



COPY

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: 70121010000208361352

March 12, 2013

Nancy McHugh, Administrator
Vision Care Center Of Idaho
3071 East Franklin Road, Suite 101
Meridian, ID 83642

RE: Vision Care Center Of Idaho, Provider #13C0001034

Dear Ms. McHugh:

Based on the survey completed at Vision Care Center Of Idaho, on February 26, 2013, by our staff, we have determined Vision Care Center Of Idaho is out of compliance with the Medicare ASC Conditions for Coverage of **Governing Body and Management (42 CFR 416.41)**, **Surgical Services (42 CFR 416.42)**, **Quality Assessment and Performance Improvement (42 CFR 416.43)**, **Medical Records (42 CFR 416.47)**, **Patient Rights (42 CFR 416.50)**, **Infection Control (42 CFR 416.51)** and **Patient Admission, Assessment and Discharge (42 CFR 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 this condition to be unmet, substantially limit the capacity of Vision Care Center Of Idaho, 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;

Nancy McHugh, Administrator
March 12, 2013
Page 2 of 2

- 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 April 12, 2013. 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 April 3, 2013.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **March 25, 2013.**

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,



REBECCA LARA
Health Facility Surveyor
Non-Long Term Care

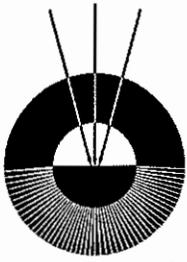


NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

RL/nw

Enclosures

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



VisionCare
CENTER OF IDAHO

3071 E. Franklin Rd. Ste. 101 Meridian, Idaho 83642 Ph: 208.288.1400

March 21, 2013

Rebecca Lara
Health Facility Surveyor
Idaho Department of Health and Welfare
3232 Elder St.
P.O. Box 83720
Boise, Idaho 83720-0009
FAX:208-364-1888

RECEIVED
MAR 25 2013

FACILITY STANDARDS

Dear Ms. Lara

Enclosed please find the completed and signed form CMS-2567 for Vision Care Center of Idaho. Thank you for affording us the opportunity to reply to and correct the deficiencies found on your inspection of February 26, 2013. If you have any further questions please do not hesitate to contact me.

Sincerely,

Jorge A. Martinez, M.D.
Medical Director

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

PRINTED: 03/11/2013
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001034	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/26/2013
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NAME OF PROVIDER OR SUPPLIER VISION CARE CENTER OF IDAHO	STREET ADDRESS, CITY, STATE, ZIP CODE 3071 EAST FRANKLIN ROAD, SUITE 101 MERIDIAN, ID 83642
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the recertification survey of your Ambulatory Surgical Center. The surveyors conducting the review were:</p> <p>Rebecca Lara RN, BA, HFS, Team Leader Susan Costa RN, HFS Libby Doane RN, BSN, HFS</p> <p>The following acronyms were used in this report:</p> <p>ACLS - Advanced Cardiac Life Support AED - Automatic External Defibrillator AORN - Association Of Perioperative Registered Nurses ASC - Ambulatory Surgical Center CDC - Centers for Disease Control CPR - Cardiopulmonary Resuscitation CRNA - Certified Registered Nurse Anesthetist CST - Certified Surgical Technician DEA - Drug Enforcement Agency EMS - Emergency Medical Service EKG - Electrocardiogram H&P - History and Physical IDAPA - Idaho Administrative Procedures Act IV - Intravenous LPN - Licensed Practical Nurse MAC - Monitored Anesthesia Care mcg - microgram mg - milligram ml - milliliter NS - Normal Saline OA - Ophthalmology Assistant OR - Operating Room PACU - Post Anesthesia Care Unit PIP - Performance Improvement Project QAPI - Quality Assurance Performance</p>	Q 000	<p><i>Pls. see DPOC response attachment DVECI supporting policy attachment</i></p> <p>PROCESSED MAR 13 2013 PRIORITY STANDARDS</p>	
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE <i>Medical Director</i>	(X6) DATE <i>3/21/2013</i>
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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Q 000	Continued From page 1 Improvement RN - Registered Nurse ST - Surgical Technician TB - Tuberculosis USP - United States Pharmacopoeia WNL - Within Normal Limits YAG - Yttrium Aluminum Garnet Laser (a specific type of laser)	Q 000			
Q 040	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan. This CONDITION is not met as evidenced by: Based on observation, staff interview, and review of policies, personnel files and contracts, medical records, and administrative documents, it was determined the ASC failed to ensure the Governing Body assumed responsibility for determining, implementing, and monitoring policies and programs. This failure prevented the ASC from providing the necessary oversight of the ASC's total operation and resulted in a lack of guidance of the facility's staff and programs. Findings include: 1. Policies and procedures had not been	Q 040			

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Q 040	<p>Continued From page 2</p> <p>developed and implemented to ensure staff were qualified and competent to perform their assigned job duties. Personnel files for Staff A - P were reviewed during the survey. Performance evaluation and competency assessment were documented as follows:</p> <ul style="list-style-type: none"> - Staff A, ST/OA, hired 4/17/12 - performance evaluation not yet required, no competency assessments - Staff B, ST/OA, hired 11/08/11 - no performance evaluations or competency assessments - Staff C, ST/OA, hired 8/23/11 - no performance evaluations or competency assessments - Staff D, ST/OA, hired 9/11/01 - performance evaluation on 7/31/07, competency assessment on 7/13/04 - Staff E, RN, hired 11/18/08 - no performance evaluations or competency assessments - Staff F, LPN, hired 10/17/06 - no performance evaluations or competency assessments - Staff G, RN, hired 8/06/02 - performance evaluation on 7/24/07, competency assessment on 7/13/04 - Staff H, CST, hired 7/27/00 - performance evaluation on 7/31/07, competency assessment on 8/03/00 - Staff I, RN/Clinical Director, hired 7/01/00 - performance evaluation on 8/01/07, competency assessment on 8/15/00 	Q 040			

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Q 040	<p>Continued From page 3</p> <ul style="list-style-type: none"> - Staff J, OA, hired 10/28/02 - performance evaluation on 7/31/07, no competency assessments - Staff K, RN, hired 10/04/05 - performance evaluation on 7/31/07, no competency assessments - Staff L, Administrator, hired 2/10/01 - no performance evaluations, competency assessment on 7/18/04 - Staff M, RN, hired 2/05/13 - performance evaluation not yet required, no competency assessments - Staff N, CRNA, initial appointment, 2001 - performance evaluation on 10/12, no competency assessments - Staff O, CRNA, initial appointment, 10/29/03 - no performance evaluations or competency assessments - Staff P, CRNA, initial appointment, 2/11/13 - performance evaluation not yet required, no competency assessments <p>The "TOTAL QUALITY MANAGEMENT PLAN," undated, was reviewed. The section related to infection control stated "The annual evaluation of each employee will include whether or not they exhibit compliance with the safe practice of infection control standards."</p> <p>In addition, the "ADMISSION POLICIES" document, undated, was reviewed. In the section</p>	Q 040			

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Q 040	<p>Continued From page 4</p> <p>titled, "Policy #13 SCOPE OF NURSING PLAN," the policy indicated nursing competencies were assessed and assured through orientation and annual evaluation of staff performance.</p> <p>The "PERSONNEL FILES" policy, undated, was reviewed. According to the policy, "an accurate and complete file" was to be maintained on each employee. The policy stated that the personnel file was to contain evidence of competency at the assigned job. The policy did not indicate how the facility would ensure all employees were competent at their job on an ongoing basis, such as with performance evaluations and competency assessments.</p> <p>The Medical Director and Clinical Director were interviewed together on 2/26/13, beginning at 2:45 PM, related to personnel files. They confirmed annual evaluations had not been completed for each employee in accordance with facility policies. They confirmed competency assessments had not been conducted for each employee specific to the employees' job description.</p> <p>The facility failed to ensure documentation of performance evaluations and competency assessments were completed.</p> <p>2. Policies were not implemented to ensure staff maintained current certifications. Personnel files for Staff A - P were reviewed during the survey. Documentation of current CPR/ACLS certification was not found in the personnel files as follows:</p> <p>- Staff A, ST/OA - no CPR certification</p>	Q 040		

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Q 040	<p>Continued From page 5</p> <ul style="list-style-type: none"> - Staff D, ST/OA - CPR certification expired 12/07 - Staff G, RN - CPR certification expired 12/11 - Staff K, RN - CPR certification expired 9/12 - Staff M, RN - no CPR certification - Staff O, CRNA - CPR certification expired 11/12, ACLS certification expired 10/12 - Staff P, CRNA - CPR certification expired 9/12, ACLS certification expired 10/12 <p>The "PERSONNEL FILES" policy, undated, stated "an accurate and complete file" was to be maintained on each employee. The policy stated the personnel file was to contain evidence of current CPR training for all employees.</p> <p>The "ANESTHESIA CARE PROVIDER" job description, undated, was reviewed. According to the job description, CRNAs must maintain "certification in ACLS."</p> <p>The Medical Director and Clinical Director were interviewed together on 2/26/13, beginning at 2:45 PM, related to personnel files. They confirmed all patient care staff were required to maintain CPR certification. Additionally, they confirmed CRNAs were required to maintain ACLS certification.</p> <p>The facility failed to ensure staff maintained current CPR and ACLS certifications.</p> <p>3. Refer to Q041 as it relates to the Governing Body's failure to ensure contract services were</p>	Q 040		

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Q 040	<p>Continued From page 6</p> <p>provided with sufficient monitoring and oversight necessary to ensure staff was competent to perform their assigned duties.</p> <p>4. Refer to Q043 as it relates to the Governing Body's failure to ensure the facility had an effective preparedness plan to include an annually conducted disaster drill.</p> <p>5. Refer to Q060 as it relates to the Governing Body's failure to ensure acceptable systems and practices for oversight of contracted anesthesia staff, a comprehensive QAPI program, an accurate and complete medical record, oversight of medication preparation and administration, a sufficiently developed, implemented and monitored infection control program and required pre-surgical assessments and H&Ps, were implemented to ensure procedures were performed in a safe manner.</p> <p>6. Refer to Q080 Condition for Coverage: Quality Assessment and Performance Improvement and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive, data driven QAPI program was fully developed, implemented and monitored.</p> <p>7. Refer to Q160 Condition for Coverage: Medical Records and associated standard level deficiencies as they related to the Governing Body's failure to ensure a complete, comprehensive, and accurate medical records system had been developed and implemented.</p> <p>8. Refer to Q181 as it relates to the Governing Body's failure to ensure medications were</p>	Q 040			

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Q 040	Continued From page 7 administered, prepared, labeled and stored in accordance with acceptable standards of practice. 9. Refer to Q220 Condition for Coverage: Patient Rights and associated standard level deficiencies as they related to the Governing Body's failure to ensure the ASC informed patients or representatives of their rights and promoted the exercise of such rights. 10. Refer to Q240 Condition for Coverage: Infection Control and associated standard level deficiencies as they related to the Governing Body's failure to ensure the facility maintained a comprehensive infection control program. 11. Refer to Q260 Condition for Coverage: Patient Admission, Assessment and Discharge and associated standard level deficiencies as they related to the Governing Body's failure to ensure appropriate assessments were completed before procedures and comprehensive H&Ps were placed in patients' medical records.	Q 040			
Q 041	416.41(a) CONTRACT SERVICES When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. This STANDARD is not met as evidenced by: Based on contract review, record review and staff interview, it was determined the ASC failed to provide oversight and monitoring for 3 of 3 contracted employees (CRNA Staff N - P). This lack of oversight of contract services resulted in	Q 041			

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Q 041	<p>Continued From page 8</p> <p>the inability of the ASC to ensure staff was competent to perform their assigned duties and had the potential to negatively impact all patients receiving care at the facility. Findings include:</p> <p>1. Credentialing and personnel files were reviewed during the survey. There was no evidence of DEA registration present in the files for CRNAs Staff N and Staff O.</p> <p>In a letter dated 5/25/11, the Executive Director of the Idaho State Board of Pharmacy referred to Idaho Code Section 37-2716 (a) Registration Requirements, which states: "Every person who manufactures, distributes, or dispenses any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, must obtain annually a registration issued by the board in accordance with its rules." The letter stated the definition of "dispense" included prescribing and administering according to Idaho Code 37-2701(i). For exemption to the registration requirement, the letter referred to Idaho Code 37-2716, which states: "The following persons need not register and may lawfully possess controlled substances under this act: An agent or employee of any registered manufacturer, distributor, or dispenser, of any controlled substance if he is acting in the usual course of his business or employment." The letter further stated that the Idaho Board of Pharmacy Rule 435 (IDAPA 27.01.01.435) required an applicant for a board of pharmacy controlled substance registration to hold a valid federal DEA registration.</p> <p>In a letter dated 3/22/11, a representative of the</p>	Q 041			

