IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

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

CERTIFIED MAIL: 7000 1670 0011 3315 1750

September 5, 2014

Wendy Binegar, Administrator
Pain Care Center Boise
301 West Myrtle
Boise, ID 83702

RE: Pain Care Center Boise, Provider #13C0001049

Dear Ms. Binegar:

Based on the survey completed at Pain Care Center Boise, on August 19, 2014, by our staff, we have determined Pain Care Center Boise is out of compliance with the Medicare ASC Conditions for Coverage of **Governing Body and Management (42 CFR 416.41), Quality Assessment and Performance (42 CFR 416.43) and Infection Control (42 CFR 416.51)**. To participate as a provider of services in the Medicare Program, a OR an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

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

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

An acceptable Plan of Correction contains the following elements:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;

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

Such corrections must be achieved and compliance verified by this office, before October 3, 2014. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than September 23, 2014.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **September 18, 2014**.

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

We urge you to begin correction immediately.

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

Sincerely,

GARY GUILES
Health Facility Surveyor
Non-Long Term Care

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001049	A. BUILDING _____ B. WING _____	08/19/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PAIN CARE CENTER BOISE	301 WEST MYRTLE BOISE, ID 83702

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Q 000	INITIAL COMMENTS The following deficiencies were cited during the Medicare recertification survey of your surgical center from 8/18/14 to 8/19/14. Surveyors conducting the recertification were: Gary Guiles, RN, HFS, Team Leader Donald Sylvester, RN, HFS Cheri Samuels, RN, HFS Acronyms used in this report include: Ambu - a bag valve mask combination used to mechanically ventilate patients AORN - Association of Perioperative Registered Nurses ASC - Ambulatory Surgery Center Aug - August CDC - Centers for Disease Control CMA - Certified Medical Assistant EMR - Electronic Medical Record IV - Intravenous mcg - microgram mg - milligram PA - Physician Assistant PI - Performance Improvement QAPI - Quality Assessment Performance Improvement RN - Registered Nurse X - times	Q 000	RECEIVED SEP 18 2014 FACILITY STANDARDS	
Q 040	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing,and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality	Q 040	See attached	

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

Nurse Administrator 9/17/14

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

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Q 040	Continued From page 1 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 medical records, policies, meeting minutes and quality documents, it was determined the ASC's governing body failed to assume responsibility for determining, implementing, and monitoring policies and failed to oversee the ASC's QAPI program. This resulted in a lack of guidance and direction to staff and the failure to sustain regulatory compliance. Findings include: 1. Refer to Q80 Condition for Coverage: Quality Assessment and Performance Improvement as it relates to the governing body's failure to ensure the ASC's quality program was developed, implemented and maintained. 2. Refer to Q240 Condition for Coverage: Infection Control as it relates to the governing body's failure to ensure a comprehensive infection control program was developed, implemented and monitored. The cumulative effect of these systemic deficient practices resulted in the lack of clear processes to guide staff in the provision of care and to evaluate its services.	Q 040		
Q 080	416.43 QUALITY ASSESSMENT AND PERFORMANCE	Q 080	See attached	

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Q 080	Continued From page 2 The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on staff interview and review of policies, meeting minutes, medical records, and quality program documents, it was determined the ASC failed to ensure a quality program was developed, implemented and maintained. This impeded the ability of the ASC to evaluate its practices and improve care. Findings include: 1. Refer to Q81 as it relates to the ASC's failure to ensure its quality program was defined and direction was provided to staff responsible for the program. 2. Refer to Q82 as it relates to the ASC's failure to ensure its quality program tracked adverse patient events and examined their causes. 3. Refer to Q83 as it relates to the ASC's failure to ensure distinct improvement projects were conducted. 4. Refer to Q84 as it relates to the governing body's failure to ensure the QAPI program was defined, implemented and maintained. The cumulative effect of these systematic failures resulted in the inability of the ASC to monitor programs and services.	Q 080		
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health	Q 081	See attached	

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Q 081	Continued From page 3 outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. (c)(1) The ASC must set priorities for its performance improvement activities that - (i) Focus on high risk, high volume, and problem-prone areas. (ii) Consider incidence, prevalence, and severity of problems in those areas. (iii) Affect health outcomes, patient safety, and quality of care. This STANDARD is not met as evidenced by: Based on staff interview and review of policies, meeting minutes and quality program documents, it was determined the ASC failed to ensure its quality program was defined and failed to ensure direction was provided to staff responsible for the program. This prevented the ASC from analyzing its processes in order to improve them. Findings include: 1. The policy "Quality Management and Improvement (QMI)," revised 5/30/14, stated "The Center maintains a plan that describes the QMI Program objectives, organization, scope and mechanisms for overseeing the effectiveness of monitoring, evaluation, improvement and problem	Q 081		

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Q 081	Continued From page 4 solving activities." The policy stated "Evaluation of those aspects of care that are most important to the health and safety of the patient are identified..." However, a plan describing the ASC's quality objectives, per facility policy, was not documented. Additionally, the policy did not address monitoring for or tracking of adverse patient events or identify high risk, high volume, or problem prone areas the ASC would or might measure. The Nurse Administrator, who also directed the ASC's quality activities, was interviewed on 8/19/14 beginning at 4:45 PM. She stated a quality plan, including quality indicators to be measured and quality activities to be performed, had not been developed. She stated areas of high risk, high volume, and problem-prone areas for the ASC had not been defined and confirmed the ASC did not monitor or track adverse patient events. A quality plan defining the scope of the ASC's QAPI program, which included the identification, monitoring and tracking of adverse patient events and high risk, high volume, or problem prone areas had not been developed.	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.	Q 082	See attached	

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Q 082	Continued From page 5 (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, policies, meeting minutes and quality program documents, it was determined the ASC failed to ensure quality indicator data was collected and analyzed to improve its processes and patient care. The ASC also failed to track an adverse patient event and examine its causes for 1 of 1 patient (#22) who had a documented adverse event. The failure to analyze adverse patient events had the potential to impact all patients receiving care at the facility. This resulted in the ASC's ability to take action to improve care and prevent future events being impeded. Findings include: 1. Patient #22's medical record documented a 58 year old female who had bilateral facet joint injections performed on 6/16/14. The "Nursing Procedure Report," dated 6/16/14, stated prior to her procedure at 12:40 PM, Patient	Q 082		

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Q 082	Continued From page 6 #22's blood pressure was 169/80. Her pulse was 65. At 1:10 PM, the report stated Patient #22 was given IV Fentanyl and Alfenta, both narcotics, and IV Versed, an anti-anxiety drug. Her pulse then rose to 95. Her pulse did not drop lower than 95 and had risen as high as 127 at 1:41 PM. A corresponding progress note by the physician, dated 6/16/14 but not timed, stated he responded to the recovery area at 1:30 PM. The note stated Patient #22 was "unresponsive and not breathing." The note stated Patient #22 required positive pressure ventilation by a bag valve mask device. The note stated Patient #22's blood pressure rose to 206/120, and there were problems getting good electrocardiogram and pulse oximetry readings. The note stated Patient #22 remained unresponsive and required a narcotic reversal agent in order to breathe on her own. The note stated Patient #22 "Otherwise then recovered uneventfully with normal respirations. Was discharged awake and oriented X3." The "Nursing Procedure Report," further documented Patient #22's pulse was 95 and her oxygen saturation level was 96% at 2:25 PM. She was discharged at that time. An "INCIDENT REPORT FORM," not dated, documented the events of Patient #22's respiratory depression. The incident report stated during the above incident, Patient #22's oxygen saturation levels dropped into the "80s and 70s." (The Mayo Clinic website, queried on 8/28/14, stated "Normal pulse oximeter readings range from 95 to 100 percent, under most circumstances. Values under 90 percent are considered low.")	Q 082		

