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IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

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

CERTIFIED MAIL: 7009 0820 0000 2807 2085

June 10, 2011

Gregory Kent, President of Medical Staff
Eagle Eye Surgery And Laser Center
3090 Gentry Way, Suite 100
Meridian, ID 83642

RE: Eagle Eye Surgery And Laser Center, Provider #13C0001032

Dear Mr. Kent:

Based on the survey completed at Eagle Eye Surgery And Laser Center, on June 3, 2011, by our staff, we have determined Eagle Eye Surgery And Laser Center is out of compliance with the Medicare ASC Condition for Coverage on **Quality Assessment & Performance Improvement (42 CFR 416.43)**. To participate as a provider of services in the Medicare Program, a OR an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiency, which caused this condition to be unmet, substantially limit the capacity of Eagle Eye Surgery And Laser Center, to furnish services of an adequate level or quality. The deficiency is 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;

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

Such corrections must be achieved and compliance verified by this office, before July 18, 2011. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than July 8, 2011.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **June 23, 2011.**

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

We urge you to begin correction immediately.

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

Sincerely,



GARY GUILLES
Health Facility Surveyor
Non-Long Term Care



NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

GG/srm

Enclosures

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

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

PRINTED: 06/09/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001032	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/03/2011
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NAME OF PROVIDER OR SUPPLIER EAGLE EYE SURGERY AND LASER CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 3090 GENTRY WAY, SUITE 100 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	INITIAL COMMENTS The following deficiencies were cited during the recertification survey of your Ambulatory Surgery Center. Surveyors conducting the recertification were: Gary Guiles, RN, HFS, Team Leader Susan Costa, RN, HFS Eric Mundell, REHS AAAHC - Accreditation Association for Ambulatory Health Care, an accrediting body ASC - Ambulatory Surgery Center CRNA - Certified Registered Nurse Anesthetist HIPAA - Health Insurance Portability and Accountability Act mg - milligram ml - milliliter NS - Normal Saline OR - Operating Room PACU - Post Anesthesia Recovery Unit RN - Registered Nurse	Q 000		
Q 080	416.43 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on staff interview and review of ASC policies, QAPI documents, and meeting minutes, it was determined the facility failed to ensure a data driven QAPI program had been developed, implemented, and monitored. This resulted in the	Q 080	Plan of Correction: The ASC will ensure development, implementation, and maintenance of an ongoing, data-driven and quality assessment and performance improvement (QAPI) program. Systemic Changes: An immediate review of the QAPI program was conducted and the QAPI program was revised on 6/17/11. The QAPI plan now includes measurement, analysis, and tracking of quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished at the center.	6/28/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Michael R N</i>	TITLE <i>Lindi Archer RN</i>	(X6) DATE <i>06-22-2011</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 080	<p>Continued From page 1</p> <p>inability of the ASC to evaluate its procedures and practices. Findings include:</p> <ol style="list-style-type: none"> 1. Refer to Q81 as it relates to the failure of the ASC to ensure the scope of the QAPI program provided sufficient direction to staff to demonstrate measurable improvement in patient health outcomes by using quality indicators and by the identification and reduction of medical errors. 2. Refer to Q82 as it relates to the failure of the ASC to ensure data was used to monitor the effectiveness and safety of its services, to track adverse patient events, and to identify opportunities that could lead to improvements in patient care. 3. Refer to Q83 as it relates to the failure of the ASC to document the projects that were conducted, including the reason for implementing the project and a description of the project's results. <p>The cumulative effect of these negative facility practices prevented the ASC from utilizing information to improve its processes.</p>	Q 080	<p>The QAPI plan includes utilization of infection control data, safety data, risk data, high risk/high volume and problem prone process data to monitor and improve the effectiveness and of its services and quality of its care. (See attachment #1)</p> <p>A "Performance Improvement Indicator" policy and procedure and monthly tracking form were developed on 6/17/11. Performance improvement (PI) indicators to be presented to the Governing Board for approval to ensure ongoing monitoring include but are not limited to:</p> <ul style="list-style-type: none"> Monitoring of post-op infections Adverse patient events Hospital transfers Post op contacts Tissue review Surgical and Anesthesia complications Employee Exposures Medication Documentation Adverse Drug reactions Medication Errors Patient satisfaction <p>(See attachment #2 and #3) Q 080 Continued on next page</p>	
Q 081	<p>416.43(a), 416.43(c)(1) PROGRAM SCOPE; PROGRAM ACTIVITIES</p> <p>(a)(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.</p>	Q 081	<p>Plan of Correction:</p> <p>The ASC will ensure the scope of the QAPI program provides sufficient direction to staff to demonstrate measurable improvement in patient health outcomes by using quality indicators and by the identification and reduction of medical errors.</p>	6/28/11

The QI focus study/project format was revised to ensure the reason for implementing the project and a description of the project's results are documented. (See attachment #4)

The "QAPI Plan", "Performance Improvement Indicators" policy and monthly tracking summary and the revised QI focus study format will be presented for approval by the Governing Board on 6/24/11.

Education regarding the QAPI program will be provided to the Governing Board on 6/24/11.

Education regarding the QAPI program will be provided to the ASC staff on 6/28/11.

Monitoring and Responsible Party:

The Center Director is responsible for ensuring QAPI data will be collected, aggregated, analyzed and trended on an ongoing basis. The Center Director or designee will monitor the QAPI performance improvement indicator monthly tracking summary each month to ensure completion of all data collection. The Center Director will report regarding the PI indicators and the ASC specific performance improvement projects to the QAPI Committee after one month and submit the report and recommendations to the Governing Board after one month then the Center Director will report to the QAPI committee and Governing Board quarterly. The Governing Board will complete a review of the QAPI program annually. (See attachment #9).

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Q 081	<p>Continued From page 2</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> <p>(i) Focus on high risk, high volume, and problem-prone areas.</p> <p>(ii) Consider incidence, prevalence, and severity of problems in those areas.</p> <p>(iii) Affect health outcomes, patient safety, and quality of care.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents and meeting minutes, it was determined the facility failed to ensure the scope of the QAPI program provided sufficient direction to staff to demonstrate measurable improvement in patient health outcomes by using quality indicators and by the identification and reduction of medical errors. This resulted in performance measures that were insufficient to measure the quality of care provided to patients. Findings include:</p> <p>1. The ASC had not developed a policy to direct staff regarding how the QAPI program should operate. A policy defining the ASC's QAPI program was not present. Four sets of minutes from the "TOTAL QUALITY COMMITTEE," none of them dated, were present. But a policy defining this committee, including which staff</p>	Q 081	<p>Systemic Changes:</p> <p>An immediate review of the QAPI program was conducted and the QAPI program was revised on 6/17/11. The QAPI plan now includes measurement, analysis, and tracking of quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished at the center.</p> <p>The QAPI plan includes utilization of infection control data, safety data, risk data, high risk/high volume and problem prone process data to monitor and improve the effectiveness and of its services and quality of its care.</p> <p>(See attachment #1)</p> <p>A "Performance Improvement Indicator s"policy and procedure and monthly tracking form were developed on 6/17/11.</p> <p>Performance improvement indicators to be presented to the Governing Board for approval to ensure ongoing monitoring include but are not limited to:</p> <ul style="list-style-type: none"> Monitoring of post-op infections Adverse patient events Hospital transfers Post op contacts Tissue review Surgical and Anesthesia complications Employee Exposures Medication Documentation Adverse Drug reactions Medication Errors Patient satisfaction <p>(See attachment #2 and #3)</p>	

