



IDAHO DEPARTMENT OF
HEALTH & WELFARE

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

TAMARA PRISOCK—ADMINISTRATOR
DIVISION OF LICENSING & CERTIFICATION
DEBBY RANSOM, R.N., R.H.I.T. – Chief
BUREAU OF FACILITY STANDARDS
3232 Elder Street
P.O. Box 83720
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CERTIFIED MAIL: 7012 3050 0001 2125 5624

August 10, 2016

Tom Thompson, Administrator
Healing Arts Day Surgery
222 West Iowa Avenue, Suite B
Nampa, ID 83686

RE: Healing Arts Day Surgery, Provider #13C0001023

Dear Mr. Thompson:

Based on the survey completed at Healing Arts Day Surgery, on July 28, 2016, by our staff, we have determined Healing Arts Day Surgery is out of compliance with the Medicare ASC Conditions for Coverage of **Governing Body and Management (42 CFR 416.41), Environment (42 CFR 416.44), Nursing Services (42 CFR 416.46), Medical Records (42 CFR 416.47), Patient Rights (42 CFR 416.50), Infection Control (42 CFR 416.51) and Patient Admission, Assessment and Discharge (42 CFR 416.52)**. To participate as a provider of services in the Medicare Program, an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

The deficiencies, which caused these conditions to be unmet, substantially limit the capacity of Healing Arts Day Surgery, to furnish services of an adequate level or quality. The deficiencies are described on the enclosed Statement of Deficiencies/Plan of Correction (CMS-2567).

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

An acceptable Plan of Correction contains the following elements:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;

Tom Thompson, Administrator
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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 September 11, 2016. To allow time for a revisit to verify corrections prior to that date, it is important that the completion dates on your Credible Allegation/Plan of Correction show compliance no later than September 1, 2016.

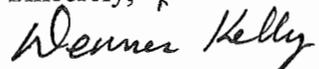
Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **August 23, 2016.**

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.

Thank you for the courtesies extended to us during the survey. If you have any questions, comments or concerns, please contact Dennis Kelly, RN or Nicole Wisenor, Co-Supervisors, Non-Long Term Care at (208) 334-6626, option 4.

Sincerely,


on behalf of

LAURA THOMPSON
Health Facility Surveyor
Non-Long Term Care


on behalf of

NICOLE WISENOR
Co-Supervisor
Non-Long Term Care

LT/pmt

Enclosures

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

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

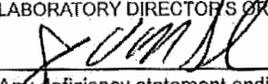
PRINTED: 08/10/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001023	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/28/2016
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NAME OF PROVIDER OR SUPPLIER HEALING ARTS DAY SURGERY	STREET ADDRESS, CITY, STATE, ZIP CODE 222 WEST IOWA AVENUE, SUITE B NAMPA, ID 83686
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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Q 000	<p>INITIAL COMMENTS</p> <p>The following deficiencies were cited during the Medicare recertification and complaint survey of your surgery center conducted from 7/18/16 to 7/28/16. Surveyors conducting the survey were:</p> <p>Laura Thompson, RN, BSN, HFS, Team Leader Gary Guiles, RN, HFS Brian Osborn, RN, HFS</p> <p>Acronyms and terms used in this report include:</p> <p>ACG - American College of Gastroenterology AED - Automated External Defibrillator AGA - American Gastroenterological Association AORN - Association of periOperative Registered Nurses ASC - Ambulatory Surgical Center ASGE - American Society for Gastrointestinal Endoscopy BLS - Basic Life Support, for healthcare providers CDC - Centers for Disease Control and Prevention Colonoscopy - viewing the lower gastrointestinal tract with a scope CRNA - Certified Registered Nurse Anesthetist DSD - Dual-sided Disinfectant EGD - Esophagogastroduodenoscopy, viewing the upper gastrointestinal tract with a scope EMT - Emergency Medical Technician GI - Gastroenterology HADS - Healing Arts Day Surgery H&P - History and Physical Examination IV - Intravenous MAC - Monitored Anesthesia Care MD - Physician mg - milligrams NS - Normal Saline</p>	Q 000	<p>RECEIVED</p> <p>SEP 01 2016</p> <p>FACILITY STANDARDS</p>	
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE <i>ADMINISTRATOR</i>	(X6) DATE <i>SEPT 1, 2016</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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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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Q 000	Continued From page 1 O2 sat - oxygen saturation level PPE - Personal Protective Equipment RN - Registered Nurse SGNA - Society of Gastroenterology Nurses and Associates TB - Tuberculosis Note: Immediate Jeopardy was identified at Q232 and the ASC was notified on 7/21/16 at 1:30 PM. The ASC submitted an Immediate Plan of Correction on 7/22/16 at 1:40 PM, which was accepted. The submitted plan alleged the circumstances which resulted in the Immediate Jeopardy would be removed by 7/25/16, and documented procedures would be suspended until 7/28/16. Prior to the first scheduled procedure on 7/28/16, on-site verification of the plan's implementation was completed by the survey team and the Immediate Jeopardy was removed on 7/28/16 at 8:55 AM. An additional Immediate Jeopardy was identified at Q232 and the ASC was notified on 7/28/16 at 10:35 AM. The ASC submitted an Immediate Plan of Correction on 7/28/16 at 11:15 AM, which was accepted. Prior to the next scheduled procedure on 7/28/16 on-site verification of the plan's implementation was completed by the survey team and the immediate jeopardy was removed on 7/28/16 at 11:15 AM.	Q 000			
Q 040	416.41 GOVERNING BODY AND MANAGEMENT The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality	Q 040			

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Q 040	<p>Continued From page 2</p> <p>assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.</p> <p>This CONDITION is not met as evidenced by: Based on observation, ASC document review, staff interview, and record review it was determined the ASC failed to ensure the Governing Body provided oversight and supervision necessary to ensure all patients of the ASC received safe and appropriate care. This resulted in a lack of operational direction for ASC staff and the implementation of practices that had the potential to place the health and safety of patients at risk. The findings include:</p> <p>1. The Governing Body failed to assume responsibility for defining and directing nursing services.</p> <p>During an interview on 7/19/16 at 1:30 PM, the Medical Director/Owner stated she did not currently employ an RN on her staff. She stated the CRNAs acted as the RN and were responsible for the patients while in the ASC. During a follow-up interview on 7/21/16 at 11:37 AM, the Medical Director stated the ASC had not employed an RN on staff for "2 to 3 months."</p> <p>The ASC Administrator was interviewed on 7/20/16 at 11:35 AM. He confirmed the ASC did not have an RN on staff. He stated CRNAs were contracted staff (CRNA A, CRNA B, and CRNA C) and not employees of the ASC. A CRNA contract was requested from the Administrator, however,</p>	Q 040			

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Q 040	<p>Continued From page 3</p> <p>he stated he was unable to locate a contract.</p> <p>At 11:30 AM on 7/20/16, the Administrator brought in the personnel files. The CRNAs did not have personnel files. They did have credentials files which were complete. The credentials files did not include the CRNA contract.</p> <p>The ASC did not have documentation of a legal relationship with the CRNAs to provide nursing services. The CRNAs had privileges to provide anesthesia but they did not have a legal obligation to provide other nursing services. The ASC did not have job descriptions or policies specifically describing the CRNAs' duties related to general nursing services.</p> <p>The Administrator was interviewed on 7/21/16 beginning at 2:30 PM. He stated the ASC did not have policies related to CRNAs providing general nursing services.</p> <p>One Governing Board meeting was documented between 7/01/15 and 7/21/16. Minutes for this meeting were dated 1/15/16. Nursing services were not mentioned in these minutes. Contracts between the ASC and 5 other entities were listed in the minutes. A contract between the ASC and CRNAs was not included in the list of contracts. No documentation was present stating the Governing Body discussed nursing services or assigned nursing duties to other personnel after the RN left the ASC.</p> <p>The Administrator was interviewed on 7/21/16 beginning at 2:30 PM. He stated there was no documentation of Governing Body activities after the 1/15/16 meeting.</p>	Q 040			

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Q 040	<p>Continued From page 4</p> <p>The Governing Body failed to hire nursing staff and failed to develop a plan to provide nursing services to patients.</p> <p>2. The ASC employed an Administrator, a Recovery Room Technician, and 2 Reprocessing Technicians (Reprocessing Technician A and Reprocessing Technician B) who reprocessed the endoscopes and assisted the physician during procedures.</p> <p>The Governing Body failed to ensure the ASC's employees were appropriately qualified and trained, as follows:</p> <p>a. At 11:30 AM on 7/20/16, the Administrator stated he did not have personnel files for Reprocessing Technician A or Reprocessing Technician B.</p> <p>b. At 11:30 AM on 7/20/16, the Administrator brought in the personnel file for the Recovery Room Technician. The Recovery Room Technician personnel file documented he was hired on 6/15/16. The file included an "Employee Orientation Checklist," undated, which was blank and not signed. The file did not include documentation of job competencies or infection control education and training. There, there was no documentation of training regarding patient assessment, life-threatening situations, or how to manage them. Documentation of BLS certification or related training was not present and there was no documentation of training regarding the use of the ASC's emergency equipment and/or what to do in the case of an emergent situation.</p>	Q 040			

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Q 040	<p>Continued From page 5</p> <p>The Administrator was interviewed on 7/20/16 at 11:35 AM and the Recovery Room Technician's personnel file was reviewed in his presence. The Administrator stated the Recovery Room Technician was a certified EMT. The Administrator confirmed the Recovery Room Technician had a blank, undated orientation sheet, no documented job training, no documented job competencies, no documented job education, and no documentation of BLS certification.</p> <p>c. Patient #6 and Patient #12's records included a "PROCEDURE FLOW SHEET," dated 6/06/16. However, the staff's signature on the flow sheet did not match any of the staff who were employed by the facility.</p> <p>When asked about the signature on the flow sheet, on 7/20/16 at 11:30 AM, the Administrator stated the signature was from a paramedic who was contracted to work at the ASC for one day (6/06/16). The Administrator was asked if he had a personnel file or contract for the paramedic to work at the ASC on that day. He stated he did not have a personnel file or contract for the paramedic.</p> <p>d. At 11:30 AM on 7/20/16, the Administrator brought in his personnel file. The personnel file included an "Employee Orientation Checklist" dated 6/07/16, his date of hire. However, there was no documentation of training or education for infection control, emergency equipment, or competencies for his job.</p> <p>On the same date and time, the Administrator stated he was just hired 3 weeks ago and had not been trained or oriented to the ASC's systems by</p>	Q 040			