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Q 082	Continued From page 7 An investigation of the incident was not documented. Additionally, the incident report stated "Protocol changes: The wheels of the crash cart will not be locked X4 and the ambu bag will be pre-assembled." However, the reason for the changes indicated on the incident report was not documented. The Nurse Administrator was interviewed on 8/19/14 beginning at 4:45 PM. She confirmed an investigation of the incident had not been conducted in order to determine the cause of the event, whether or not staff had followed emergency procedures, and if those procedures were adequate. Further, the facility's "Quality Management and Improvement (QMI)" policy, revised 5/30/14, did not address the tracking of adverse patient events, no quality reports or data related to adverse events was documented from 8/01/13 to 8/01/14, and the facility's "Governing Body Meeting Minutes," dated 6/30/14, stated "Adverse events...none this month." Documentation of the adverse event experienced by Patient #22 on 6/16/14 was not present. The Nurse Administrator was interviewed on 8/19/14 beginning at 4:45 PM. She confirmed the ASC did not monitor or track adverse patient events as part of the QAPI program and she confirmed data regarding adverse patient events was not documented for the year prior to survey. The ASC did not track and analyze adverse patient events.	Q 082		

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Q 082	Continued From page 8 2. The "Quality Management and Improvement (QMI)," policy stated "The Center maintains a plan that describes the QMI Program objectives, organization, scope and mechanisms for overseeing the effectiveness of monitoring, evaluation, improvement and problem solving activities." The policy stated "Evaluation of those aspects of care that are most important to the health and safety of the patient are identified..." However, the only data documented from 8/01/13 to 8/01/14 that measured processes to patient care was hand hygiene data. A document, titled "Quality Improvement Study," dated the second quarter of 2014, stated the ASC had a "...goal of increasing the compliance rate of hand hygiene to 90%." Facility records documented hand hygiene data was collected on a monthly basis since January 2011, with the data from 2012 measuring consistently above 90%. Data from January 2013 - April 2013 was above 90%. No data was available for May 2013. Hand hygiene data from June through September 2013 were all above 90%. Data from October 2013 - February 2014 was not available. However, data collection for the remainder of 2014 documented the following: - 3/13/14: 20% - 4/15/14: 80% - 5/19/14: 75% - 6/17/14: 90% - 7/22/14: 79% The facility's "Governing Body Meeting Minutes," dated 7/31/14, stated "Hand hygiene. Yes, in	Q 082		

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Q 082	Continued From page 9 progress-high risk, high volume. Data collection continues. Data looks good. Up to 75 - 90% from 20%." The meeting minutes did not include information related to meeting their goal only 1 time in 5 months in 2014 and no documentation was present to establish the ASC had examined the causes for the drop in hand hygiene rates from over 90% in 2013 to 20% in March 2014. The Nurse Administrator was interviewed on 8/19/14 beginning at 4:45 PM. She confirmed the hand hygiene data. She stated this was the only data related to ASC patient care practices that had been gathered in the past year. The Nurse Administrator was again interviewed on 8/28/14 beginning at 11:10 AM. She stated that after the surveyors questioned the data she investigated and found prior to 3/14 staff measured hand hygiene only between patient procedures. She stated beginning in 3/14 staff measured all opportunities for hand hygiene. However, she confirmed prior to the survey, the data had not been analyzed to determine why the discrepancy had occurred. The ASC failed to analyze data in order to change facility practices.	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	Q 083	See attached	

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Q 083	Continued From page 10 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 policies and quality program documents, it was determined the ASC failed to ensure distinct quality improvement projects were conducted. This limited the ASC's opportunities to improve performance and patient care. Findings include: The policy "Quality Management and Improvement (QMI)," revised 5/30/14, did not contain a definition for performance improvement projects nor did it specify the ASC would conduct such projects. The Nurse Administrator was interviewed on 8/19/14 beginning at 4:45 PM. She confirmed the ASC did not have a definition for performance improvement projects and had not conducted any such projects related to how it cared for patients since at least 8/01/13. The ASC did not 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,	Q 084	See attached	

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Q 084	Continued From page 11 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 policies and meeting minutes, it was determined the ASC's governing body failed to ensure the QAPI program was defined, implemented and maintained. This resulted in a lack of direction to staff responsible for implementing the program. Findings include: The policy "PERFORMANCE IMPROVEMENT," revised 5/30/14, stated "The Governing Body will support and have the final authority and responsibility for the assurance of a flexible, comprehensive and integrated Organizational Performance Improvement Program and will delegate the authority and accountability for the operation of the program to the administration and the medical staff." The policy stated the ASC's PI program would be "reappraised annually" and the results would be presented in writing to the governing body. The policy stated the governing body "...sets priorities for organization-wide [Quality Management and Improvement]." A current plan stating how the ASC would accomplish these goals was not documented. An appraisal of the ASC's quality activities was not documented in "Governing Body Meeting Minutes" since at least 8/01/13. The Nurse Administrator, who also directed the ASC's quality activities, was interviewed on	Q 084		

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Q 084	Continued From page 12 8/19/14 beginning at 4:45 PM. She stated a quality plan, including quality indicators to be measured and quality activities to be performed, had not been developed. She stated areas of high risk, high volume, and problem-prone areas for the ASC had not been defined. She confirmed an appraisal of the ASC's quality activities had not been conducted in the past year. The governing body did not ensure a plan for QAPI activities had been developed or the quality program had been evaluated. Additionally, the owner and the Nurse Administrator were interviewed together on 8/19/14 beginning at 5:00 PM. Both stated the time and resources spent on QAPI activities were not tracked. Neither could state how much time staff used attending to QAPI activities. The Governing Body did not monitor resources used for the QAPI program in order to determine whether or not sufficient resources were utilized.	Q 084		
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	Q 162	See attached	

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PAIN CARE CENTER BOISE	301 WEST MYRTLE BOISE, ID 83702

(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 162	Continued From page 13 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 review of medical records and staff interview, it was determined the ASC failed to ensure medical records were complete and accurate for 23 of 23 patients (#1 - #23) whose records were reviewed. This resulted in in a lack of clarity as to the patients' course of treatment during their time in the ASC. Findings include: 1. The ASC used an software system to keep EMRs for all patients including Patients #1 - #23. When asked about the medical records, during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the medical records were written by more than one person. However, Patient #1 - #23's printed records appeared to by written by 1 person. The records did not include information related to who authored various sections of the records or the date and time of when the sections were written. Examples included, but were not limited to, the following: a. Patient #23's medical record documented a 46 year old female who had a cervical epidural steroid injection performed on 8/19/14. Patient #23's printed record did not include clear documentation, as follows:	Q 162		