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Q 081	<p>Continued From page 3</p> <p>were responsible for the quality program, how often they would meet, and how they would monitor the program, was not present.</p> <p>The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She stated she was responsible for the facility's QAPI program. She stated the minutes documented meetings from the past year. She confirmed they were not dated. She stated policies defining the ASC's QAPI program and the "TOTAL QUALITY COMMITTEE" had not been developed.</p> <p>2. The ASC had not developed a QAPI plan. A plan, including a delineation of the ASC's high risk, high volume, and problem prone areas, was not present. A list of service areas participating in the QAPI program, such as anesthesia and pre-operative holding, had not been developed.</p> <p>The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She stated a plan defining the ASC's QAPI expectations for the year had not been developed.</p> <p>3. The ASC had conducted 4 patient care related "Performance Improvement Studies" between 6/01/10 and 5/31/11. These included a study of surgical start times, a study of surgery cancellations, a study of times certain processes happened during a patient's treatment, and a clinical record review. The relevance of these studies to the ASC was not defined. The ASC had not developed a plan as to how the information gathered from the studies would be used to improve care. No other quality indicators had been developed.</p>	Q 081	<p>A QAPI meeting minute template was developed on 6/17/11 to ensure reporting of all components of the QAPI program.(See attachment #5)</p> <p>The QI focus study/project format was revised to ensure the reason for implementing the project and a description of the project's results are documented. (See attachment #4)</p> <p>An "Occurrence Reporting" policy and procedure was written on 6/17/11. An occurrence reporting form with a section for follow up was developed and will be presented to the Governing Board for approval on 6/24/11. (See attachment # 6 and #7)</p> <p>The "QAPI Plan", "Performance Improvement Indicators "policy and procedure and monthly tracking form, revised QI foeus study format, "Occurrence Reporting" policy and procedure and Occurrence Reporting form will be presented for approval by the Governing Board on 6/24/11.</p> <p>Education regarding the QAPI program will be provided to the Governing Board on 6/24/11.</p> <p>Education regarding the QAPI program and the Occurrence Reporting process and reporting form will be provided to the ASC staff on 6/28/11.</p>	

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Q 081	Continued From page 4 The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She stated a plan defining the relevance of the studies to Eagle Eye Surgery and Laser Center had not been developed. 4. A policy directing how incident reports would be used at the ASC, including what incidents would be investigated and what data would be collected, was not present. Reports of 38 incidents, occurring from 3/01/11 through 5/31/11 were reviewed. None of these incident reports documented an investigation of the event or actions that were taken to prevent further incidents. The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She confirmed documentation of investigations was not present. She stated she had been told by her attorney not to document the investigations of incidents. The ASC failed to develop and implement a QAPI program that would lead to improved health outcomes and increased safety.	Q 081	Monitoring and Responsible Party: The Center Director is responsible for ensuring QAPI and occurrence reporting data will be collected, aggregated, analyzed and trended on an ongoing basis. The Center Director or designee will monitor the QAPI performance improvement indicator monthly tracking summary each month to ensure completion of all data collection. The Center Director or designee will ensure completion of follow up regarding "each center occurrence on an ongoing basis by reviewing each report. The Center Director will report regarding the PI indicators, ASC specific performance improvement projects and center occurrences to the QAPI Committee after one month and submit the report and recommendations to the Governing Board after one month then the Center Director will report to the QAPI committee and Governing Board quarterly. The Governing Board will complete a review of the QAPI program annually. (See attachment #9).	
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.	Q 082	Plan of Correction: The ASC will ensure data is used to monitor the effectiveness and safety of its service, to track adverse patient events, and to identify opportunities that could lead to improvements in patient care. Systemic Changes: A "Performance Improvement Indicators" policy and procedure and monthly tracking form were developed on 6/17/11.	6/28/11

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Q 082	<p>Continued From page 5</p> <p>(c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.</p> <p>(c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and review of ASC policies and QAPI documents and meeting minutes, it was determined the facility failed to ensure data was used to monitor the effectiveness and safety of its services, to track adverse patient events, and to identify opportunities that could lead to improvements in patient care. This resulted in the inability of the ASC to make changes to improve care. Findings include:</p> <p>1. The ASC had not used data to monitor the effectiveness and safety of its services and quality of its care. The ASC had conducted 4 patient care related "Performance Improvement Studies" between 6/01/10 and 5/31/11. These included a study of surgical start times, a study of surgery cancellations, a study of times certain processes happened during a patient's treatment, and a clinical record review. While data had been gathered for all of these studies, no documentation was present to indicate the data had been evaluated or otherwise utilized. For example, a document titled "AAAHC Institute for Quality Improvement Benchmark Study on Cataracts 2010," not dated, documented how</p>	Q 082	<p>Performance improvement indicators to be presented to the Governing Board for approval to ensure ongoing monitoring include but are not limited to:</p> <ul style="list-style-type: none"> Monitoring of post-op infections Adverse patient events Hospital transfers Post op contacts Tissue review Surgical and Anesthesia complications Employee Exposures Medication Documentation Adverse Drug reactions Medication Errors Patient satisfaction <p>(See attachment #2 and #3)</p> <p>The QI focus study/project format was revised to ensure the reason for implementing the project; an analysis of the data collected and a description of the project's results are documented. (See attachment #4) The "Surgical Start Times" QI focus study has been rewritten on this format to demonstrate the reason for implementing the project and that an analysis of the data has been conducted. (See attachment # 8) Results of the "Surgical Start Times" focus study will be presented to the QAPI Committee on 6/22/11 for review and recommendations then recommendations will be submitted to the Governing Board on 6/24/11.</p> <p>An "Occurrence Reporting" policy and procedure was written on 6/17/11. An occurrence reporting form with a section for follow up was developed and will be presented to the Governing Board for approval on</p>	

