality indicators, adverse patient events and infection control.	Indicators such as wrong side injection, wrong injection, inadvertent dural puncture, antibiotic prophylaxis prior to certain procedures, patient fall, hospital transfer of patient, etc. will be tracked. These will be measured against national indicators when possible, but for some (i.e., inadvertent dural puncture) national data may be hard to find, so comparing to latest literature will be done.	Nov. 1, 2011 and ongoing	Ongoing	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 082	In Addition to what has already been discussed for Q 080 and Q 081, we will continue to track patient satisfaction.	This data will be collated and tracked to show changes. Our patient satisfaction survey will be updated to reflect the entire range of services the patient comes in contact with (front desk, nursing, surgeon, preop, postop instructions, facility, etc.). Results will be tracked and goals for improvements will be made. The Governing Body will determine the priorities for performance improvement projects based on the survey results.	We will continue to track our current survey data. Once a more comprehensive survey is decided upon (by the Governing Body with input from the administrator and QAPI director) a strategy for implementation will be made.	01NOV2011	Ongoing	Michele Magnuson, RN and Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 083	Our goal is to achieve 2 or more performance improvement projects per year. With a small single specialty ASC with a limited scope, it is felt that this would be both appropriate and meaningful. Each project will be kept in a binder with subheadings of: Scope, Data, Analysis, Action, and Reporting. This will ensure clear and accurate documentation of each performance improvement project.	We will have an ongoing program to monitor performance improvement.	This is starting. Project is starting 01Nov2011.	01Nov2011	Ongoing.	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 084	The Governing Body policy regarding QAPI has been set.	The Governing Body previously did not take an appropriate active role in assuring that ASC policies were adequate and establishing the QAPI program. The policy manual has been updated and the Governing Body will meet on a regular basis and take an active role in the QAPI program.	This has been implemented.	11/1/2011/ ongoing.	Minimum of yearly meetings of Governing Body. Meeting notes will be taken.	Scott Magnuson, MD

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 100 & Q 105	The ASC has all emergency equipment necessary in the procedure area and not down the hall. This includes: an emergency call system, oxygen, mechanical ventilators assistance equipment, cardiac defibrillator, cardiac monitoring equipment, cricothyroidotomy set, laryngoscopes, and endotracheal tubes. This was verified at the last visit to the site by the surveyors. During the first visit to the site while Scott Magnuson, MD was out of town, [redacted] RN was interviewed and incorrectly stated that the lease agreement included coverage in the hospital's emergency response system. This was never the case. I was not asked this question. The ASC is part of the hospital's emergency response system, but no formal agreement was necessary. Regardless, the physician, both ARNPs, and both RNs are all ACLS certified. The active staff is BCLS	The necessary emergency equipment is present and now just steps away from the patient treatment areas.	Has been implemented	Nov 1, 2011	Equipment is checked on a daily basis when the ASC is open. A log of this is kept by the emergency cart.	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 140	Abated. Propofol no longer used in ASC as of 26SEP2011.	Increased risk of using Propofol abated.	Policy in effect for use of only conscious sedation and not anesthesia.	26SEP2011	N/A	Scott Magnuson, MD
Q 141	Policies & Procedures have been reviewed and revised for all clinical personnel in the ASC. To ensure compliance, our UAPs are not removing IVs and this is not in their job descriptions. Another reason cited for noncompliance was the RN administration of Propofol which was addressed previously in Q 063.	Policy & Procedures have been updated to reflect an appropriate job description for RNs, MAs and CNAs.	This has been implemented. Staff has been trained on the Policy & Procedures.	26OCT2011	These Policies & Procedures are reviewed every 2 years	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 160, Q 161, Q 162	Policy & Procedures updated for medical record keeping. This includes policy for documentation of vital signs, medications and nursing notes, as well as physician orders. The current EMR system is being updated to ensure that these events are date/time/name stamped for all these nursing actions. In addition, a new template is being developed for a comprehensive document to be made encompassing the entire medical record documentation of the patient visit to the ASC on that day. In addition, during the surveyor interview with Machel Barnhart,RN she stated that after a form was completed the EMR does not allow you to add information to it, as in the case of documenting an adverse response. This is incorrect. The entire nursing staff has been educated on how to correctly do this in the EMR.	The EMR will be able to more accurately portray the clinical care as a patient is treated in the ASC.	The Governing Body is working with the template editor for our EMR system to accomplish these changes. These are already under way, but will take some time for adequate development and testing. In the meanwhile, paper forms which cover this information have been developed and are in use. These are scanned into the EMR.	01NOV2011 Paper forms are in use. EMR templates in development .	Ongoing	Georgia Henry, Scott Magnuson, MD