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Q 162	Continued From page 14 - The printed record included a section for Present Illness Information. The section included check boxes to indicate various information, such as any recent hospitalizations or changes in medical condition, etc. The author of the section was not indicated. The section stated the updated history, the last physical exam, and the patient history update had been completed on 8/12/14. However, when asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the patient history update and the information entered into the checkboxes had been completed by the physician on 8/19/14, not 8/12/14. - The printed record included a section for Review of Systems and Past, Family and Social History. The section did not include a date, time or author. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the PA had completed Patient #23's History and Physical on 8/12/14. The Nurse Administrator stated the EMR then brought the information forward into Patient #23's ASC medical record. However, the author of the section, and the date and time it was completed was not apparent in Patient #23's printed record. - The Tests and Procedures section included information regarding Patient #23's cervical injections and was dated 8/19/14, but not timed. The end of the section included a physician's name. However, it was not clear if the physician's name appeared as the physician who preformed the procedure or if the physician had authored the section.	Q 162		

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Q 162	Continued From page 15 When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the physician had written the section but confirmed the author was not clearly identified. - The Plan section, at the end of Patient #23's medical record stated "Schedule Follow-up: in 1 week..." The physician's name was listed under the plan section. However, the section did not include a date or time and it was not clear if the physician's name appeared as the physician who developed the plan or the physician who authored the section. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the plan section had been complete by the PA on 8/12/14. The author of the sections and the date and time they were completed was not apparent in Patient #23's printed record. b. Patient #19's medical record documented a 67 year old female who had bilateral sacroiliac joint injections performed on 7/23/14. Patient #19's printed record did not include clear documentation, as follows: - The printed record included a section for Present Illness Information. The section included check boxes to indicate various information, such as any recent hospitalizations or changes in medical condition, etc. The author of the section was not indicated. The section stated the updated history, the last physical exam, and the patient history update had been completed on 7/15/14.	Q 162		

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Q 162	Continued From page 16 However, when asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated Patient #19's patient history update and the information entered into the checkboxes had been completed by the physician on 7/23/14, not 7/15/14. - The printed record included a section for Review of Systems and Past, Family and Social History. The section did not include a date, time or author. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the PA had completed Patient #19's History and Physical on 7/15/14. The Nurse Administrator stated the EMR then brought the information forward into Patient #19's ASC medical record. However, she stated the author of the section and the date and time it was completed were not apparent in Patient #19's printed record. - The Tests and Procedures section included information regarding Patient #19's sacroiliac injections and was dated 8/19/14, but not timed. The end of the section included a physician's name. However, it was not clear if the physician's name appeared as the physician who preformed the procedure or if the physician had authored the section. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the physician had written the section but confirmed the author was not clearly identified. - The Plan section, at the end of the medical record stated "Schedule Follow-up: in 1 week..."	Q 162		

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Q 162	Continued From page 17 The physician's name was listed under the plan section. However, the section did not include a date or time and it was not clear if the physician's name appeared as the physician who developed the plan or the physician who authored the section. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the plan section of Patient #19's record had been completed by the PA on 8/12/14. The author of the sections, and the date and time they were completed was not apparent in Patient #19's printed record. c. Patient #12's medical record documented a 76 year old female who had caudal epidural steroid injections performed on 8/04/14. Patient #12's printed record did not include clear documentation, as follows: - The printed record included a section for Present Illness Information. The section included check boxes to indicate various information, such as any recent hospitalizations or changes in medical condition, etc. The author of the section was not indicated. The section stated the updated history, the last physical exam, and the patient history update had been completed on 7/03/14. However, when asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the patient history update and the information entered into the checkboxes had been completed by the physician on 7/03/14, not 8/04/14.	Q 162		

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Q 162	Continued From page 18 - The printed record included a section for Review of Systems and Past, Family and Social History. The section did not include a date, time or author. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the PA had completed Patient #12's History and Physical on 7/03/14. The Nurse Administrator stated the EMR then brought the information forward into Patient #12's ASC medical record. However, the author of the section, and the date and time it was completed was not apparent in Patient #12's printed record. - The Tests and Procedures section included information regarding Patient #12's sacroiliac injections and was dated 8/04/14, but not timed. The end of the section included a physician's name. However, it was not clear, if the physician's name appeared as the physician who performed the procedure or if the physician had authored the section. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the physician had written the section but confirmed the author was not clearly identified. - The Plan section, at the end of the medical record stated "Schedule Follow-up: in 1 week..." The physician's name was listed under the plan section. However, the section did not include a date or time and it was not clear if the physician's name appeared as the physician who developed the plan or the physician who authored the section. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator	Q 162		

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Q 162	Continued From page 19 stated the PA had completed the plan section of Patient #12's record on 7/03/14. The author of the sections, and the date and time they were completed was not apparent in Patient #12's printed record. d. Patient #4's medical record documented an 83 year old female who had cervical injections performed on 6/02/14. Patient #4's printed record did not include clear documentation, as follows: - The printed record included a section for Present Illness Information. The section included check boxes to indicate various information, such as any recent hospitalizations or changes in medical condition, etc. The author of the section was not indicated. The section stated the updated history, the last physical exam, and the patient history update had been completed on 5/20/14. However, when asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the patient history update and the information entered into the checkboxes had been completed by the physician on 6/02/14, not 5/20/14. - The printed record included a section for Review of Systems and Past, Family and Social History. The section did not include a date, time or author. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the PA had completed Patient #4's History and Physical on 5/20/14. The Nurse Administrator stated the EMR then brought the information forward into Patient #4's ASC medical	Q 162		

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Q 162	Continued From page 20 record. However, the author of the section, and the date and time it was completed was not apparent in Patient #4's printed record. - The Tests and Procedures section included information regarding Patient #4's cervical injections and was dated 6/02/14, but not timed. The end of the section included a physician's name. However, it was not clear, if the physician's name appeared as the physician who performed the procedure or if the physician had authored the section. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the physician had written the section but confirmed the author was not clearly identified. - The Plan section, at the end of the medical record stated "Schedule Follow-up: in 1 month..." The physician's name was listed under the plan section. However, the section did not include a date or time and it was not clear if the physician's name appeared as the physician who developed the plan or the physician who authored the section. When asked during an interview on 8/19/14 beginning at 4:45 p.m., the Nurse Administrator stated the PA had completed the plan section of Patient #4's record on 5/20/14. The author of the sections, and the date and time they were completed was not apparent in Patient #4's printed record. The ASC's EMR system did not include provisions to ensure the printed records contained clear documentation of when	Q 162		

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Q 162	Continued From page 21 assessments and treatments were completed and by whom. The facility failed to ensure patient medical records contained comprehensive, accurate information. 2. The ASC's medical records did not reflect that patients were accompanied by a responsible adult at the time of discharge, as follows: a. Patient #9's medical record documented a 69 year old female who had back transforaminal epidural steroid injections with fluoroscopic assistance performed on 7/03/14. Patient #9's record stated she was discharged from the ASC at approximately 3:10 PM. Her record did not include documentation of who accompanied her at the time of her discharge. b. Patient #11's medical record documented a 46 year old male who had a lumbar epidural steroid injection with fluoroscopic assistance performed on 7/17/14. Patient #11's record stated he was discharged from the ASC at approximately 4:05 PM. His record did not include documentation of who accompanied him at the time of his discharge. c. Patient #12's medical record documented a 76 year old female who had a caudal epidural steroid injection with fluoroscopic assistance performed on 8/04/14. Patient #12's record stated she was discharged from the ASC at 10:40 AM. Her record did not include documentation of who accompanied her at the time of her discharge.	Q 162		