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Q 041	Continued From page 9 DEA to the Idaho State Board of Pharmacy clearly stated that a CRNA could not independently administer, dispense, or prescribe controlled substances without being registered with the DEA. Documentation in records indicated CRNA Staff N administered Versed (midazolam), a Schedule IV substance, and Fentanyl, a Schedule II substance, to Patients #1 - #10, Patients #12 - #14 and Patients # 16 - #23. Documentation in records indicated CRNA Staff O administered Versed and Fentanyl to Patient #17. Beginning at approximately 2:30 PM on 2/26/13, the Medical Director was interviewed. He confirmed CRNA Staff N did not retain DEA registration, and DEA registration for Staff O was not current in the personnel records. The ASC did not ensure DEA registration for CRNA staff. 2. Facility contracts were reviewed during the survey. Contracts were not found for CRNA Staff N, Staff O or Staff P. The Medical Director was interviewed on 2/26/13, beginning at 2:30 PM. He confirmed there were no contracts in existence between the facility and contracted CRNA Staff N, Staff O or Staff P at the time of the survey. The ASC did not ensure contracts were implemented for all CRNAs.	Q 041		
Q 043	416.41(c) DISASTER PREPAREDNESS PLAN (1) The ASC must maintain a written disaster	Q 043		

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Q 043	<p>Continued From page 10</p> <p>preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.</p> <p>(2) The ASC coordinates the plan with State and local authorities, as appropriate.</p> <p>(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the Governing Body failed to ensure that the facility had an effective preparedness plan to include an annually conducted disaster drill. This deficiency resulted in the potential for the facility's inability to effectively manage the care and health and safety of patients and other individuals when a major disruptive event may occurred. Findings include:</p> <p>The facility's disaster plan was reviewed on 2/21/13 at 10:00 AM. The plan did not include a documented hazard vulnerability analysis, hazard response activities during and after a disaster to address the immediate and short-term effects of an emergency, or activities to be undertaken for disaster recovery to return the ASC to its usual state.</p> <p>Further, there was documentation of an disaster plan of an annual disaster drill conducted with</p>	Q 043		

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Q 043	Continued From page 11 coordination or attempted coordination with local and state authorities within the previous twelve month period. When questioned about the facility's lack of a documented annual disaster drill the Administrator stated, 2/21/13 at approximately 10:45 AM, that the disaster plan and an annual disaster drill was not her responsibility and that a different staff member was responsible for ensuring that they had an effective plan and that an annual disaster drill was conducted.	Q 043		
Q 060	The facility failed to implement an effective preparedness plan to include an annually conducted disaster drill. 416.42 SURGICAL SERVICES Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC This CONDITION is not met as evidenced by: Based on observation, review of policies and acceptable standards of practice, staff interview, and review of medical records, it was determined the facility failed to ensure acceptable systems and practices for oversight of contracted anesthesia staff, a comprehensive QAPI program, an accurate and complete medical record, oversight of medication preparation and administration, a sufficiently developed, implemented and monitored infection control program and required pre-surgical assessments and H&Ps, were implemented to ensure	Q 060		

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Q 060	<p>Continued From page 12</p> <p>procedures were performed in a safe manner. These systemic failures directly impacted 3 of 3 patients (Patients #14, #21 and #22) whose procedures was observed, and had the potential to impact all patients receiving care at the facility. This resulted in patients being placed at risk as a result of unsafe practices. Findings include:</p> <p>1. Refer to Q040 Condition for Coverage: Governing Body and related standard level deficiencies as they relate to the ASC's systemic failures as follows:</p> <ul style="list-style-type: none"> - The ASC failed to ensure contract services (CRNA Staff N - P) were provided with sufficient monitoring and oversight necessary to ensure staff was competent to perform their assigned duties. <p>2. Refer to Q080 Condition for Coverage: Quality Assessment and Performance Improvement and associated standard level deficiencies as they relate to the ASC's systemic failures as follows:</p> <ul style="list-style-type: none"> - The ASC failed to ensure the development of a comprehensive quality improvement plan that promoted patient safety and improved patient outcomes. - The ASC failed to ensure quality indicator data was collected and used to monitor the effectiveness and safety of its services. - The ASC failed to ensure annual PIPs were conducted that adequately reflected and evaluated the complex scope of surgical services in the ASC. 	Q 060		

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Q 060	<p>Continued From page 13</p> <p>3. Refer to Q160 Condition for Coverage: Medical Records and associated standard level deficiencies as they relate to the ASC's system failures as follows:</p> <ul style="list-style-type: none"> - The ASC failed to ensure medical records were complete and accurate which resulted in untimed physician orders and consents, lack of documentation related to allergies, and inaccurate documentation of events while being cared for at the facility. <p>4. Refer to Q181 as it relates to the ASC's failure to ensure medications were administered, prepared, labeled and stored in accordance with acceptable standards of practice, which resulted in potential for adverse drug reactions and medication errors.</p> <p>5. Refer to Q240 Condition for Coverage: Infection Control and associated standard level deficiencies as they relate to the ASC's systemic failures as follows:</p> <ul style="list-style-type: none"> - The ASC failed to ensure it provided a sanitary environment for patient care. - The ASC failed to ensure there was documentation of consideration, selection, and implementation of nationally recognized infection control guidelines used to maintain an ongoing program to prevent and control the risk of infections. - The ASC failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control. 	Q 060			

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Q 060	Continued From page 14 - The ASC failed to ensure infection control was integrated in to the QAPI program. - The ASC failed to provide a plan of action to prevent, identify, and manage infections. 6. Refer to Q260 Condition for Coverage: Patient Admission, Assessment and Discharge and associated standard level deficiencies as they related to the ASC's systemic failures as follows: - The ASC failed to ensure patients received a pre-surgical assessment, which had the potential to impact patient safety during and after the procedure. - The ASC failed to ensure an identifiable H&P, completed within 30 days of the surgery, was included in the medical records, which had the potential to compromise patient safety. The cumulative effect of these deficient practices resulted in the ASC's inability to ensure patients' procedures were performed in a safe manner, necessary to ensure patient rights were protected and surgical risks, before during and after procedures were minimized.	Q 060		
Q 080	416.43 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by:	Q 080		

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Q 080	Continued From page 15 Based on staff interview and review of ASC policies and QAPI documents, it was determined the facility failed to ensure a comprehensive QAPI program had been developed and implemented. This resulted in the inability of the ASC to adequately 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 allow them to demonstrate measurable improvement in patient health outcomes by using quality indicators. 2. Refer to Q082 as it relates to the failure of the ASC to ensure quality indicator data was collected and used to monitor the effectiveness and safety of its services. 3. Refer to Q083 as it relates to the failure of the ASC to ensure performance improvement projects were developed and conducted. 4. Refer to Q084 as it relates to the failure of the ASC to ensure the Governing Body defined, implemented and maintained a QAPI program that gathered and collected data in order to evaluate processes of care. The lack of a comprehensive QAPI program impeded the ASC's ability to adequately monitor programs and services, while constantly striving to improve patient care.	Q 080			
Q 081	416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES (a)(1) The program must include, but not be	Q 081			

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Q 081	<p>Continued From page 16</p> <p>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.</p> <p>(a)(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.</p> <p>(c)(1) The ASC must set priorities for its performance improvement activities that -</p> <ul style="list-style-type: none"> (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. <p>This STANDARD is not met as evidenced by: Based on staff interview, review of facility policies, QAPI documents and meeting minutes, it was determined the facility failed to ensure the development of a comprehensive quality improvement plan which included performance measures that promoted patient safety and improved patient outcomes. This prevented the ASC from effectively evaluating delivery of patient care and had the potential to impact all patients receiving care at the facility. Findings include:</p> <p>1. The "TOTAL QUALITY MANAGEMENT</p>	Q 081			

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Q 081	<p>Continued From page 17</p> <p>PLAN," undated, was reviewed. The policy indicated that the quality management program would assure the "facility's full range of practice and service" was reviewed to identify the important aspects and that "important aspects of care and service that affect large numbers of patient are of high benefit or high risk for individual patients and/or are suspected of producing problems for patients or employees are identified." The policy also stated that "indicators and realistic thresholds" would be established and that results would be evaluated and appropriate action taken.</p> <p>All supporting documentation related to the facility's QAPI program was requested during the survey. The "QUARTERLY GOVERNING BODY/MEDICAL ADVISORY COMMITTEE MEETING" minutes for the first, second and third quarters of 2012 were provided and reviewed. A "QUALITY ASSURANCE: TOOL #1" was found in the minutes for each quarter. The document included information related to the legibility and completeness of the medical record.</p> <p>The Clinical Director was interviewed on 2/19/13, beginning at 10:00 AM. She indicated the "QUARTERLY GOVERNING BODY/MEDICAL ADVISORY COMMITTEE MEETING" minutes contained the only documentation related to QAPI. The Clinical Director was unable to identify current quality indicators/performance measures. She indicated the ASC was not tracking specific data that would address high risk, high volume and problem-prone areas in the facility.</p> <p>On 2/19/13, beginning at 12:45 PM, the Clinical Director explained the form was a chart audit</p>	Q 081			

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Q 081	Continued From page 18 document for ensuring charts were legible and complete. She indicated random audits were performed quarterly. There was no evidence indicating the ASC was identifying and tracking high risk, high volume and problem-prone areas in order to prioritize a quality plan. The facility did not adequately identify methods that could have been used to improve processes and patient care. The ASC failed to ensure a comprehensive quality improvement program was sufficiently developed, implemented and monitored.	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. (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.	Q 082		

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Q 082	<p>Continued From page 19</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents, it was determined the facility failed to ensure quality indicator data was collected and used to monitor the effectiveness and safety of its services. The ASC also failed to use data to identify opportunities to improve its processes. This prevented the ASC from objectively evaluating its processes and services. Findings include:</p> <p>The "TOTAL QUALITY MANAGEMENT PLAN," undated, was reviewed. The policy did not include that the Quality Program must incorporate quality indicator data that is relevant to all services provided in the ASC. It did not state the ASC must use the collected data to monitor the safety of it's services and quality of care provided in the facility. The policy did not explain the process the ASC used to track and investigate adverse patient events or how sustained improvements would be made. Additionally, the process by which the ASC planned to implement preventative strategies that targeted adverse patient events was not found in the policy.</p> <p>All supporting documentation related to the facility's QAPI program was requested during the survey. The "QUARTERLY GOVERNING BODY/MEDICAL ADVISORY COMMITTEE MEETING" minutes for the first, second and third quarters of 2012 were provided and reviewed. Documentation in the meeting minutes for each quarter contained, "Quality Assurance: All testing parameters of autoclaves, and AED on crash cart and back up for electrical systems have been met and are working as expected." There was no evidence that objective data had been gathered</p>	Q 082			

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Q 082	Continued From page 20 or analyzed. The Clinical Director was interviewed on 2/19/13, beginning at 10:00 AM. She indicated the "QUARTERLY GOVERNING BODY/MEDICAL ADVISORY COMMITTEE MEETING" minutes contained the only documentation related to QAPI. The Clinical Director was unable to provide evidence of objective data collection or data analysis that resulted in the formulation of a process for monitoring adverse patient outcomes.	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 policies and QAPI documentation, it was determined the facility failed to ensure annual performance improvement projects were conducted that adequately reflected the scope of services provided in the ASC. This resulted in the inability of the ASC to conduct studies to evaluate	Q 083			

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Q 083	<p>Continued From page 21</p> <p>complex processes and had the potential to impact all patients receiving care at the facility. Findings include:</p> <p>1. The Clinical Director was interviewed on 2/19/13, beginning at 12:45 PM. The type of procedures performed in the facility were discussed. She stated procedures conducted in the ASC included the following: cataract surgery, laser surgery to address clouding in the back lining of the lenses, Lasik/laser surgery to correct vision and eyelid reconstruction.</p> <p>"QUARTERLY GOVERNING BODY/MEDICAL ADVISORY COMMITTEE MEETING" minutes for the first quarter of 2012, dated 4/10/12, included information related to performance improvement. The documentation stated "After having had several patients who had to return to the facility after their cataract surgeries due to painful eyes to get a bandage contact lens, we had serious discussion about what can be the cause. Dr. [physician's name] noted that the areas of irritation he sees look very much like a chemically caused event. In line with that, and him knowing that a povidone-iodine solution of even less than 5% is still very effective at killing bacteria on the eye, he has requested that we dilute the Betadine solution to a 2.5 % strength."</p> <p>The Clinical Director was interviewed on 2/19/13, beginning at 12:45 PM. She confirmed the only PIP implemented in 2012 was related to the use of bandage contact lens secondary to the strength of the pre-operative povidone-iodine eye wash. She also confirmed the facility had not implemented a performance improvement project since the second quarter of 2012.</p>	Q 083			

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Q 083	Continued From page 22	Q 083		
Q 084	<p>The facility did not adequately identify performance improvement projects annually that reflected the scope and complexity of the ASC's services.</p> <p>416.43(e) GOVERNING BODY RESPONSIBILITIES</p> <p>The governing body must ensure that the QAPI program-</p> <p>(1) Is defined, implemented, and maintained by the ASC.</p> <p>(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.</p> <p>(3) Specifies data collection methods, frequency, and details.</p> <p>(4) Clearly establishes its expectations for safety.</p> <p>(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of meeting minutes and QAPI documentation, it was determined the ASC's Governing Body failed to ensure a comprehensive QAPI program was fully defined, implemented, and maintained by the ASC. This resulted in a lack of leadership to provide direction of QAPI activities at the ASC and had the potential to impede the development of a comprehensive QAPI program. Findings include:</p> <p>1. The "TOTAL QUALITY MANAGEMENT PLAN," undated, was reviewed. According to the policy the Governing Body and Medical Advisory</p>	Q 084		

