

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

PRINTED: 02/15/2018
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 34C0001017	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 02/02/2018
NAME OF PROVIDER OR SUPPLIER HEALTHSOUTH BLUE RIDGE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 2308 WESVILL COURT RALEIGH, NC 27607		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
Q 000	INITIAL COMMENTS A complaint investigation was conducted January 30, 2018 through February 2, 2018 to determine the Ambulatory Surgery Center's (ASC) compliance with the Federal Medicare Conditions for Coverage for Ambulatory Surgery Centers. The investigation resulted in the identification of an immediate jeopardy to the safety of patients as evidenced by a systematic failure to ensure thorough, accurate pre-procedure verification processes that allowed opportunities for wrong site surgeries to occur. Facility staff and physicians failed to effectively implement the time-out policy prior to surgery, creating an unsafe environment for surgical patients, and resulting in wrong site / wrong implant surgeries. The facility administrator was notified on February 2, 2018 at 1440 of the identification of the potential immediate jeopardy. Based on the action plan submitted and the lack of time for developing actions and monitoring systems, the potential immediate jeopardy was determined to be on-going.	Q 000	Title Abbreviations: Chief Executive Officer CEO, Director of Nursing DON, Medical Director, MD, OR Charge ORC, Pre-op/Recovery Charge PRC SCA as a corporation allows their facilities to adopt an SCA-available policy and alter to accommodate local processes. A policy was in place at that time, used by Blue Ridge Surgery Center named Surgical Procedures and Site Validation Policy. This policy addressed the time-out process and the safety checklist for surgical procedure validation. Changes to current policy included separating the Time-out process from the safe surgical checklist. Revisions to the Time-out policy include the addition of responsibilities of each member of the peri-operative team and anesthesia provider, with hands on a patient. An action plan was drafted to include the time-out audits completed by members of the management team and chosen anesthesiologists. Our processes will be further detailed in the plan of corrections at each prefix tag.	2/1/2018 2/1/2018	
Q 040	GOVERNING BODY AND MANAGEMENT CFR(s): 416.41 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	Q 040	The Quality Council (QC) met on January 24, 2018 for the first time in 2018, reviewing 4 th quarter 2017. Discussions in this meeting included quality activities, risk management events, safety and life safety review and policy changes to include the facility time-out policy. Due to the lack of information available from 4 th quarter 2017, this meeting included only known information. This information included infection control, risk management, safety and facilities. The DON reformulated the committee and informed the membership of their responsibilities going forward from January 24, 2018. On	1/24/2018	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE



CEO

3/1/2018

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

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Q 040	Continued From page 1 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 policy and procedure reviews, event report reviews, ASC document reviews and staff and physician interviews the Governing Body failed to provide oversight and accountability to ensure safe surgical services processes and effective quality assessment and performance improvement (QAPI) programs and prioritization, including trending and monitoring performance improvement activities after adverse events. The findings include: 1. Based on policy and procedure review, medical record review, and staff and physician interviews the ASC failed to ensure safe surgical services by failing to ensure thorough and accurate pre-procedure verification processes, including marking of the intended procedure site when indicated, in a manner that was unambiguously clear and accurately and thoroughly completing the time out procedure prior to every surgery performed. This failure led to the opportunity for wrong site surgeries that resulted in wrong site / wrong implant surgeries. ~Cross refer to 416.42, Condition for Coverage: Surgical Services 2. Based on Quality Improvement Plan review, Quality Improvement Committee Meeting minutes review, Event Report and Root cause analysis review, and staff and physician interviews, the ASC failed to develop, implement and maintain	Q 040	February 13, 2018, the QC met a second time for a special meeting, to review information that was not available for presentation at the January 24th meeting. On February 7th, 2018, there was an MEC meeting, where there was a discussion of the visit by the DHSR, and the most recent draft of the time-out policy. The intent was to review the policy, make necessary revisions to the policy before rolling it out to the medical staff, allied health staff and teammates of Blue Ridge Surgery Center. The policy was approved as written with recommendation by the MEC for governing body approval on 2/28/2018. Based on MEC discussions, a validation process was drafted by the management team to be able to track compliance and trend non-compliance. Every member of the above groups will receive a copy of the time-out policy, and attest to their understanding and willingness to abide by the policy. The management team consists of the CEO, DON, OR Manager, Pre-op/Recovery Manager and Medical Director. Their responsibility is to audit compliance by active surveillance during the time-out in rooms before procedures from the time the patient enters the room to the time of injection or incision. Audit sheets were completed and collected daily, starting 2/5/18 with 50% of volumes. The DON aggregates the data from audit sheets and the 12 components identified as critical to the process in the room. Initial compliance with the time-out policy must reach 90% with the 12 required components. The number of audits done is based on 100% of case volumes for the day and compliance must remain in the 90% range each day for one month. Less of volumes audited than the targeted compliance with the 12 components of the time-out, prompts immediate	2/13/2018 2/1/2018 Started 2/5/2018 Update for 3/2/2018, continues for 30 days	