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Q 162	Continued From page 22 d. Patient #2's medical record documented a 57 year old female who had a right lumbar sympathetic block with fluoroscopic assistance performed on 8/11/14. Patient #2's record stated she was discharged from the ASC at 1:35 PM. Her record did not include documentation of who accompanied her at the time of her discharge. During an interview on 8/18/14 at 3:15 PM, the Nurse Administrator confirmed the medical records above did not document who the patients were discharged with. The Nurse Administrator stated it was the policy of the ASC to discharge patients in the care of a responsible adult and confirmed staff should discharge patients to a responsible adult.	Q 162		
Q 181	416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to adhere to acceptable standards of practice for medication administration. This had the potential to impact all patients receiving medications at the facility. This resulted medications being inappropriately labeled and the potential for patients to experience adverse drug reactions and medication administration errors. Findings	Q 181	See attached	

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Q 181	Continued From page 23 include: 1. 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 according to acceptable standards of practice, as follows: a. During a tour of the ASC on 8/18/14, beginning at 9:45 AM. an RN was observed drawing a medication into a syringe for an unknown patient. After drawing up the medication, the RN placed a preprinted drug label onto the syringe. The label stated "Versed." However, the label did not include the medication dose, time, date, or initials of the RN. The Nurse Administrator was interviewed on 8/19/14 at 4:35 PM. She confirmed the RN should have labeled the syringe with the dose, time, date and her initials. The facility failed to ensure medications were labeled in accordance with acceptable standards of practice. b. On 8/19/14 at 1:08 PM, a syringe with fluid in it was observed on a counter in the procedure room. The syringe was labeled "4 ml 1/2 lidocaine & deca." "Deca" is not a medication. The label did not state what the specific medication was nor did it state what the dosage was. The RN in the procedure room was interviewed on 8/19/14 at 1:50 PM. She confirmed the label	Q 181		

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Q 181	Continued From page 24 of the syringe was not complete. The facility failed to ensure medications were labeled in accordance with acceptable standards of practice.	Q 181		
Q 229	416.50(e)(1)(iii) EXERCISE OF RIGHTS - INFORMED CONSENT [(1) The patient has the right to the following:] (iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the ASC failed to ensure that patients were fully informed about procedures and the expected outcomes before it was performed for 1 of 23 patients (#9) whose records were reviewed. This resulted in the potential lack of information being provided to a patient on which to based informed consent decisions. Findings include: Patient #9's medical record documented a 69 year old female who had back transforaminal epidural steroid injections with fluoroscopic assistance performed on 7/03/14. Her record included a consent for the procedure dated 7/03/14. However, the consent was not signed or dated by Patient #9 and did not include a staff witness signature or date. Additionally, the consent documented that Xanax was to be administered prior to procedure. However, the section was not signed or dated. The ASC failed to document Patient #9 was fully informed of the procedure.	Q 229	See attached	

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Q 240	416.51 INFECTION CONTROL The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview, it was determined the facility failed to ensure a comprehensive infection control program was developed, implemented and monitored for staff and all patients receiving care at the facility. This resulted in the inability of the facility to minimize infections and communicable diseases. Findings include: 1. Refer to Q241 as it relates to the facility's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice. 2. Refer to Q242 as it relates to the facility's failure to ensure an ongoing program to prevent, control, and investigate infections and communicable diseases was maintained. 3. Refer to Q243 as it relates to the facility's failure to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control. 4. Refer to Q244 as it relates to the facility's failure to ensure infection control was addressed as an integral part of the ASC's QAPI program.	Q 240	See attached	
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	Q 241	See attached	

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Q 241	Continued From page 26 standards of practice. This STANDARD is not met as evidenced by: Based on observation, interview and policy review, it was determined the facility failed to maintain a sanitary and functional environment for all patients receiving care at the facility. This resulted in the potential for infections to occur. Findings include: 1. The ASC's 5/30/14 Policy and Procedure Manual, Infection Control, section V part D stated, "Surgery center; flat table surfaces are cleaned first. Furniture is thoroughly scrubbed with disinfectant using effective mechanical friction. All wall mounted equipment, view boxes, etc. are cleaned with a detergent germicide solution and disposable wipe." However, during a tour of the ASC on 8/18/14 beginning at 9:30 AM, 2 procedure rooms and patient recovery areas were observed. The condition of the rooms did not support the facility's policy had been implemented, as follows: a. There was a build-up of dust on the monitor and fluoroscope flat surfaces in the procedure rooms. b. The procedure room trash cans had soiled rolls of tape holding the lids opened. c. There was discoloration on the arm of the chair in the recovery area. Additionally, staff was observed attempting to clean a chair. However, the chair upholstery was made of a cloth-like, porous material, rendering it an unclean surface.	Q 241		

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Q 241	Continued From page 27 During an interview on 8/19/14 beginning at 1:00 PM, the CMA stated the ASC staff cleans rooms after procedures, and at the end of the day. She also stated the ASC has a contractor performing housekeeping duties such as cleaning procedure rooms, recovery areas, and common areas. Additionally, on 8/19/14 beginning at 1:45 PM, the CMA accompanied the surveyor during a tour of the laundry facilities and housekeeping storage, which was located in the ASC. During that time it was noted that the housekeeping cart contained one dirty mop head. The CMA stated she did not know when the mop heads were changed or cleaned. The Nurse Administrator was interviewed on 8/19/14 beginning at 1:55 PM, she stated the housekeeping contractor had many years of experience at a local hospital and assumed they were doing a good job. The ASC failed to ensure the housekeeping contract was sufficiently monitored necessary to maintain a sanitary environment.	Q 241		
Q 242	416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by:	Q 242	See attached	

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Q 242	Continued From page 28 Based on policy review and staff interview, it was determined the ASC failed to ensure an ongoing infection control program was maintained for staff and all patients receiving care at the facility. This resulted in the facility's inability to minimize patients' risks of infection. Findings include: 1. When asked, during an interview on 8/18/14 at 11:20 AM, the Nurse Administrator stated she was responsible for the ASC's infection control program. The ASC's Infection Control Plan, effective 5/30/14, stated, "The center maintains an effective organizational wide program for the surveillance, prevention, and control of infection in which all patient care and patient care support services are included." The infection control plan was based on guidelines from the CDC and AORN standards. The policy also included Recommended Practices for Environmental Cleaning in the Surgical Practice Setting nationally accredited guidelines. However, there was no evidence the ASC had implemented an infection control program that reflected the use of the nationally recognized guidelines identified in the policy. The facility failed to ensure an ongoing infection control program based on nationally recognized standards was maintained. 2. Refer to Q241 as it relates to the facility's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice. 3. Refer to Q243 as it relates to the facility's	Q 242		