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Q 084	<p>Continued From page 23</p> <p>Committee were "responsible for overseeing the process which drives the delivery of quality service..." In addition, the Governing Body was responsible to participate "in annual strategic planning to establish priorities and define goals in five key areas..."</p> <p>The Clinical Director was interviewed on 2/19/13, beginning at 10:00 AM. She indicated the "QUARTERLY GOVERNING BODY/MEDICAL ADVISORY COMMITTEE MEETING" minutes contained the only documentation related to QAPI. She confirmed a QAPI committee had not been appointed and therefore had not met to discuss quality improvement activities.</p> <p>The Medical Director and Clinical Director were interviewed together on 2/26/13, beginning at 2:45 PM. They confirmed there was no QAPI committee.</p> <p>2. Refer to Q081 as it relates to the Governing Body's failure to ensure the development of a comprehensive quality improvement plan which included performance measures that promoted patient safety and improved patient outcomes.</p> <p>3. Refer to Q082 as it relates to the Governing Body's failure to ensure quality indicator data was collected and used to monitor the effectiveness and safety of its services and failure to use data to identify opportunities to improve its processes.</p> <p>4. Refer to Q083 as it relates to the Governing Body's failure to ensure annual performance improvement projects were conducted that adequately reflected the scope of services provided in the ASC.</p>	Q 084		

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Q 160	416.47 MEDICAL RECORDS The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. This CONDITION is not met as evidenced by: Based on observation, 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 Q162 as it relates to the Governing Body's failure to ensure the ASC's medical records were complete and accurate.	Q 160			
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.	Q 162			

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Q 162	<p>Continued From page 25</p> <p>(7) Documentation of properly executed informed patient consent.</p> <p>(8) Discharge diagnosis.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of medical records and policies, and staff interview it was determined the facility failed to ensure medical records were complete and accurate for 23 of 23 sample patients (#1 - #23) whose records were reviewed. This failure resulted in untimed physician orders and consents, lack of documentation related to allergies, and inaccurate documentation of events while being cared for at the facility. Findings include:</p> <p>1. Medical records for Patients #1 - #23 were reviewed. Each medical record contained a "Consent to Operation And Administration of Anesthetics" form. The form contained a line for the patient and a witness to sign. All forms were signed by the patient, witnessed and dated, but forms did not include a time to indicate the consent was signed prior to receiving sedation.</p> <p>- Consent forms for Patients #1 - #14, #16 and #19 - #23 indicated they were admitted for cataract procedures. Consent forms were signed, witnessed and dated, but signature times were not documented.</p> <p>- Consent forms for Patients #17 and #18 indicated they were admitted for eye lid surgery. Consent forms were signed, witnessed and dated, but signature times were not documented.</p>	Q 162			

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Q 162	<p>Continued From page 26</p> <p>- The consent form for Patients #15 indicated the patient was admitted for a YAG procedure. The consent form was signed, witnessed and dated, but the signature time was not documented.</p> <p>The Medical Director was interviewed on 2/26/13 beginning at 2:30 PM. He reviewed the consent form used by the facility and agreed there no place to indicate the time the patient signed the consent form. He confirmed consents for Patient's #1 - #23 were not timed.</p> <p>Medical records did not contain informed consents that included the time consents were signed.</p> <p>2. Medical records for Patients #1 - #23 were reviewed. Physician orders were not timed as follows:</p> <p>- The records for Patients #1 - #14 and #16 - #23 contained a form titled "Physician's Orders." The form contained a pre-printed list of physician pre-operative and post-operative orders, which included medication administration orders. The forms for Patients #1 - #14 and #16 - #23 were dated at the top of the form and signed by the physician. The physician did not document the time when he signed the orders. It was unclear whether or not the orders were carried out before, or after, the physician signed them.</p> <p>- The medical record for Patient #15 contained a form titled "Yag Laser Record," dated 5/08/12. This form contained pre-printed list of pre-operative orders, including medications to be administered. The physician did not document the time when he signed the orders. It was</p>	Q 162		

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Q 162	<p>Continued From page 27</p> <p>unclear whether or not the orders were carried out before, or after, the physician signed them.</p> <p>The Medical Director was interviewed on 2/26/13 beginning at 2:30 PM. He confirmed the preprinted order forms did not contain a time indicating when he signed them. He agreed the order forms for Patients #1 - #23 were not timed.</p> <p>3. Medical records for Patients #1 - #14 and #16 - #23 contained a pre-operative form to document assessments and care provided prior to surgery. One section of the form was titled, "Patient Preparation and Assessment And Care Plan." This section contained pre-printed instructions which stated "Eye prepped for surgery w/[with] 5% povidone iodine solution followed by saline rinse." Facility staff were to indicate in which eye(s) the solution was administered.</p> <p>Additionally, Patients #1 - #14 and #16 - #23's records included an "OPERATIVE REPORT" document which was generated from a template. One portion of the template stated "Povidone 5% drops were placed on the eye and then irrigated out of the eye prior to commencing surgery."</p> <p>However, meeting minutes in the "QUARTERLY GOVERNING BODY/MEDICAL ADVISORY COMMITTEE MEETING 1st. QUARTER, 2012," dated 4/10/12, described a post cataract complication experienced by several patients. After determining the cause of the complication to be a chemically caused event, the Medical Director requested the ASC dilute the prep solution to a 2.5% strength.</p> <p>During an interview with the Clinical Director on</p>	Q 162		

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Q 162	<p>Continued From page 28</p> <p>2/26/13 beginning at 2:45 PM, she confirmed the pre-operative eye prep solution was actually a 3% povidone solution, not the 5% or 2.5% povidone solution. The Clinical Director was unable to explain when the change from 2.5% to 3% occurred.</p> <p>Records contained inaccurate documentation of the administration of the 5% povidone iodine solution as follows:</p> <ul style="list-style-type: none"> - Patient #1 was an 83 year old male admitted to the facility on 11/06/12. His record indicated 5% povidone iodine solution was administered in his left eye prior to cataract surgery. - Patient #2 was a 76 year old male admitted to the facility on 12/04/12. His record indicated 5% povidone iodine solution was administered in his left eye prior to cataract surgery. - Patient #3 was a 74 year old female admitted to the facility on 11/20/12. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery. - Patient #7 was a 69 year old female admitted to the facility on 11/06/12. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery. - Patient #10 was a 69 year old female admitted to the facility on 12/11/12. Her record indicated 5% povidone iodine solution was administered in her right eye prior to cataract surgery. - Patient #11 was a 69 year old female admitted to the facility on 2/12/13. Her record indicated 5% 	Q 162		

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Q 162	<p>Continued From page 29</p> <p>povidone iodine solution was administered in her left eye prior to cataract surgery.</p> <p>- Patient #13 was a 55 year old male admitted to the facility on 1/29/13. His record indicated 5% povidone iodine solution was administered in his left eye prior to cataract surgery.</p> <p>- Patient #14 was a 53 year old female admitted to the facility on 1/08/13. Her record indicated 5% povidone iodine solution was administered in her right eye prior to cataract surgery.</p> <p>- Patient #16 was a 69 year old female admitted to the facility on 5/08/12. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery.</p> <p>- Patient #17 was an 86 year old female admitted to the facility on 1/24/12. Her record indicated 5% povidone iodine solution was administered in both eyes for surgery on her eyelids.</p> <p>- Patient #18 was a 73 year old male admitted to the facility on 1/24/12. His record indicated 5% povidone iodine solution was administered in both eyes for surgery on his eyelids.</p> <p>- Patient #19 was a 58 year old female admitted to the facility on 3/13/12. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery.</p> <p>- Patient #20 was a 74 year old female admitted to the facility on 9/11/12. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery.</p>	Q 162			

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Q 162	Continued From page 30 - Patient #4 was a 60 year old male admitted to the facility on 2/19/13. His record indicated 5% povidone iodine solution was administered in his right eye prior to cataract surgery. - Patient #5 was a 61 year old female admitted to the facility on 2/19/13. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery. - Patient #6 was a 69 year old female admitted to the facility on 2/19/13. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery. - Patient #8 was a 66 year old female admitted to the facility on 2/19/13. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery. - Patient #9 was a 61 year old male admitted to the facility on 2/19/13. His record indicated 5% povidone iodine solution was administered in his left eye prior to cataract surgery. - Patient #12 was an 81 year old female admitted to the facility on 1/19/13. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery. - Patient #22 was an 85 year old female admitted to the facility on 2/26/13. Her record indicated 5% povidone iodine solution was administered in her left eye prior to cataract surgery. - Patient #23 was a 62 year old male admitted to the facility on 1/22/13. His record indicated 5% povidone iodine solution was administered in his	Q 162			

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Q 162	<p>Continued From page 31 right eye prior to cataract surgery.</p> <p>- Patient #21 was a 67 year old female admitted to the facility on 2/26/13. Her record indicated 5% povidone iodine solution was administered in her right eye prior to cataract surgery.</p> <p>During an interview with the Clinical Director on 2/26/13 beginning at 2:45 PM, she confirmed the documentation in Patient #1 - #14 and #16- #23's was inaccurate regarding the strength of the povidone solution used.</p> <p>During an interview with the Medical Director on 2/26/13 beginning at 2:30 PM, he confirmed the operative report template that described the 5% povidone drops was inaccurate. He confirmed this was the template used for the cataract surgeries for Patients #1 - #14, #16 and #19 - #23.</p> <p>5. Medical records contained pages without proper patient identification as follows:</p> <p>- Patient #16 was a 69 year old female admitted to the facility on 5/08/12 for left eye cataract surgery. Her medical record contained a page with an EKG strip taped to it. There was no name on the EKG strip or the paper it was taped to. The date on the EKG strip was 5/07/12. It was not clear that this EKG strip was for Patient #16.</p> <p>- Patient #17 was an 86 year old female admitted to the facility on 1/24/12 for surgery on both of her eyelids. Her medical record contained a page with an EKG strip taped to it. There was no name or date on the EKG strip or the paper it was taped to. It was not clear that this EKG strip was for</p>	Q 162		

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Q 162	<p>Continued From page 32 Patient #17.</p> <p>- Patient #18 was a 73 year old male admitted to the facility on 1/24/12 for bilateral repair of droopy eyelids. His medical record contained a page with an EKG strip taped to it. There was no name on the EKG strip or the paper it was taped to. The date on the EKG strip was 1/23/12. It was not clear that this EKG strip was for Patient #18.</p> <p>The Medical Director was interviewed on 2/26/13 beginning at 2:30 PM. He reviewed the medical records and confirmed the EKG strips had been placed in the record without proper identification.</p> <p>Medical records did not contain patient identifying information on each page of the record.</p> <p>6. Medication administration was not documented in the medical record.</p> <p>- Patient #21 was a 67 year old female who was admitted to the facility on 2/26/13 for cataract surgery on her right eye. Her procedure was observed from 7:05 AM to 7:56 AM.</p> <p>On 2/26/13 at 7:23 AM an RN Staff K was observed to administer one drop of Neosynephrine 10% to Patient #21's right eye. RN Staff K explained that Neosynephrine is used if the eye has not dilated enough for the procedure. RN Staff K stated that patient's are only allowed to receive two drops of this medication, so the practice was to document the drop was given on a red sticker placed above the patient's eye. RN Staff K was observed to do this, but she did not document the medication administration in Patient #21's chart.</p>	Q 162		

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Q 162	<p>Continued From page 33</p> <p>The Clinical Director came to assess Patient #21's eye at 7:35 AM on 2/26/13. She administered a second drop of Neosynephrine and documented this on the red sticker. The Clinical Director did not document the medication administration in Patient #21's record. At 7:40 AM Patient #21 was taken to the OR.</p> <p>Patient #21's record was reviewed. There was no documentation in the medical record to indicate the two drops of Neosynephrine had been given.</p> <p>The policy "Medication Administration," approved 7/08/03, stated "All administered medications are documented in the patient chart by the person who administered them." In addition, the policy also stated that to "minimize the possibility of medication errors" the "time, dose, and route of administration [of medication]" must be documented in the patient chart.</p> <p>RN Staff K was interviewed at 2:10 PM on 2/26/13. She confirmed she did not document the Neosynephrine drops in Patient #21's record. She stated she has never documented these drops in any medical record.</p> <p>The Clinical Director and the Medical Director were interviewed at 2:45 PM on 2/26/13. The Clinical Director confirmed she did not document the Neosynephrine drop she administered in Patient #21's record. She also acknowledged that she had never documented the Neosynephrine drops on any medical record. The Medical Director acknowledged this practice did not follow the ASC's policy. The Clinical Director and the Medical Director agreed this</p>	Q 162		