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Q 040	<p>Continued From page 6</p> <p>the Medical Director. He stated he was still learning about his job responsibilities and how the processes and procedures were performed at the ASC according to the policies and procedures. The Administrator stated he was still not familiar with all policies and procedures.</p> <p>The Governing Body failed to ensure the ASC's employees were appropriately qualified and trained, necessary to ensure patients' health and safety was not compromised.</p> <p>2. Refer to Q100 Condition for Coverage: Environment and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a safe and sanitary environment was provided and maintained.</p> <p>3. Refer to Q140 Condition for Coverage: Nursing Service and the associated standard level deficiency as it relates to the Governing Body's failure to ensure an RN had oversight of patients nursing needs and provided direction to staff.</p> <p>4. Refer to Q160 Condition for Coverage: Medical Records and the associated standard level deficiency as it relates to the Governing Body's failure to ensure a complete, comprehensive, and accurate medical records system had been developed and implemented.</p> <p>5. Refer to Q219 Condition for Coverage: Patient Rights and the associated standard level deficiencies as they relate to the Governing Body's failure to ensure patients were fully informed of their rights and that patient rights were upheld.</p>	Q 040			

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Q 040	Continued From page 7 6. Refer to Q240 Condition for Coverage: Infection Control and associated standard level deficiencies as they relate to the Governing Body's failure to ensure a comprehensive infection control program was developed, implemented, and monitored. 7. Refer to Q260 Condition for Coverage: Patient Admission, Assessment, and Discharge and associated standard level deficiencies as they relate to the Governing Body's failure to ensure each patient had appropriate post-surgical assessments completed and that they were discharged by a physician. The cumulative effects of these systemic deficient practices resulted in the inability of the ASC to furnish patient care in a manner which ensured each patient's health and safety was protected and that patient rights were upheld.	Q 040			
Q 100	416.44 ENVIRONMENT The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. This CONDITION is not met as evidenced by: Based on observation, ASC policy review, record review, and staff interview, it was determined the ASC failed to ensure a safe environment was provided and maintained for all patients receiving care at the facility. This resulted in a lack of operational equipment and trained personnel being readily available to ensure patient health and safety. The findings include: 1. Refer to Q105 as it relates to the ASC's failure	Q 100			

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Q 100	Continued From page 8 to ensure staff were trained to ensure emergency medical equipment was operational prior to providing patient care. 2. Refer to Q106 as it relates to the ASC's failure to ensure staff who were trained in the use of emergency medical equipment and cardiopulmonary resuscitation were readily available for all patients receiving care at the facility. The cumulative effect of these systemic deficient practices resulted in the inability of the ASC to furnish a safe environment for patients receiving care at the facility.	Q 100			
Q 105	416.44(c) EMERGENCY EQUIPMENT The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC' s operating room. The equipment must meet the following requirements: (1) Be immediately available for use during emergency situations. (2) Be appropriate for the facility's patient population. (3) Be maintained by appropriate personnel. This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to ensure staff were trained to ensure emergency medical equipment was operational prior to providing patient care. This failure directly impacted 1 of 19 patients (Patient #19) whose procedures were observed and had the potential to impact all patients receiving care at the facility. This resulted in the	Q 105			

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Q 105	<p>Continued From page 9</p> <p>potential for patients' health and safety to be compromised in the event of a medical emergency. Findings include:</p> <p>An observation was conducted beginning at 9:20 AM on 7/28/16. Patient #19 was a 38 year old female who underwent a scheduled outpatient EGD.</p> <p>Patient #19 was taken to the Procedure Room at 9:25 AM. A nasal cannula, for the purpose of delivering supplemental oxygen during the procedure, was placed on Patient #19 at 9:34 AM. Fentanyl and Versed (sedative medications) were administered by CRNA A through Patient #19's IV at 9:36 AM. Technician A attempted to turn on the oxygen via the oxygen wall regulator at 9:36 AM, however, no oxygen was present. At 9:40 AM, the patient was asleep and under the direct care of CRNA A.</p> <p>At 9:44 AM, the oxygen was still not working and the issue was being investigated by the Medical Director, Administrator, Technician A, and Recovery Room Technician. The procedure was placed on hold at this time by the Medical Director until the oxygen was confirmed to be working. At 9:50 AM, 14 minutes after medications had been administered by CRNA A, the oxygen began working. The procedure was restarted by the Medical Director at 9:51 AM. No further issues were noted and the procedure ended at 10:06 AM. Patient #19 was then transferred to the Recovery Room.</p> <p>The ASC Administrator and Medical Director were interviewed together on 7/28/16, at 10:35 AM. A policy regarding checking emergency equipment prior to scheduled procedures was requested.</p>	Q 105			

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Q 105	<p>Continued From page 10</p> <p>The Administrator stated the ASC did not have a policy for checking emergency and/or safety equipment. A procedure or protocol regarding checking emergency equipment prior to scheduled procedures was requested. The Administrator stated the ASC did not have a procedure or protocol which outlined a process.</p> <p>The Administrator stated the oxygen delivery system was checked on a weekly basis, not prior to scheduled procedures. The Administrator confirmed the oxygen delivery system was not checked on 7/28/16, prior to the first procedure of the day. The Medical Director stated it was the ASC's practice to not test the oxygen delivery system until the patient was already in the Procedure Room. The Medical Director and Administrator confirmed the medications should not have been administered prior to ensuring the oxygen was on and working properly.</p> <p>CRNA A, who was responsible for monitoring Patient #19 during the procedure, was interviewed on 7/28/16, at 10:42 AM. She stated the medications she administered to Patient #19, before the oxygen was confirmed to be working, were for "anxiety." She confirmed the medications should not have been administered prior to ensuring the oxygen was on and working properly.</p> <p>The ASC failed to ensure emergency equipment was on and functional prior to administration of sedatives and/or anesthetic medications to patients undergoing procedures.</p> <p>The ASC failed to maintain and train personnel who were responsible for maintaining the emergency equipment.</p>	Q 105			

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Q 106	<p>416.44(d) EMERGENCY PERSONNEL</p> <p>Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.</p> <p>This STANDARD is not met as evidenced by: Based on ASC document review, personnel file review, ASC policy review, and staff interview, it was determined the ASC failed to ensure staff who were trained in the use of emergency medical equipment and cardiopulmonary resuscitation were available for all patients receiving care at the facility. This resulted in the potential for patient health and safety to be compromised in the event of a medical emergency. The findings include:</p> <p>The "CRNA JOB DESCRIPTION," undated and unsigned, stated as part of their responsibilities and functions "7) Provide management of cardiopulmonary resuscitation. 8) Provide management of problems in pulmonary care 9) Provide on-site direction of any non-physician who participates in the delivery of care to the patient."</p> <p>During the interviewed on 7/21/16 at 11:25 AM, CRNAA stated once she would report the patient off to the Recovery Room staff, she would then begin preparing for her next patient. The "CRNA JOB DESCRIPTION" was reviewed with CRNAA. CRNAA stated she was unaware of the responsibilities listed above. She also stated she was unaware if patients were discharged prior to her beginning sedation with another patient in the Procedure Room.</p>	Q 106			

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Q 106	<p>Continued From page 12</p> <p>When asked during an interview on 7/21/16 at 8:50 AM, what the average census was for a procedure day, the Recovery Room Technician stated there may be as many as 5 to 6 patients on one day. He stated there were times when he would be recovering a patient in the Recovery Room and the CRNA and Medical Director would be in the Procedure Room at the same time.</p> <p>However, the Recovery Room Technician was not trained and did not demonstrate the competencies necessary to manage patient medical emergencies, as follows:</p> <p>1. The ASC's policy "Medical Emergency in The Recovery Room," revised 1/10/16, was reviewed. The policy stated "Assess the individual for any life-threatening situations and manage accordingly. Follow BLS protocol."</p> <p>Additionally, an ASC document "Recovery Room Personnel Job Description," dated 1/16/16, was reviewed. The document included "Knowledge and skills: Must demonstrate ability to perform all duties. BLS [sic]."</p> <p>The ASC Recovery Room Technician personnel file, dated 6/15/16, was reviewed. The file did not include documentation of the employee's BLS certification or related training. The file did not include training regarding patient assessment, life-threatening situations, or how to manage them.</p> <p>The Recovery Room Technician was interviewed on 7/21/16 at 8:50 AM. The Recovery Room Technician was asked if he had a current BLS card and training. He stated he had a current card, but he was unable to provide</p>	Q 106			

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Q 106	Continued From page 13 documentation of one. The ASC Administrator was interviewed on 7/20/16 at 11:25 AM, and the Recovery Room Technician Personnel file was reviewed in his presence. He confirmed the file did not include BLS certification. 2. An ASC policy "Emergency Equipment," revised 1/02/15, was reviewed. The policy stated "Ancillary medical personnel will be trained in the use of the AED." The Recovery Room Technician was interviewed and observed on 7/21/16 at 8:50 AM. He stated he only checked the battery indicator and the AED pad expiration dates. When asked if he had been trained on checking and operating ASC emergency equipment, he stated he had, but the training was verbal. The ASC Administrator was interviewed on 7/20/16 at 11:25 AM, and the Recovery Room Technician Personnel file was reviewed in his presence. He confirmed the file did not include emergency equipment training. The Administrator stated training for checking and operating emergency equipment was verbal, but not documented. The ASC failed to ensure staff trained in the use of emergency medical equipment and cardiopulmonary resuscitation were readily available for patients.	Q 106			
Q 140	416.46 NURSING SERVICES The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all	Q 140			