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Q 040	Continued From page 2 an ongoing data-driven quality assessment and performance improvement program, including developing thorough and consistent actions and responses to adverse patient events, and evaluating and trending results to sustain improvements and prevent future events over time. ~Cross refer to 416.43, Condition for Coverage: Quality Assessment and Performance Improvement	Q 040	documentation of this coaching on audit sheets. Refer to sustainable goals on pgs. 27, 29, & 33. Once compliance is reached, in month one, the target moves to 92% compliance with the 12 components, 50% of case volumes. Tracking of compliance will be noted on common missed time-out opportunities. Trending of non-compliance will be specific to those individuals so that education can be immediate and tailored accordingly. If we fail to reach our goal within the first month, the DON and ORC will re-educate the outliers. The anesthesiologist who is also the MD will re-educate the anesthesia providers and physicians that are outliers. This re-education will be documented. Staff meetings will be held monthly to review compliance progress and discuss common faults encountered.	4/1/2018	
Q 060	SURGICAL SERVICES CFR(s): 416.42 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 policy and procedure review, medical record review, and staff and physician interviews the ASC failed to ensure safe surgical services by failing to ensure thorough and accurate pre-procedure verification processes, including marking of the intended procedure site when indicated, in a manner that was unambiguously clear and accurately and thoroughly completing the time out procedure prior to every surgery performed. This failure led to the opportunity for wrong site surgeries that resulted in wrong site / wrong implant surgeries. The findings include: Based on policy review, medical record review,	Q 060	The first revision of the time-out policy was approved by the QC on 1/24/2018 and recommended for approved by the MEC that met on February 7 th , 2018. The MEC has made recommendation to the governing body for approval at their meeting scheduled for February 28, 2018. Per the time-out policy, the circulating nurse prepares documents for physician review and the circulating nurse initiates the process with physician verbal confirmation. The change to the time-out process now requires a verbal confirmation by each member of the surgical team and a validation of an unambiguous mark before and after prepping and draping and prior to the incision. The policy was altered to include site marking with initials only, mark visible before and after prepping and draping, implants requested, and responsibilities of individuals of the surgical team	1/24/2018 Added 3/1/2018 2/1/2018 2/1/2018	

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Q 060	Continued From page 3 event report review and staff and physician interviews, facility staff failed to ensure ALL relevant members of the procedural team actively communicated and participated during the "Time Out" process for 3 of 3 wrong site / wrong implant surgical procedures (#2, 3, 5) and failed to ensure the intended procedure site was marked in a manner that was unambiguously clear for 2 of 3 procedures (#2, 5). ~Cross refer to 416.42, Standard Level Tag for Condition for Coverage Surgical Services, Q-0064	Q 060	before, during and after the time-out. In addition to the requirements of the facility's time-out policy, a further required step includes delayed placement of the knife blade onto the handle, the removal of the bovie tip from the pencil until the final time-out has been performed successfully.	2/1/2018	
Q 064	STANDARD LEVEL TAG FOR SURGICAL SERVICES CFR(s): 416.42 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 STANDARD is not met as evidenced by: Based on policy review, medical record review, event report review and staff and physician interviews, facility staff failed to ensure ALL relevant members of the procedural team actively communicated and participated during the "Time Out" process for 3 of 3 wrong site / wrong implant surgical procedures (#2, 3, 5) and failed to ensure the intended procedure site was marked in a manner that was unambiguously clear for 2 of 3 procedures (#2, 5). The findings include: Policy and Procedure review of a policy titled	Q 064	SCA as a corporation allows their facilities to adopt an SCA-available policy and alter to accommodate local processes. A policy was in place at that time, used by Blue Ridge Surgery Center named Surgical Procedures and Site Validation Policy. This policy addressed the time-out process and the safety checklist for surgical procedure validation. Changes to current policy included separating the Time-out process from the safe surgical checklist. Revisions to the Time-out policy include the addition of responsibilities of each member of the peri-operative team and anesthesia provider, with hands on a patient. The policy was also altered to include site marking with initials only, mark visible before and after prepping and draping, and responsibilities of individuals of the surgical team before, during and after the time-out.	2/1/2018 2/1/2018	

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Q 064	Continued From page 4 "Surgical Procedures and Site Validation Policy", dated 03/15/2017 revealed "...The purpose of this policy is to establish consistent guidelines....promote patient care and safety by verifying the correct patient, operative procedure, surgical site and, as applicable, correct implant....Policy Statement: Each facility is responsible for implementing standard procedure to address the following....2. Unambiguous identification of the intended site of incision or insertion. 3. Ensure final verification (TIME OUT) of the correct patient, procedure, site, and as applicable, implants is conducted....PROCEDURE FOR SITE MARKING....At a minimum, sites are marked when there is more than one possible location from the procedure and when performing the procedure in a different location would have a negative impact on the patient...The procedure is marked before the procedure and if possible, with the patient involved....The procedure site is marked by the licensed independent practitioner (LIP) ultimately accountable for the procedure who will be present when the procedure is performed. In limited circumstances, the LIP may delegate site marking to an individual permitted to participate in the procedure, who will be present during the procedure....The mark is made at or near the procedure or incision site with a marker that is sufficiently permanent and positioned to be visible after the patient has his or her skin prepped, is in his or her final position and draped....PROCEDURE FOR TIME OUT A. A standardized "TIME OUT" occurs: 1. Prior to any regional block....to verify correct patient, procedure and site 2. The final "TIME OUT" occurs IMMEDIATELY prior to incision or procedure start....D. The "TIME OUT" involves all the immediate members of the procedure	Q 064	The first revision of the time-out policy was approved by the QC on 1/24/2018 and recommended for approved by the MEC that met on February 7 th , 2018. The MEC has made recommendation to the governing body for approval at their meeting scheduled for February 28, 2018. The change to the time-out process now requires a verbal confirmation by each member of the surgical team and a validation of an unambiguous mark before and after prepping and draping and prior to the incision. The policy was altered to include site marking with initials only, mark visible before and after prepping and draping, implants requested, and responsibilities of individuals of the surgical team before, during and after the time-out. The policy regarding time-out for procedures includes new information on who may mark the site. Blue Ridge Surgery Center allows only the physician performing the procedure to mark the site in pre-op or just before the procedure incision. The inclusion of practitioners under the title of LIP in most institutions includes physicians and allied health practitioners. Blue Ridge Surgery Center no longer uses the term LIP in the time-out policy nor does the policy allow allied health practitioner to mark. Physicians of the center agreed that PA's will not place a tourniquet on an operative extremity. Our time-out policy will be revised with this language for presentation at the next QC, MEC, and GB. Once the patient is in the OR/procedure room, the team is identified, and the circulating nurse initiates the time-out and physician confirms. All members of the surgery/procedure team must state their role and their responsibility to the	1/24/2018	2/1/2018	2/1/2018	2/1/2018