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Q 242	Continued From page 29 failure to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.	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 personnel record review and staff interview, 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. This prevented the ASC from utilizing the knowledge base of a trained professional to develop and monitor an infection control program. Findings include: When asked, during an interview on 8/18/14 at 11:20 AM, the Nurse Administrator stated she was responsible for the ASC's infection control program. However, the Nurse Administrator's personnel file did not contain documentation of training in infection control. The staff member responsible for the infection control program was not qualified.	Q 243	See attached	
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	Q 244	See attached	

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Q 244	Continued From page 30 program This STANDARD is not met as evidenced by: Based on staff interview and review of facility policies and records, it was determined the ASC failed to ensure the infection control program was incorporated into the facility QAPI program for all patients receiving services at the ASC. This resulted in the inability of the ASC to evaluate its infection control processes necessary for improving the quality of patient care. The findings include: The "Quality Management and Improvement (QMI)," policy stated "The Center maintains a plan that describes the QMI Program objectives, organization, scope and mechanisms for overseeing the effectiveness of monitoring, evaluation, improvement and problem solving activities." The policy stated "Evaluation of those aspects of care that are most important to the health and safety of the patient are identified..." However, the only data documented from 8/01/13 to 8/01/14 that measured processes to patient care was hand hygiene data. A document, titled "Quality Improvement Study," dated the second quarter of 2014, stated the ASC had a "...goal of increasing the compliance rate of hand hygiene to 90%." Facility records documented hand hygiene data was collected on a monthly basis since January 2011, with the data from 2012 measuring consistently above 90%. Data from January 2013 - April 2013 was above 90%. No data was available for May 2013. Hand hygiene data from	Q 244		

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Q 244	Continued From page 31 June through September 2013 were all above 90%. Data from October 2013 - February 2014 was not available. However, data collection for the remainder of 2014 documented the following: - 3/13/14: 20% - 4/15/14: 80% - 5/19/14: 75% - 6/17/14: 90% - 7/22/14: 79% The facility's "Governing Body Meeting Minutes," dated 7/31/14, stated "Hand hygiene. Yes, in progress-high risk, high volume. Data collection continues. Data looks good. Up to 75 - 90% from 20%." The meeting minutes did not include information related to meeting their goal only 1 time in 5 months in 2014 and no documentation was present to establish the ASC had examined the causes for the drop in hand hygiene rates from over 90% in 2013 to 20% in March 2014. The Nurse Administrator was interviewed on 8/28/14 beginning at 11:10 AM. She stated that after the surveyors questioned the data she investigated and found prior to 3/14 staff measured hand hygiene only between patient procedures. She stated beginning in 3/14 staff measured all opportunities for hand hygiene. However, she confirmed prior to the survey, the data had not been analyzed to determine why the discrepancy had occurred. Additionally, during observation of instrument cleaning and disinfection on 8/19/14 beginning at 9:00 AM, the CMA demonstrated how she cleaned instruments, and prepared them for processing. She picked up an item, with her bare hands, placed it into a package, sealed the	Q 244		

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Q 244	Continued From page 32 package and placed it onto a tray. She then gloved, and completed the remaining instrument packaging. She did not wash her hands before or after her tasks. The CMA was interviewed on 8/19/14 at 9:20 AM. She stated, she should have washed her hands and gloved before preparing the instruments for processing. The facility's hand washing surveillance was not effective in ensuring hand-washing protocols were consistently implemented. The Nurse Administrator stated on 8/19/14 at 5:50 PM, the prior Nurse Administrator had a different method in surveillance and she had changed the method of internal surveillance in June 2014, due to poor response by staff members. She stated, she was attempting to find other methods to perform staff surveillance of adherence to infection control policies and procedures but had yet to develop a new system by the time of the survey. The facility failed to ensure the infection control program was effectively incorporated into the facility QAPI program.	Q 244		
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.	Q 266	See attached	

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Q 266	Continued From page 33 This STANDARD is not met as evidenced by: Based on staff interview and review of medical records, it was determined the ASC failed to ensure discharge orders were present for 1 of 23 patients (#22), whose records were reviewed. The resulted in the potential for patients to experience complications following discharge. Findings include: Patient #22's medical record documented a 58 year old female who had bilateral facet joint injections performed on 6/16/14. A progress note by the physician, titled "RECOVERY AREA NOTE" and dated 6/16/14 but not timed, stated he responded to the recovery area at 1:30 PM. The note stated Patient #22 was "unresponsive and not breathing." The note stated Patient #22 required positive pressure ventilation by a bag valve mask device. The note stated Patient #22's blood pressure rose to 206/120. The note stated there were problems getting good electrocardiogram and pulse oximetry readings. The note stated Patient #22 remained unresponsive and required a narcotic reversal agent in order to breathe on her own. The progress note stated Patient #22 "Otherwise then recovered uneventfully with normal respirations. Was discharged awake and oriented X3." A corresponding "Nursing Procedure Report," dated 6/16/14, stated at 2:25 PM Patient #22's pulse was 95, her oxygen saturation level was 96% and she was discharged. The "RECOVERY AREA NOTE" by the physician, dated 6/16/14, stated the physician responded to Patient #22 at at 1:30 PM. No documentation	Q 266		

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Q 266	Continued From page 34 was present that the physician saw Patient #22 after 1:30 PM, which was 55 minutes before discharge and no discharge order was documented. The Nurse Administrator was interviewed on 8/19/14 beginning at 4:45 PM. She confirmed the lack of a discharge order for Patient #22. The facility failed to ensure a discharge order was completed for Patient #22.	Q 266		
Q 267	416.52(c)(3) DISCHARGE WITH RESPONSIBLE ADULT [The ASC must -] Ensure all patients are discharged in the company of a responsible adult except those patients exempted by the attending physician. This STANDARD is not met as evidenced by: Based on observation, staff interview, and review of records and policies, it was determined the ASC failed to ensure patients were discharged post-procedure in the company of responsible adults for 1 of 1 patients (#21) observed to be discharged. This resulted in an increased potential for patients to suffer adverse events following their procedures. Findings include: 1. A Patient Discharge Criteria policy dated 3/29/04, unsigned, stated, "patients are accompanied at discharge by a designated person who is responsible for the patient." However, the policy was not observed to be implemented as follows:	Q 267	See attached	

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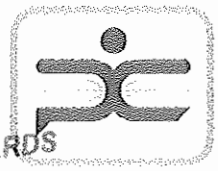
Q 267	Continued From page 35 Patient #21's medical record documented a 62 year old male who had cervical steroid injections with fluoroscopic assistance on 8/18/14. Patient #21's discharge was observed on 8/18/14. After Patient #21 was released from the recovery area, he was escorted only to the doorway of the recovery area. He then went to the front desk area to check out, left the ASC, and was observed by the surveyor to enter the passenger side of a vehicle. However, facility staff were not present and did not observe Patient #21 once he left the facility's front desk. During an interview on 8/18/14 at 3:45 PM, the Nurse Administrator stated, when patients have met discharge criteria, recovery staff would escort the patient out of the ASC, with a responsible adult. The ASC's practices were not sufficient to ensure patients were discharged in the accompaniment of a responsible adult. Additionally, the facility's policy did not include information related to discharge criteria for exempting patients from the requirement. During an interview on 8/18/14 at 3:15 PM, the Nurse Administrator confirmed the policy of the ASC to discharge patients in the care of a responsible adult and confirmed staff should discharge patients to a responsible adult. The ASC failed to ensure all patients were discharged in the company of a responsible adult or that a policy was established with criteria for exempting patients from the requirement.	Q 267		



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Credible Allegation of Compliance

Medicare ASC Condition for Coverage
Q040 GOVERNING BODY AND MANAGEMENT

Deficiency – 416.41

The ASC's governing body failed to assume responsibility for determining, implementing and monitoring policies and failed to oversee the ASC's QAPI program.