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Q 140	Continued From page 14 patients are met. This CONDITION is not met as evidenced by: Based on record review and staff interview, it was determined the ASC failed to ensure nursing staff were present and provided sufficient direction and supervision for all patients receiving care at the facility. This resulted in the inability of the ASC to ensure qualified personnel were available to provide routine and emergency care in accordance with recognized standards of practice, thereby compromising patient health and safety. The findings include: 1. Refer to Q141 as it relates to the ASC's failure to ensure appropriate nursing care services were provided to all patients.	Q 140		
Q 141	416.46(a) ORGANIZATION AND STAFFING Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC. This STANDARD is not met as evidenced by: Based on observation, record review, ASC document review, personnel file review, and staff interview, it was determined the ASC failed to ensure nursing services were clearly delineated and provided to meet each patient's routine and emergency care needs. This failure directly impacted 7 of 19 patients (#6, #8, #10, #11, #13, and #17) whose care was observed and/or whose records were reviewed and had the potential to	Q 141		

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Q 141	<p>Continued From page 15</p> <p>impact all patients receiving care at the facility. This resulted in CRNAs who were unaware of their responsibilities to provide routine and emergent care to patients in recovery and the CRNAs being unaware of their responsibilities to provide training and oversight of the Recovery Room Technician. The cumulative effect of these systemic failures resulted in the Recovery Room Technician being unable to consistently demonstrate the competencies to perform the nursing duties assigned to him and resulted in patients experiencing abnormal post-procedure vital signs, which were not identified or reported to the CRNA. Without appropriate monitoring and reporting, the ASC was not able to ensure patients' received timely medical interventions, which placed patients at risk of experiencing negative health outcomes due to medical complications. The findings include:</p> <p>1. During an interview on 7/19/16 at 1:30 PM, the Medical Director stated she did not currently employ an RN on her staff. She stated the CRNAs acted as the RN and were responsible for the patients while in the ASC. During a follow-up interview on 7/21/16 at 11:37 AM, the Medical Director stated the ASC had not had an RN on staff for "2 to 3 months."</p> <p>The ASC Administrator was interviewed on 7/20/16 at 11:35 AM. He stated he was not an RN. The Administrator confirmed the ASC did not have an RN on staff. He stated CRNAs were contracted staff and not employees of the ASC. A CRNA contract was requested from the Administrator; however, he stated he was unable to locate a contract.</p> <p>An ASC document "CRNA JOB DESCRIPTION,"</p>	Q 141			

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Q 141	<p>Continued From page 16</p> <p>undated, was reviewed. The document stated "Provide on-site direction of any non-physician who participates in the delivery of care to the patient." The job descriptions were not signed by the CRNAs.</p> <p>The ASC's CRNAs were not consistently aware of their responsibilities. This resulted in a lack of direction and delineation of nursing services necessary to ensure patient safety because the ASC had not formally assigned them any responsibilities. Examples include:</p> <p>a. CRNA B and CRNA C were not available for interview. CRNA A was interviewed on 7/21/16 at 11:25 AM, and the "CRNA JOB DESCRIPTION" was reviewed in her presence. CRNA A stated she was unaware the ASC did not employ RNs. She stated she did not provide oversight for staff members at the ASC and that she was unaware she was responsible for directing non-physician staff, who had been assigned patient care responsibilities.</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities, necessary to ensure all nursing services were directed and clearly delineated.</p> <p>b. During the interview on 7/21/16 at 11:25 AM, CRNA A stated she was unaware she was responsible for patients during the post operative period. CRNA A stated she would report the patient off to the Recovery Room staff.</p> <p>The Recovery Room Technician's job description for Recovery Room Personnel, dated 1/16/16, was reviewed. The job description stated "Knowledge and skills: Must demonstrate ability</p>	Q 141			

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Q 141	<p>Continued From page 17</p> <p>to perform all duties. BLS [sic]. If not currently certified, will need to certify at the next class held." Additionally, the job description stated "Areas of responsibility include, but are not limited to":</p> <ul style="list-style-type: none"> - "Give immediate attention to the patient on arrival." - "Check for patent airway and adequate respiratory effort; position, turn or suction as needed." - "Get report from the procedure CRNA." - "If indicated apply nasal cannula and administer oxygen at 2L [liter]; if more than this required (or is higher than what pt [patient] was on at home) and notify the MD, or CRNA, immediately." - "Monitor blood pressure and pulse per policy." - "Discontinue the IV per physician's orders." <p>However, the Recovery Room Technician personnel file, dated 6/15/16, did not include job competencies or emergency equipment training documentation. The file included an "Employee Orientation Checklist," undated, which was blank and not signed. The file did not include documentation of the employee's BLS certification or related training. The file did not include training regarding patient assessment, life-threatening situations, or how to manage them.</p> <p>The Administrator was interviewed on 7/20/16 at 11:35 AM. The Administrator stated the Recovery Room Technician was a certified EMT. The</p>	Q 141			

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Q 141	<p>Continued From page 18</p> <p>Administrator confirmed he did not have documentation of this in the Recovery Room Technician's personnel record. He confirmed there was no documentation the Recovery Room Technician received training or orientation for working in the ASC, and he did not have documentation for the other components listed above.</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities to ensure all staff performing nursing care services were provided with direction and oversight. This resulted in the Recovery Room Technician not being appropriately trained or qualified to perform the duties he was assigned and led to patients not receiving care in accordance with accepted standards of practice or in accordance with their individualized needs, as follows:</p> <p>i. The Recovery Room Technician was not observed to demonstrate the competencies necessary to ensure patients received safe care in accordance with accepted standards of practice.</p> <p>An observation of a procedure was conducted on 7/21/16 beginning at 9:50 AM. Patient #17 was a 47 year old female admitted to the ASC for a colonoscopy. She was taken to the procedure room at 10:15 AM.</p> <p>The "ANESTHESIA RECORD," dated 7/21/16, documented Patient #17 received Versed 2 mg (a benzodiazepine used for drowsiness and relaxation), Fentanyl 100 mcg (a pain medication and sedative), and Propofol 150 mg (an anesthetic used for sedation and anesthesia). The last dose of Propofol was given at 10:46 AM,</p>	Q 141		

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Q 141	<p>Continued From page 19 per observation. Patient #17 was then taken to the Recovery Room.</p> <p>The "PROCEDURE FLOW SHEET," dated 7/21/16, documented the Recovery Room Technician received Patient #17 at 10:55 AM. At 11:02 AM the Recovery Room Technician documented "Sat the pt. [patient] up." At 11:12 AM, he documented "Pt feels woozy [sic] Gave pt water [sic]." Patient #17 was discharged at 11:25 AM. There was no documentation in the record Patient #17 was reassessed for dizziness, nausea, or if the "woozy" feeling had improved or ceased.</p> <p>Patient #17's vital signs were documented at 10:55 AM, 11:00 AM, and 11:23 AM. The vital signs did not include documentation of an assessment for her level of consciousness or pain level.</p> <p>The AORN's Guidelines for Perioperative Practice, 2015, stated "The perioperative nurse should evaluate the patient for discharge readiness based on specific discharge criteria." The guidelines also stated "Criteria for discharge may include, but are not limited to: return to preoperative, baseline LOC [level of consciousness]; stability of vital signs; sufficient time interval ..." Additionally, the guidelines stated "Patients should remain awake for at least 20 minutes without stimulation before they are considered ready for discharge."</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities to ensure the Recovery Room Technician provided nursing care in accordance with accepted standards of practice.</p>	Q 141			

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Q 141	<p>Continued From page 20</p> <p>ii. Patients #6, #8, #10, #11, and #13's medical records did not include documentation that the Recovery Room Technician provided appropriate monitoring of patients or identified and reported abnormal recovery findings to the CRNA. Without such reporting, the CRNA could not ensure patients were provided with appropriate medical interventions as indicated by each patient's status. Examples included, but were not limited to, the following:</p> <ul style="list-style-type: none"> - Patient #8 was a 46 year old female admitted to the ASC on 4/28/16, for a colonoscopy. <p>Patient #8's record included a "PROCEDURE FLOW SHEET," dated 4/28/16, which documented Patient #8's pre-procedure vital signs at 2:00 PM, 1 hour and 22 minutes prior to the start of her procedure. The vital signs documented her blood pressure was 115/84, an oxygen saturation of 98%, pulse of 89, and respirations of 16. Patient #8's pain level was not documented.</p> <p>Patient #8's record included an "ANESTHESIA RECORD," dated 4/28/16, signed by CRNA A and the Medical Director. Patient #8's baseline vital signs were a blood pressure of 145/87, a heart rate of 67, respirations of 16, and an oxygen saturation level of 97%. The "RECOVERY" section documented Patient #8's vital signs at 3:48 PM, 1 minute after the completion of her procedure. The vital signs documented Patient #8's oxygen saturation level was 96%, a heart rate of 83, respirations of 16, and a temperature of 97.3. Patient #8's blood pressure was not documented.</p> <p>There was no documentation indicating the time</p>	Q 141			