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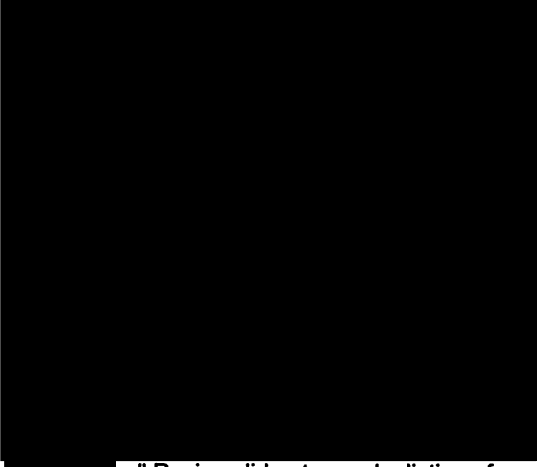
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Q 064	Continued From page 6 consent form was signed by Patient #5 on [REDACTED] at 1145. Record review revealed a [REDACTED] Procedure Note, signed [REDACTED] at 1236, which stated the procedure was a "[REDACTED]" Record review revealed "Safe Surgical Checklist", dated [REDACTED] with all sections checked and initialed. Review revealed a section labeled "Before Incision" and checks made beside each of the following: "...Confirm procedure, site, side...Confirm consent....Confirm site mark is visible..." Anesthesia Record review, dated [REDACTED] revealed the patient was identified and the chart reviewed. Review revealed Anesthesia was started at [REDACTED] and ended at [REDACTED] Further review revealed the Procedure was handwritten as left [with the word left crossed out and the word right written above it] [REDACTED] [REDACTED] Another handwritten note stated [REDACTED] [REDACTED] " Review of the Operating Room Record, dated [REDACTED], revealed the surgery began at [REDACTED] and ended at [REDACTED] Review revealed a time out at 1425 and revealed the site was verified with a check mark beside the word "[REDACTED]". Further review of the Operating Room Record revealed the Pre Op Diagnosis was handwritten as "[REDACTED]" [REDACTED], along with the handwritten note "[REDACTED]" The operation was written on the form as "[REDACTED]" the word [REDACTED] crossed out and "[REDACTED]" handwritten under it [REDACTED]...([initials] incorrect entry)." Review of the Operative Report, dated [REDACTED] at 1451, revealed "...DESCRIPTION OF PROCEDURE: [REDACTED]"	Q 064	The first revision of the time-out policy was approved by the QC on 1/24/2018 and recommended for approved by the MEC that met on February 7 th , 2018. The MEC has made recommendation to the governing body for approval at their meeting scheduled for February 28, 2018. The change to the time-out process now requires a verbal confirmation by each member of the surgical team and a validation of an unambiguous mark before and after prepping and draping and prior to the incision. The policy was altered to include site marking with initials only, mark visible before and after prepping and draping, implants requested, and responsibilities of individuals of the surgical team before, during and after the time-out. The policy regarding time-out for procedures includes new information on who may mark the site. Blue Ridge Surgery Center allows only the physician performing the procedure to mark the site in pre-op or just before the procedure incision. The inclusion of practitioners under the title of LIP in most institutions includes physicians and allied health practitioners. Blue Ridge Surgery Center no longer uses the term LIP in the time-out policy nor does the policy allow allied health practitioner to mark. Physicians of the center agreed that PA's will not place a tourniquet on an operative extremity. Our time-out policy will be revised with this language for presentation at the next QC, MEC, and GB. Additionally, the mark must be clear before and after prepping and draping and the physician must be present for the final time-out just prior to the incision. The DON maintains time-out audit sheets used to track compliance and trend areas	1/24/2018	2/1/2018	2/1/2018	2/1/2018

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Q 064	Continued From page 8  ..." Review did not reveal a listing of planned action items or risk reduction strategies. Staff Interview with RN #3, on 01/31/2018 at 1115, revealed he was the Operating Room RN during Patient #5's surgery. Interview revealed the OR was set up for a left  RN #3 stated he was not sure how it happened. When Patient #5 came into the OR, RN #3 stated, the "post" [used during surgery] was placed on the right side which "may have confused the PA. The PA placed the tourniquet on the right  and the OR team prepped and draped the right  Interview revealed when the surgeon came into the OR, the surgeon questioned the room set up and RN #3, thinking he had set the room up incorrectly, then moved the equipment so it was set up for the right  Interview revealed the site mark was higher up and was not visible after Patient #5 was draped. Further interview revealed it was a very busy day and speed seemed to be a priority. Interview revealed RN #3 did not recall if during the time out anyone specifically stated the site was the left  RN # 3 stated in some cases,	Q 064	The policy regarding time-out for procedures includes new information on who may mark the site. Blue Ridge Surgery Center allows only the physician performing the procedure to mark the site in pre-op or just before the procedure incision. The inclusion of practitioners under the title of LIP in most institutions includes physicians and allied health practitioners. Blue Ridge Surgery Center no longer uses the term LIP in the time-out policy nor does the policy allow allied health practitioner to mark. Physicians of the center agreed that PA's will not place a tourniquet on an operative extremity. Our time-out policy will be revised with this language for presentation at the next QC, MEC, and GB. The policy was altered to include site marking with initials only, mark visible before and after prepping and draping, implants requested, and responsibilities of individuals of the surgical team before, during and after the time-out.	2/1/2018	2/1/2018