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Q 082	<p>Continued From page 6</p> <p>long it took for various processes during cataract procedures, including pre-procedure times, procedure times, discharge times, and overall facility time. These times were compared to other facilities who also completed the study. However, no conclusions were drawn by the ASC. None of the study reports discussed the data that had been gathered and how it related to the operation of Eagle Eye Surgery and Laser Center. Also, none of the minutes from the 4 "TOTAL QUALITY COMMITTEE" meetings discussed the data that had been gathered and how it related to the operation of the ASC.</p> <p>The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She confirmed documentation of how program data had been utilized was not present.</p> <p>2. The ASC had not tracked adverse patient events or examined their causes. Reports of 38 incidents, occurring from 3/01/11 through 5/31/11 were reviewed. None of these incident reports documented an investigation of the event or actions that were taken to prevent further incidents. No reports tracking incidents over time or comparing them to the number of events in previous quarters or years were present.</p> <p>The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She confirmed adverse events were not analyzed or tracked.</p> <p>3. The ASC had not identified opportunities that could lead to improvements and changes in its patient care. The past 4 "TOTAL QUALITY COMMITTEE" meeting minutes, none of them dated, were reviewed. None of the minutes</p>	Q 082	<p>6/11. (See attachment # 6 and #7)</p> <p>A QAPI meeting minute template was developed on 6/17/11 to ensure reporting of all components of the QAPI program.(See attachment #5)</p> <p>The "Performance Improvement Indicators" policy and procedure and monthly tracking form, revised QI focus study format, the revised "Surgical Start Times" focus study, "Occurrence Reporting" policy and Occurrence Reporting form will be presented for approval by the Governing Board on 6/24/11.</p> <p>Education regarding the PI Indicators policy and procedure and the Occurrence Reporting process and reporting form will be provided to the ASC staff on 6/28/11.</p> <p>Monitoring and Responsible Party: The Center Director is responsible for ensuring QAPI and occurrence reporting data will be collected, aggregated, analyzed and trended on an ongoing basis. The Center Director or designee will monitor the QAPI performance improvement indicator monthly tracking summary each month to ensure the completion of all data collection. The Center Director or designee will ensure completion of follow up on each center occurrence on an ongoing basis by reviewing each report. The Center Director will report regarding the PI indicators, ASC specific performance improvement projects and center occurrences to the QAPI Committee after one month and submit the report and recommendations to the Governing Board after one month then the</p>	

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Q 082	Continued From page 7 documented how data collected in the previous quarter had been used to improve care. None of the minutes included a discussion of ways to improve care at the ASC. The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She stated she did not have evidence that the ASC had discussed ways to improve care. She also said she could not think of any changes that had been made to procedures or facility practices at the ASC in the past year as a result of the QAPI program. The ASC had not utilized its QAPI program to monitor and make improvements to care.	Q 082	Center Director will report to the QAPI committee and Governing Board quarterly. The Governing Board will complete a review of the QAPI program annually. (See attachment #9).		
Q 083	416.43(d) PERFORMANCE IMPROVEMENT PROJECTS (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results This STANDARD is not met as evidenced by: Based on staff interview and review of QAPI documents and meeting minutes, it was determined the facility failed to ensure the ASC documented the projects that were conducted, including the reason for implementing the project and a description of the project's results. This resulted in the ASC's inability to derive	Q 083	Plan of Correction: The ASC will ensure documentation of the QAPI projects conducted including the reason for implementing the project and a description of the project's results. Systemic Changes: The QI focus study/project format was revised to ensure the reason for implementing the project, an analysis of the data collected and a description of the project's results are documented. (See attachment #4) The "Surgical Start Times" QI focus study has been rewritten on this format to demonstrate the reason for implementing the project and an analysis of the data has been conducted. (See attachment # 8) Results of the "Surgical Start Times" focus study will be presented to the QAPI Committee on 6/22/11 for review and recommendations then recommendations will be submitted to the Governing Board on 6/24/11.	6/28/11	

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Q 083	<p>Continued From page 8</p> <p>meaningful data from the studies. Findings include:</p> <p>1. The ASC had conducted 4 patient care related "Performance Improvement Studies" between 6/01/10 and 5/31/11. None of these studies were dated. They studied surgical start times, a surgery cancellations, a study titled "AAAHC Institute for Quality Improvement Benchmark Study on Cataracts 2010," and clinical record review. Studies included:</p> <p>a. The document "Performance Improvement Study-Surgical Start Time" documented gathering data to determine how many surgeries started within 7 minutes of their scheduled start times. The document "TOTAL QUALITY COMMITTEE MEETING MINUTES," not dated but stating it was the report for the first quarter of 2011, did not mention the study.</p> <p>The Clinical Director, interviewed on 6/02/11 beginning at 8:20 AM, stated the study was currently gathering data and had been since January 2011. She stated physicians had widely different percentages of adherence to surgical start times. She stated the TOTAL QUALITY COMMITTEE had not approved the study. She stated no changes had been made to facility practices based on the data. She stated she did not know how the data would be used when the study was completed.</p> <p>b. The document "Performance Improvement Study-Surgery Cancellations," not dated, stated the goal was to compare the number of cancelled surgeries at Eagle Eye Surgery and Laser Center with other ASCs. The document "TOTAL</p>	Q 083	<p>A QAPI meeting minute template was developed on 6/17/11 to ensure reporting of all components of the QAPI program.(See attachment #5)</p> <p>The medical record chart audit form was revised on 6/18/11 to remove criteria which RN reviewers are not qualified to review. Criteria regarding some of the medical record documentation deficiencies cited during the CMS survey were added. (See attachment # 10)</p> <p>The revised QI focus study format, the "Surgical Start Times" focus study, and the medical record audit tool will be presented for approval by the Governing Board on 6/24/11.</p> <p>Education regarding the revised medical record audit tool and the results of the "Surgical Start Times" focus study will be presented to the ASC staff on 6/28/11.</p> <p>Monitoring and Responsible Party: The Center Director is responsible for ensuring complete documentation all QAPI projects to derive meaningful data from the studies. The Center Director will report regarding the ASC specific performance improvement projects to the QAPI Committee after one month and submit the report and recommendations to the Governing Board after one month then the Center Director will report to the QAPI committee and Governing Board quarterly.</p>	

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Q 083	<p>Continued From page 9</p> <p>QUALITY COMMITTEE MEETING MINUTES," not dated, stated it was the report for the third quarter of 2010. The report stated a final report was to follow next quarter. The document "TOTAL QUALITY COMMITTEE MEETING MINUTES," not dated, stated it was the report for the fourth quarter of 2010. This report stated the results of the surgery cancellation study were compared to small group as well as national benchmarks. The report did not state how the ASC compared to other facilities. No further mention of the study was documented and no analysis of the data was documented.</p> <p>The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She stated the data had not been analyzed and no process changes were made as a result of the study.</p> <p>c. A document titled "AAHC Institute for Quality Improvement Benchmark Study on Cataracts 2010," not dated, stated a national study of cataract surgeries was done. It stated different types of facilities participated. It stated different types of anesthesia were used. It gave a range of pre-procedure times, procedure times, and discharge times for facilities and listed these times in relation to national averages. No value judgements were drawn by the study. The document did not state if more or less time for these procedures had an impact on the quality of care provided. No suggestions to improve care were included.</p> <p>The document "TOTAL QUALITY COMMITTEE MEETING MINUTES," not dated, stated it was the report for the fourth quarter of 2010. The minutes stated the AAHC study had occurred</p>	Q 083		