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Q 141	<p>Continued From page 21</p> <p>Patient #8 was discharged home. The "PROCEDURE FLOW SHEET" did not document vital signs prior to her discharge. There was no documentation regarding her status or whether the Medical Director or CRNA A were informed of her vital signs. There was no documentation Patient #8 was assessed by the Medical Director or CRNA A prior to her discharge. There was no documentation the Medical Director or CRNA A had cleared Patient #8 for discharge.</p> <p>- Patient #6 was a 73 year old female admitted to the ASC on 6/13/16, for a colonoscopy.</p> <p>Patient #6's record included a "PROCEDURE FLOW SHEET," dated 6/13/16. The form included a section titled "VITALS" which was used for documenting patients' pre and post-procedure vital signs. This section documented Patient #6's pre-procedure vital signs at 8:55 AM. The vital signs documented her blood pressure was 98/58, an oxygen saturation level of 97%, a heart rate of 82, and respirations of 12. Patient #6's temperature and pain level were not documented.</p> <p>The National Library of Medicine website, accessed 7/29/16, www.medlineplus.gov, stated "Normal blood pressure for adults is defined as a systolic pressure below 120 mmHg and a diastolic pressure below 80 mmHg. It is normal for blood pressures to change when you sleep, wake up, or are excited or nervous. When you are active, it is normal for your blood pressure to increase. However, once the activity stops, your blood pressure returns to your normal baseline range. Blood pressure normally rises with age and body size. Newborn babies often have very low blood pressure numbers that are considered normal for babies, while older teens have</p>	Q 141			

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Q 141	<p>Continued From page 22 numbers similar to adults."</p> <p>The website further stated "Blood pressure varies from one person to another. A drop as little as 20 mmHg [millimeters of mercury], can cause problems for some people. There are different types and causes of low blood pressure. Severe hypotension can be caused by sudden loss of blood (shock), severe infection, heart attack, or severe allergic reaction (anaphylaxis). Sudden sever drops in your blood pressure starves your body of oxygen. This can lead to damage of the heart, brain, and other organs. This type of low blood pressure can be life threatening if not treated right away."</p> <p>The Mayo Clinic website, accessed 8/05/16, stated "Normal pulse oximeter readings [oxygen saturation levels] range from 95 to 100 percent, under most circumstances. Values under 90 percent are considered low."</p> <p>Patient #6's record included an "ANESTHESIA RECORD," dated 6/13/16, signed by CRNA A and the Medical Director. The form included a section titled "Baseline Values" which was used for documenting patients' baseline vital signs. This section was blank. The form also included a section titled "RECOVERY" which was used for documenting patients' post procedure vital signs. This section documented Patient #6's vital signs at 10:12 AM, 3 minutes after the completion of her procedure. The vital signs documented her blood pressure was 80/46, an oxygen saturation level of 96%, a heart rate of 69, and respirations of 16. Patient #6's temperature and pain level were not documented.</p> <p>Patient #6's post procedure vital signs were</p>	Q 141			

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Q 141	<p>Continued From page 23</p> <p>documented at 10:16 AM, 7 minutes after the completion of her procedure, on the "PROCEDURE FLOW SHEET." The vital signs documented her blood pressure was 70/36, an oxygen saturation level of 85%, a heart rate of 69, and respirations of 12.</p> <p>Patient #6 was discharged home at 10:30 AM. Patient #6 had no further vital signs documented after 10:16 AM. There was no documentation regarding her status or whether the Medical Director or CRNA were informed of her abnormal vital signs prior to her discharge. There was no documentation Patient #6 was assessed by the Medical Director or CRNA prior to Patient #6's discharge.</p> <p>The Recovery Room Technician was interviewed on 7/21/16 at 10:45 AM, and Patient #6's record was reviewed in his presence. He confirmed he was the Recovery Room Technician assigned to Patient #6 on 6/13/16. The Recovery Room Technician stated he was not aware of a procedure or protocol to follow regarding when to notify the physician or CRNA of patients' vital sign values. He stated "I would use common sense if I needed clarification." Additionally, he stated "I usually only do one set of vital signs." The Recovery Room Technician stated he should have documented Patient #6's presentation and notified either the physician or CRNA regarding her vital sign values.</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities to ensure the Recovery Room Technician provided appropriate monitoring of patients and was able to identify abnormal recovery findings and report them to the CRNA.</p>	Q 141			

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Q 141	Continued From page 24 c. The "CRNA JOB DESCRIPTION," undated and unsigned, stated as part of their responsibilities and functions "7) Provide management of cardiopulmonary resuscitation. 8) Provide management of problems in pulmonary care 9) Provide on-site direction of any non-physician who participates in the delivery of care to the patient." During the interviewed on 7/21/16, at 11:25 AM, CRNA A stated CRNA A stated once she would report the patient off to the Recovery Room staff, she would then begin preparing for her next patient. The "CRNA JOB DESCRIPTION" was reviewed with CRNA A. CRNA A stated she was unaware of the responsibilities listed above. She also stated she was unaware if patients were discharged prior to her beginning sedation with another patient in the Procedure Room. When asked on 7/21/16 at 8:50 AM, what the average census was for a procedure day, the Recovery Room Technician stated there may be as many as 5 to 6 patients on one day. He stated there were times when he would be recovering a patient in the Recovery Room and the CRNA and Medical Director would be in the Procedure Room at the same time.	Q 141			
Q 160	416.47 MEDICAL RECORDS The ASC failed to ensure the CRNA was readily available and aware of her responsibilities in the event of a patient medical emergency. The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. This CONDITION is not met as evidenced by:	Q 160			

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Q 160	Continued From page 25 Based on record review, ASC policy review, and staff interview, it was determined the ASC failed to ensure a complete, comprehensive, and accurate medical records system had been developed and implemented. This resulted in the potential for misinterpretation of information and had the potential to negatively impact the quality and safety of patient care. The findings include:	Q 160			
Q 162	416.47(b) FORM AND CONTENT OF RECORD The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following: (1) Patient identification. (2) Significant medical history and results of physical examination. (3) Pre-operative diagnostic studies (entered before surgery), if performed. (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. (5) Any allergies and abnormal drug reactions. (6) Entries related to anesthesia administration. (7) Documentation of properly executed informed patient consent. (8) Discharge diagnosis. This STANDARD is not met as evidenced by: Based on ASC policy review, record review, and staff interview, it was determined the ASC failed	Q 162			

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Q 162	<p>Continued From page 26</p> <p>to ensure medical records were complete for 19 of 19 patients (#1 - #19) whose records were reviewed. This failure resulted in a lack of complete and comprehensive information being available in patient records. Findings include:</p> <p>An ASC policy "Documenting in The Medical Record," revised 1/06/16, was reviewed. The policy stated "Documentation must include specific details so that when the entry is viewed by another healthcare member i.e. another employee, another provider, an insurance company or auditing company the entry provides a clear and complete picture of the patient, content of the interaction, what services were provided and the reasons they were provided." The policy also stated documentation in the record must be noted with the date and time, using a 24 hour clock.</p> <p>The ASC failed to follow their policies and ensure complete and accurate documentation. Examples include:</p> <p>1. Patient #1 - #19's records included a "PROCEDURE FLOW SHEET." The flow sheets were dated at the top of the form with the date of the procedure. The flow sheet included sections which were incomplete or left blank.</p> <p>a. The "PROCEDURE FLOW SHEET" included a section titled "PRE PROCEDURE ORDERS." The orders under this section included "Titrate medications per verbal orders." Titration of medications requires the continual adjustment of a dose based on patient response. The orders did not state which medications were to be titrated or document the order was carried out. There was no documentation in the records of</p>	Q 162			

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Q 162	<p>Continued From page 27</p> <p>verbal orders for titrated medications. Additionally, the pre-procedure orders were not signed or timed by the Medical Director or a CRNA.</p> <p>CRNA A was interviewed on 7/21/16 at 11:25 AM and records were reviewed in her presence. CRNA A confirmed the patients' "PRE PROCEDURE ORDERS" were incomplete.</p> <p>b. The "PROCEDURE FLOW SHEET" included a section titled "ASSESSMENTS." This section was completed by the CRNA. The form did not indicate if this was a pre-procedure assessment or a post-procedure assessment. This section documented a physical examination; however the time of the examination was not documented.</p> <p>c. The section, "PROCEDURE ASSESSMENT SIGN OFF," documented the pre-procedure assessment for anesthesia risk. The section included signature lines for the CRNA and the MD. However, there was no documented time when the assessments were performed.</p> <p>d. The section, "POST PROCEDURE ORDERS," documented the orders to monitor the patient per protocol, treat nausea/pain per protocol, and to discharge patients per protocol. The orders were signed by the Medical Director, but were not timed.</p> <p>The Medical Director was interviewed on 7/21/16 at 2:05 PM and patient records were reviewed in her presence. She confirmed the records were incomplete and missing required elements.</p> <p>2. An ASC policy "Acute Pain Assessment and Management," revised 1/02/15, stated "Pain shall</p>	Q 162			

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Q 162	<p>Continued From page 28</p> <p>be assessed for each patient using the Aldrete scoring system. Documentation of the pain score shall be assessed and recorded for all patients during the pre-admission, post procedure, and prior to discharge on the Procedure Flow Sheet." Additionally, it stated "Final assessment of patients prior to discharge shall include a pain assessment. No patient may be discharged with an Aldrete pain level higher than admission unless specifically cleared by a physician for the pain, as if pain is present it may be an indication of a complication."</p> <p>Another ASC policy "Sedation Guidelines," revised 1/16/16, stated "...[discharge Aldrete score must equal or be better than admitting score]." These policies were not followed.</p> <p>The "PROCEDURE FLOW SHEET" included a section "PATIENT ALDRETE ASSESSMENT," with areas for documentation of the patient's status pre-procedure, post-procedure, and at discharge. The American Society of PeriAnesthesia Nurses website, www.aspan.org <http://www.aspan.org>, accessed 7/27/16, stated the Aldrete scoring system is used to assess patients readiness for discharge based on several factors which may include level of consciousness, activity, pain, respirations, and oxygen saturation.</p> <p>The Aldrete assessment section on the flow sheet included the following areas: level of consciousness, physical status, circulation, respirations, oxygen saturation level, pain, and nausea.</p> <p>Patient #1- #3, #6 - #12, and #17 - #18's records did not include documentation in the Aldrete</p>	Q 162		