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Q 064	Continued From page 10 stated that her process during handoff was to state the correct site, the exact surgery, and the block. Telephone interview, on 02/01/2018 at 1230, revealed MD #2 performed surgery on Patient #5. Interview revealed there were numerous cases done that day and when the MD #2 came into the OR the case had already been set up and the extremity prepped and draped. Interview revealed MD #2 could not recall who marked the site, but it was either himself or PA #1. Interview revealed a Time Out was not done and revealed MD #2 depended on the nurse to initiate it. Interview revealed a Time Out should be done and everyone should stop, read out loud, and verify the surgical site. Interview revealed MD #2 did not see the site mark and did not uncover the patient to see it. Interview revealed that now, the site mark should be visible before and after draping and everyone stops and participates in the time out. MD #2 stated he learned of the error when Patient #5 was in the PACU and immediately went out to the waiting room and saw the family. Telephone interview, on 02/01/2018 at 1256, with PA #1 revealed he saw Patient #5 in the pre-operative area, signed off the history and physical, confirmed the surgical site, marked the left side, and then continued on to the next patient. PA #1 stated he went into the OR after Patient #5 was already sedated. Interview revealed there was a post on the right side of the OR table. PA #1 said the post should be placed on the operative side and is used as an aide in surgery, and he placed the tourniquet on the right knee, the same side as the post. Interview revealed PA #1 did not recall a time out and stated he normally was not in the room for the	Q 064	The revised time-out policy allows only the surgeon to mark the intended site. PA's are not to apply tourniquets on extremities. On February 7 th , 2018, the MEC approved this process and the policy will be sent to the governing body for final approval on February 28, 2018. The surgical team has a responsibility to identify the patient when entering the room, where a discussion occurs that includes a validation of the patient, procedure, side, and site. A child is verbally introduced to the technician in the room by the circulating nurse. All included in the surgical team are require to state their name, role, and responsibility to their part of the procedure preparation. The knife handle and bovie tip are not placed until the time-out is complete and accurately performed. At no time will anyone in the room be allowed to focus on anything else in the room during the time-out validation. The only event that may shift attention is an urgent issue related to anesthesia caring for the patient. Once the event has resolved, the time-out would restart from the beginning.	2/1/2018	2/1/2018

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Q 064	Continued From page 13 ST #2 [Surgical Technologist] was in the Operating Room for Patient #3's surgery. Interview revealed they were focused on the patient and trying to keep the patient calm. ST #2 stated the circulating RN handed off the [REDACTED] and they were supposed to check the expiration date, but ST #2 stated it was not done. Interview revealed the OR circulating RN and ST #2 remained focused on the patient. Interview revealed staff did not follow the portion of the time out process related to checking expiration dates and confirmed an expired [REDACTED] was implanted. Further interview revealed there had been changes in the storage area to identify [REDACTED] with upcoming expiration dates and stated that four to six staff members review the expiration dates now. Interview on 02/01/2018 at 1545 with AS # 1 revealed the [REDACTED] stand down did not occur because the presenter could not attend. Interview revealed the stand down education was done by facility staff on 01/16/2018. 3. Medical record review on 01/31/2018 of Patient #2 revealed a 9 year old who arrived to the facility on [REDACTED] for a scheduled [REDACTED]. Review of the consent revealed "Proposed Procedure: [REDACTED]" Further review revealed the consent was signed for an [REDACTED] by Patient #2's [REDACTED] and witnessed by the nurse on [REDACTED] at 1300. Review revealed the anesthesia consent was signed by Patient #2's [REDACTED] and witnessed by the nurse on [REDACTED] at 1300. Review of the history and physical dated [REDACTED] and updated on [REDACTED] by MD #1 revealed "	Q 064	Implant information must be verified according to policy to include the following: Vendor, implant type, implant size, and implant expiration date. At no time will anyone on the surgical team be allowed distractions during this validation and time-out process. Once the implant is confirmed, the implant will be placed on the back table for the tech to prepare. The implant will be verified by the circulating nurse, the physician, and the technician in the room. This implant will also be validated by any order and/or documentation from the physician's office, such as their H&P. A review of the [REDACTED] verification process was initiated by the management team immediately following the outdated [REDACTED] procedure that occurred on [REDACTED]. The [REDACTED] placed expired [REDACTED] Documentation to review for a correct consent includes the H&P and physician orders. The Pre-op RN and circulating nurse are required to review this documentation by the physician. The surgical team has a responsibility to identify the patient when entering the room, where a discussion occurs that includes a validation of the patient, procedure, side, and site. A child is verbally introduced to the technician in the room by the circulating nurse.	2/1/2018	2/1/2018	2/1/2018

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Q 064	Continued From page 16 have felt more comfortable stopping MD #1 if she had been more confident about the type of surgery. Interview on 02/01/2018 at 0900 with MD #1 revealed this was his first wrong site surgery in 33 years of being a surgeon. Interview revealed Patient #2 was set-up for an [REDACTED] and scheduled for an [REDACTED]. Interview revealed Patient #2 had a [REDACTED] but also a [REDACTED]. Interview revealed on [REDACTED] a [REDACTED] was performed initially on Patient #2 which was wrong site surgery. Interview revealed MD #1 stated "there was a perfect storm of distractions" or [REDACTED]. Interview revealed the day prior to [REDACTED] MD #1 saw a patient in his office similar to Patient #2's age that needed a [REDACTED]. Interview revealed before Patient #2's surgery in the OR area "Reps (representatives) were trying to sell me a product." Interview revealed the time-out was "quick and I hardly listened to it." Interview revealed the surgical technician was "new and did not have the confidence to stop me." Interview revealed a [REDACTED] was performed initially and Patient #2 was taken to PACU. Interview revealed NM #1 called MD #1 and explained the wrong site surgery had been performed. MD #1 stated when he found out he performed a wrong site surgery he "was shocked." Interview revealed "I wished my teammates had stopped me." Interview revealed he explained to Patient #2 and her [REDACTED] the wrong site surgery and it was agreed Patient #2 would go back to the OR to have the correct procedure. Interview revealed Patient #2 had an [REDACTED] and was discharged home with [REDACTED]. Interview revealed after the	Q 064	The revised time-out policy allows only the surgeon to mark the intended site. PA's are not to apply tourniquets on extremities. On February 7 th , 2018, the MEC approved this process and the policy will be sent to the governing body for final approval on February 28, 2018. The surgical team has a responsibility to identify the patient when entering the room, where a discussion occurs that includes a validation of the patient, procedure, side, and site. A child is verbally introduced to the technician in the room by the circulating nurse. All included in the surgical team are require to state their name, role, and responsibility to their part of the procedure preparation. The knife handle and bovie tip are not placed until the time-out is complete and accurately performed. At no time will anyone in the room be allowed to focus on anything else during the time-out validation. The only event that may shift attention is an urgent issue related to anesthesia caring for the patient. Once the event has resolved, the time-out would restart from the beginning.	2/7/2018	2/1/2018	2/1/2018