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Q 162	<p>Continued From page 34 resulted in an incomplete medical record.</p> <p>The facility failed to ensure medication was documented in the medical record.</p> <p>7. The preoperative evaluations of 3 patients were observed. Medical records for 2 of the 3 observations (Patient #21 and Patient #22) were reviewed. The medical records failed to accurately reflect preoperative evaluations/assessments, as follows:</p> <p>- Patient #21 was a 67 year old female admitted to the facility on 2/26/13 for cataract surgery on her right eye. At approximately 7:15 AM, CRNA Staff N was observed performing Patient #21's preoperative assessment. She reviewed Patient #21's medical history, discussed the upcoming surgical procedure and the type of anesthesia she planned to administer. The CRNA also evaluated Patient #21 for prior problems with anesthesia and asked if she had been ill or if her health status had changed since last seeing the physician. The CRNA did not examine Patient #21. She did not listen to her heart and lungs with a stethoscope.</p> <p>However, Patient #21's medical record included a "PREANESTHESIA EVALUATION" form, signed by CRNA Staff N on 2/26/13 and initialed by the Medical Director/Physician. CRNA Staff N listed Patient #21's prior surgeries and documented an assessment of her airway. She included hayfever and reflux in the "Problem List/Diagnosis" section of the form. The same problems were listed in the "SYSTEMS" evaluation section of the form. CRNA Staff N did not include documentation of a pre-surgical, physical assessment. Additionally,</p>	Q 162			

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Q 162	<p>Continued From page 35</p> <p>an identifiable H&P, which included listening to heart and lungs with a stethoscope, could not be found in Patient #21's record on the day of surgery.</p> <p>Patient #21's record failed to reflect a complete preoperative examination (failure to listen to her heart and lungs with a stethoscope).</p> <p>- Patient #22 was an 85 year old female admitted to the facility on 2/26/13 for cataract surgery on her left eye. At approximately 7:38 AM, CRNA Staff N was observed performing Patient #22's preoperative assessment. She reviewed Patient #22's medical history, discussed the upcoming surgical procedure and the type of anesthesia she planned to administer. She also evaluated Patient #22 for prior problems with anesthesia and asked if she had been ill or if her health status had changed since last seeing the physician. The CRNA did not examine Patient #22. She did not listen to her heart and lungs with a stethoscope.</p> <p>However, Patient #22's medical record included a "PREANESTHESIA EVALUATION" form, signed by CRNA Staff N on 2/26/13 and initialed by the Medical Director/Physician. CRNA Staff N listed Patient #21's prior surgeries and documented an assessment of her airway. She included arthritis, asthma, hypertension and reflux in the "Problem List/Diagnosis" section of the form. The same problems were listed in the "SYSTEMS" evaluation section of the form. The "SYSTEMS" section also documented Patient #22 had a cold, was a smoker and used an inhaler the morning of surgery before arriving at the clinic. CRNA Staff N did not include documentation of a pre-surgical,</p>	Q 162		

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Q 162	Continued From page 36 physical assessment. Additionally, an identifiable H&P, which included listening to heart and lungs with a stethoscope, could not be found in Patient #22's record on the day of surgery. Patient #22's record failed to reflect a complete preoperative examination (failure to listen to her heart and lungs with a stethoscope). The CRNA who cared for Patient #21 and #22 was interviewed at 7:38 AM on 2/26/13. The preoperative examinations were discussed. She stated she would "very rarely" listen to a patient's heart and lungs. She stated she would only listen to heart and lungs if the patient was presenting with an illness, such a cough or cold. The Medical Director/physician for Patients #21 and #22 was interviewed on 2/26/13 beginning at 2:30 PM. He stated he would review and verify the findings from the CRNA's evaluation. He stated he performed a thorough physical examination on all patients during the office visit prior to surgery, but did not include documentation of the exam in the ASC records. Additionally, he confirmed he did not listen to patients heart or lungs on the day of surgery.	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.	Q 181			

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Q 181	<p>Continued From page 37</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of drug labeling information and policies, and staff interview, it was determined the facility failed to administer, prepare, label and store medications in accordance with acceptable standards of practice. The failure to adhere to acceptable standards of practice resulted in the potential for all patients receiving medications in the ASC to experience adverse drug reactions and/or medication administration errors. Findings include:</p> <p>1. The facility failed to ensure single dose medications were used appropriately as follows:</p> <p>a. Surgical procedures were observed on 2/26/13 between 7:00 AM and 10:30 AM. The anesthesia cart was noted to contain the following medications:</p> <ul style="list-style-type: none"> - 2 syringes, containing 0.5 ml of clear fluid each with labels which read "Fentanyl." - 2 syringes, empty, with labels which read "Fentanyl." - 10 syringes, containing 3 ml of clear fluid, each with labels which read "NS." - An uncapped, partially full 20 ml vial of preservative free 0.9% Sodium Chloride was on the top of the anesthesia cart. The vial was label for single use. <p>CRNA Staff N was interviewed on 2/26/13 at 1:45 PM, and confirmed she had prepared the syringes found in the anesthesia cart in the operating room. She stated she used the 5 ml</p>	Q 181		

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Q 181	<p>Continued From page 38</p> <p>ampule of Fentanyl. She confirmed she dispensed multiple doses from the Fentanyl and NS from single use vials in an effort to save the medication as it was sometimes in short supply.</p> <p>A drug insert for Fentanyl 50 mcg/ml, 5 ml ampules, stated: "Do not administer unless solution is clear and container undamaged. Discard unused portion. Fentanyl Citrate Injection, USP equivalent to 50 mcg (0.05 mg) Fentanyl/ml, is supplied in single-dose glass containers. The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose injection. When smaller doses are required, the unused portion should be discarded in an appropriate manner."</p> <p>b. The process of preparing medications to start IV sites was observed on 2/26/13 beginning at 6:40 AM. RN Staff K stated all medications used to start IV sites was prepared at the start of the day and the medications were used on patients throughout the day. She was observed to open a vial of 0.9% saline labeled for single patient use. She used the vial to fill three syringes. She then opened a second vial of 0.9% saline labeled for single patient use and proceeded to fill three more syringes. RN Staff K continued this until she had filled 12 syringes. RN Staff K explained that each syringe would be used for a separate patient.</p> <p>The policy "PHARMACY POLICIES AND PROCEDURES," dated July 2003, under the heading "Storage and Disposal of Drug Products" stated Single use vials/ampules/bottles may be used for multiple patients only if: the entire</p>	Q 181			

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Q 181	<p>Continued From page 39</p> <p>contents are removed into separate syringes immediately upon opening...each syringe is labeled with name dosage strength, date and time of preparation and initials of the person preparing the drug...each syringe is used only once and then discarded in a 'sharps' container."</p> <p>However, Centers for Disease Control and Prevention's "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007" indicated safe injection practices include "Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use."</p> <p>The Medical Director and Clinical Director were interviewed on 2/26/13, at 2:45 PM. They acknowledged the facility did use single dose medications for multiple patients.</p> <p>The facility used single dose vials for multiple patients.</p> <p>2. The facility failed to properly label medications as follows:</p> <p>a. RN Staff M was observed preparing saline used to start IV sites on 2/26/13 at 6:40 AM. She was observed to open a vial of 0.9% saline labeled for single patient use. She used the vial to fill three syringes. She then opened a second vial of 0.9% saline labeled for single patient use and proceeded to fill three more syringes. RN Staff M continued this until she had filled 12 syringes. She then labeled the syringes as saline but did not include a date or time on the label.</p>	Q 181		

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Q 181	<p>Continued From page 40</p> <p>b. At 6:40 AM on 2/26/13, RN Staff K was observed to open a multidose vial of lidocaine and used it to fill several syringes. RN Staff K labeled the syringes as lidocaine but did not include a date and time on the label. RN Staff K explained each syringe would be used for a separate patient. The syringes of lidocaine were also placed on the cart with the IV equipment.</p> <p>c. On 2/26/13 at 6:40 AM, RN Staff K was observed to prepare a solution consisting of Proparacaine, Vigamox, Nevanac, Neosynephrine and AK pentolate. RN Staff K explained that the solution would be administered to each patient by a small piece of gel foam dipped in the solution and placed in the the patient's eye. These medications were dropped from eye drop bottles into an open specimen cup. The cup was not labeled.</p> <p>c. During an observation in the OR on 2/26/13 between 7:00 AM and 10:30 AM the following inappropriately labeled syringes were noted in the anesthesia cart:</p> <ul style="list-style-type: none"> - 2 syringes, containing 0.5 ml of clear fluid each with labels which read "Fentanyl." The labels were not timed, dated, or initialed. - 2 syringes, empty, with labels which read "Fentanyl." The labels were not timed, dated, or initialed. - 10 syringes, containing 3 ml of clear fluid, each with labels which read "NS." The labels were not timed, dated, or initialed. - An uncapped, partially full 20 ml vial of preservative free 0.9% Sodium Chloride was on the top of the anesthesia cart. The vial was not timed, dated, or initialed to indicate when and 	Q 181			

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Q 181	<p>Continued From page 41 who had opened the vial.</p> <ul style="list-style-type: none"> - 3 syringes, with labels which read "Versed," but were empty. - An uncapped vial of 5 ml vial of Midazolam (generic form of Versed) which was not timed, dated, or initialed. <p>The policies "Medication Administration" and "PHARMACY POLICIES AND PROCEDURES" were reviewed. Neither policy contained language related to the labeling of medication.</p> <p>The Clinical Director and the Medical Director were interviewed on 2/26/13 at 2:45 PM. They acknowledged that the facility was not labeling medication in accordance with acceptable standards of practice.</p> <p>3. The facility failed to properly store medication as follows:</p> <p>The process of preparing medications was observed on 2/26/13 beginning at 6:40 AM. RN Staff K was observed to prepare a solution that she explained would be used to soak a small piece of gel foam that would be placed in the patients eyes. The solution consisted of five medications, dropped from eye drop bottles, into an open specimen cup. The specimen cup was then placed on a cart along with the pieces of gel foam, equipment to start IV sites, and other bottles of eye medication. The specimen cup remained open. The cart was located next to the sink where staff members washed their hands. RN Staff K explained that the cart would move from patient to patient throughout the day and then returned to its central location next to the sink.</p>	Q 181		

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Q 181	Continued From page 42 RN Staff K was interviewed at 2:10 PM. She confirmed a lid was never placed on the solution. She agreed that this practice resulted in the risk of the solution becoming contaminated from splashes from the sink area or from other sources as it traveled from patient to patient. The Medical Director and Clinical Director were interviewed on 2/26/13 at 2:45 PM. They agreed the medication was not being properly stored to avoid contamination.	Q 181			
Q 220	The facility failed to properly store medications. 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, interview, and review of patient rights information and ASC policies and procedures, it was determined the ASC failed to inform patients or representatives of their rights and failed to promote the exercise of such rights. These failures impacted all patients at the facility and carried the potential for patients' rights to be violated. Findings include: 1. Refer to Q222 as it relates to the failure of the ASC to post written notice of patient rights that included contact information for the State agency and Medicare Beneficiary Ombudsman. 2. Refer to Q224 as it relates to the failure of the ASC to provide patients or their representatives	Q 220			

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Q 220	Continued From page 43 with a clear statement regarding ASC policies on advance directives, information on applicable State health and safety laws, and, if requested, provide official State advance directive forms. 3. Refer to Q225 as it relates to the failure of the ASC to establish a grievance procedure for documenting the existence, submission, investigation, and disposition of grievances, timeframes for review, provisions of a response, and necessity of providing patients with written notice. The cumulative effect of these systemic practices resulted in an inability to ensure patient rights were communicated and upheld.	Q 220		
Q 222	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 and staff interview, it was determined the ASC failed to ensure posted patient rights information included the name, address, and telephone number of a representative in the State agency to whom patients could report complaints, as well as the Web site for the Office of the Medicare	Q 222		

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Q 222	Continued From page 44 Beneficiary Ombudsman. This resulted in the potential for patients and their representatives to not be fully informed of their rights. Findings include: The ASC was toured on 2/19/13 between 10:30 AM and 3:30 PM with the Administrator. Patient rights information was observed to be posted in the waiting area. The information did not include contact information for the State agency to which patients could report complaints. It also did not include the Web site for the Office of the Medicare Beneficiary Ombudsman. During the morning tour, beginning at 10:30 AM, Administrator confirmed the information was not on the patient rights information posted in the ASC. The facility did not ensure written patient rights information was posted in the facility that included contact information for the State agency and the Web site for the Office of the Medicare Beneficiary Ombudsman.	Q 222			
Q 224	416.50(a)(2) ADVANCE DIRECTIVES The ASC must comply with the following requirements: (i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws, and, if requested, official State advance directive forms. (ii) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.	Q 224			

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Q 224	<p>Continued From page 45</p> <p>(iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.</p> <p>This STANDARD is not met as evidenced by: Based on medical record review, staff interview, and review of patient rights information, it was determined the ASC failed to ensure comprehensive rights information related to Advance Directives was provided to patients and/or their representatives. This failure directly impacted 23 of 23 patients (#1 - #23) whose records were reviewed, and had the potential to impact all patients receiving services from the ASC. This resulted in a lack of information related to the provision of life sustaining measures during emergencies and missed opportunities to execute advance directives, if desired, and/or have them honored. Findings include:</p> <p>1. The "Patient Bill of Rights" information, undated, provided to patients prior to a procedure was reviewed. According to the document, the ASC "Makes no recommendations for Advance Directives: therefore, [the ASC] does not require Advance Directive information from our patients." The document instructed patients to search for "Advance Directives" on their internet search engine for further information.</p> <p>In an interview on 2/26/13 beginning at 2:45 PM, the Medical Director confirmed the facility did not provide information to patients about formulating Advance Directives.</p> <p>2. On 2/19/13 at approximately 10:30 AM,</p>	Q 224			