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Q 083	<p>Continued From page 10 and the report had been reviewed. No evaluation of the report's findings was documented. No mention of the study was mentioned in subsequent "TOTAL QUALITY COMMITTEE MEETING MINUTES."</p> <p>The Clinical Director was interviewed on 6/02/11, beginning at 8:20 AM. She stated the data had not been analyzed and no process changes were made as a result of the study.</p> <p>d. The document "TOTAL QUALITY COMMITTEE MEETING MINUTES," not dated, stated it was the report for the first quarter of 2011. The minutes stated "Clinical Staff [were] asked to complete Clinical Records Worksheet on 5 charts each, chosen randomly." The worksheet consisted of 41 items. The items mirrored the AAAHC accrediting standards. The "clinical staff" who completed the worksheets were RNs. The "TOTAL QUALITY COMMITTEE MEETING MINUTES" stated the results yielded 2 "changes/improvements." These included having patients sign a new "HIPPA" sticker and to develop a new form for documentation of pre and post-operative calls to patients. The results of the record reviews was not documented in the meeting minutes and no suggestions to improve care were documented. Also, the "Clinical Records Worksheet" contained questions such as "The diagnosis is appropriate for the findings in the current history and physical examination." and "Treatment, diagnostic and therapeutic procedures are consistent with clinical impression or working diagnosis." RN reviewers were not qualified to answer these questions.</p> <p>The Clinical Director was interviewed on 6/02/11,</p>	Q 083			

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Q 083	Continued From page 11 beginning at 8:20 AM. She stated RNs who completed the worksheets had not received any training specific to completing the worksheets. She stated she did not have documentation that further analysis of the "Clinical Records Worksheet" study had been completed. She stated she could not think of other changes to facility practices that had occurred as a result of this study.	Q 083		
Q 162	416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. This STANDARD is not met as evidenced by:	Q 162	Plan of Correction: The ASC will maintain a medical record for each patient and ensure medical records are complete and accurate. Systemic Changes: 1. A policy addressing anesthesia documentation was written on 6/17/11 and titled "Documentation of Anesthesia Care." The policy addresses documentation of drugs including name, dosage, route and time of administration. . (See attachment #11) The "Documentation of Anesthesia Care" policy will be presented for approval by the Governing Board on 6/24/11. The policy will be reviewed with anesthesia providers with specific emphasis regarding documentation of medication dosages on 6/28/11.	6/28/11

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Q 162	<p>Continued From page 12</p> <p>Based on record review and staff interview it was determined the facility failed to ensure medical records were complete and accurate for 12 of 20 patients (#3, #4, #7, #8, #9, #10, #11, #12, #14, #16, #19 and #20) whose records were reviewed, and who had surgical procedures with sedation or general anesthesia. Failure to ensure completeness and clarity in the medical record had the potential to negatively impact patient care. Findings included:</p> <p>1. Anesthesia records lacked clarity in the documentation of drug dosage and administration as follows:</p> <p>a. Patient #4 was a 69 year old male who was admitted on 5/05/11 for the removal of his left eye. The anesthesia record, dated 5/05/11 indicated Patient #4 had conscious sedation. The Anesthesia Record was unclear as to the amount of medications Patient #4 had received, and the CRNA documentation included a number after the medications as detailed below:</p> <ul style="list-style-type: none"> - Versed, 2 - Fent, 1, 1 (Fentanyl) - Propofol, 80,30,30 - Ketamine, 50, 50 - Labetalol, 10 <p>In an interview on 6/01/11 beginning at 3:00 PM, the CRNA reviewed the record and confirmed the lack of documentation that provided clarity of medication dosages administered.</p> <p>b. Patient #11 was a 79 year old male, who was admitted on 6/01/11 for a cataract removal of his left eye. The anesthesia record, dated 6/01/11</p>	Q 162	<p>2. and 4. A policy addressing completion of a History and Physical was revised on 6/17/11. (See attachment # 12). The H&P form was revised to include a date of completion on page 1 and clarification of who completed the form and who provided the information on both page 1 and page 2. The section for documentation of the pre -anesthesia risk and evaluation and the H&P update was revised to show separation of the two components. (See attachment # 13).</p> <p>The revised "History and Physical" policy and revised H&P form will be presented for approval by the Governing Board on 6/24/11.</p> <p>The Center Director will be meeting with the various physician's office staff to review the revised form and completion of the patient's history including signature dates and times.</p> <p>Education regarding the revised "History and Physical" policy and revised H&P form will be provided to the ASC staff and medical staff on 6/28/11.</p> <p>3. A policy was written on 6/17/11 regarding writing and noting of physician's orders and titled "Physician's Orders." (See attachment # 14)</p> <p>The "Physician's Orders" policy will be presented for approval by the Governing Board on 6/24/11</p> <p>Education regarding the "Physician's Orders" policy will be provided to the ASC staff and medical staff on 6/28/11.</p>	

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Q 162	<p>Continued From page 13</p> <p>was unclear as to the amount of medications Patient #11 had received, and the CRNA documentation had not been specific with documentation of the drug dosages administered as detailed below:</p> <p>-Versed/mg, 11 -Fentanyl/ml, 11 -NS flush, 2</p> <p>In an interview on 6/01/11 beginning at 3:00 PM, the CRNA reviewed the record and stated eleven mg of Versed and Fentanyl had not been administered. He stated 1 mg and then an additional 1 mg had been administered to Patient #11 during the interval between 11:00 AM and 11:15 AM. The CRNA confirmed the lack of documentation that provided clarity of medication dosages administered.</p> <p>c. Patient #10 was a 46 year old male, who was admitted on 6/01/11 for a cataract removal of his left eye. The anesthesia record, dated 6/01/11 was unclear as to the amount of medications Patient #10 had received, and the CRNA documentation had not been specific with documentation of the drug dosages administered as detailed below:</p> <p>-Versed/mg, 11 -Fentanyl/ml, 11</p> <p>In an interview on 6/01/11 beginning at 3:00 PM, the CRNA reviewed the record and stated eleven mg of Versed and Fentanyl had not been administered. He stated 1 mg and then an additional 1 mg had been administered to Patient #10 during the interval between 9:30 AM and 9:45</p>	Q 162	<p>5. A policy addressing documentation of an operative procedure was written on 6/18/11 and titled "Documentation of Operative Procedure." (See attachment # 20) This policy clarifies operative reports will contain dates of dictation and transcription as applicable and operative reports are signed and dated by the surgeon.</p> <p>The "Documentation of Operative Procedure" policy will be presented for approval by the Governing Board on 6/24/11</p> <p>Education regarding the "Documentation of Operative Procedure" policy will be provided to the ASC staff and medical staff on 6/28/11.</p> <p>Monitoring and Responsible Party: The Center Director is responsible for ensuring medical records are complete and accurate. The operating surgeon is responsible for ensuring accuracy of operating report post dictation and will be confirmed by his/her signature. The Center Director or designee will audit 100% of the Medical Records for a period of 2 weeks beginning on 6/30/11. The audits will include documentation of anesthesia medication; dates and signatures on H&Ps; noting of physicians orders; dates of transcription and dictation on operative reports as applicable; and authentication of the operative report by the surgeon. If 100 % compliance is achieved, then this will be monitored on an ongoing basis as part of the monthly chart audit process. (See attachment # 10) If 100% compliance is not achieved, the education will be repeated and the monitoring process will start over.</p>	