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Q 064	Continued From page 18 protocols were followed during this surgery, but the time-out was "quick." Interview revealed MD #1 stated an [REDACTED] during the initial surgery time-out. Interview revealed RN #2 did not see Patient #2's mouth during the surgery because MD #1, ST #1, and CRNA #2 were all around Patient #2. Interview revealed when RN #2 took Patient #2 to PACU she checked the surgical site with RN #1 and saw there was no evidence of an [REDACTED]. Interview revealed a [REDACTED] had been performed. Interview on 01/31/2018 at 1250 with MD #4 revealed he asked MD #1 prior to putting Patient #2 asleep if he wanted to use a LMA [laryngeal mask airway], since Patient #2 was having an [REDACTED] and MD #1 agreed. Interview revealed MD #4 was not in the OR during the time-out for Patient #2's surgery. Interview revealed MD #1 immediately took responsibility for the wrong site surgery and explained it to Patient #2's mother. Interview revealed Patient #2 was taken back to the OR and the correct procedure an [REDACTED] was performed. Interview revealed MD #4 stated "time-outs got to be too routine", and stated staff were not being mindful of what they were saying. Interview on 01/31/2018 at 1455 with CRNA #2 revealed she was present during Patient #2's surgery. Interview revealed usually when an [REDACTED] was performed the patient would be masked for sedation. Interview revealed Patient #2 had a [REDACTED] that was difficult to maintain. Interview revealed a time-out was performed prior to the surgery and the time-out was the correct surgery and	Q 064	The revised time-out policy allows only the surgeon to mark the intended site. PA's are not to apply tourniquets on extremities. On February 7th, 2018, the MEC approved this process and the policy will be sent to the governing body for final approval on February 28, 2018. The surgical team has a responsibility to identify the patient when entering the room, where a discussion occurs that includes a validation of the patient, procedure, side, and site. There are to be no distractions during the time-out, until complete and accurate.	2/7/2018 2/1/2018	

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Q 064	Continued From page 19 everyone agreed. Interview revealed during the initial surgery CRNA #2 was focused on maintaining Patient #2's airway and did not pay attention to MD #1 performing wrong site surgery on the [REDACTED] Interview revealed on the second surgery a mask was used to sedate Patient #2 and an [REDACTED] was performed. Interview on 02/01/2018 at 0845 with NM #1 revealed RN #1 had spoken to her on [REDACTED] and asked her to look at Patient #2's surgical site. Interview revealed NM #1 informed MD #1 that it was a wrong site surgery who stated "oh my god." Interview revealed MD #1 saw Patient #2's [REDACTED] and explained what happened. Interview revealed Patient #2 went back to surgery to have the correct procedure, an [REDACTED], performed.	Q 064		2/1/2018	
Q 080	QUALITY ASSESSMENT AND PERFORMANCE CFR(s): 416.43 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 Quality Improvement Plan review, Quality Improvement Committee Meeting minutes review, Event Report and Root cause analysis review, and staff and physician interviews, the ASC failed to develop, implement and maintain an ongoing data-driven quality assessment and performance improvement program, including developing thorough and consistent actions and responses to adverse patient events, and evaluating and trending results to sustain improvements and prevent future events over time.	Q 080	The Quality Council (QC) is the facility's Quality Committee. The membership consists of the CEO, Medical Director, an appointed physician as chairman, the DON, the OR Manager, the Pre-op/PACU Manager, the Safety and Life Safety Officer, the Business Office Manager, the Medication Management Nurse, the Credentialing Coordinator, the Infection Control Coordinator, the Quality Coordinator, the Surgery Scheduler/POL, and the Purchaser. The policy Performance/Quality Improvement and Patient Safety Plan is Blue Ridge Surgery Center's quality program. Each year, SCA requires each facility to update their Performance/Quality Improvement and Patient Safety Plan. Blue Ridge has a separate plan that includes risk management reporting, adverse events and root cause analysis documentation.	1/24/2018 3/1/2018	

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Q 082	Continued From page 21 (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies. This STANDARD is not met as evidenced by: Based on Quality Assurance and Performance Improvement Plan review, Quality Improvement Committee meeting minutes review, Event Reports and RCA [Root Cause Analysis] review, ASC [Ambulatory Surgery Center] documents review, and staff interviews, the ASC failed to monitor the quality and safety of patient care by failing to systematically analyze and track adverse patient events including wrong site/wrong implant surgeries, examining the cause of the wrong site/wrong implant surgery, implementing improvements and evaluating those improvements to ensure they were sustained over time. Review of Facility "PERFORMANCE/QUALITY IMPROVEMENT and PATIENT SAFETY PLAN 2017" revealed "...The purpose of [Facility name] Performance/Quality Improvement and Patient Safety Program is to strive to improve the quality	Q 082	The program is designed to systematically collect data related to identified performance issues, processes, and outcome measures. Identified areas to be tracked when reported are all adverse events, wrong site and/or side surgery, wrong patient surgery, wrong procedure, the right procedure on the wrong patient, infections, hospital transfers, and complications to include ER visits, DVT's, falls at home with injury, and death. Risk management education on adverse events will be completed annually by the ORC and the PRC with all members of the Blue Ridge team. Included in this education is information on current risk management policies that include adverse event identification and reporting.	3/1/2018	3/1/2018	3/2018