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Q 224	Continued From page 46 "Patient Bill of Rights" information was also noted in a frame on a desk in the waiting room of the ASC. The information provided to patients did not clearly indicate how the facility would respond to a respiratory and/or cardiac arrest. In an interview on 2/26/13 at 2:45 PM, RN Staff K, stated she did not know if patients had Advance Directive information in the record and did not discuss with patients the facility response in an emergency. Staff K stated she would stabilize the patient and send them to the hospital after contacting EMS. The Medical Director was interviewed on 2/26/13 at 3:00 PM. He reviewed the Advance Directive information on the form provided to patients. He stated in an emergency he would stabilize a patient and transfer them for acute care. He confirmed the patient information was unclear, and did not contain verbiage describing how the facility would respond to a respiratory and/or cardiac arrest.	Q 224		
Q 225	Patients were not notified of the facility's practice regarding emergency care provided. 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	Q 225		

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Q 225	<p>Continued From page 47</p> <p>or the patient's representative regarding treatment or care that is (or fails to be) furnished. (vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and patient rights information and interview, it was determined the facility failed to ensure a procedure for identifying and documenting the existence and submission of grievances was developed and implemented. This impacted all patients who received care at the facility and had the potential to result in unidentified and unresolved grievances. Findings include:</p> <p>The "PATIENT BILL OF RIGHTS," undated, was reviewed. The form stated "You will be provided with a means to register a complaint concerning any aspect of the service/care provided by the center. The clinical director will handle the complaint to resolve the matter (if unable to obtain immediate satisfaction, will assess priority and forward accordingly)." The form did not define the difference between a grievance and a complaint.</p> <p>The Clinical Director was interviewed on 2/19/13 at 3:30 PM. She stated the ASC did not have a procedure or policy for documentation,</p>	Q 225			

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Q 225	Continued From page 48 submission, or investigation of grievances. She stated the ASC did not have complaints or grievances, and patients were fully satisfied with the care provided. She stated she did not maintain a record of complaints or grievances, and there had been no grievances within the last 12 months.	Q 225		
Q 240	The facility failed to ensure a procedure for identifying and documenting the existence and submission of grievances was thoroughly developed and implemented. 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, review of medical records and policies, 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.	Q 240		

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Q 240	Continued From page 49 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. 5. Refer to Q245 as it relates to a lack of surveillance to monitor for infections after procedures were performed. The cumulative effect of these systemic omissions resulted in the inability of the ASC to ensure all reasonable steps had been taken to identify and prevent infections.	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. This STANDARD is not met as evidenced by: Based on observation, interview and review of control policies, it was determined the facility failed to maintain a sanitary environment. This impacted all staff and patients cared for at the ASC. These failures had the potential to result in infections. Findings include: 1. During a tour of the ASC on 2/19/13 at 3:30 PM with the Clinical Director, a small room approximately 4 feet by 5 feet in size, had a sign on the door identifying it as "MEDICATION ROOM." Inside the room was a cart which held	Q 241			

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Q 241	<p>Continued From page 50</p> <p>clean and folded linens. Beside the cart, resting on the floor, were 3 large cloth bags about 3 feet tall stuffed with soiled linens. On the floor in the corner below the medication cabinet, was a pile of soiled pillow cases. The Clinical Director stated the soiled linens were stored in another area, but placed in the Medication Room at the end of the day for the contracted linen service to pick up. She stated the soiled pillow cases were laundered at home by her and returned each week.</p> <p>The "INFECTION CONTROL POLICY," undated, was reviewed. According to the "UNIVERSAL PRECAUTIONS" section, "Linen is contained and removed weekly by the contracted linen service for cleaning and return to the facility."</p> <p>The ASC did not separate clean and soiled linens or launder linens in accordance with facility policy.</p> <p>2. During a tour of the ASC with the Clinical Director on 2/19/13 starting at 3:00 PM, it was noted there was no immediate access to hand sanitizing equipment for staff in the pre-operative, PACU, and operative rooms. There were 5 patient care areas in the combined pre and post operative area with curtains between each stretcher to provide patient privacy. There was no hand sanitizer at the patient care areas. A sink off to the side of the nurse work area had a container of foam hand sanitizer mounted on the wall with tubing that connected a foot pedal to the container. The operating room had a sink just outside of the door with a container of foam hand sanitizer mounted to the wall. The operating room had a can of foam sanitizer resting on the anesthesia cart to the right of where the patient</p>	Q 241			

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Q 241	Continued From page 51 stretcher would be positioned. When the Clinical Director was questioned about staff hand hygiene, she stated the staff would go out of the operating room after opening the door, use the foam sanitizer by the scrub sink, open the door and return to the operating room. During an interview on 2/18/13 beginning at 3:00 PM, the ASC's Clinical Director stated staff would either wash their hands or use foam sanitizer at the sink in the pre-operative and PACU areas or outside the OR. She could not explain how staff prevented the spread of infection when there was no hand sanitizing equipment available. Without appropriately placed hand sanitizing equipment in the pre-operative, post-operative area as well as in the operating rooms, the ASC could not ensure the risk of infection from cross-contamination was minimized.	Q 241			
Q 242	416.51(b) INFECTION CONTROL PROGRAM The facility failed to maintain a sanitary environment. The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. This STANDARD is not met as evidenced by: Based on observation, staff interview and review of policies and infection control documents, it was	Q 242			

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Q 242	<p>Continued From page 52</p> <p>determined the ASC failed to ensure an infection control program was sufficiently implemented and monitored to ensure patient health and safety. This impacted staff and patients receiving care at the ASC. The lack of sufficient infection control program development and implementation resulted in the potential for patients to experience increased exposure to infectious agents. Findings include:</p> <p>1. Infection control breaches were observed in patient care as follows:</p> <p>a. Patient #21 was a 67 year old female admitted to the facility on 2/26/13 for cataract surgery with placement of an intraocular lens and astigmatism correction in her right eye. Her care was observed from 7:05 AM to 7:56 AM.</p> <p>At 7:05 AM on 2/26/13 RN Staff K was observed administering eye drops to Patient #21. RN Staff K did not perform hand hygiene prior to this observation. RN Staff K was not wearing gloves. RN Staff K removed a bottle of eye medication from a cart and held Patient #21's eye open with her hand. The RN administered a drop in Patient #21's right eye and used a tissue to wipe moisture off Patient #21's face and around her eye. RN Staff K placed the bottle back on the cart and picked up another. RN Staff K then held Patient #21's eye open to administer a drop of medication and again used a tissue to wipe moisture from Patient #21's face and around her eye. RN Staff K placed the bottle back on the cart and picked up a third bottle and repeated the above procedure. RN Staff K did not perform hand hygiene after administering the eye drops. RN Staff K did not clean the bottles of medication</p>	Q 242		
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Q 242	<p>Continued From page 53 after handling them and coming in contact with Patient #21's eye.</p> <p>Immediately following the administration of the eye drops, RN Staff K was observed placing a piece of gel foam in Patient #21's eye. The RN removed a pair of forceps from the cart and held Patient #21's eye open with her hand. RN Staff K used the forceps to place the piece of gel foam under Patient #21's lower eyelid next to her eye. The forceps came in contact with the inner surface of the lower eyelid (a mucous membrane). Once the gel foam was placed, RN Staff K used a tissue to wipe moisture from Patient #21's face and around the eye. RN Staff K then placed the tips of the forceps into an open package containing an alcohol prep pad and placed the forceps back on the cart. RN Staff K did not clean the forceps and did not perform hand hygiene after this procedure. RN Staff K did not wear gloves during this procedure.</p> <p>At 7:10 AM, RN Staff K donned gloves to insert an IV site on Patient #21. She did not perform hand hygiene prior to donning gloves. After inserting the IV, RN Staff K removed her gloves and washed her hands.</p> <p>At approximately 7:38 AM, CRNA Staff N was observed evaluating Patient #21 in the PACU area, prior to surgery. Before she approached Patient #21, she did not perform hand hygiene. Patient #21 was transported via stretcher to the OR at approximately 7:35 AM. At approximately 7:46 AM, CRNA Staff N donned gloves and administered IV medication to Patient #21. The CRNA then connected the monitor leads that were attached to Patient #21, to the monitor. She</p>	Q 242		

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Q 242	<p>Continued From page 54</p> <p>then removed her gloves and began documenting on Patient #21's medical record. The CRNA did not wash her hands or use hand sanitizer before donning gloves or after removing them.</p> <p>b. Patient #22 was an 85 year old female admitted to the ASC on 2/26/13 for cataract surgery with placement of an intraocular lens in her left eye. Her care was observed from 7:20 AM to 8:10 AM.</p> <p>At 7:25 AM on 2/26/13, OA Staff #A was observed to perform hand hygiene and administer eye drops to Patient #22. He did not don gloves prior to this procedure. He removed a bottle of medication from the cart that had been used previously on Patient #21. He held Patient #22's eye open with his hand and administered the medication to her left eye. He then used a tissue to wipe moisture from Patient #22's face and around her eye. He replaced the bottle on the cart and repeated this process with two more medications. He did not clean the medication bottles after handling them. He performed hand hygiene after this procedure.</p> <p>Immediately following the administration of the eyes drops, RN Staff K was observed placing a piece of gel foam under Patient #22's eyelid next to the eye. RN Staff K did not perform hand hygiene prior to this task. RN Staff K removed a pair of forceps from the cart and held Patient #22's eye open with her hand and used the forceps to place the piece of gel foam into Patient #22's lower eyelid. The forceps came in contact with the inner surface of the lower eyelid. Once the gel foam was placed, RN Staff K used a tissue to wipe moisture from Patient #22's face</p>	Q 242		
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Q 242	<p>Continued From page 55 and around the eye. RN Staff K then placed the tips of the forceps into an open package containing an alcohol prep pad and placed the forceps back on the cart. RN Staff K did not clean the forceps and did not perform hand hygiene after this procedure. RN Staff K did not wear gloves during this procedure.</p> <p>At approximately 7:42 AM, CRNA Staff N was observed evaluating Patient #22 in the PACU area, prior to surgery. Before she left Patient #21 and approached Patient #22, she did not perform hand hygiene. Patient #22 was transported via stretcher to the OR at approximately 8:03 AM. At approximately 8:05 AM, CRNA Staff N donned gloves and administered IV medication to Patient #22. The CRNA then connected the monitor leads that were attached to Patient #22, to the monitor. She then removed her gloves and began documenting on Patient #22's medical record. The CRNA did not wash her hands or use hand sanitizer before donning gloves or after removing them.</p> <p>c. Patient #14 was a 53 year old female who was admitted to the ASC on 2/26/13 for the removal of a cataract and placement of an intraocular lens in her left eye. Her care was observed from 8:55 AM to 9:45 AM.</p> <p>During the pre-operative stage, RN Staff K was observed donning gloves in preparation to start an IV site. RN Staff K did not perform hand hygiene prior to donning gloves. After the IV site was placed, the RN removed gloves but did not perform hand hygiene.</p> <p>When Patient #14 was in the operating room, it</p>	Q 242		

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Q 242	<p>Continued From page 56</p> <p>was noted that RN Staff I applied the prep solution to Patient #14's left eye. Staff I removed her gloves, picked up the medical record and initiated the "time out" process, she then began to write notes in the patient record. Upon completion of the surgical procedure, Staff I pulled a bottle out of her right pant pocket and administered eye drops into Patient #14's left eye. The eye drops were placed back into her pant pocket, and Staff I proceeded to assist with moving Patient #14 to the recovery area. During the entire procedure, Staff I was not observed to perform hand hygiene. The bottle of eye drops was not cleaned after administration to Patient #14.</p> <p>At approximately 9:20 AM, CRNA Staff N was observed evaluating Patient #14 in the PACU area, prior to surgery. Before she approached Patient #14, she did not perform hand hygiene. Patient #14 was transported via stretcher to the OR at approximately 9:28 AM. At approximately 9:35 AM, CRNA Staff N donned gloves and administered IV medication to Patient #14. The CRNA then connected the monitor leads that were attached to Patient #14, to the monitor. She then removed her gloves and began documenting on Patient #14's medical record. The CRNA did not wash her hands or use hand sanitizer before donning gloves or after removing them.</p> <p>The "INFECTION CONTROL POLICY," undated, was reviewed. According to the "HAND WASHING" section, "All personnel are required to wash their hands before and after caring for each patient. At no time shall care be administered to a patient without hand washing prior to treatment." The "INFECTION CONTROL</p>	Q 242			