- **Corrective Action that was or will be taken to correct the deficiency:** The ASC's Infection Control and Quality Management and Improvement policies that were in place were lengthy and redundant. These have been condensed and re-written.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Having clear and relevant policies in place will allow for better implementation and oversight. Proper documentation of this program and its studies will be assured through the increased involvement of the Medical Director and Governing Body. Having an ongoing data driven QAPI program will improve patient health outcomes and patient safety in the ASC.
- **Plan:** The QAPI program was reviewed, rewritten and approved at Governing Body meeting on 9/13/14. The Nurse Administrator has researched QAPI and consulted with other ASCs and has a much better understanding of QAPI requirements and activities as well as documentation requirements. Staffing resources have been modified so that each week the Nurse Administrator has a block of time in her weekly schedule to devote to the QAPI program.
- **Monitoring/Tracking:** The Nurse Administrator is responsible for the QAPI program and will report on all QAPI activities to the Medical Director quarterly at the Governing Body meetings.
- **Please refer to Q080 Credible Allegation and Q240 and Q242 Plans of Correction.**

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Credible Allegation of Compliance

Medicare ASC Condition for Coverage
Q080 QUALITY ASSESSMENT AND PERFORMANCE
Deficiency – 416.43 – Quality Assessment and Performance
The ASC failed to ensure a quality program was developed, implemented and maintained.
Please refer to Q040 Credible Allegation of Compliance and Q081, Q082, Q083 and Q084 Plans of Correction.

Plan of Correction

Q081 PROGRAM SCOPE
Deficiency – 416.43(a), 416.43(c)(1)
The ASC failed to ensure its quality program was defined and failed to ensure direction was provided to staff responsible for the program.

- **Correction:** The facility's Policy and Procedure manual had a description of the program and its Objectives (Section V, pg. 2), which did include review of adverse events (Section V pg. 14, under d. Procedure, item vi.) A separate section previously titled "The QMI Program" (Section V pgs. 14-20) had, for previous surveying purposes, historically been considered by other agencies to fulfill the role of the "plan." The "Quality Management/Improvement Program" was reviewed annually (by previous administrators) as documented in Governing Body meeting minutes.
  The ASC does monitor and track adverse patient events and has records of this. This tracking was discussed with the survey team as it was an electronic file located on the z: drive. The Nurse Administrator failed to print and present a copy to the survey team.
- **Additional Action that was taken to correct the deficiency:** To better define the program and its objectives and to prevent further lack of direction, the policy has been re-written and titled "QAPI Policy." This project was completed on 9/11/2014, reviewed and approved by the Governing Body on 9/13/2014. A copy of the policy will be provided to all employees on 9/19/2014 and the entire policy as well as it current activities will be thoroughly reviewed with all staff members at the staff in-service day on 9/26/14.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Having a separate, concise, defined and relevant QAPI Policy will not only make implementation and oversight of the plan much more effective for anyone in the role of Nurse Administrator, it will also help us in our continuous efforts to improve, promote and measure the quality of care and safety for our patients and staff.

- **Plan:** The Nurse Administrator is responsible for the QAPI program and will devote time on Thursday afternoons to ensure that the implementation and direction of the QAPI program continues.
- **Monitoring/Tracking:** The Nurse Administrator will report QAPI quarterly to the Medical Director at the Governing Body Meetings. The QAPI program will be reviewed and updated annually each October.

Q082 PROGRAM DATA; PROGRAM ACTIVITIES

Deficiency – 416.43(b), 416.43(c)(2), 416.43(c)(3)

The ASC failed to ensure quality indicator data was collected and analyzed to improve its processes and patient care.

- **Corrective Action that was or will be taken to correct deficiency:** The new QAPI policy includes all of the data components, quality indicators and tracking activities that take place at the facility. New quality studies have been initiated and prior quality activities have been better documented.
  The Governing Body met on 8/21/14 and fully reviewed, investigated, and documented the incident. It was determined that our emergency policies were followed and the procedures were adequate. The changes that we made after the incident (but failed to document the reason for) were simply to improve the speed of equipment delivery to the provider and patient in an emergent situation. The speed of delivery was adequate, but we simply identified a way to further improve upon it.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Better investigation and tracking of all adverse events and incorporating data into quality studies will decrease the likelihood of repeat occurrences thereby increasing quality of care promoting safety in our ASC.
- **Plan:** The Incident Reports log book (which now also contains a printed copy of the adverse events log) will be present at every Governing Body meeting to ensure that this lack of a full investigation of an incident will not happen again.
- **Monitoring/Tracking:** The Nurse Administrator is responsible and the Governing Body will monitor and track all adverse events at each monthly meeting. The data collected is also integrated into the QAPI program which is reviewed quarterly and updated annually.

Q083 PERFORMANCE IMPROVEMENT PROJECTS

Deficiency – 416.43(d)

The ASC failed to ensure distinct quality improvement projects were conducted.

- **Action that was or will be taken to correct deficiency:** The Governing Body met on 8/21/14 and reviewed its list of "Proposed Quality Improvement Studies" and reconfirmed its current study of "Hand Hygiene" as its 2014-15 Performance Improvement Project. This project had been underway since being implemented in March by a previous Nurse Administrator. The current Nurse Administrator had been collecting data, as well as implementing changes, however the study had not been updated or documented to show results, and therefore the study had not been maintained and evaluated.

- **Description of how the actions will improve the processes that led to the deficiency being cited:** Keeping our quality studies and performance improvement projects updated and more clearly defined will improve the process upon which we make the changes that allow us to provide high quality driven healthcare in a safe environment for all our patients.
- **Plan:** The Nurse Administrator is responsible and will devote more time to implementation and oversight of the QAPI program.
- **Monitoring/Tracking:** The Governing Body will be updated quarterly as to the status and results of the current studies. The list of proposed studies will be reviewed and updated annually each October at the same time of QAPI policy review. Studies will be chosen as performance improvement projects at that time.

Q084 GOVERNING BODY RESPONSIBILITIES

Deficiency – 416.43(e)

The ASC's Governing Body failed to ensure the QAPI program was defined, implemented and maintained.

- **Action that was or will be taken to correct deficiency:** The facilities original QMI program was rewritten, titled "QAPI Policy," on 09/11/2014, reviewed and approved by the Governing Body on 09/13/2014.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Having a clearly defined QAPI program will make it easier for the Nurse Administrator to implement and maintain the program projects and studies so they can be easily maintained and evaluated for effectiveness.
- **Plan:** The Nurse Administrator is responsible for oversight of the QAPI program, its direction, evaluation, analysis, implementation and documentation. A block of time in her weekly schedule will now allow for this.
- **Monitoring/Tracking:** The Nurse Administrator will document all quality activities as they relate to the QAPI program in the entire organization and will report quarterly to the Governing Body.