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Q 082	Continued From page 22 of care and promote more effective and efficient utilization of centers and service, maintain an active, ongoing, integrated, organized, peer-based program of quality management and improvement that links peer review, quality improvement activities and risk management in an organized, systematic way....The program assesses processes, systems and patient outcomes and improves them on a priority basis by selecting quality indicators, measuring and analyzing information related to these indicators, adverse patient events, and other aspects of performance, regularly. When identified, necessary changes are implemented and incorporated into appropriate processes, products or services and performance is tracked to assure improvements are sustained over time....Reporting, reviewing and appropriate analysis of all incidents reported by employees, patients, and healthcare professionals and others will be reviewed by the Quality Council, including all deaths, trauma, other adverse events, medical errors, patient complaints, and clinical records/policies. Data are systematically aggregated and analyzed. Data related to established criteria are collected in an ongoing manner and are periodically evaluated to identify acceptable or unacceptable trends or occurrences that affect patient outcomes. ...Data are analyzed and compared internally over time....Adverse Events Leadership establishes processes for the identification, reporting, analysis, and prevention of adverse patient incidents and ensuring their consistent and effective implementation by developing a system that includes:...d. An action plan that identifies the strategies that the center intends to implement to reduce the risk of a similar event occurring in the future. e. An evaluation of the improvements to	Q 082	SCA has contracted with RL Solutions as their risk management reporting system. Access to the system is available to all members of the Blue Ridge team. In order to have consistency, only certain members of management are allowed to input live into RL Solutions. The Blue Ridge Surgery Center team is provided a paper copy of the electronic system for reporting events that occur. When an event occurs, the teammate involved will complete a paper incident report and forward this document to their immediate supervisor before close of business on the day the incident occurs. The member of the management team, CEO, DON, ORC or PRC inputs the report electronically. Once the report is in RL Solutions, the management team and SCA corporate representatives are notified of the event by email. Those notified are to review the details of the incidents reported, whether significant or routine. Significant events require a root-cause analysis report to be completed that includes prevention strategies to avoid future similar occurrences. Verbal notification to their supervisor and to the risk manager of record is required for these events of significance. The risk manager will review and discuss with the CEO (Blue Ridge, the CEO is the risk manager) and the Medical Director. Each month, the DON/Quality Coordinator is responsible to gather submitted and prepare a monthly summary of events. This information is trended for common causes. A follow-up to the initial root-cause will be completed 90 days following the original incident.	2/1/2018 2/1/2018 2/1/2018 2/1/2018	

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Q 082	Continued From page 23 ensure they are sustained over time. f. Educating staff to ensure their familiarity with the implemented strategies....All performance improvement activities are reported up to the Governing Body. ..." Review on 02/01/2018 of the Quality Improvement Committee Meeting minutes revealed there [REDACTED] [REDACTED] Meeting minute review revealed [REDACTED] [REDACTED] Review failed to reveal [REDACTED] [REDACTED] 1. Review of a RCA Form, for Patient #20, event date listed [REDACTED] revealed a written summary where the ST stated " ... [REDACTED] [REDACTED] [REDACTED] t." Review revealed a RN stated "[REDACTED] [REDACTED] [REDACTED] [REDACTED] " Review of root cause findings revealed "[REDACTED] [REDACTED] [REDACTED] " Form review revealed an action item "to perform a second time out when a back up [REDACTED] is	Q 082	Data collected monthly and reported quarterly is tracked and trended for commonalities by the DON/Quality Coordinator. Significant event will prompt a root-cause analysis of the event that, will address action plans items that focus on prevention of the same occurrence. Each root- cause analysis requires a 90-day follow up for compliance and sustainability. The [REDACTED] Verification Policy describes the process for choosing the correct [REDACTED]. The [REDACTED] intended for the patient must be the only [REDACTED] in the room during the time-out process with the surgical team. Back-up [REDACTED] pulled for procedures may be nearby. This policy will be submitted for review at the next QC, MEC and GB meeting. If the back-up [REDACTED] is required, the time-out process for the [REDACTED] begins over again to ensure the proper [REDACTED] diopter and expiration for the patient on the operating room table. Compliance with this will be maintained by the ORC.	12/2017	2/20/2018
				2/20/2018	

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Q 082	Continued From page 25 not reveal if a 90-120 day review occurred and did not reveal whether the action items were completed or if other action items were needed. Requests on 02/01/2018 for data on action plan evaluations for these cases did not provide any additional information. 3. Review on 01/31/2018 of the RCA dated [REDACTED] revealed Patient #2 was [REDACTED] Review [REDACTED] Review of the "Root Cause Analysis Findings and Contributing Factors" revealed "[REDACTED]" Review revealed the action items were: "[REDACTED]" [REDACTED] Review of the 90-120 day follow up revealed "[REDACTED]" Requests on 02/01/2018 for data on action plan evaluations for these cases did not provide any additional information. Interview on 02/01/2018 at 1335 with NM #2 revealed after the [REDACTED] incident some changes were put into place. Auditing of time outs began after the [REDACTED] wrong site surgery incident. Interview revealed if staff were	Q 082	Going forward, for each event that falls under the definition of an adverse event, a full investigation with root cause analysis will be completed. A follow up of the event will be completed within 90 days of the event so that tracking of compliance can be proven as sustained over time. The risk manager will initiate the investigation and may request assistance from the MD, ORC, or the PRC to complete. Time-out audits were being done by management and anesthesia providers with consistency, but the information gathered was not used to make necessary changes in processes or prevention of other wrongs related to procedure identification or correct implant placement.	2/1/2018 2/1/2018	