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Q 242	<p>Continued From page 57</p> <p>STANDARDS" section specified, "Hand cleaning either by washing with soap and water or using foamed alcohol is essential when entering and leaving the surgical area, after glove removal, between each procedure, patient contact and after performing any personal hygiene." Hand hygiene was not performed appropriately when providing patient care.</p> <p>According to the CDC Guidelines to Disinfection and Sterilization in Healthcare Facilities, 2008, "Semi-critical items contact mucous membranes or nonintact skin...Semi-critical items minimally require high-level disinfection using chemical disinfectants..." The use of the forceps to place gel foam in patient's eyes resulted in the forceps being a semi-critical item which required high-level disinfection between each patient use.</p> <p>RN Staff K, who provided care for Patients #14, #21 and #22, was interviewed at 2:10 PM on 2/26/13. She confirmed the forceps used to place gel foam in Patient #21's and Patient #22's eyes were used for multiple patients throughout the day. She confirmed the forceps were not cleaned after patient use. She stated the best practice would be to have one pair of forceps per patient. She also confirmed the possibility of cross contamination by not cleaning the eye drop medication bottles after each use.</p> <p>The Clinical Director and the Medical Director were interviewed on 2/26/13 at 2:45 PM. They also confirmed the forceps used to place the gel foam were not being cleaned after each use. They confirmed the eye drop medication bottles were not being cleaned after each use. They agreed that these practices led to possible cross</p>	Q 242			

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Q 242	<p>Continued From page 58</p> <p>contamination between patients. They also confirmed RN Staff K and CRNA Staff N did not follow facility policy or CDC guidelines related to handwashing before and/or after patient contact.</p> <p>2. Staff N, the CRNA that provided sedation for Patients #14, #22 and #23 was noted to have artificial nails.</p> <p>According to AORN, 2010 Perioperative Standards and Recommended Practices (found at www.workingtowardzero.com), "Artificial nails should not be worn. Studies show that artificial (e.g. acrylic) nails on healthy hands increase the risk of surgical site infection. Artificial nails harbor organisms and prevent effective hand antisepsis. Higher counts of gram-negative microorganisms have been cultured from the fingertips of personnel wearing artificial nails than from personnel with natural nails, both before and after hand washing. Fungal growth occurs frequently under artificial nails as a result of moisture becoming trapped between the natural and artificial nail."</p> <p>During an interview on 2/26/13 beginning at 1:45 PM, CRNA Staff N confirmed her nails were artificial.</p> <p>3. The "INFECTION CONTROL POLICY," undated, did not contain reference to nationally recognized infection control guidelines.</p> <p>On 2/18/13, the Clinic Director was interviewed starting at 3:00 PM. She stated the ASC had not followed policies, procedures, and/or protocols for the infection control program.</p>	Q 242		

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Q 242	Continued From page 59	Q 242		
Q 243	<p>The facility failed to mitigate risks of healthcare-associated infections.</p> <p>416.51(b)(1) INFECTION CONTROL PROGRAM - DIRECTION</p> <p>The program is - Under the direction of a designated and qualified professional who has training in infection control.</p> <p>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. This impacted staff and all patients receiving care at the facility and prevented the ASC from utilizing the knowledge base of a trained professional to develop and monitor an infection control program. Findings include:</p> <p>1. Facility records, including personnel records, were reviewed. A job description for the Infection Control Officer could not be found.</p> <p>The ASC's Clinical Director who also identified herself as the Infection Control Officer was interviewed on 2/18/13 starting at 3:00 PM. She stated she had no formal training in infection control and was not involved in any outside infection control groups. She stated she spent .5 hours a week dedicated to the infection control program for the ASC. She stated she read articles related to infection control topics and discussed the articles with staff during meetings.</p>	Q 243		

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NAME OF PROVIDER OR SUPPLIER VISION CARE CENTER OF IDAHO			STREET ADDRESS, CITY, STATE, ZIP CODE 3071 EAST FRANKLIN ROAD, SUITE 101 MERIDIAN, ID 83642		
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Q 243	Continued From page 60	Q 243			
Q 244	<p>The facility failed to ensure the infection control program functioned under the direction of a qualified professional who had training in infection control.</p> <p>416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI</p> <p>[The program is -] An integral part of the ASC's quality assessment and performance improvement program</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of quality assurance and infection control documentation, it was determined the ASC failed to ensure an infection control program was integrated into a QAPI program. This failed practice had the potential to impact to impact all patients receiving care in the facility and inhibit the ASC's ability to identify infections and improve infection control practices at the ASC. Findings include:</p> <p>1. The ASC's quality assurance documentation was reviewed. Information relevant to the collection, analysis and monitoring of infection control data was not found.</p> <p>The Clinical Director was interviewed on 2/19/13 beginning at 12:45 PM. She confirmed the infection control program was not a component of the QAPI program.</p> <p>The ASC failed to ensure infection control data and activities were integrated into a QAPI program.</p>	Q 244			

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Q 245	<p>416.51(b)(3) INFECTION CONTROL PROGRAM - RESPONSIBILITIES</p> <p>The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of policies and infection control documents, it was determined the ASC failed to ensure a process for identifying and investigation infections was sufficiently developed. This impacted all patients who received care at the facility and had the potential to result in unidentified infections. Findings include:</p> <p>1. The "INFECTION CONTROL POLICY," undated, stated a program for identifying and preventing infections was to be established.</p> <p>During an interview on 2/18/13 beginning at 3:00 PM, the Clinic Director, who was also the Infection Control Officer, stated the ASC had no infections over the last year. When asked about surveillance, she stated the ASC informed patients of the signs and symptoms of infection. Patients were instructed that if they developed complications after their surgery, they were to notify the surgery center. She confirmed the ASC did not have an active infection control surveillance process.</p> <p>The Medical Director was interviewed on 2/26/13 beginning at 2:30 PM. He stated patients</p>	Q 245			

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Q 245	Continued From page 62 followed up with him in the clinic but that he had not considered infections that developed after a period a time to be related to a surgery completed at the ASC. He stated this information was not reported. He also stated that patients followed up with him in the clinic for at least one visit. Following that visit, the patient may follow up with their referring provider. He confirmed there was no identified process to follow up with referring physicians to report infections that may develop.	Q 245			
Q 260	This failure resulted in and a lack of adequate patient surveillance necessary to monitor for infections after procedures were performed. 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 procedures and that comprehensive H&Ps were placed in the patients' medical records. These failures had the potential to result in negative patient outcomes. Findings include: 1. Refer to Q262 as it relates to the ASC's failure to ensure a physician examined patients prior to procedures.	Q 260			

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Q 260	Continued From page 63 3. 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. The cumulative effect of these systemic failures had to the potential to impact patient care and safety.	Q 260			
Q 262	416.52(a)(2) PRE-SURGICAL ASSESSMENT Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals. This STANDARD is not met as evidenced by: Based on observation, interview, and review of medical records and policies, it was determined the facility failed to ensure patients received a pre-surgical assessment for 3 of 3 patients (Patients #14, #21, and #22) whose preoperative process was observed. Failure to perform this pre-surgical assessment had the potential to impact patient safety during and after the procedure. Findings include: 1. Pre-surgical assessments were not comprehensive, as follows: a. Patient #21 was a 67 year old female admitted	Q 262			

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Q 262	<p>Continued From page 64</p> <p>to the facility on 2/26/13 for cataract surgery on her right eye. At approximately 7:15 AM, CRNA Staff N was observed performing Patient #21's preoperative assessment. The CRNA reviewed Patient #21's medical history, discussed the upcoming surgical procedure and the type of anesthesia she planned to administer. She also evaluated Patient #21 for prior problems with anesthesia and asked if she had been ill or if her health status had changed since last seeing the physician. The CRNA did not examine Patient #21. She did not listen to her heart and lungs with a stethoscope.</p> <p>At approximately 7:35 AM, the physician was observed performing Patient #21's preoperative assessment. The physician examined Patient #21's eyes and discussed the upcoming surgical procedure. The physician did not perform a full examination of Patient #21. He did not listen to her heart and lungs with a stethoscope.</p> <p>b. Patient #22 was an 85 year old female admitted to the facility on 2/26/13 for cataract surgery on her left eye. At approximately 7:38 AM, CRNA Staff N was observed performing Patient #22's preoperative assessment. The CRNA reviewed Patient #22's medical history, discussed the upcoming surgical procedure and the type of anesthesia she planned to administer. She also evaluated Patient #22 for prior problems with anesthesia and asked if she had been ill or if her health status had changed since last seeing the physician. The CRNA did not examine Patient #22. She did not listen to her heart and lungs with a stethoscope.</p> <p>At approximately 7:57 AM, the physician was</p>	Q 262		

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Q 262	<p>Continued From page 65</p> <p>observed performing Patient #22's preoperative assessment. The physician examined Patient #22's eyes and discussed the upcoming surgical procedure. The physician did not perform a full examination of Patient #22. He did not listen to her heart and lungs with a stethoscope.</p> <p>c. Patient #14 was a 53 year old female admitted to the facility on 2/26/13 for cataract surgery on her left eye. At approximately 9:20 AM, the CRNA Staff N was observed performing Patient #14's preoperative assessment. CRNA Staff N reviewed Patient #14's medical history, discussed the upcoming surgical procedure and the type of anesthesia she planned to administer. She also evaluated Patient #14 for prior problems with anesthesia and asked if she had been ill or if her health status had changed since last seeing the physician. CRNA Staff N did not examine Patient #14. She did not listen to her heart and lungs with a stethoscope.</p> <p>At approximately 9:25 AM, the physician was observed performing Patient #14's preoperative assessment. The physician examined Patient #14's eyes and discussed the upcoming surgical procedure. The physician did not perform a full examination of Patient #14. He did not listen to her heart and lungs with a stethoscope.</p> <p>CRNA Staff N, who cared for Patient #14, #21 and #22 was interviewed at 7:38 AM on 2/26/13. The preoperative examinations were discussed. She stated she would "very rarely" listen to a patient's heart and lungs. She stated she would only listen to heart and lungs if the patient was presenting with an illness, such a cough or cold.</p>	Q 262			

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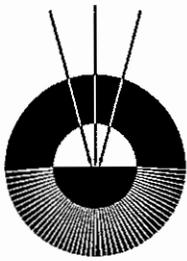
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Q 262	Continued From page 66 The physician for Patient #14, #21, and #22 was interviewed on 2/26/13 beginning at 2:30 PM. He stated he would review and verify the findings from the CRNA's evaluation. He stated he would perform a thorough physical examination during the office visit and did not listen to a patient's heart or lungs on the day of surgery. A policy related to preoperative examinations was requested but the facility did not furnish such a policy. The facility failed to ensure policies were sufficiently developed and implemented necessary to ensure patients received a comprehensive preoperative physical examination.	Q 262		
Q 263	416.52(a)(3) ADMISSION ASSESSMENT - RECORD The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the ASC failed to ensure an identifiable H&P, completed within 30 days of the surgery, was included in the medical records for 23 of 23 patients (Patients #1 - #23) whose records were reviewed. This resulted in ASC staff not having access to medical information for review prior to surgical procedures. It had the potential to compromise patient safety. Findings include: 1. Medical records for Patients #1 - #23 were	Q 263		

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Q 263	<p>Continued From page 67 reviewed. The records lacked an identifiable medical H&P.</p> <p>According to the "MEDICAL RECORDS POLICIES," undated, "A history and physical (H&P) must be on the chart prior to surgery for patients having MAC anesthesia...for patients having receiving [sic] local anesthesia...no formal H&P will be required."</p> <p>The Medical Director was interviewed on 2/26/13 at 2:30 PM. He confirmed the records for Patients #1 - #23 did not contain an identifiable medical H&P.</p> <p>Medical records did not contain an identifiable medical H&P.</p>	Q 263			



VisionCare
CENTER OF IDAHO

3071 E. Franklin Rd. Ste. 101 Meridian, Idaho 83642 Ph: 208.288.1400

March 21, 2013

Rebecca Lara
Health Facility Surveyor
Idaho Department of Health and Welfare
3232 Elder St.
P.O. Box 83720
Boise, Idaho 83720-0009
FAX:208-364-1888

RECEIVED
MAR 23 2013
FACILITY STANDARDS

Dear Ms. Lara

Enclosed please find the POC reply attachments by Q codes and completion dates per your instructions. If you have any further questions please do not hesitate to contact me.