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Q 162	<p>Continued From page 29 assessment section. The section was blank.</p> <p>CRNA A was interviewed on 7/21/16 at 11:25 AM and records were reviewed in her presence. She stated the ASC staff were instructed not to use the "PROCEDURE FLOW SHEET, PATIENT ALDRETE ASSESSMENT" by the Medical Director due to the ASC only using conscious sedation and Managed Anesthesia Care. This instruction was not documented by the Medical Director for staff to follow. CRNA A confirmed the "PATIENT ALDRETE ASSESSMENT" was blank despite the ASC policy to complete them.</p> <p>The Medical Director was interviewed on 7/21/16 at 2:05 PM and patient records were reviewed in her presence. The Medical Director confirmed staff were instructed not to complete Aldrete scores on the "PROCEDURE FLOW SHEET," but stated this instruction was not documented and was contradictory to the "Acute Pain Assessment and Management Policy."</p> <p>3. Patient #1 - #19's records included an "ANESTHESIA RECORD." The forms were dated at the top with the date of the procedure. The anesthesia flow sheet included sections which were incomplete or left blank.</p> <p>a. The form included a section titled "REMARKS." Under this section was an entry titled "Pre Procedure Time Out." No time was documented when the pre-procedure time-out occurred. The Joint Commission website, www.jointcommission.org <http://www.jointcommission.org>, accessed on 7/26/16, stated it is a universal protocol to conduct a time-out prior to starting an invasive procedure. The time-out involves agreement of</p>	Q 162			

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Q 162	Continued From page 30 the procedure team members of the correct patient identity, the procedure to be performed, and the correct site for the procedure. b. A section of the form, "RECOVERY," included an area for documentation of recovery notes. This section was blank. CRNA A was interviewed on 7/21/16 at 11:25 AM and records were reviewed in her presence. CRNA A also confirmed no time was documented for the patients' pre-procedure time-out, listed on their respective "ANESTHESIA RECORDS." The Medical Director was interviewed on 7/21/16 at 2:05 PM and patient records were reviewed in her presence. She confirmed the records were incomplete and missing required elements. The ASC failed to follow their policies and maintain an accurate and complete medical record for each patient. 4. Refer to Q264 as it relates to the ASC's failure to ensure patients' post-surgical conditions were assessed and documented in each patient's medical record. 5. Refer to Q266 as it relates to the ASC's failure to ensure patients were discharged with a valid order from the physician who performed their procedures.	Q 162		
Q 181	416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice.	Q 181		

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Q 181	<p>Continued From page 31</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, it was determined the ASC failed to ensure a developed and comprehensive system was in place to ensure drugs disposed of in accordance with accepted standards of practice for all patients receiving medications at the ASC. This resulted in the potential for patients to receive drugs in an unsafe and ineffective manner. Findings include:</p> <p>The U.S. Food and Drug Administration website, www.fda.gov, accessed 8/05/16, stated using expired medication is risky and possibly harmful to your health. The U.S. Food and Drug Administration began requiring an expiration date on prescription and over-the counter medicines in the 1970's. "Expiration dates on medical products are a critical part of determining if the product is safe to use and will work as intended."</p> <p>A tour of the ASC was conducted with the Administrator on 7/19/16, beginning at 8:45 AM. During the tour, 40 single-use vials of Naloxone 0.4 mg, (an opioid reversal medication), were noted to have expired on 6/2016. Additionally, 1 Ventolin inhaler, (a medication to help with breathing), expired on 4/2016.</p> <p>The ASC Administrator was interviewed on 7/19/16, at 9:00 AM. The medications were shown to the Administrator and he confirmed they were expired. The medications were then discarded by the Administrator.</p> <p>The facility failed to ensure expired medications were removed.</p>	Q 181		

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Q 219	<p>416.50 PATIENT RIGHTS</p> <p>Condition for Coverage - Patient Rights</p> <p>The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.</p> <p>This CONDITION is not met as evidenced by: Based on observation, ASC policy review, record review, and staff interview, it was determined the ASC failed to ensure patients receiving services at the ASC were fully informed of their rights and that patient rights were upheld. This failure resulted in a lack of accurate consent information being provided to patients and patient rights being violated. Findings include:</p> <p>1. Refer to Q229 as it relates to the ASC's failure to ensure patients were provided with accurate, comprehensive information on which to base informed consent decisions.</p> <p>2. Refer to Q232 as it relates to the ASC's failure to ensure patients' rights to receive care in a safe setting was upheld.</p>	Q 219		
Q 229	<p>416.50(e)(1)(iii) EXERCISE OF RIGHTS - INFORMED CONSENT</p> <p>[[(1) The patient has the right to the following:]</p> <p>(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.</p> <p>This STANDARD is not met as evidenced by:</p>	Q 229		

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Q 229	<p>Continued From page 33</p> <p>Based on record review, ASC policy review, and staff interview, it was determined the ASC failed to ensure patients were provided with accurate, comprehensive information prior to their scheduled procedures for 19 of 19 patients (#1 - #19), whose records were reviewed. This resulted in a lack of information being provided to patients on which to base informed consent decisions. Findings include:</p> <p>An ASC policy "Rules and Regulations," revised 1/09/16, stated "It is the responsibility of the physician to obtain this informed consent by the patient, parent, or legal guardian, for any procedure to be performed. In addition, the informed consent of the patient for the nature of the sedation/anesthesia planned is obtained before the procedure is performed. Both consents may be documented on one consent form."</p> <p>Patient consents were reviewed. The consents did not contain accurate, comprehensive information, as follows:</p> <p>1. The consent forms, for EGDs and colonoscopies, including the consents signed by Patients #1 - #19, stated "I consent to the use of blood and blood products/components/derivatives as deemed necessary. Risks and hazards associated with the administration of blood components mat [sic] include, fever, transfusion reaction, which includes kidney failure and anemia, heart failure, hepatitis, AIDS (acquired Immune Deficiency Syndrome [sic]), or other infections.</p> <p>During an interview on 7/20/16, at 8:50 AM, the Administrator reviewed a sample patient consent</p>	Q 229		

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Q 229	<p>Continued From page 34</p> <p>form. He confirmed the ASC did not administer blood or blood products and the consent form should not include verbiage of them.</p> <p>2. Patient #11's record included a "CONSENT FOR ESOPHAGOGASTRODUODENOSCOPY," dated 5/17/16, and signed by the patient, a witness, and the Medical Director. However, Patient #11 had a colonoscopy, not an EGD, as documented on the "COLONOSCOPY PROCEDURE REPORT," dated 6/06/16, and electronically signed by the Medical Director. There was no documentation indicating Patient #11 was screened, evaluated, or scheduled for an EGD.</p> <p>The ASC failed to ensure the proper informed consent was signed by the patient for the procedure performed.</p> <p>3. Patient #7, #8, #14 and #15's records included consent for endoscopic procedures which were signed by the patients. The consent forms were dated on the same day of the patients' procedures. However, the consents did not include a documented time next to the patients' signatures. It could not be determined if the informed consents were obtained prior to the procedures.</p> <p>During an interview on 7/20/16, beginning at 10:50 AM, the Administrator reviewed the records and confirmed there were no times next to the patients' signatures to verify each patient's consent was garnered prior to their procedures.</p> <p>The ASC failed to ensure accurate consent information was provided to patients.</p>	Q 229		

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Q 232 Q 232	Continued From page 35 416.50(f)(2) SAFETY [The patient has the right to -] (2) Receive care in a safe setting This STANDARD is not met as evidenced by: Based on observation, record review, ASC policy review, ASC document review, personnel file review, and staff interview, it was determined the ASC failed to ensure patients received care in a safe setting. These failures directly impacted 6 of 19 patients (#6, #10, #11, #13, #17, and #19) whose care was observed and/or whose records were reviewed. These systemic failures resulted in the inability of the facility to ensure patient safety and placed patients in immediate jeopardy of the potential to experience serious harm, impairment, or death as a result of procedural complications. Findings include: 1. The ASC employed an Administrator, a Recovery Room Technician, and 2 Reprocessing Technicians (Reprocessing Technician A and Reprocessing Technician B) who reprocessed the endoscopes and assisted the physician during procedures. The ASC also had a CRNA group with privileges to provide anesthesia services. During an interview on 7/19/16, at 1:30 PM, the Medical Director stated she did not currently employ an RN on her staff. She stated the CRNAs acted as the RN and were responsible for the patients while in the ASC. During a follow-up interview on 7/21/16, at 11:37 AM, the Medical Director stated the ASC had not had an RN on staff for "2 to 3 months." The ASC Administrator was interviewed on 7/20/16, at 11:35 AM. He stated he was not an	Q 232 Q 232		

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Q 232	<p>Continued From page 36</p> <p>RN. The Administrator confirmed the ASC did not have an RN on staff. He stated CRNAs were contracted staff and not employees of the ASC. A CRNA contract was requested from the Administrator; however, he stated he was unable to locate a contract.</p> <p>An ASC document "CRNA JOB DESCRIPTION," undated, was reviewed. The document stated "Provide on-site direction of any non-physician who participates in the delivery of care to the patient." The job descriptions were unsigned.</p> <p>However, The ASC's CRNAs were not consistently aware of their responsibilities. This resulted in a lack of direction and delineation of nursing services necessary to ensure patient safety because the ASC had not formally assigned them any responsibilities. Examples include:</p> <p>a. CRNA B and CRNA C were not available for interview. CRNA A was interviewed on 7/21/16, at 11:25 AM, and the "CRNA JOB DESCRIPTION" was reviewed in her presence. CRNA A stated she was unaware the ASC did not employ RNs. She stated she did not provide oversight for staff members at the ASC and that she was unaware she was responsible for directing non-physician staff, who had been assigned patient care responsibilities.</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities, necessary to ensure all nursing services were directed and clearly delineated.</p> <p>b. During the interviewed on 7/21/16, at 11:25 AM, CRNA A stated she was unaware she was</p>	Q 232			