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Plan of Correction

Medicare ASC Condition for Coverage
Q162 FORM AND CONTENT OF RECORD

Deficiency – 416.47(b)

The ASC failed to ensure medical records were complete and accurate.

- **Corrective Action that was or will be taken to correct the deficiency:** The visit summary of the medical record is completed solely by the physician with the exception of the pre-surgical checklist, which is completed by the nurses. A new form has been created that has a line immediately beneath the checklist where nurses initial, date and time upon completion. The section of this checklist that indicates when the most recent updated health history and PE were done now includes checkboxes to indicate which provider performed them.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Proper documentation of which provider completed the updated Health History and PE, and the signing off by the nurses will eliminate any confusion as to who authored any sections of the chart.
- **Plan:** The Nurse Administrator is responsible and the staff was educated on the new form and its documentation requirements at a staff meeting on 9/12/14. The form was put into use on 9/15/2014.
- **Monitoring/Tracking:** The Nurse Manager and the Nurse Administrator will continue to monitor proper documentation in all areas of the patient record each day during "Encounters." Any failure to complete the check boxes or sign off properly will be referred to the Nurse Administrator and she will follow up with staff members individually.

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Plan of Correction

Medicare ASC Condition for Coverage
Q181 ADMINISTRATION OF DRUGS

Deficiency – 416.48(a)

The facility failed to ensure medications were labeled in accordance with acceptable standards of practice.

- **Action that was or will be taken to correct deficiency:** New labels have been created and are in use that include the full name and dosage information of the medications so the nurses have no need to write this information on the labels.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** The labels include the full name and dosage of the medications, and blanks for amount, initials, date, and time. This will eliminate the potential for any use of abbreviations that could lead to confusion and/or medication errors.
- **Plan:** The Nurse Administrator is responsible and the staff were educated on the requirement of all 5 labeling agents at a staff meeting held on 8/22/14. The new labels were put into use the next day the ASC was open, 8/25/14. Laminated visual reminders titled "**5** Required Elements of Medication Labeling" were created, and are posted above all medication carts.
- **Monitoring/Tracking:** The Medical Director, a practicing physician at the ASC, will be monitoring compliance by ensuring that any syringe he is given for use is appropriately labeled. He will report any non-compliance to the Nurse Administrator who would then address the issue directly with the staff member involved.

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Plan of Correction

Medicare ASC Condition for Coverage
Q229 EXERCISE OF RIGHTS – INFORMED CONSENT

Deficiency – 416.50(e)(1)(iii)

The ASC failed to ensure that patients were fully informed about procedures and the expected outcomes before it was performed for 1 of 23 patients whose records were reviewed.

- **Corrective Action:** Patient #9's consent form was missing the required signatures at the bottom, however the patient had initialed her consent at the top of the form. After investigation we believe that this was due to the fact that the consent form was printed incorrectly. It indicated consent for bilateral facet injections, however the procedure the patient was scheduled for that day was bilateral nerve root injections. The patient initialed at the top of the consent form, indicating that she was informed and agreed with the change to the form, however the staff person checking the patient in chose not to have the patient sign the incorrect consent form. This was an error of judgment, as she should have either a.) printed a new correct consent form for the patient to sign or b.) had the patient sign the bottom AND initial the top indicating where a change was made to the form. The Nurse Administrator talked to the staff members individually and they agreed that they had made an error and that they would always ensure the consent form is signed correctly.
- **Action that was already in place to prevent this deficiency:** Upon check-in, every patient is required to review and sign the consent form at the front desk before the document is scanned into the EMR. The signed consent is then placed in a tray as this process is used by staff to indicate that there is a patient ready to room.

  When rooming a patient, the consent form is then referred to several times in the procedure room both by the nurses and the MD. During the surgical safety checklist, the procedure is read back to the patient from the form and at this time the consent form is checked for accuracy against the original provider order. The Nursing Procedure report is printed *on the back of* the consent form and it is also required during the rooming phase, for documentation of vital signs, again ensuring the consent form is in the room at each visit.

  At the end of each surgery center day all RNs and MAs are required to complete chart checks, using our "Daily Charting" list as a guide, prior to going home. The chart checks include assuring that the consent forms are scanned and assigned correctly in the patient's electronic health record. Then, an RN or Nurse Administrator does "Encounters," or a final check of the charts before they are finalized, which also includes making sure all scanned documents are accounted

for. This practice (chart checks and encounters) has been in place since our staff meeting on 7/2/14. Therefore, we suspect this case to be an isolated incident.

- **Description of how the actions will improve the processes that led to the deficiency being cited:** The process above assures that all patients are given all the information needed to make an informed decision about whether to proceed with a procedure in the ASC.
- **Plan:** The Nurse Administrator is responsible and the staff were informed at the staff meeting on 8/22/14 of the importance of informed consent and maintaining accurate documentation and *always* verifying the signature lines are filled out prior to rooming the patient. "Daily Charting" lists were reprinted and distributed to staff, with consent information in bold, red capitals.
- **Monitoring/Tracking:** On 9/6/14 the Nurse Administrator performed an audit of 25 charts (from DOS 8/1/14 forward) and found 100% compliance. The Nurse Manager will perform quarterly audits of 25 charts over the next year to ensure future compliance, and any non-compliance will be reported to the Nurse Administrator who will follow up with the staff member involved.

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Credible Allegation of Compliance

Medicare ASC Condition for Coverage
Q240 INFECTION CONTROL

Deficiency – 416.51 – Infection Control
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.
Please refer to Q241, Q242, Q243 and Q244 Plans of Correction.

Plan of Correction

Q241 SANITARY ENVIRONMENT

Deficiency – 416.51(a)
The ASC failed to ensure the housekeeping contract was sufficiently monitored necessary to maintain a sanitary environment.

- **Action that was or will be taken to correct deficiency:** The contract with the cleaning company was terminated on 8/25/2014. The new cleaning contractor started providing services on 8/28/14.

  The tape rolls were immediately removed and all staff were informed of the inappropriate use of tape rolls to hold open trash receptacles at the staff meeting on 8/22/14.

  The medical recliners were professionally steam cleaned on 9/10/2014, and will be cleaned in this manner biannually at the same time as the privacy curtains and lead aprons (January and June). They will continue to be wiped down with a Sani-cloth between each patient are now sprayed with bleach solution according to the manufacturer specifications with each terminal cleaning.

  The new cleaning company brings clean mop heads and rags each evening and takes the soiled ones out of the facility after each terminal cleaning.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** The actions above will help to ensure a sanitary environment for all patients receiving care at the facility thereby decreasing potential for infections, working toward our goal of keeping our 10+ year infection rate at zero.
- **Plan:** The Nurse Administrator is responsible and she instituted a new terminal cleaning checklist and inspection form on 9/8/2014. The cleaning contractor signs the cleaning checklist each day that the facility is terminally cleaned. This checklist is located in a log book in the clean storage area.
- **Monitoring/Tracking:** The Nurse Administrator is performing a "white wipe" (in lieu of white glove) inspection prior to the ASC being used each day being in direct contact with the cleaning supervisor regarding any issues or concerns she may have. After 30 days of maintaining performance to our standards, a staff nurse assigned to the ASC each day will assume responsibility for the inspection. Nurse Administrator will then perform quarterly random inspections.