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Q 162	<p>Continued From page 14</p> <p>AM. The CRNA confirmed the lack of documentation that provided clarity of medication dosages administered.</p> <p>d. Patient #12 was a 74 year old female, who was admitted on 6/01/11 for a cataract removal of her left eye. The anesthesia record, dated 6/01/11 was unclear as to the amount of medications Patient #12 had received, and the CRNA documentation had not been specific with documentation of the drug dosages administered as detailed below:</p> <p>-Versed/mg, 11 -Fentanyl/ml, 11 -NS flush, 2</p> <p>In an interview on 6/01/11 beginning at 3:00 PM, the CRNA reviewed the record and stated eleven mg of Versed and Fentanyl had not been administered. He stated 1 mg and then an additional 1 mg had been administered to Patient #12 during the interval between 10:30 AM and 10:45 AM. The CRNA confirmed the lack of documentation that provided clarity of medication dosages administered.</p> <p>e. Patient #19 was a 68 year old female who was admitted on 5/11/11 for cataract extraction of her left eye. The anesthesia record, dated 5/11/11 was unclear as to the amount of medications Patient #19 had received, and the CRNA documentation was not specific with documentation of the drug dosages administered as detailed below:</p> <p>-Versed, 2 -Fen, 1</p>	Q 162	The Center Director will report the results of the audits to the QAPI Committee quarterly and will submit report and recommendations to the Governing Board on a quarterly basis.	

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Q 162	<p>Continued From page 15</p> <p>During an interview on 6/02/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed the medication administration documentation was not clear.</p> <p>f. Patient #3 was a 68 year old male with a diagnosis of glaucoma. He had a revision of operative wound to his right eye on 3/01/11. The anesthesia record, dated 3/01/11 documented:</p> <p>-Versed, 3 -Propofol, 90</p> <p>During an interview on 6/02/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed the medication administration documentation was not clear.</p> <p>Medications administered by the CRNA did not include dosages, and it was unclear what the patients had actually received.</p> <p>2. Patient H&P forms lacked clarity of who had completed the form, the date they had been completed, as well as documentation of who had made additions to the forms after the written date of completion as follows:</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director reviewed an untitled two page form. She stated the form was used by the all the physicians who performed surgery at the ASC for the pre-operative H&P. There was no section on the first page of the form for the date it had been completed. The second page was divided into four sections; the first section was a continuation of the H&P. The bottom of that</p>	Q 162		

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Q 162	<p>Continued From page 16</p> <p>section had the notation: "Signature of person completing this form....Relationship.....Date." The Clinical Director stated the patient usually completed and signed the second page of the H&P. She stated the clinic staff in the office would often assist the patient in filling out the form.</p> <p>a. Patient #4 was a 69 year old male who was admitted on 5/05/11 for the removal of his left eye. On the second page of the H&P, after the notation: "Signature of person completing this form...Relationship...Date," the spaces to be filled in remained blank.</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director stated the patient usually completed and signed the second page of the H&P. She stated sometimes the clinic staff in the office would assist the patient in filling out the form. The Clinical Director stated the physician, CRNA, or admitting RN would sometimes add to the sheet if information had changed. She stated there was no policy regarding how the H&P form was to be completed, or how to document when it had been amended.</p> <p>b. Patient #11 was a 79 year old male, who was admitted on 6/01/11 for a cataract removal of his left eye. The second page of the H&P, after the notation: "Signature of person completing this form....Relationship.....Date" the spaces to be filled in remained blank.</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director reviewed the record and confirmed Patient #11 had not completed or dated the first section of the form.</p>	Q 162		

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Q 162	<p>Continued From page 17</p> <p>c. Patient #14 was a 6 year old male with a diagnosis of glaucoma who had an examination of his eyes under anesthesia on 4/21/11. The "Pediatric Medical History and Physical," was dated 4/20/11. The statement "History reviewed without changes" on the bottom of the form was not dated.</p> <p>During an interview on 6/2/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed Patient #14's H&P had not been dated.</p> <p>d. Patient #3 was a 68 year old male with a diagnosis of glaucoma. He had a revision of an operative wound to his right eye on 3/01/11. The untitled H&P was signed but not dated. The statement "History reviewed without changes" on the bottom of the form also was not dated.</p> <p>During an interview on 6/2/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed Patient #3's H&P had not been dated.</p> <p>3. Physician Orders as well as notation of Physician Orders were not dated and/or timed as follows:</p> <p>a. Patient #4 was a 69 year old male who was admitted on 5/05/11 for the removal of his left eye. A form, titled "ORDERS" undated, was divided into 2 sections, "Pre-Operative, and Post-Operative." Both sections had been signed by the physician who performed the surgical procedure, but there was no date or time when the orders had been written. The Post-Operative section was dated and noted with initials only, and there was no time included.</p>	Q 162		

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NAME OF PROVIDER OR SUPPLIER EAGLE EYE SURGERY AND LASER CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 3090 GENTRY WAY, SUITE 100 MERIDIAN, ID 83642		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
Q 162	<p>Continued From page 18</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director stated there was no facility policy for writing and the noting of orders. She stated she had instructed the nursing staff to only include initials, as well as not writing the time the orders had been noted. The Clinical Director stated her staff noted only the Post-Operative section of the orders because they usually included instructions for discharge medications. The Clinical Director stated the orders were written and signed by the physician during the pre-operative visit in the office.</p> <p>b. Patient #11 was a 79 year old male, who was admitted on 6/01/11 for a cataract removal of his left eye. A form, titled "ORDERS" undated, was divided into 2 sections, "Pre-Operative, and Post-Operative." Both sections had been signed by the physician who performed the surgical procedure, but there was no date or time when the orders had been written.</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director stated the orders were written and signed by the physician during the pre-operative visit in the office.</p> <p>c. Patient #20 was a 41 year old female, admitted on 5/23/11 for a corneal transplant. A form, titled "ORDERS" undated, was divided into 2 sections, "Pre-Operative, and Post-Operative." Both sections had been signed by the physician who performed the surgical procedure, but there was no date or time when the orders had been written. The Pre-Operative orders had not been noted.</p> <p>During an interview on 6/2/11 beginning at 11:10</p>	Q 162			