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Q 082	Continued From page 27 [REDACTED] Further review revealed three nurses checked the implant [REDACTED] the day before but failed to note the expiration date and the purchaser did not see the expiration date when checking and putting in the lens orders. Further review of the RCA revealed three action items. The first was [REDACTED]. [REDACTED] The second action item was [REDACTED]. [REDACTED] [REDACTED] The third action item was to [REDACTED] [REDACTED] Further review revealed a 90-120 day review date of [REDACTED] and stated "[REDACTED]". Form review failed to reveal any further documented tracking of the action items. Interview with NM #2, on 02/01/2018 at 1335 revealed there was no current written policy and procedure for the [REDACTED] verification process and NM #2 would be writing it. Requests on 02/01/2018 for data on action plan evaluations for these cases did not provide any additional information. Interview on 02/02/2018 at 1130 with Purchaser #1 revealed prior to the [REDACTED] incident he was only looking to see if there were correct lenses	Con't from pg 27	May 25% volumes, 97% compliance June 25% volumes, 99% compliance Q 082 The purchase of lenses occurs at least 2 days prior to the procedure based on when physician offices supply the information. The lens is ordered and pulled for the procedure. A validation of the correct lens by the purchaser is followed by a verification of the [REDACTED] by two clinical teammates the day before the procedure. Following the initial clinical validation, two additional teammates verify the [REDACTED] pulled and places the [REDACTED] in a bin designated for each patient specifically. On the morning of the procedure, the technician in the room and the daily runner for [REDACTED] ophthalmology verifies the correct [REDACTED] is in the bin for the patient they have on the operating room table. Before the procedure, the [REDACTED] is verified by patient, left or right [REDACTED] size IOL # and expiration date with the team, to include the surgeon as part of the time-out process before the start of the procedure. A mock survey "stand down" will be completed over 2 full days to validate compliance with the time-out policy and to verify that the QC minutes and activities appropriately cover required components. The survey will not be announced, and QC minutes and activities will be reviewed by an SCA corporate designee.		5/2018 6/2018 2/20/2018 2/20/2018 2/20/2018 2/20/2018 2/20/2018 2/20/2018 3/2018 3/2018

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Q 082	Continued From page 28 available for surgeons, he was not focused on the expiration date. Interview revealed the verification process had changed since this incident. Interview revealed Purchaser #1 was not sure if there was a documented procedure. Interview on 02/01/2018 at 1335 with NM #2 revealed the verification process had changed since this incident. Interview failed to reveal any written policy and procedure specific to eye surgery and verification or any update to the "Surgical Procedures and Site Validation" policy. Interview failed to reveal documented education of staff about this procedure change. Interview revealed time-outs were being audited and NM #2 attempted to audit 10% of the patients daily. Interview revealed more structure was needed with clearly defined processes and roles. Interview revealed there had been several updates to the "Operating Room Surgical Safety Expectations" form that was placed in each OR and outlined the time-out process. Interview failed to reveal any policy and procedure updates. Interview on 02/02/2018 at 1200 with AS #1 revealed a stand down (mock time out process) had been planned for but the presenter was unable to attend. Interview revealed the facility planned and implemented mandatory education on 01/16/2018. Interview failed to reveal any updated policy and procedure after the incident. Interview revealed if there was any data related to the lens verification event she was not aware of it. 5. Review of an Event Summary on Patient #5, dated revealed the event date was Review revealed " ...	Q 082	Beginning February 5th, the Quality Coordinator began aggregating data from the time-out audits done by management and anesthesiologists. Goals were set for compliance with the time-out process. Management and anesthesiologist audits are completed on 100% of daily volumes. The team must reach 90% compliance with these 12 components in month one. See below for subsequent months through June 2018. Twelve components of the time-out process were evaluated as most important elements. These twelve elements are reviewed from audit documentation and percentages totaled. 12 Components include: Pre-op 13. Patient confirmed identity, side, procedure and consent 14. Allergies addressed 15. Confirm site is marked Operating Room 16. Confirm patient identity 17. Surgeon confirms procedure, side and site 18. Confirm consent 19. Confirm site mark is visible before draping 20. Confirm site mark is visible after draping 21. Patient allergies 22. Confirm implants, includes expirations 23. Confirm all teammates introduced, name and role 24. Antibiotic prophylaxis within 60 minutes of the procedure start Following the first month, the plans is as follows related to compliance with the 12 components: March 100% of volumes, 92% compliance April 50% of volumes, 95% compliance May 25% volumes, 97% compliance June 25% volumes, 99% compliance	2/5/2018 2/5/2018 Amended 3/1/2018 3/2018 4/2018 5/2018 6/2018	