Q242 INFECTION CONTROL PROGRAM

Deficiency – 416.51(b)

The ASC failed to ensure an ongoing infection control program was maintained for staff and all patients receiving care at the facility.

- **Action that was or will be taken to correct deficiency:** The ASC's Infection Control Policies, located in Section V, pages 34-55 and the CDC/HICPAC, AORN national guidelines were thoroughly reviewed by the Governing Body. It decided to maintain the use of these same standards, but to re-write the Policy and Procedure manual's section on Infection Control to integrate all of the component parts (the policy, processes and activities) that are clearly relevant and pertinent to our practice. The new program was completed on 9/9/2014, reviewed and approved by the Governing Body on 9/13/2014.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Having a customized, concise and relevant infection control policy will better allow for implementation and surveillance and thereby reducing the risk of infections and helping us maintain a sanitary environment.
- **Plan:** The Nurse Administrator is responsible and will oversee all aspects of the infection control program in the surgery center.
- **Monitoring/Tracking:** The Infection Control Plan will be reviewed and updated at Governing Body meetings annually in October and monitoring and modifications will take place through the QAPI program.

Further Corrective Actions – See Q241 and Q243.

Q243 INFECTION CONTROL PROGRAM – DIRECTION

Deficiency – 416.51(b)(1)

The ASC failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.

- **Action that was or will be taken to correct deficiency:** The Nurse Administrator had done a self-study of materials from APIC's 2 day course, "Infection Prevention for ASCs" which was documented in her file.

  The Nurse Administrator completed a webinar by the Infection Control Education Institute, "Challenges and Solutions for Measuring Hand Hygiene Compliance" on 8/18/2014 and has updated her employee file to reflect this.

  The Nurse Administrator joined AORN and registered for their one year course "Ambulatory Infection Prevention" on 9/7/2014. Successful completion of this course before July 2015 is eligible for 6.8 CEUs.

  Additionally, the job description of the Nurse Administrator which previously read "Minimum 1 hour CEU in Infection Control annually" has been updated and approved by the Governing Body to read "Minimum of 4 hours" (or 1 CEU hour quarterly).
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Having a qualified professional trained in the principles and methods of infection control will allow the ASC to better develop and monitor its infection control program.

- **Plan:** The Nurse Administrator will continue to report educational opportunities of infection control webinars and/or courses as well as local and national meetings to the Medical Director for approval.
- **Monitoring/Tracking:** The Medical Director is responsible for allowing time and resources for CEUs in Infection Control. The Nurse Administrator's employee evaluation will evaluate her infection control education and takes place annually, each October.

Q244 INFECTION CONTROL PROGRAM – QAPI

Deficiency – 416.51(b)(2)

The ASC failed to ensure the infection control program was incorporated into the facility QAPI program.

- **Action that was or will be taken to correct deficiency:** Both the Policies and Procedure sections on Infection Control and Quality Program have been re-written and the Infection Control Program is now fully incorporated into the QAPI program.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Having the Infection Control Program incorporated with the QAPI program will help to ensure that the activities result in specific actions to improve infection control in the facility.
- **Plan:** One of the Performance Improvement Studies that was chosen by a previous administrator for 2014 was Hand Hygiene. This study had been initiated in March and has since been adopted, updated and will be maintained by the current Nurse Administrator. The Nurse Administrator also is initiating a quality study involving the sanitary environment and ensuring that the cleaning contractor is performing to our standards.
- **Monitoring/Tracking:** The Nurse Administrator is responsible for the activities of both the QAPI program and the Infection Control Program. She will report to the Medical Director quarterly at the monthly Governing Body meetings.

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Plan of Correction

Medicare ASC Condition for Coverage
Q266 DISCHARGE - ORDER

Deficiency – 416.52(c)(2)
The ASC failed to ensure discharge orders were present for 1 of 23 patients whose records were reviewed.

- **Action that was or will be taken to correct deficiency:** A signature line for discharge by the MD was added to the bottom of the Nursing Procedure report and the physician is signing off on all patients leaving the ASC.
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Physically signing off on each patient in the recovery room will decrease the potential for patients to experience complications following discharge.
- **Plan:** The form was put into use on 8/25/14 after approval by the Governing Body on 8/21/14, and updating the nursing staff at the employee meeting on 8/22/14. The nurse in the recovery room ensures that the physician signs the NP report prior to discharging any patients.
- **Monitoring/Tracking:** The RN or nurse administrator who performs the "Encounters" checklist at the end of the day will monitor compliance. If any forms are missing the signature of the MD, the RN will report to the Nurse Administrator who is responsible and will follow up with the Medical Director.

Q267 DISCHARGE WITH RESPONSIBLE ADULT

Deficiency – 416.52(c)(3)
The ASC failed to ensure patients were discharged post-procedure in the company of responsible adults to 1 of 1 patients observed to be discharged.

- **Action that was or will be taken to correct deficiency:** All staff have been notified that as they walk a patient out to the waiting area, if for any reason their driver is not immediately available, the patient will be taken back to the recovery area until said person arrives. A line was also added to the Nursing Procedure report that says "Patient discharged to the care of_____."
- **Description of how the actions will improve the processes that led to the deficiency being cited:** Specifying with whom is responsible for the care of the patient upon discharge and making sure the patient leaves with the designated adult will decrease the potential for patients to suffer adverse events following their procedures.
- **Plan:** The Nurse Administrator is responsible and she put the form into use on 8/25/14 after approval by the Governing Body on 8/21/14, and updating the nursing staff at the employee meeting on 8/22/14.

- **Monitoring/Tracking:** The Medical Director and the Nurse Administrator will use the "secret shopper" method of observation to monitor compliance with walking the patient out to the care of the responsible adult. The RN performing "Encounters" checklist at the end of the day will also monitor charting compliance. If any forms are missing the name of the responsible adult to whom the nursing staff discharged the patient, the RN will report to the Nurse Administrator who will follow up directly with the staff who discharged the patient.

PAIN CARE

William G. Binegar, M.D.
Board Certified Pain Medicine
Board Certified Anesthesiology

301 West Myrtle St. Boise, Idaho 83702
Ph: 208.342.8200 Fax: 208.342.8202
www.paincareboise.com

September 22, 2014

Gary Guiles, RN
PO Box 83720
Boise, ID 83720-0009

RE: Pain Care Center Boise, Provider #13C0001049

Dear Mr. Guiles,

As requested, the following is a listing of our dates of compliance on each of the deficiencies cited.

Q040: 9/19/2014

Q080: 9/19/2014
Q081: 9/19/2014
Q082: 8/21/2014
Q083: 8/21/2014
Q084: 9/13/2014

Q162: 9/15/2014
Q181: 8/25/2014
Q229: 8/22/2014

Q240: 9/13/2014
Q241: 8/28/2014
Q242: 9/13/2014
Q243: 9/13/2014
Q244: 9/13/2014

Q266: 8/25/2014
Q267: 8/25/2014

Please let me know if you need anything else.

Sincerely,

Wendy Binegar, RN
Nurse Administrator, Pain Care Boise