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Q 162	<p>Continued From page 19</p> <p>AM, the Clinical Director stated the orders were written and signed by the physician during the pre-operative visit in the office. The Clinical Director stated her staff noted only the Post-Operative section of the orders because they usually included instructions for discharge medications.</p> <p>d. Patient #19 was a 68 year old female who was admitted on 5/11/11 for cataract extraction of her left eye. A form titled "EAGLE EYE SURGERY AND LASER CENTER CATARACT ORDERS," was divided into 2 sections, "Pre-Operative, and Post-Operative." Both sections had been signed by the physician who performed the surgical procedure, but there was no date or time when the orders had been written. The Pre-Operative orders had not been noted.</p> <p>The surgeon on duty was interviewed on 6/01/11 at 3:50 PM. He reviewed the order form. He stated both pre-operative and post-operative orders were signed in the office prior to the date of the procedure. He stated he typically did not date orders when they were written.</p> <p>e. Patient #3 was a 68 year old male with a diagnosis of glaucoma. He had a revision of operative wound to his right eye on 3/01/11. The form "EAGLE EYE SURGERY AND LASER CENTER ORDERS" did not contain the date or time the pre-operative and post-operative orders were written.</p> <p>During an interview on 6/2/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed Patient #3's orders were not timed or dated.</p>	Q 162		

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Q 162	<p>Continued From page 20</p> <p>4. Pre surgical review of the H&P by physician and/or CRNA lacked signature and date, or were signed before the assessment had been done as follows:</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director reviewed a two page form titled "Past Medical History." She stated the form was used by the all of the physicians who performed surgery at the ASC for the pre-operative H&P. The second and third sections of the form were labeled: "Following sections for Ophthalmologist use," and "History reviewed without changes." The Clinical Director stated the second section was completed by the physician when the pre operative evaluation was done. She said the third section was completed on the day of surgery. The fourth section was labeled "Following section for Anesthesia Use." Each of the sections contained an area to be signed and dated.</p> <p>a. Patient #4 was a 69 year old male who was admitted on 5/05/11 for the removal of his left eye. On the second page of the H&P, after the notation: "History reviewed without changes," and "Following section for Anesthesia Use," contained an area to be signed and dated. The "History reviewed without changes" section had not been signed or dated. The Anesthesia section had been signed but not dated.</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director reviewed the record and confirmed the physician had not signed or dated the form and the CRNA had not dated the form.</p>	Q 162		

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Q 162	<p>Continued From page 21</p> <p>b. Patient #20 was a 41 year old female, who was admitted on 5/23/11 for a corneal transplant to her left eye. The second section of the H&P, completed by the ophthalmologist stating the history had been reviewed without changes, had not been signed.</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director reviewed the record and confirmed the H&P review on the day of surgery had not been signed.</p> <p>c. The following patients' H&P's were completed by the ophthalmologist, and signed 5/30/11, a recognized holiday.</p> <p>i. Patient #9 was a 63 year old female, who had a cataract removal of her left eye on 6/01/11. Her history and physical form was not titled but was dated 5/30/11 (Memorial Day). A pre-printed statement at the bottom of the form reading "History reviewed without changes" was dated 6/01/11.</p> <p>Patient #9's surgeon was interviewed on 6/01/11 beginning at 3:50 PM. He stated the history and physical had been completed in the office the week before surgery (5/23/11-5/27/11). He stated he did not know why it was dated 5/30/11. He also said the statement "History reviewed without changes" was dated with the date of surgery but was signed in the office prior to the date of surgery.</p> <p>ii. Patient #10 was a 46 year old male, who was admitted on 6/01/11 for a cataract removal of his left eye. His H&P was dated 5/30/11.</p>	Q 162		
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Q 162	<p>Continued From page 22</p> <p>iii. Patient #12 was a 74 year old female, who was admitted on 6/01/11 for a cataract removal of her left eye. Her H&P was dated 5/30/11.</p> <p>iv. Patient #11 was a 79 year old male, who was admitted on 6/01/11 for a cataract removal of his left eye. The second page of the H&P was dated 5/30/11. The third section, was noted to be signed before Patient #11 was admitted for surgery and it was not dated.</p> <p>After the surgery on 6/01/11, the record for Patient #11 was reviewed again, and the signature in that section was then dated 6/01/11.</p> <p>During an interview on 6/2/11 beginning at 11:10 AM, the Clinical Director reviewed the records and confirmed the second section of the forms had been dated on a holiday. She said she knew the clinic offices had not been open that day, and was unable to explain why they had been signed and dated 5/30/11. The Clinical Director stated physicians would often sign "both sections" then would date the third section on the day of surgery in an effort to "save time."</p> <p>5. Operative reports were not accurate, and did not contain dates of dictation and transcription as follows:</p> <p>a. Patient #4 was a 69 year old male who was admitted on 5/05/11 for the removal of his left eye. The Anesthesia Record, dated 5/05/11 documented Patient #4 had conscious sedation. The undated typed Operative Report included documentation that Patient #4 had general endotracheal anesthesia. The report did not provide information regarding the dictation date,</p>	Q 162		

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Q 162	<p>Continued From page 23 by whom, and the transcription date, by whom.</p> <p>In an interview on 6/2/11 at 10:15 AM, the receptionist stated she had typed the operative report for Patient #4. She stated she had made an error in the transcription of his report. She showed how she gathered information from the patient record and "plugged in" the information into a template on her computer that made up the report. The receptionist stated she transcribed most of the reports, and explained the reports she transcribed would not have a dictation date or a transcription date, as they had not been "dictated." She said the physician reports that had actually been dictated would be sent to the contracted dictation service, and those reports would be transcribed.</p> <p>b. Patient #8 was a 13 year old female who was admitted on 5/12/11 for the removal of a chalazion, a bump caused by a blockage of an oil duct, from her left eye lid. The operative report stated it was faxed to the facility on 5/31/11 but did not state when it was written.</p> <p>During an interview on 6/01/11 beginning at 11:10 AM, the Clinical Director reviewed the record and confirmed the operative report was not dated.</p> <p>c. Patient #19 was a 68 year old female who was admitted on 5/11/11 for cataract extraction of her left eye. The operative report was not dated.</p> <p>During an interview on 6/02/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed the operative report was not dated.</p> <p>d. Patient #16 was an 80 year old female who</p>	Q 162		