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NAME OF PROVIDER OR SUPPLIER HEALTHSOUTH BLUE RIDGE SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 2308 WESVILL COURT RALEIGH, NC 27607			
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Q 082	Continued From page 30 revealed emailed communications on [REDACTED] and [REDACTED] sent from MD #4 and AS #2 to medical staff related to the importance of everyone coming to a complete stop and following the time-out process. Review on 02/02/2018 of ASC documents revealed a letter sent on [REDACTED] by AS #2 to physician colleagues that outlined the time out process and stressed the importance of proper attention to the established time out procedures prior to surgery and when selecting implants. Letter review revealed "...random audits will be done and reported back to the MEC to ensure that time outs are being done correctly and consistently by everyone; following the procedure consistently will be a requirement for employment at [the facility name], and a requirement for the physicians who post cases at the center..." Review on 02/02/2018 of ASC documents failed to reveal any evidence of a documented updated policy and procedure for surgical site verification, time outs, or implant verification. Review on 02/01/2018 of the MEC (Medical Executive Committee) meeting minutes revealed a meeting was held on [REDACTED]. Review of the minutes revealed during the meeting there was a discussion about "[REDACTED]" [REDACTED] "..." Review failed to reveal any data about surgical site verification being tracked, trended, and monitored. Review of the [REDACTED] MEC meeting minutes revealed [REDACTED] [REDACTED] "..." Review failed to reveal any data about surgical	Q 082	The revised time-out policy allows only the surgeon to mark the intended site. PA's are not to apply tourniquets on extremities. On February 7 th , 2018, the MEC approved this process and the policy will be sent to the governing body for final approval on February 28, 2018. The surgical team has a responsibility to identify the patient when entering the room, where a discussion occurs that includes a validation of the patient, procedure, side, and site. A child is verbally introduced to the technician in the room by the circulating nurse. All included in the surgical team are require to state their name, role, and responsibility to their part of the procedure preparation. The knife handle and bovie tip are not placed until the time-out is complete and accurately performed. At no time will anyone in the room be allowed to focus on anything else during the time-out validation. The only event that may shift attention is an urgent issue related to anesthesia caring for the patient. Once the event has resolved, the time-out would restart from the beginning.	1/24/2018	1/24/2018	1/24/2018

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Q 082	Continued From page 33 of the quality program for 2016 or any quality goals or priorities documented for 2017. Further interview revealed AS #3 was currently working on the annual report for 2017 and goals for 2018. Interview revealed the facility had not aggregated any data related to the adverse events and was not aware of any trending. Further interview revealed there were no updates to the policy or process related to the adverse patient events.	Q 082			
Q 083	PERFORMANCE IMPROVEMENT PROJECTS CFR(s): 416.43(d) (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 Quality Improvement Plan review, Quality Improvement Committee Meeting minutes review and staff interviews, the ASC [Ambulatory Surgery Center] failed to have ongoing committee meetings for 2017, failed to evaluate the quality program and failed to identify, implement, monitor and report performance improvement projects. Review of Facility "PERFORMANCE/QUALITY IMPROVEMENT and PATIENT SAFETY PLAN 2017" revealed "...The purpose of [Facility name] Performance/Quality Improvement and Patient Safety Program is to strive to improve the quality	Q 083	Performance Improvement projects will be initiated on areas where the facility feels improvement is needed. These activities will be based the procedure types and volumes at Blue Ridge Surgery Center. Blue Ridge Surgery Center is accredited by the Joint Commission so we will follow TJC's PDCA format for quality activities. During the February 13, 2018 meeting, there were two potential studies discussed which were instrument turn-over and need for purchase of additional instrumentation and hand hygiene surveillance and Time-out audits. These activities will be initiated by the DON/Quality Coordinator. The PRC may decide to initiate activities specific to The Joint Commission Total Knee and Spine Certifications. Also suggested on February 13 th , 2018 were the following: OR Delays Cancellations Block Utilization Case Lost Due to Block Holds		3/1/2018

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Q 083	Continued From page 34 of care and promote more effective and efficient utilization of centers and service, maintain an active, ongoing, integrated, organized, peer-based program of quality management and improvement that links peer review, quality improvement activities and risk management in an organized, systematic way...6. Identify performance improvement/risk assessment and patient safety projects. 7. Act on information to improve facility performance. 8. Prioritize Performance Improvement projects using the PI Project Priority Assessment Grid form.....The [Facility Name] QC [Quality Committee] shall meet at least quarterly and will maintain documented minutes of each meeting....The center QC also serves as the venue for Safety, Infection Control and Risk Management data review and analysis...." Review on 02/01/2018 of the Quality Improvement Committee Meeting minutes revealed only two meetings were held in 2017 on 01/19/2017 and a second meeting on 03/06/2017. Review revealed [REDACTED] Review failed to reveal evidence of identifying and prioritizing quality projects for 2017. Review revealed no evidence of a quality project for 2017. Review failed to reveal an annual evaluation of the quality program in 2016 or 2017. Interview on 02/01/2018 at 1545 with AS #1 revealed the previous employee responsible for quality in 2017 was no longer employed at the facility. Interview revealed AS #1 could not recall any 2017 quality projects and could not provide documentation of projects, but knew the previous employee had been working on them. Interview confirmed no additional quality data could be	Q 083	A meeting was held on January 24, 2018 that included the agenda items listed below: - Review and approval of previous minutes - Annual review of programs - Policy and procedure approvals - Physician utilization - Anesthesia review - QAPI Program and projects - Infection control & surveillance activities - presented - Employee relations and health - Education - Facility and life safety – presented - Risk Management - Medication safety - Credentialing - Medical records - Purchasing - Pathology - Patient Satisfaction - Teammate and Physician satisfaction - Accreditation At the time this meeting was held, many items from the above were not available for presentation. The focus of this meeting was an introduction of the membership and a review of quarterly data and responsibilities of each new member, for scheduled meetings in 2018 and in subsequent years.	1/24/2018	

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Q 083	Continued From page 35 located. Interview confirmed there was no annual quality evaluation for 2016 available and no goals or priorities related to quality for 2017. Further interview revealed AS #3 was currently responsible for quality and was working on the 2017 report and the goals for 2018. NC00135100	Q 083	The QC decided to have a special meeting on February 13, 2018, in order to complete required reports from 2017. Areas that were discussed on January 24, 2018 were not re-reviewed, noted below as "not discussed". The QC met on February 13, 2018 and the following was discussed with supporting documentation: Review and approval of previous minutes Annual review of programs Policy and procedure approvals Physician utilization Anesthesia review QAPI Program and projects Infection control and surveillance activities Employee relations and health Education Facility and life safety – not discussed Medication safety Credentialing Medical records Purchasing Pathology Patient Satisfaction Teammate and Physician satisfaction Accreditation	2/13/2018	