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Q 232	<p>Continued From page 37</p> <p>responsible for patients during the post-operative period. CRNA A stated she would report the patient off to the Recovery Room staff.</p> <p>A job description for Recovery Room Personnel, dated 1/16/16, was reviewed. The job description stated "Knowledge and skills: Must demonstrate ability to perform all duties. BLS [sic]. If not currently certified, will need to certify at the next class held." Additionally, the job description stated the personnel must monitor patients' blood pressure and pulse per policy.</p> <p>A request was made for policies related to monitoring patients' vital signs in the recovery room. An ASC policy "Rules and Regulations," revised 1/16/16, was presented by the Administrator on 7/20/16. The policy stated "15. A patient is still at risk after the procedure is completed. Post procedure observation and recovery observation is required. Decreased procedural stimulation, delayed drug absorption, slow drug elimination may contribute to residual sedation and cardio [sic] respiratory depression during the recovery period." Therefore:</p> <ul style="list-style-type: none"> - "Patients will be evaluated post-op [post-operatively], for progression toward meeting discharge criteria." - "Blood pressure, pulse, respiratory rate and ventilatory function, level of consciousness, and oxygen saturation will be monitored and documented every fifteen (15) minutes until recovered from sedation." <p>The policy also stated the CRNA or physician must be consulted if any complications arise post-procedure. However, there were no</p>	Q 232			

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Q 232	<p>Continued From page 38</p> <p>parameters or description of when recovery room personnel should consult or notify the CRNA or physician.</p> <p>The Medical Director presented a "Discharge Protocol," undated, on 7/21/16, at 3:05 PM. The protocol stated "The patient is awake, alert and oriented. The patient's vital signs are not significantly different from their baseline status: Example: Blood pressure within 20-30% of baseline. Pulse within 20-30% of baseline."</p> <p>However, the American Heart Association website, www.heart.org, accessed on 8/05/16, stated "A single lower-than-normal reading is not cause for alarm if you are not experiencing any other symptoms or problems. However, a sudden drop in blood pressure --- even a change of just 20 mm Hg --- can cause dizziness or fainting. Sometimes a rapid decrease in blood pressure can indicate an underlying problem such as: Uncontrolled bleeding, severe infections, allergic reaction, postural (orthostatic) hypotension."</p> <p>Additionally, Mayo Clinic website, www.mayoclinic.org <http://www.mayoclinic.org>, accessed 8/05/16, stated "Some experts define low blood pressure as readings lower than 90 mm Hg systolic or 60 mm Hg diastolic - you need to have only one number in the low range for your blood pressure to be considered lower than normal. In other words, if your systolic pressure is a perfect 115, but your diastolic pressure is 50, you're considered to have lower than normal pressure."</p> <p>The Mayo Clinic website also stated "A sudden fall in blood pressure also can be dangerous. A change of just 20 mm Hg - a drop from 110</p>	Q 232			

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Q 232	<p>Continued From page 39</p> <p>systolic to 90 mm Hg systolic, for example - can cause dizziness and fainting when the brain fails to receive an adequate supply of blood. And big plunges, especially those caused by uncontrolled bleeding, severe infections or allergic reactions, can be life-threatening."</p> <p>The Recovery Room Technician personnel file documented he was hired on 6/15/16. The file included an "Employee Orientation Checklist," undated, which was blank and not signed. The file did not include documentation of job competencies or training. There, there was no documentation of training regarding patient assessment, life-threatening situations, or how to manage them. Documentation of BLS certification or related training was not present and there was no documentation of training regarding the use of the ASC's emergency equipment and/or what to do in the case of an emergent situation.</p> <p>The Administrator was interview on 7/20/16, at 11:35 AM and the Recovery Room Technician's personnel file was reviewed in his presence. The Administrator stated the Recovery Room Technician was a certified EMT. The Administrator confirmed the Recovery Room Technician had a blank, undated orientation sheet, no documented job training, no documented job competencies, no documented job education, and no documentation of BLS certification.</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities to ensure all staff performing nursing care services were provided with direction and oversight. This resulted the Recovery Room Technician not being</p>	Q 232		

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Q 232	<p>Continued From page 40</p> <p>appropriately trained or qualified to perform the duties he was assigned and led to patients not receiving care in accordance with accepted standards of practice or in accordance with their individualized needs, as follows:</p> <p>i. The Recovery Room Technician was not observed to demonstrate the competencies necessary to ensure patients received safe care in accordance with accepted standards of practice.</p> <p>The AORN's Guidelines for Perioperative Practice, 2015, stated "The perioperative nurse should evaluate the patient for discharge readiness based on specific discharge criteria." The guidelines also stated "Criteria for discharge may include, but are not limited to: return to preoperative, baseline LOC [level of consciousness]; stability of vital signs; sufficient time interval ..." Additionally, the guidelines stated "Patients should remain awake for at least 20 minutes without stimulation before they are considered ready for discharge."</p> <p>Further, the National Library of Medicine website, www.ncbi.nlm.nih.gov <http://www.ncbi.nlm.nih.gov> accessed 7/27/16, included an article dated 2/16/13, from the "The World Journal of Gastrointestinal Endoscopy." The article "Sedation and monitoring for gastrointestinal endoscopy," stated "Blood pressure, heart rate, respiratory rate, oxygen saturation, and level of consciousness are monitored and documented at least every 15 minutes or less, for a minimum of thirty minutes after the last dose of sedation medication. A written record of these parameters should be maintained in the recovery phase. Additionally,</p>	Q 232			

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Q 232	<p>Continued From page 41 patients must be able to tolerate fluids."</p> <p>An observation of a procedure was conducted on 7/21/16, beginning at 9:50 AM. Patient #17 was a 47 year old female admitted to the ASC for a colonoscopy. She was taken to the procedure room at 10:15 AM.</p> <p>The "ANESTHESIA RECORD," dated 7/21/16, documented Patient #17 received Versed 2 mg (a benzodiazepine used for drowsiness and relaxation), Fentanyl 100 mcg (a pain medication and sedative), and Propofol 150 mg (an anesthetic used for sedation and anesthesia). The last dose of Propofol was given at 10:46 AM, per observation. Patient #17 was then taken to the Recovery Room.</p> <p>The "PROCEDURE FLOW SHEET," dated 7/21/16, documented the Recovery Room Technician received Patient #17 at 10:55 AM. At 11:02 AM the Recovery Room Technician documented "Sat the pt. [patient] up." At 11:12 AM, he documented "Pt feels woozy [sic] Gave pt water [sic]." Patient #17 was discharged at 11:25 AM. There was no documentation in the record Patient #17 was reassessed for dizziness, nausea, or if the "woozy" feeling had improved or ceased.</p> <p>Patient #17's vital signs were documented at 10:55 AM, 11:00 AM, and 11:23 AM. The vital signs did not include documentation of an assessment for her level of consciousness or pain level.</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities to ensure the Recovery Room Technician provided nursing care in</p>	Q 232		

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Q 232	<p>Continued From page 42</p> <p>accordance with accepted standards of practice and was able to identify abnormal recovery findings and report them to the CRNA.</p> <p>ii. Patients #6, #10, #11, and #13's medical records did not include documentation that the Recovery Room Technician provided appropriate monitoring of patients or identified and reported abnormal recovery findings to the CRNA. Without such reporting, the CRNA could not ensure patients were provided with appropriate medical interventions as indicated by each patient's status, as follows:</p> <p>- Patient #11 was a 63 year old male admitted to the ASC on 6/06/16, for a colonoscopy.</p> <p>Patient #11's record included a "PROCEDURE FLOW SHEET," dated 6/06/16, which documented his pre-procedure vital signs at 11:05 AM. The vital signs were a blood pressure of 131/70, oxygen saturation of 93%, a heart rate of 86, and respirations of 16. The pre-procedure vitals were obtained 2 hours prior to his procedure.</p> <p>Patient #11's record included an "ANESTHESIA RECORD," dated 6/06/16, signed by CRNA A and the Medical Director. There was no documentation of baseline vital signs. The "RECOVERY" section documented Patient #11's vital signs at 1:36 PM, 6 minutes after the completion of his procedure. The vital signs were a blood pressure of 86/50, an oxygen saturation level of 92%, and a heart rate of 70. Patient #11's respirations, temperature, and pain level were not documented.</p> <p>His post procedure vital signs were documented</p>	Q 232			

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Q 232	<p>Continued From page 43</p> <p>at 1:42 PM, 12 minutes after the completion of his procedure. The vital signs documented a blood pressure of 103/55, an oxygen saturation level of 95%, a heart rate of 74, and respirations of 16. Patient #11's temperature and pain level were not documented.</p> <p>The National Library of Medicine website, accessed 8/05/16, www.medlineplus.gov, stated "Normal blood pressure for adults is defined as a systolic pressure below 120 mmHg and a diastolic pressure below 80 mmHg. It is normal for blood pressures to change when you sleep, wake up, or are excited or nervous." Patient #11's blood pressure was more than 30% lower than his baseline blood pressure.</p> <p>Patient #11 was discharged home at 1:47 PM. Patient #11 had no further vital signs documented after 1:42 PM. There was no documentation regarding his status or whether the Medical Director or CRNAA were informed of his abnormal vital signs. There was no documentation Patient #11 was assessed by the Medical Director or CRNAA prior to his discharge.</p> <p>- Patient #13 was a 67 year old female admitted to the ASC on 3/17/16, for a colonoscopy.</p> <p>The "PROCEDURE FLOW SHEET" documented Patient #13's pre-procedure vital signs were obtained at 12:42 PM. Patient #13's blood pressure was documented as 118/66, a heart rate of 76, respirations of 16, and an oxygen saturation level of 96%. Patient #13's temperature and pain level were not documented.</p> <p>The "ANESTHESIA RECORD," dated 3/17/16,</p>	Q 232		
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Q 232	<p>Continued From page 44</p> <p>documented she was taken to the procedure room and the anesthesia start time was 1:13 PM. The record documented Patient #13's baseline vital signs were a blood pressure of 124/65, a heart rate of 66, a respiratory rate of 16, and an oxygen saturation level of 96%. There was no time documented for the baseline vital signs to indicate if they were obtained just prior to the procedure or after receiving medications.</p> <p>At 2:06 PM, the procedure ended and Patient #13 was taken to the recovery room. CRNA B documented her vital signs were a blood pressure of 87/64, a heart rate of 86, respirations of 16, and an oxygen saturation level of 96%. There was no documentation of a pain level or a temperature.</p> <p>The National Library of Medicine website, accessed 8/05/16, www.medlineplus.gov, stated "Normal blood pressure for adults is defined as a systolic pressure below 120 mmHg and a diastolic pressure below 80 mmHg. It is normal for blood pressures to change when you sleep, wake up, or are excited or nervous." Patient #13's systolic (upper number) blood pressure was at 30%, 87 mmHg systolic, of her baseline. However, this was a significant drop of 37 mmHg in her systolic number.</p> <p>Patient #13 was discharged from the ASC at 2:59 PM. There were no further vital signs documented in her record prior to discharge. There was no documentation regarding her status or whether the Medical Director or CRNA A were informed of her vital signs prior to her discharge. There was no documentation Patient #13 was assessed by the Medical Director or CRNA A prior to Patient #13's discharge.</p>	Q 232			