Sincerely,

Jorge A. Martinez, M.D.
Medical Director

POC Reply Attachment

VISION CARE CENTER OF IDAHO
 PLAN OF CORRECTION

Q Tag	Plan of Correction	Date
Q040	<p>Medical Director and Clinical Director met on 3.15.13 to review and discuss findings of deficiencies. Governing Body has engaged the services of Progressive Surgical Solutions to assist with education of current standards to ensure future compliance with areas of deficiency. The Governing Body reviewed the responsibilities required of it in the Governing Body and Management Condition in the CMS CfC to ensure full knowledge of facility responsibility.</p> <p>Monitor: The Clinical Director will monitor correction of deficiencies specified on the CMS 2567.</p> <p>Responsible: Governing Body</p> <p>1. Policy titled COMPETENCY, was approved and implemented to ensure staff is qualified and competent to perform their job duties. Competencies are assessed and assured through orientation and annual evaluation of staff performance. Performance evaluations and competency assessments completed and are current with all staff. Policy attached.</p> <p>Monitor: Clinical Director will monitor all employee and CRNA credentialing files to ensure all required documentation is current.</p> <p>Responsible: Governing Body</p> <p>2. Policies titled BLS and CODE BLUE RESPONSE were implemented to ensure staff maintains current BLS/ACLS certification as required. All staff has obtained BLS and/or ACLS certification as required. 2 of 3 RNs have obtained ACLS certification. Third RN is scheduled to attend ACLS certification course. Revised policies attached.</p> <p>Monitor: Clinical Director will monitor all employee and CRNA credentialing files to ensure all required documentation is current.</p>	<p></p> <p>3/15/13</p> <p>3/21/13</p> <p>3/21/13</p>

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<p>Responsible: Governing Body</p> <p>3. Policy titled ANCILLARY SERVICES was approved and implemented to ensure contracted services are provided with sufficient monitoring necessary to ensure surgical procedures are performed in a safe manner. 2 of 3 CRNAs have own DEA numbers and are on each credential file. 3rd CRNA has applied for certification. Clinical Director will monitor CRNA credential files to ensure all required documentation is verified and current. Policy attached.</p> <p>Monitor: Clinical Director will monitor all CRNA credential files to ensure all required documentation is current.</p> <p>Responsible: Governing Body</p>	<p>3/21/13</p>
<p>4. Clinical Director notified local authorities regarding disaster preparedness to determine if a formal disaster plan is in place. Ada County's Hazard Specific Emergency Response Plans does not have a specific role for Vision Care Center of Idaho at the present time. A disaster preparedness plan was written, approved and implemented and a disaster drill will be conducted on 4/2/13.</p> <p>Monitor: Clinical Director will conduct an annual internal disaster drill and submit a written evaluation to the Governing Body. Needed corrections will be implanted immediately.</p> <p>Responsible: Governing Body</p>	<p>3/20/13</p>
<p>5. The facility QAPI program was developed, approved and implemented by the governing body. Performance improvement studies will be conducted on an ongoing basis and will focus on high risk, high volume and problem prone areas. The QAPI program will include annual evaluation of contracted services to ensure services are provided in a safe manner, medical chart audits are conducted to ensure completion, Clinical Director is conducting a written medication preparation and administration PI study and will continue QI studies on a regular basis.</p> <p>The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical</p>	<p>3/21/13</p>

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<p>services by adhering to professionally acceptable standards of practice. Medical staff was informed of the need to perform a comprehensive medical history and physical examination within 30 days of the patient's procedure. In addition, an update note must be made immediately prior to surgery. A physical assessment to include but not limited to auscultation of heart and lungs, shall be performed by MD or anesthesia provider immediately prior to surgery and findings documented on medical record. QAPI program attached. Monitor: Clinical Director will monitor and document compliance report findings to the Governing Body at quarterly Governing Body meetings. Responsible: Governing Body</p>	
<p>6.The facility QAPI program was developed, approved by the Governing Body and implemented. Performance improvement studies (PI) are conducted on an ongoing basis and will focus on high risk, high volume and problem prone areas. PI activities are identified through tracking and trending of incidents and exceptions that occur in the facility. Quality Indicators will be tracked and will include: falls, burns, transfers, wrong site/side/implant, infections, adverse patient outcomes and medication errors. Findings from PI activities are taken into account and changes implemented as needed for optimal health outcomes and patient safety. Staff will be inserviced on the QAPI program on 3/26/13. Monitor: Clinical Director and QAPI Committee will report quarterly on QI activities to the Governing Body Responsible: Governing Body</p>	3/21/13
<p>7.Medical records forms edited, approved and implemented to ensure complete, comprehensive and accurate documentation of patients care. Staff will be inserviced on medical record documentation requirements on 3/26/13. Monitor: Clinical Director will conduct inservice on medical record documentation requirements on 3/26/13 and monitors compliance weekly. Results will be reported to QAPI Committee and quarterly Governing Body</p>	3/21/13

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	<p>meetings for 6 months. Responsible: Governing Body</p> <p>8.Policies titled Single-Dose Vials (SDV) and Multi-Dose (MDV) were reviewed with staff. All syringes containing medication will be labeled with medication, date and time. The dilation solution and pledgetts will be covered with a lid between uses. Medication cups will be labeled with medication, date and time. Policies and Procedures titled Single-Dose Vials and Multi-Dose Vials contain language related to the labeling of medication. Revised policies attached. Monitor: Clinical Director conducted inservice on Medication Management and medication administration on 3/26/13 and monitors compliance through observation of staff and inspecting medication areas weekly for 6 months. Results will be reported to the QAPI Committee and quarterly Governing Body meetings. Responsible: Governing Body</p> <p>9.a.Patient's Rights and Responsibilities, including the Medicare Ombudsman and state agency is prominently displayed at the reception desk. Monitor: Clinical Director will stay current with changes in the CfC's related to patient rights and adjust forms accordingly. Clinical Director will ensure that Patient Rights stays posted. Responsible: Governing Body</p> <p>b.Policy titled ADVANCED DIRECTIVES was developed regarding advanced directive recognition at the facility. Patients will be notified of this policy prior to the procedure. Information will be available, if requested, and provided to patients regarding applicable State health and safety laws and state advance directive forms. A sticker will be placed on the front of patient records indicating an advance directive, if one exists. Staff will be inserviced on 3/26/13. Policy attached. Monitor: Clinical Director will include distribution of advance directive notification and existence of sticker, if applicable, in MR audits and report</p>	<p>3/21/13</p> <p>3/22/13</p> <p>3/21/13</p>
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	<p>results quarterly to the QAPI Committee and Governing Body. Responsible: Governing Body</p> <p>c.A process and policy were developed for receipt and investigation of patient grievances. The staff will be inserviced on this policy on 3/26/13. Revised poicy titled ADVANCED DIRECTIVE attached. Monitor: Clinical Director will document and report all patient grievances to the Governing Body at quarterly Governing Body meetings. Responsible: Governing Body</p> <p>10. The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. Program will include documentation of meeting minutes that reflect infection control activities and a written plan of action for infection control activities requiring action. Clinical Director will inservice on 3/26/13 on Infection Control Program. INFECTION CONTROL PROGRAM attached. Monitor: Clinical Director and QAPI Committee will implement and report activities, results and actions to the Governing Body at all quarterly meetings. Responsible: Governing Body</p> <p>Refer to Q242</p> <p>1.All eye drop medication bottles are cleansed with alcohol pad/germicidal wipe between each use. All eye drop bottles are labeled at opening with a 28 day expiration and then discarded as appropriate. Forceps used to place gelfoam pledgetts will be individually peel packed and sterilized and a new discrete forceps will be used for each patient. The Clinical Director completed an inservice on Infection Control policies and procedures with specific attention to professionally acceptable standards of practice related to hand hygiene and use of hand hygiene products. Inservice conducted on 3/26/13. Monitor: Clinical Director will monitor compliance level weekly for 6 months and report compliance level at the quarterly Governing Body meetings for 6</p>	<p>3/21/13</p> <p>3/21/13</p> <p>3/15/13</p>
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VISION CARE CENTER OF IDAHO
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	<p>months. Responsible: Governing Body</p> <p>2.Healthcare providers will not wear artificial nails. Any staff wearing artificial nails will be instructed to have them removed. Monitor: Clinical Director will monitor compliance level weekly for 6 months and report compliance level at the quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p> <p>3.The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice including but not limited to the CDC and AORN guidelines. Monitor: Clinical Director and QAPI Committee will implement and report activities, results and actions to the Governing Body at all quarterly meetings. Responsible: Governing Body</p> <p>Refer to Q243 1.A job description for the Infection Control Officer was written to include training in infection control. Monitor: The Clinical Director, who assumes the role of Infection Control Officer, will meet the regulatory guidelines and is appropriately trained in infection control. Responsible: Governing Body</p> <p>Refer to Q244 1.The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. The Infection Control Program will be part of the QAPI process and includes a tool to collect, analyze and monitor infection control data.</p>	<p>3/15/13</p> <p>3/21/13</p> <p>3/21/13</p> <p>3/21/13</p>
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	<p>Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed Responsible: Governing Body</p> <p>Refer to Q245 1.A surveillance form was developed to query the Surgeon about surgical site infections. This information will be requested monthly and will be reported to the QAPI Committee. Monitor: Clinical Director will ensure surveillance forms are completed in a timely manner and results presented to the Governing Body and documented in the minutes. Responsible: Governing Body</p> <p>11.1.Refer to Q262 & 3. Q263 Medical staff was informed of the need to write an update note immediately prior to surgery updating the H&P if there were changes or stating that there no changes in H&P since it was performed. Medical staff was also informed of the requirement perform a physical assessment including but not limited to auscultation of heart and lungs immediately prior to surgery. Monitor: Clinical Director will monitor compliance level weekly for 6 months and report compliance level at the quarterly Governing Body meetings for 6 months. Responsible: Governing</p>	<p>3/21/13</p> <p>3/16/13</p>
<p>Q 041</p>	<p>1.All CRNAs now have signed contracts. 2 of 3 CRNAs work under their DEA number which is included on each credential file. 3rd CRNA has applied for DEA certification. Monitor: Clinical Director will monitor CRNA credential files to ensure all required documentation is verified and current. Responsible: Governing Body</p> <p>2.Policy titled ANCILLARY SERVICES was approved and implemented to</p>	<p>3/21/13</p> <p>3/21/13</p>

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<p>adverse patient outcomes and medication errors. Findings from PI activities are taken into account and changes implemented as needed for optimal health outcomes and patient safety. Staff will be inserviced on the QAPI program on 3/26/13.</p>	
<p>Monitor: Clinical Director and QAPI Committee will report quarterly on QI activities to the Governing Body</p>	
<p>Responsible: Governing Body</p>	
<p>3. All medical record forms edited to include signature times and documentation of allergies. Staff was inserviced on medical record documentation requirements on 3/26/13.</p>	3/21/13
<p>Monitor: Clinical Director conducted inservice on medical record documentation requirements on 3/26/13 and monitors compliance weekly. Results will be reported to QAPI Committee and quarterly Governing Body meetings for 6 months.</p>	
<p>Responsible: Governing Body</p>	
<p>4 The new facility policies on Single-Dose Vials (SDV) and Multi-Dose (MDV) were reviewed with staff. Single-dose vials (SDV) will be used immediately upon opening, on one patient only and discarded appropriately after use. The healthcare provider will initial and label Multi-Dose vials (MDV) with new expiration date (28 days from day of opening). All syringes containing medication will be labeled with medication, date and time. The dilation solution and pledgetts will be covered with a lid between uses. Medication cups will be labeled with medication, date and time. Policies and Procedures titled Single-Dose Vials and Multi-Dose Vials contain language related to the labeling of medication.</p>	3/21/13
<p>Monitor: Clinical Director conducted inservice on medication management and administration on 3/26/13 and monitors compliance through observation of staff and inspecting medication areas weekly for 6 months. Results will be reported to the QAPI Committee and quarterly Governing Body meetings.</p>	

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	<p>Responsible: Governing Body</p> <p>5. The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice including the CDC and AORN standards. The Infection Control Program will be part of the QAPI process and includes a tool to collect, analyze and monitor infection control data. A job description for the Infection Control Officer was written to include training in infection control. A surveillance form was developed to query the Surgeon about surgical site infections. This information will be requested monthly and will be reported to the QAPI Committee.</p> <p>Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed.</p> <p>Responsible: Governing Body</p>	<p style="text-align: right;"><i>[Signature]</i></p> <p>3/21/13</p>
	<p>6. Medical staff was informed of the need to perform a comprehensive medical history and physical examination, including medications and allergies within 30 days of the patient's procedure. In addition, an update note immediately prior to surgery updating the H&P if there were changes or stating that there no changes in H&P since it was performed. Medical staff was also informed of the requirement perform a physical assessment including but not limited to auscultation of heart and lungs immediately prior to surgery.</p> <p>Monitor: Clinical Director will monitor compliance weekly for 6 months and report results to the Governing Body at quarterly Governing Body meetings.</p> <p>Responsible: Governing Body</p>	<p>3/16/13</p>
<p>Q 080</p>	<p>1, 2, 4. The facility QAPI program was developed, approved by the Governing Body and implemented. Performance improvement studies (PI) are conducted on an ongoing basis and will focus on high risk, high volume and problem prone areas. PI activities are identified through tracking and trending of incidents and exceptions that occur in the facility. Quality Indicators will be</p>	<p>3/21/13</p>