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Q 162	<p>Continued From page 24</p> <p>had a cataract removal and lens implant on her right eye on 3/23/11. The operative report was signed but was not dated.</p> <p>During an interview on 6/02/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed the operative report was not dated.</p> <p>e. Patient #7 was a 73 year old male who had cataract surgery on his right eye on 5/03/11. The untitled operative report was not dated.</p> <p>During an interview on 6/02/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed the operative report was not dated.</p>	Q 162		
Q 181	<p>416.48(a) ADMINISTRATION OF DRUGS</p> <p>Drugs must be prepared and administered according to established policies and acceptable standards of practice.</p> <p>This STANDARD is not met as evidenced by: Based on observations and staff interview, it was determined the facility failed to ensure drugs and biologicals were stored, labeled, utilized, and monitored in accordance with accepted standards of practice. This had the potential to impact all patients who received drugs and biologicals at the ASC. This resulted in the potential for administration errors and/or the loss of integrity, stability, effectiveness, and sterility of medications. Findings include:</p>	Q 181	<p>Plan of Correction: The ASC will ensure drugs are prepared and administered according to established policies and acceptable standards of practice.</p> <p>Systemic Changes: The Center Director immediately removed all expired medications. A policy for procurement and storage of medications was written on 6/19/11 and titled "Drugs Procurement and Storage." The policy addresses monthly checks for expired medications. (See attachment # 15) A check for expired medications is conducted monthly. An ASC staff member will be assigned to each location where medication is stored. The ASC staff member will check their assigned area monthly and remove expired medications. The expiration date for the first medication to expire next will be documented on the Quality Assurance tool #2. (See attachment # 16).</p>	6/28/11

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Q 181	<p>Continued From page 25</p> <p>1. The following expired medications were available for patient use:</p> <p>a. During a tour of the facility treatment rooms on 5/31/11 at 11:00 AM, the following expired medications were found, still in circulation for patient use:</p> <ul style="list-style-type: none"> -an opened bottle of Goniovisc, with an expiration date of 10/20/10 -an opened bottle of Refresh, with an expiration date of 5/25/11 -an opened bottle of Tetcain, with an expiration date of 5/30/11 -three packages of Durezol with an expiration date of 4/11 -a bottle of Optive, with an expiration date of 11/10 -three bottles of sterile irrigation solution, with expiration dates of 9/10, 2/11 and 3/11 <p>The Clinical Director, who was present during the tour, removed and discarded the medications. She stated the nursing staff were supposed to check all medications for outdates, even in the treatment rooms.</p> <p>b. During a tour of the ASC nurses station starting at 11:15 AM, the following expired medications were found, still in circulation for patient use:</p> <ul style="list-style-type: none"> -Marcain/Cyclo/Neosyn, 2 vials, expired 3/09/11 	Q 181	<p>A policy and procedure for Safe Injection Practices was written on 6/19/11 and titled "Safe Injection Practices." The policy addresses labeling of multi dose medication vials and pre-drawn syringes which are not used immediately. (See attachment # 17)</p> <p>The "Drugs Procurement and Storage" policy and the "Safe Injection Practices" policy will be presented for approval by the Governing Board on 6/24/11</p> <p>Education regarding the "Drugs Procurement and Storage" will be provided to the ASC staff on 6/28/11. Education regarding the "Safe Injection Practices" will be provided to the ASC staff and anesthesia personnel on 6/28/11.</p> <p><u>Responsible Party/Monitoring:</u> The Center Director is responsible for ensuring drugs are prepared and administered according to established policies and acceptable standards of practice. The Center Director or designee will perform spot checks for compliance with the "Safe Injection Practices" policy and procedure and medication outdate checks for a period of two weeks beginning on 6/30/11. If 100% compliance is achieved, then this will be monitored on an ongoing basis as part of the quality assurance tool checks. If 100% compliance is not achieved, the education will be repeated and the monitoring process will start over. The Center Director will report the results of the audits to the QAPI Committee quarterly and will submit report and recommendations to the Governing Board on a quarterly basis.</p>	
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Q 181	<p>Continued From page 26 and 5/11/11</p> <p>-C-Tetra/cyclo/Neo, 2 vials, expired 5/11/11</p> <p>The expired medications were witnessed and removed by the Clinical Director, who was present during the tour.</p> <p>c. A tour of the ASC OR suites was conducted on 6/01/11, starting at 8:00 AM. During the tour, the following opened medications were found, available for patient use:</p> <p>-an opened vial of 2% Lidocaine 20 mg/ml, opened 5/03/11,</p> <p>-a needle capped syringe, with a strip of clear tape, on which was written "Haldol 0.5 mg/ml 5/19/11 at 12:09" with initials.</p> <p>-a needle capped syringe, with a label which read "Benadryl 10 mg/ml 5/31/11." The label was not initialed or timed.</p> <p>Both syringes contained 4.4 ml of medications.</p> <p>The medications had not been labeled with dates that indicated when they were to expire. The medications were witnessed by the CRNA in the room at the time of the tour on 6/01/11 at 8:10 AM.</p> <p>In an interview on 6/01/11 at 8:45 AM, the Clinical Director stated the medications that had been drawn up in syringes were good for 28 days as was the standard for opened medications in vials. She was not able to provide a policy for the practice of storing medications in syringes. She</p>	Q 181		

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Q 181	Continued From page 27 stated she was going to check with the ASC pharmacist. In an second interview on 6/03/11 at 11:25 AM, the Clinical Director stated the Haldol was supplied in 5 mg/ml 1 ml vials, and had been diluted to 0.5 mg/ml. She was unable to say what diluents had been used, but thought it was Normal Saline. The Clinical Director stated the ASC pharmacist had not returned her call regarding the stability of the medications that had been drawn up in the syringes.	Q 181		
Q 261	The facility did not ensure the medication system adhered to acceptable standards of practice. 416.52(a)(1) ADMISSION ASSESSMENT Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy. This STANDARD is not met as evidenced by: Based on record review, review of policies, and staff interview it was determined the facility failed to document a current H&P in the medical records of 3 of 20 patients (#2, #15 and #16), whose records were reviewed. This failure led to the potential for patients to receive inadequate care during and after the procedure. Findings included: 1. The ASC's "HISTORY AND PHYSICAL"	Q 261	Plan of Correction: The ASC will ensure a significant medical history and physical examination is completed by a physician within 30 days of the procedure and is present on the patient's chart prior to surgery. Systemic Change: The policy addressing completion of a History and Physical was revised on 6/17/11. (See attachment # 12). The revised "History and Physical" policy will be presented for approval by the Governing Board on 6/24/11. The Center Director will be meeting with the various physicians' office staff to review the requirement regarding completion of the H&P within 30 days of the procedure.	6/28/11