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Q 232	<p>Continued From page 45</p> <p>- Patient #10 was a 66 year old female admitted to the ASC on 5/05/16, for an EGD with biopsy.</p> <p>The "PROCEDURE FLOW SHEET" documented Patient #10's pre-procedure vital signs were obtained at 8:55 AM. Patient #10's blood pressure was documented as 117/57, a heart rate of 59, respirations of 16, and an oxygen saturation level of 97%.</p> <p>The "ANESTHESIA RECORD," dated 5/05/16, documented she was taken to the procedure room and the anesthesia start time was 9:20 AM. The record documented Patient #10's baseline vital signs were a blood pressure of 109/53, a heart rate of 57, a respiratory rate of 16, and an oxygen saturation level of 98%. There was no time documented for the baseline vital signs to indicate if they were obtained just prior to the procedure or after receiving medications.</p> <p>At 10:11 AM, the procedure ended and Patient #10 was taken to recovery. CRNA B documented her blood pressure was 90/39 and there were no problems during the procedure. Patient #10 was discharged from the ASC at 10:55 AM. There were no further vital signs documented in her record prior to discharge.</p> <p>The National Library of Medicine website, accessed 8/05/16, www.medlineplus.gov, stated "Normal blood pressure for adults is defined as a systolic pressure below 120 mmHg and a diastolic pressure below 80 mmHg. It is normal for blood pressures to change when you sleep, wake up, or are excited or nervous." Patient #10's systolic blood pressure was within 20 to 30% of her baseline. However, this was a</p>	Q 232			

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Q 232	<p>Continued From page 46</p> <p>significant drop of 19 mmHg in her systolic number.</p> <p>There was no further documentation regarding Patient #10's status. There was no documentation Patient #10 was assessed by the Medical Director or CRNA B prior to Patient #10's discharge.</p> <p>- Patient #6 was a 73 year old female admitted to the ASC on 6/13/16, for a colonoscopy.</p> <p>Patient #6's record included a "PROCEDURE FLOW SHEET," dated 6/13/16. The form included a section titled "VITALS" which was used for documenting patients' pre and post-procedure vital signs. This section documented Patient #6's pre-procedure vital signs at 8:55 AM. The vital signs documented her blood pressure was 98/58, an oxygen saturation level of 97%, a heart rate of 82, and respirations of 12. Patient #6's temperature and pain level were not documented.</p> <p>Patient #6's record included an "ANESTHESIA RECORD," dated 6/13/16, signed by CRNA A and the Medical Director. The form included a section titled "Baseline Values" which was used for documenting patients' baseline vital signs. This section was blank. The form also included a section titled "RECOVERY" which was used for documenting post procedure vital signs. This section documented Patient #6's vital signs at 10:12 AM, 3 minutes after the completion of her procedure. The vital signs documented her blood pressure was 80/46, an oxygen saturation level of 96%, a heart rate of 69, and respirations of 16. Patient #6's temperature and pain level were not documented.</p>	Q 232			

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Q 232	<p>Continued From page 47</p> <p>Patient #6's post procedure vital signs were documented at 10:16 AM, 7 minutes after the completion of her procedure, on the "PROCEDURE FLOW SHEET." The vital signs documented her blood pressure was 70/36, an oxygen saturation level of 85%, a heart rate of 69, and respirations of 12.</p> <p>The National Library of Medicine website, accessed 8/05/16, www.medlineplus.gov, stated "Normal blood pressure for adults is defined as a systolic pressure below 120 mmHg and a diastolic pressure below 80 mmHg. It is normal for blood pressures to change when you sleep, wake up, or are excited or nervous." Patient #6's blood pressure was more than 30% lower than her baseline blood pressure.</p> <p>Patient #6 was discharged home at 10:30 AM. Patient #6 had no further vital signs documented after 10:16 AM. There was no documentation regarding her status or whether the Medical Director or CRNA A were informed of her abnormal vital signs prior to her discharge. There was no documentation Patient #6 was assessed by the Medical Director or CRNA A prior to Patient #6's discharge.</p> <p>The National Library of Medicine website, accessed 7/29/16, www.medlineplus.gov, stated "Blood pressure varies from one person to another. A drop as little as 20 mmHg [millimeters of mercury], can cause problems for some people. There are different types and causes of low blood pressure. Severe hypotension can be caused by sudden loss of blood (shock), severe infection, heart attack, or severe allergic reaction (anaphylaxis). Sudden sever drops in your blood pressure starves your body of oxygen. This can</p>	Q 232			

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Q 232	<p>Continued From page 48</p> <p>lead to damage of the heart, brain, and other organs. This type of low blood pressure can be life threatening if not treated right away."</p> <p>The Recovery Room Technician was interviewed on 7/21/16, at 10:45 AM, and Patient #6's record was reviewed in his presence. He confirmed he was the Recovery Room Technician assigned to Patient #6 on 6/13/16. The Recovery Room Technician stated he was not aware of a procedure or protocol to follow regarding when to notify the physician or CRNA of patients' vital sign values. He stated "I would use common sense if I needed clarification." Additionally, he stated "I usually only do one set of vital signs." The Recovery Room Technician stated he should have documented Patient #6's presentation and notified either the physician or CRNA regarding her vital sign values.</p> <p>The ASC failed to ensure each CRNA was aware of their responsibilities to ensure the Recovery Room Technician provided appropriate monitoring of patients and was able to identify abnormal recovery findings and report them to the CRNA.</p> <p>c. The "CRNA JOB DESCRIPTION," undated and unsigned, stated as part of their responsibilities and functions "7) Provide management of cardiopulmonary resuscitation. 8) Provide management of problems in pulmonary care 9) Provide on-site direction of any non-physician who participates in the delivery of care to the patient."</p> <p>During the interviewed on 7/21/16 at 11:25 AM, CRNA A stated once she reported the patient off to the Recovery Room staff, she would then begin preparing for her next patient. The "CRNA</p>	Q 232			

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Q 232	<p>Continued From page 49</p> <p>JOB DESCRIPTION" was reviewed with CRNAA. CRNAA stated she was unaware of the responsibilities listed above. She also stated she was unaware if patients were discharged prior to her beginning sedation with another patient in the Procedure Room.</p> <p>When asked on 7/21/16 at 8:50 AM, what the average census was for a procedure day, the Recovery Room Technician stated there may be as many as 5 to 6 patients on one day. He stated there were times when he would be recovering a patient in the Recovery Room and the CRNA and Medical Director would be in the Procedure Room at the same time.</p> <p>The ASC Recovery Room Technician personnel file, dated 6/15/16, was reviewed. The file did not include documentation of the employee's BLS certification or related training. The file did not include training regarding patient assessment, life-threatening situations, or how to manage them.</p> <p>The Recovery Room Technician was interviewed on 7/21/16 at 8:50 AM. The Recovery Room Technician was asked if he had a current BLS card and training. He stated he had a current card, but he was unable to provide documentation of one.</p> <p>The ASC Administrator was interviewed on 7/20/16 at 11:25 AM, and the Recovery Room Technician Personnel file was reviewed in his presence. He confirmed the file did not include BLS certification.</p> <p>The ASC failed to ensure staff, including an RN who were trained in the use of emergency</p>	Q 232		

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Q 232	<p>Continued From page 50</p> <p>medical equipment and cardiopulmonary resuscitation, were readily available for patients.</p> <p>In summary, the ASC failed to ensure each CRNA was aware of their responsibilities, necessary to ensure all nursing services were directed and clearly delineated. This resulted in the Recovery Room Technician who did not demonstrate the competencies necessary to safely perform the nursing care duties which were assigned to him, including the appropriate identification of patients' abnormal post-operative findings which warranted follow-up by either the CRNA or Medical Director. Further, the ASC failed to ensure staff, including an RN who were trained in the use of emergency medical equipment and cardiopulmonary resuscitation were readily available for patients and that emergency medical equipment was tested to ensure it was operational.</p> <p>The cumulative effect of these systemic failures resulted in the patient's rights to care in a safe setting being violated and patients in immediate jeopardy of the potential to experience serious harm, impairment, or death as a result of procedural complications.</p> <p>Note: The facility was notified of the Immediate Jeopardy on 7/21/16 at 1:30 PM. The ASC submitted an Immediate Plan of Correction on 7/22/16 at 1:40 PM, which stated the "PROCEDURE FLOW SHEET" would be revised for clarification of documentation. All training and competencies were to be completed for current staff, including certifications and current BLS. Additionally, the discharge protocol was revised and clearly defined for staff members, including parameters for patient vital signs.</p>	Q 232			