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<p>Q 081</p>	<p>tracked and will include: falls, burns, transfers, wrong site/side/implant, infections, adverse patient outcomes and medication errors. Findings from PI activities are taken into account and changes implemented as needed for optimal health outcomes and patient safety. Staff will be inserviced on the QAPI program on 3/26/13. Monitor: Clinical Director and QAPI Committee will report quarterly on QI activities to the Governing Body Responsible: Governing Body</p> <p>3. Clinical Director has written handwashing PI study and will continue with new studies on an ongoing basis. Findings from QI studies will determine implementation of change as needed for optimal health outcomes, patient safety and quality of care. These activities will reflect the need for altering processes to improve patient care. Monitor: Clinical Director and QAPI Committee will report quarterly on QI activities to the Governing Body Responsible: Governing Body</p> <p>1.The facility QAPI program was developed, approved and implemented. Quality indicators are clearly identified within the program and will be monitored and reported quarterly for the effectiveness and safety of the facility's services and quality of care. Performance Improvement (PI) activities will be conducted on an ongoing basis and will focus on high risk, high volume and problem-prone areas. These areas will be identified through tracking and trending of incidents including adverse patient events and exceptions that occur in the facility. These activities will reflect the need for altering processes to improve patient care. A form for tracking surgical infections was developed and will be utilized monthly to query the surgeon about SSIs. Monitor: Clinical Director and QAPI Committee to implement an ongoing program and report quarterly to the Governing Body. Responsible: Governing Body</p>	<p style="text-align: right;"><i>[Signature]</i></p> <p>3/21/13</p> <p>3/21/13</p>
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Q 082	<p>The facility QAPI program was developed, approved and implemented. Quality indicators are clearly identified within the program and are monitored and reported quarterly for the effectiveness and safety of the facility's services and quality of care. Performance Improvement (PI) activities will be conducted on an ongoing basis and will focus on high risk, high volume and problem-prone areas. These areas will be identified through tracking and trending of incidents including adverse patient events and exceptions that occur in the facility. These activities will reflect the need for altering processes to improve patient care. The staff will be inserviced on the program on 3/26/13.</p> <p>Monitor: Clinical Director and QAPI Committee to implement an ongoing program and report quarterly to the Governing Body. Responsible: Governing Body</p>	3/21/13
Q 083	<p>1.The facility QAPI program was developed, approved and implemented. Performance Improvement (PI) activities will be conducted on an ongoing basis and will focus on high risk, high volume and problem-prone areas. Clinical Director has written handwashing PI study and will continue to add studies on an ongoing basis based on scope and complexity of services. Findings from QI studies will determine implementation of change as needed for optimal health outcomes, patient safety and quality of care.</p> <p>Monitor: Clinical Director and QAPI Committee to implement an ongoing program and report quarterly to the Governing Body. Responsible: Governing Body</p>	3/21/13
Q 084	<p>1.,2.,3.,4.The facility QAPI program and QAPI Committee, [REDACTED], [REDACTED] and [REDACTED], was approved by the Governing Body and implemented. Activities to be implemented include but are not limited to monitoring direct and indirect patient quality indicators, PI activities, risk management, infection control and peer review. The QAPI Committee will gather data and report to the Governing Body quarterly,</p>	3/21/13

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	<p>annually or more frequently as needed. An annual review of the QAPI program will be performed as well. Sufficient time will be allocated to the Clinical Director to perform all activities quarterly to the Governing Body. Monitor: Clinical Director and QAPI Committee to implement an ongoing program and report quarterly to the Governing Body. Responsible: Governing Body</p> <p>Q 160 1.All medical record forms edited to include signature times. The concentration of Povidine 3% has been updated on all appropriate and applicable documents. All EKG monitors have been calibrated and date-verified weekly and all appended data such as EKG rhythm strips will have the patient name denoted. All medication administered will be documented on the medical record to include time and signature of licensed personnel administering medication. Medical staff was informed of the need to perform a comprehensive medical history and physical examination, including medications and allergies within 30 days of the patient's procedure. In addition, an update note must be made immediately prior to surgery by updating the H&P if there were changes or stating that there were no changes in H&P since it was performed. A physical assessment to include but not limited to auscultation of heart and lungs, shall be performed by MD or anesthesia provider immediately prior to surgery and findings documented on medical record. Staff was inserviced on medical record documentation requirements on 3/26/13. Monitor: Clinical Director conducted inservice on medical record documentation requirements on 3/26/13 and monitors compliance weekly. Results will be reported to QAPI Committee and quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p> <p>Q 162 1.&2.All medical record forms edited to include signature times.</p>	<p style="text-align: right;"><i>[Handwritten Signature]</i></p> <p>3/16/13</p> <p>3/16/13</p>
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<p>Monitor: Clinical Director conducted inservice on medical record documentation requirements on 3/26/13 and monitors compliance weekly. Results will be reported to QAPI Committee and quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p>	
<p>3.The concentration of Povidine 3% has been updated on all appropriate and applicable documents. Monitor: Clinical Director conducted inservice on medical record documentation requirements on 3/26/13 and monitors compliance weekly. Results will be reported to QAPI Committee and quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p>	<p>3/16/13</p>
<p>5.All EKG monitors have been calibrated and date- verified weekly and all appended data such as EKG rhythm strips will have the patient name denoted. Monitor: Clinical Director conducted inservice on medical record documentation requirements on 3/26/13 and monitors compliance weekly. Results will be reported to QAPI Committee and quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p>	<p>3/16/13</p>
<p>6.All medication administered will be documented on the medical record to include time and signature of licensed personnel administering medication. Monitor: Clinical Director conducted inservice on medical record documentation requirements on 3/26/13 and monitors compliance weekly. Results will be reported to QAPI Committee and quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p>	<p>3/16/13</p>
<p>7.A physical assessment to include but not limited to auscultation of heart and lungs, shall be performed by MD or anesthesia provider immediately prior to</p>	<p>3/16/13</p>

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	<p>Monitor: Clinical Director will stay current with changes in the CfC's related to patient rights and adjust forms accordingly. Clinical Director will ensure that Patient Rights stays posted. Responsible: Governing Body</p>	
	<p>2. A policy was developed regarding advanced directive recognition at the facility. Patients will be notified of this policy prior to the procedure. Information will be available, if requested, and provided to patients regarding applicable State health and safety laws and state advance directive forms. A sticker will be placed on the front of patient records indicating an advance directive, if one exists. Staff will be inserviced on 3/26/13. Policy attached. Monitor: Clinical Director will include distribution of advance directive notification and existence of sticker, if applicable, in MR audits and report results quarterly to the QAPI Committee and Governing Body. Responsible: Governing Body</p>	3/21/13
	<p>3. A process and policy were developed for receipt and investigation of patient grievances. The staff will be inserviced on this policy on 3/26/13. Monitor: Clinical Director will document and report all patient grievances to the Governing Body at quarterly Governing Body meetings. Responsible: Governing Body</p>	3/21/13
Q 222	<p>Patient's Rights and Responsibilities, including the Medicare Ombudsman and state agency is prominently displayed at the reception desk. Monitor: Clinical Director will stay current with changes in the CfC's related to patient rights and adjust forms accordingly. Clinical Director will ensure that Patient Rights stays posted. Responsible: Governing Body</p>	3/22/13
Q 224	<p>1. & 2. Policy titled ADVANCED DIRECTIVES was developed regarding advanced directive recognition at the facility. Patients will be notified of this policy prior to the procedure. Information will be available, if requested, and</p>	3/21/13

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	<p>provided to patients regarding applicable State health and safety laws and state advance directive forms. A sticker will be placed on the front of patient records indicating an advance directive, if one exists. Staff will be inserviced on 3/26/13. Policy attached.</p> <p>Monitor: Clinical Director will include distribution of advance directive notification and existence of sticker, if applicable, in MR audits and report results quarterly to the QAPI Committee and Governing Body.</p> <p>Responsible: Governing Body</p>	
Q 225	<p>Policy titled PATIENT GRIEVANCE was developed for receipt and investigation of patient grievances. The staff will be inserviced on this policy on 3/26/13. Policy attached.</p> <p>Monitor: Clinical Director will document and report all patient grievances to the Governing Body at quarterly Governing Body meetings.</p> <p>Responsible: Governing Body</p>	3/21/13
Q 240	<p>1. Soiled linen bags are now stored in a location physically removed from the clean linens. All soiled linens will be laundered by the contracted linen service.</p> <p>Monitor: Clinical Director will monitor storage of clean and soiled linen weekly and report compliance at the quarterly Governing Body meetings for 6 months.</p> <p>Responsible: Governing Body</p>	3/16/13
	<p>2. The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice including the CDC and AORN standards. Program will include documentation of meeting minutes that reflect infection control activities and a written plan of action for infection control activities requiring action.</p> <p>Monitor: Clinical Director and QAPI Committee will implement and report activities, results and actions to the Governing Body at all quarterly meetings.</p>	3/21/13

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<p>Responsible: Governing Body All health care providers will perform hand hygiene and don gloves before and after care provided to each patient. All eye drop medication bottles are wiped with an alcohol pad/germicidal wipe between each use. All eye drop bottles are labeled at opening with a 28 day expiration and then discarded as appropriate. Forceps used to place gelfoam pledgetts will be individually peel packed and sterilized and a new discrete forceps will be used for each patient. The Clinical Director completed an inservice on Infection Control policies and procedures with specific attention to professionally acceptable standards of practice related to hand hygiene and use of hand hygiene products. Inservice completed 3/26/13. Monitor: Clinical Director will monitor compliance level weekly for 6 months and report compliance level at the quarterly Governing Body meetings for 6 months.</p>	
<p>Responsible: Governing Body 3. A job description for the Infection Control Officer was written to include training in infection control. Monitor: Clinical Director will ensure she meets the regulatory guidelines and is appropriately trained and experienced in infection control.</p>	3/21/13
<p>Responsible: Governing Body 4. The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice including the CDC Guidelines and AORN standards. The Infection Control Program will be part of the QAPI process. Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed.</p>	3/21/13
<p>5. A surveillance form was developed to query the Surgeon about surgical site</p>	3/21/13

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	<p>infections. This information will be requested monthly and will be reported to the QAPI Committee. Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed. Responsible: Governing Body</p>	
Q 241	<p>1. Soiled linen bags are now stored in a location physically removed from the clean linens. All soiled linens will be laundered by the contracted linen service. Monitor: Clinical Director will monitor storage of clean and soiled linen weekly and report compliance at the quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p>	3/16/13
	<p>2. Hand sanitizer is now available between patient beds, on all work desks and in all pre-post and intra-op locations. Monitor: Clinical Director will monitor availability of hand sanitizer at required locations and report compliance at the quarterly Governing Body meetings for 6 months. Responsible: Governing Body</p>	3/16/13
Q 242	<p>The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice including the CDC Guidelines and AORN standards. The Infection Control Program will be part of the QAPI process. Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed. Responsible: Governing Body</p>	3/21/13
	<p>1. All health care providers will perform hand hygiene and don gloves before and after providing care to each patient. All eye drop medication bottles are</p>	3/16/13

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	<p>wiped with an alcohol pad/germicidal wipe between each use. All eye drop bottles are labeled at opening with a 28 day expiration and then discarded as appropriate. Forceps used to place gelfoam pledgets will be individually peel packed and sterilized and a new discrete forceps will be used for each patient. The Clinical Director completed an inservice on Infection Control policies and procedures with specific attention to professionally acceptable standards of practice related to hand hygiene and use of hand hygiene products. Inservice completed on 3/26/13.</p> <p>Monitor: Clinical Director will monitor compliance level weekly for 6 months and report compliance level at the quarterly Governing Body meetings for 6 months.</p> <p>Responsible: Governing Body</p> <p>2. Healthcare providers will not wear artificial nails. Any staff wearing artificial nails will be instructed to have them removed.</p> <p>Monitor: Clinical Director will monitor compliance level weekly for 6 months and report compliance level at the quarterly Governing Body meetings for 6 months.</p> <p>Responsible: Governing Body</p> <p>3. The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice including the CDC Guidelines and AORN standards. The Infection Control Program will be part of the QAPI process.</p> <p>Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed.</p> <p>Responsible: Governing Body</p>	<p style="text-align: right;"><i>[Handwritten mark]</i></p> <p>3/16/13</p> <p>3/21/13</p>
<p>Q 243</p>	<p>1. A job description for the Infection Control Officer was written to include training in infection control.</p> <p>Monitor: Clinical Director will ensure she meets the regulatory guidelines</p>	<p>3/21/13</p>

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	and is appropriately trained and experienced in infection control. Responsible: Governing Body	
Q 244	1. The facility Infection Control Program was developed, approved and implemented to ensure a sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice including the CDC Guidelines and AORN standards. Program will include documentation of meeting minutes that reflect infection control activities and a written plan of action for infection control activities requiring action. The Infection Control Program will be part of the QAPI process. Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed. Responsible: Governing Body	3/21/13
Q 245	1. A surveillance form was developed to query the Surgeon about surgical site infections. This information will be requested monthly and will be reported to the QAPI Committee. Monitor: Clinical Director and QAPI Committee will implement and report quarterly and more often as needed. Responsible: Governing Body	3/21/13
Q 260	1. Medical staff was informed of the requirement to perform a physical assessment including but not limited to auscultation of heart and lungs immediately prior to surgery. Monitor: Clinical Director will monitor compliance level weekly for 6 months and report compliance level at the quarterly Governing Body meetings for 6 months. Responsible: Governing Body	3/21/13
	2. Medical staff was informed of the need to perform a comprehensive medical history and physical examination, including medications and allergies within 30 days of the patient's procedure. In addition, an update note immediately	3/21/13