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
Q 261	<p>Continued From page 28</p> <p>policy, revised March 2011, stated that an H&P was to be performed by the physician within 30 days prior to the scheduled surgery date. The facility failed to ensure the policy was consistently implemented as follows:</p> <p>a. Patient #15 was a 3 year old female admitted to the facility on 4/21/11 for surgical repair of exotropia (an outward deviation of both eyes). The record contained an H&P, dated 3/10/11. The H&P was completed more than 30 days before the operative procedure.</p> <p>The medical chart was reviewed with the Clinical Director on 6/2/11, during an interview that started at 11:10 AM. She confirmed the H&P was completed more than 30 days before the operative procedure.</p> <p>b. Patient #2 was a 64 year old male admitted to the facility on 4/11/11 for a cataract removal and lens implant on his right eye. The record contained an H&P, dated 3/11/11. The H&P was completed more than 30 days before the operative procedure.</p> <p>The medical chart was reviewed with the Clinical Director on 6/2/11, during an interview that started at 11:10 AM. She confirmed the H&P was completed more than 30 days before the operative procedure.</p> <p>c. Patient #16 was an 80 year old female who had a cataract removal and lens implant on her right eye on 3/23/11. Patient #16's medical record contained a H&P on an untitled form, dated 1/31/11, 51 days prior to the procedure.</p>	Q 261	<p>Education regarding the revised "History and Physical" policy will be provided to the ASC staff and medical staff on 6/28/11. Specific emphasis will be placed regarding completion of the H&P within 30 days of the procedure.</p> <p>Responsible Party/Monitoring: The Center Director is responsible for ensuring compliance with the CMS history and physical requirements. The Center Director or designee will audit 100% of the Medical Records for a period of 2 weeks beginning on 6/30/11. If 100 % compliance is achieved, then this will be monitored on an ongoing basis as part of the monthly chart audit process. (See attachment # 10) If 100% compliance is not achieved, the education will be repeated and the monitoring process will start over.</p> <p>The Center Director will report the results of the audits to the QAPI Committee quarterly and will submit report and recommendations to the Governing Board on a quarterly basis.</p>		

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

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Q 261	Continued From page 29 The Clinical Director was interviewed on 6/2/11 at 1:25 PM. She acknowledged the H&P was completed more than 30 days before the operative procedure.	Q 261		
Q 266	The facility failed to ensure that an H&P was completed 30 days prior to patients' procedures. 416.52(c)(2) DISCHARGE - ORDER [The ASC must -] Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy. This STANDARD is not met as evidenced by: Based on review of medical records, facility policy and staff interview, it was determined the ASC failed to ensure 4 of 4 patients (#5, #14, #15 and #18), who had surgical procedures with general anesthesia, were discharged with a physician's order. This had the potential to result in patients being discharged prematurely. Findings include: 1. Two facility policies, "DISCHARGE FROM OPERATING ROOM" policy, revised April 2011, and the "GENERAL POLICIES (PACU)" policy, revised April 2011, contained a list of criteria to be met prior to patient discharge. They both stated that patients who received general anesthesia were to be discharged upon the order of a physician. Medical records of patients who had received general anesthesia were reviewed and did not	Q 266	<u>Plan of Correction</u> The ASC will ensure that each patient has a discharge order signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and the ASC policy. <u>Systemic Changes:</u> A policy addressing patient discharge was written on 6/18/11 and titled "Patient Discharge." The policy addresses the requirement for the operating surgeon to sign a discharge order for all patients. (See attachment #18) In addition, the facility policy "General Policies (PACU)" was revised to clarify the requirement for the operating surgeon to sign the discharge order for all patients not only general anesthesia patients. (See attachments # 19) The "Patient Discharge" policy and the revised "General Policies (PACU)" will be presented to the Governing Board for approval on 6/24/11. Education regarding the Patient Discharge" policy and the revised "General Policies (PACU)" will be provided to the ASC staff and medical staff on 6/28/11.	6/28/11

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Q 266	<p>Continued From page 30</p> <p>contain documentation of a specific discharge order written by the physician after recovery from general anesthesia.</p> <p>a. Patient #15 was a 3 year old female who had a surgical correction of bilateral exotropia (an outward deviation of each eye) on 4/21/11. Patient #15 received general anesthesia for the procedure, and the anesthesia record indicated she went to the PACU in stable condition. The "Post Anesthesia" record indicated Patient #15 was discharged home with family members at 10:15 AM. There was no documentation that a physician had ordered the discharge as per policy.</p> <p>b. Patient #18 was a 39 year old female who had a surgical procedure to correct a blocked tear duct on her right eye on 5/02/11. Patient #18 received general anesthesia for the procedure, and the anesthesia record indicated she went to the PACU in stable condition. The "Post Anesthesia" record indicated Patient #18 was discharged home with her husband at 5:15 PM. There was no documentation that a physician had ordered the discharge as per policy.</p> <p>During an interview on 6/01/11 beginning at 11:10 AM, the Clinical Director reviewed the records and confirmed there had not been a discharge assessment and order signed by the physician as per policy.</p> <p>c. Patient #5 was a 69 year old male who had a biopsy of his right eye on 3/03/11 due to a mass on his eye. Patient #5's untitled procedure form stated he received general anesthesia using sevoflurane for the procedure. He was</p>	Q 266	<p>Responsible Party/Monitoring:</p> <p>The Center Director is responsible for ensuring that each patient has a discharge order signed by the physician who performed the surgery or procedure.</p> <p>The Center Director or designee will audit 100% of the Medical Records to include discharge orders with the operating surgeon's signature for a period of two weeks beginning on 6/30/11. If 100% compliance is achieved, then this will be monitored on an ongoing basis as part of the monthly medical record review process. (See attachment #10). If 100% compliance is not achieved, the education will be repeated and the monitoring process will start over. The Center Director will report the results of the audits to the QAPI Committee quarterly and will submit report and recommendations to the Governing Board on a quarterly basis.</p>	

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Q 266	<p>Continued From page 31 transferred to the PACU at 12:21 PM. The last nursing note was timed at 1:30 PM. There was no documentation that a physician had ordered the discharge as per policy.</p> <p>During an interview on 6/02/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed a discharge order was not present.</p> <p>d. Patient #14 was a 6 year old male with a diagnosis of glaucoma who had an examination of his eyes under anesthesia on 4/21/11. Patient #14's untitled procedure form stated he received general anesthesia using sevoflurane for the procedure. An order to discharge Patient #14 following the procedure was not present in his medical record.</p> <p>During an interview on 6/2/11 beginning at 1:25 PM, the Clinical Director reviewed the record and confirmed an order to discharge Patient #14's was not present.</p> <p>Medical records did not contain a physician order for patient discharge.</p>	Q 266		