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 180, Q 181, Q 184	The Policy & Procedures have been reviewed and updated. There is now a written order sheet to document medication administration and orders. This will be incorporated into the EMR. All prefilled syringes will be labeled appropriately with medication, date and time filled, expiration, and initials of person nurse/ physician filling syringe. Single use medications are used only for one patient. A system has been set up to routinely check for expired products. Propofol is not being used and is not present in the ASC.	A better understanding of the Policy & Procedures related to medication administration will improve patient safety. Better oversight by the Governing Body will ensure compliance.	Education of the nursing staff and physician staff on the ASCs policies has been done. As policy is reviewed in the future it will provide another opportunity for education.	26OCT2011	This policy will be reviewed at least every 2 years.	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 220, Q 221, Q 222, Q 223	Policy & Procedures reviewed and updated. Patient Rights and Responsibilities are completed and displayed in the waiting room. This information is entirely consistent with CfC 416.50. Reception staff will provide patient with a verbal and written form of Rights and Responsibilities upon scheduling a procedure in the ASC the first time, and thereafter upon patient request. In addition, copies of the Rights And Responsibilities will be in a display folder in the waiting room for a patient to take if they desire. Included in this information is information regarding physician ownership in the ASC.	This will better enable us to inform the patient of their rights.	A Rights and Responsibilities poster has been made and the individual information sheets for patients have been made. Patients will sign a document indicating they have been provided with a copy of their rights and this will be part of the EMR.	01NOV2011	As with our other policies, this will be reviewed at least every 2 years or sooner should CMS policy change in this regard.	Michele Magnuson

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 224	Policy and Procedure manual reviewed and revised. Reception staff has been trained on informing patients about Advance Directive information at the time of scheduling a procedure. This will be documented in the EMR. This documentation will be placed on the home page of the ASC record in the EMR.	This will ensure compliance and will give the treating personnel needed information regarding a patient's wishes regarding Advance Directives and give the patients a chance to receive information on Advance Directives should they desire.	This is part of the Rights and Responsibilities information. In addition, the Patients Bill of Rights has been updated to reflect this policy and that Advance Directives would be suspended while undergoing treatment at the ASC.	01NOV2011	Policy will be reviewed at least every 2 years.	Michele Magnuson
Q 225	Policy and Procedures reviewed and revised to come into compliance with Q 225 (i), (v), (vi), and (vii). A grievance log book has been established to document all complaints per policy.	The procedure for a patient filing a grievance and for how that grievance will be investigated and responded to is clear.	The Policy and Procedure has been updated. The front desk staff are educated on what to do if a patient expresses a desire to file a grievance.	19OCT2011	This policy will be reviewed at least every 2 years.	Michele Magnuson
Q 227	This is included in the patient's Rights and Responsibilities.	This will help to fully inform patients of their rights.	This has been implemented by the new policy regarding patient's Rights and Responsibilities.	19OCT2011	This policy will be reviewed at least every 2 years.	Michele Magnuson

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 230	This is included in the patient's Rights and Responsibilities.	This will help to fully inform patients of their rights.	This has been implemented by the new policy regarding patient's Rights and Responsibilities.	19OCT2011	This policy will be reviewed at least every 2 years.	Michele Magnuson
Q 231	This is included in the patient's Rights and Responsibilities.	This will help to fully inform patients of their rights.	This has been implemented by the new policy regarding patient's Rights and Responsibilities.	19OCT2011	This policy will be reviewed at least every 2 years.	Michele Magnuson
Q 232	This is included in the patient's Rights and Responsibilities.	This will help to fully inform patients of their rights.	This has been implemented by the new policy regarding patient's Rights and Responsibilities.	19OCT2011	This policy will be reviewed at least every 2 years.	Michele Magnuson
Q 233	This is included in the patient's Rights and Responsibilities.	This will help to fully inform patients of their rights.	This has been implemented by the new policy regarding patient's Rights and Responsibilities.	19OCT2011	This policy will be reviewed at least every 2 years.	Michele Magnuson

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 240	The Policy and Procedures have been rewritten and revised to ensure a comprehensive infection control program.	By establishing an active infection control program, we seek to minimize the risk of infections and spreading of communicable diseases in our ASC. This is a single specialty ASC that does not perform open procedures, so our risk for certain infections is very minimal. However, am active program is the only way to ensure that we are meeting as high standards as possible for infection control. This program will be based on nationally recognized standards (such as CDC) and will be ongoing.	The P&P has been revised. Initial training on the policy has begun and will be ongoing.	01NOV2011	Ongoing	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 241	(1). The ASC has changed procedure for sterilization to be consistent with our policy and has initiated an autoclave log for better tracking of instrument sterilization. (2). Handwashing policy was reviewed and revised. It has been decided by the Governing Board that this will be a QAPI study for this year. This protocol has been written. The study will begin on 01NOV2011. (3). The Policy has been updated to reflect CDC Guidelines for environmental infection control.	Our infection control guidelines are updated and in line with nationally recognized guidelines.	The Policy and Procedures have been updated. Education of staff will be done on 31OCT2011.	31oct2011	This policy will be updated at least every 2 years.	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 242	An Infection Control Program is being established. This is based on a number of CDC guidelines including Safe Injection Practices, Guidelines for Environmental Infection Control in Healthcare Facilities, Guideline for Hand Hygiene in Health Care Settings, and Guideline for Infection Control in Healthcare Personnel.	The infection control program will be based on standardized, nationally accepted practices.	Through revised Policies & Procedures followed by staff education.	01NOV2011 and ongoing	These policies will be reviewed at least every 2 years.	Machel Barnhart, RN
Q 243	The Infection Control Program is under the direction of a nurse who will have ongoing training in infection control.	This will ensure that the person responsible for the IC program will have adequate knowledge and training to carry out an effective program.	Education training will include courses through CDC, APIC, AORN, etc pertains to infection control.	01NOV2011	Education will be ongoing. This policy will be reviewed and revised at least every 2 years.	Machel Barnhart, RN
Q 244	The infection control program is part of the QAPI program. This is evidenced by the fact that our QAPI project deals with an identified weakness in infection control, handwashing.	Making IC part of QAPI will ensure adequate attention is placed on critically looking at our IC practices.	This is being implemented onanongoing basis.	01NOV2011	This policy will be reviewed and revised every 2 years. An IC committee will be formed and will meet regularly (at least quarterly).	Machel Barnhart, RN

	Action	Improvement	Implementation	Completion date	Monitoring/ tracking	Responsible person
Q 245	The infection control program has been established and is ongoing in it's development.	This will ensure a directed action plan for implementing infection prevention and control efforts.	This program has been started. An IC committee will be set up.	01NOV2011	This policy will be reviewed and revised every 2 years. An IC committee will be formed and will meet regularly (at least quarterly).	MACHEL Barnhart, RN
Q 260, Q 261, Q 263, Q 264, Q 266	The ASCs Policies and Procedures were reviewed and revised. Our practices and workflow have been changed to ensure compliance with this CfC. H&Ps within 30 days are on the charts. Standing orders have been initiated and are signed by the treating physician. Medication administration orders are also in the chart. This is currently in paper form being scanned into the chart, but templates are being developed to make this part of the EMR.	This will bring us into compliance for this CfC.	This has been implemented.	01NOV2011	Utilization review screening will be done on a scheduled basis to ensure we continue to meet this standard.	Scott Magnuson, MD