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Q 232	<p>Continued From page 51</p> <p>The plan stated the corrective action would be implemented by 7/25/16. The plan also stated all procedures would be suspended until 7/28/16, to ensure the Immediate Jeopardy was removed.</p> <p>Prior to the first scheduled procedure on 7/28/16, on-site verification of the plan's implementation was completed by the survey team and the Immediate Jeopardy was removed on 7/28/16 at 8:55 AM.</p> <p>2. An observation was conducted beginning at 9:20 AM on 7/28/16. Patient #19 was a 38 year old female who underwent a scheduled outpatient EGD.</p> <p>Patient #19 was taken to the Procedure Room at 9:25 AM. A nasal cannula, for the purpose of delivering supplemental oxygen during the procedure, was placed on Patient #19 at 9:34 AM. Fentanyl and Versed (sedative medications) were administered by CRNAA through Patient #19's IV at 9:36 AM. Technician A attempted to turn on the oxygen via the oxygen wall regulator at 9:36 AM, however, no oxygen was present. At 9:40 AM, the patient was asleep and under the direct care of CRNAA.</p> <p>At 9:44 AM, the oxygen was still not working and the issue was being investigated by the Medical Director, Administrator, Technician A, and Recovery Room Technician. The procedure was placed on hold at this time by the Medical Director until the oxygen was confirmed to be working. At 9:50 AM, 14 minutes after medications had been administered by CRNAA, the oxygen began working. The procedure was restarted by the Medical Director at 9:51 AM. No further issues were noted and the procedure ended at 10:06</p>	Q 232			

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Q 232	<p>Continued From page 52</p> <p>AM. Patient #19 was then transferred to the Recovery Room.</p> <p>The Administrator stated oxygen tanks were delivered and hooked up to oxygen bank A and B on 7/27/16, by the ASC oxygen contract vendor. However, he stated the contract vendor did not turn on the oxygen master valve to the ASC oxygen delivery system after hooking the oxygen tanks up. The Administrator stated the oxygen delivery system was checked on a weekly basis, not prior to scheduled procedures. The Administrator confirmed the oxygen delivery system was not checked on 7/28/16, prior to the first procedure of the day. The Medical Director stated it was the ASC's practice to not test the oxygen delivery system until the patient was already in the Procedure Room. The Medical Director and Administrator confirmed the medications should not have been administered prior to ensuring the oxygen was on and working properly.</p> <p>The ASC Administrator and Medical Director were interviewed together on 7/28/16, at 10:35 AM. A policy regarding checking emergency equipment prior to scheduled procedures was requested. The Administrator stated the ASC did not have a policy for checking emergency and/or safety equipment. A procedure or protocol regarding checking emergency equipment prior to scheduled procedures was requested. The Administrator stated the ASC did not have a procedure or protocol which outlined a process.</p> <p>CRNAA, who was responsible for monitoring Patient #19 during the procedure, was interviewed on 7/28/16 at 10:42 AM. She stated the medications she administered to Patient #19,</p>	Q 232		

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Q 232	Continued From page 53 before the oxygen was confirmed to be working, were for "anxiety." She confirmed the medications should not have been administered prior to ensuring the oxygen was on and working properly. The ASC failed to ensure emergency equipment was on and functional prior to administration of sedatives and/or anesthetic medications to patients undergoing procedures. This resulted in Patient #19's right to care in a safe setting being violated and placed Patient #19 in immediate jeopardy of the potential to experience serious harm, impairment, or death as a result of procedural complications. Note: The facility was notified of the Immediate Jeopardy on 7/28/16 at 10:35 AM. The ASC submitted an Immediate Plan of Correction on 7/28/16 at 11:10 AM, which stated the "Emergency Equipment" policy was revised to include safety checks for equipment by 2 staff members and the safety check was to take place prior to the start of the procedure day. The safety check was to include the main oxygen supply, as well as, the oxygen delivery to the procedure and recovery rooms prior to the procedure day starting. Staff were immediately educated and trained on the new oxygen safety check, procedures, and policy changes. Prior to the next scheduled procedure on 7/28/16, on-site verification of the plan's implementation was completed by the survey team and the Immediate Jeopardy was removed on 7/28/16 at 11:15 AM.	Q 232			
Q 240	416.51 INFECTION CONTROL	Q 240			

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Q 240	Continued From page 54 The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, ASC policy review, ASC document review, and staff interview, it was determined the ASC failed to ensure a comprehensive infection control program was implemented and monitored for all facility staff and patients receiving care at the facility. This resulted in the the potential for increased risk of patient infections. Findings include: 1. Refer to Q241 as it relates to the ASC's failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice and nationally recognized guidelines. 2. Refer to Q242 as it relates to the ASC's failure to ensure that an explicit, ongoing infection control program based on nationally recognized guidelines was developed, implemented and monitored to ensure the health and safety of all patients receiving care in the ASC. The cumulative effect of these systemic deficient practices resulted in the inability of the facility to ensure patient risk of infections and communicable diseases was minimized.	Q 240			
Q 241	416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.	Q 241			

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Q 241	Continued From page 55 This STANDARD is not met as evidenced by: Based on observation, ASC document review, ASC policy review, personnel file review, and staff interview, it was determined the ASC failed to ensure a sanitary and functional environment for patients receiving care at the facility. This directly impacted 1 of 2 patients (Patient #17) whose procedure was observed and had the potential to impact all patients receiving services at the ASC. This resulted in patients being placed at an increased risk for infections. Findings include: An ASC policy "Infection Control Plan," revised 1/23/16, stated "To remain in compliance with state and federal requirement, various regulatory agencies, the Infection Control and Blood Borne Pathogens education will be included in orientation of new employees and at a minimum annually, and in in-service sessions, which are mandatory for all staff." This policy was not followed. 1. The ASC employed an Administrator, a Recovery Room Technician, and 2 other technicians for reprocessing of the endoscopes and assisting the physician during procedures, Reprocessing Technician A and Technician B. Additionally, the ASC contracted with a CRNA group for anesthesia administration during procedures. A request was made at 9:00 AM on 7/19/16, to the Administrator, to review personnel records for the ASC staff. On 7/20/16, at 9:30 AM, the request for personnel files was made again. At 11:30 AM on 7/20/16, the Administrator brought in the personnel file for the Recovery Room Technician and stated he did not have personnel	Q 241			

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Q 241	<p>Continued From page 56 files for Reprocessing Technician A or Technician B.</p> <p>The Administrator, CRNAs, and Recovery Room Technician's personnel records did not include documentation of training and education in Infection Control.</p> <p>The Medical Director, who was also the Infection Control Officer, was interviewed on 7/28/16, at 2:10 PM. She stated infection control related training was provided to staff during orientation and when she provided mandatory in-services. The Medical Director confirmed there was no documentation of this education in the staff personnel records.</p> <p>The lack of education and training related to Infection Control practices, standards, and ASC policies directly impacted care of patients at the ASC. Examples include:</p> <p>An observation of a procedure was conducted on 7/21/16, beginning at 9:50 AM. Patient #17 was a 47 year old female admitted to the ASC for a colonoscopy.</p> <p>a. The Recovery Room Technician admitted Patient #17 to the ASC at 9:50 AM. He weighed Patient #17, assisted her before and after she changed clothing, asked intake questions and charted them, and put on an identification band on Patient #17. He assisted her onto a gurney at 10:14 AM when she was taken to the procedure room. During this time, the Recovery Technician did not perform hand hygiene.</p> <p>Patient #17 returned to the recovery room at 10:55 AM after her colonoscopy. The Recovery</p>	Q 241			

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Q 241	<p>Continued From page 57</p> <p>Room Technician positioned Patient #17 and took vital sign readings. He discontinued Patient #17's IV at 10:57, and disposed of the equipment. He retrieved a cup of water for the patient. He reviewed the discharge forms with Patient #17. He disconnected the vital sign machine from Patient #17 and assisted her to sit on the gurney. He obtained a last set of vital signs at 11:23 AM, and assisted Patient #17 out in a wheelchair. During this time, the Recovery Technician did not perform hand hygiene.</p> <p>The CDC "Guidelines for Hand Hygiene in Health-Care Settings" and "Hand Hygiene Basics" information accessed via the CDC website www.cdc.gov on 7/29/16, stated "Healthcare providers should practice hand hygiene at key points in time to disrupt the transmission of microorganisms to patients including: before patient contact; after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn); before invasive procedures; and after removing gloves (wearing gloves is not enough to prevent the transmission of pathogens in healthcare settings)." The guidelines stated hand hygiene, either hand washing or decontamination with an alcohol based hand sanitizer, was recommended including when hands were not visibly soiled, after contact with patient's intact skin, when moving from a contaminated body site to a clean body site, and after contact with inanimate objects in the immediate vicinity of the patients.</p> <p>The Recovery Room Technician was interviewed on 7/21/16, at 10:45 AM, he stated he had received training for this position verbally. He stated he was aware of hand hygiene practices and standards, but confirmed he did not have</p>	Q 241			

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Q 241	<p>Continued From page 58 formal education or training from the ASC.</p> <p>b. An ASC policy "Procedures Performed at HADS," revised 1/06/16, stated "viii. Each staff member involved in cleaning the equipment will have an orientation period and demonstrate competency in cleaning of all endoscopes and accessories. This competency will be reviewed at a minimum annually." There was no documentation of Reprocessing Technician A's orientation or competency in endoscope reprocessing.</p> <p>During the interview, the Medical Director was asked about staff training and monitoring for reprocessing endoscopes. The Medical Director stated Technician A had worked for her previously doing reprocessing. She stated she had observed Reprocessing Technician A during reprocessing to ensure she was following national guidelines, but stated she did not document observations.</p> <p>Reprocessing Technician A was interviewed at 9:10 AM on 7/20/16, the day prior to the procedure, regarding her orientation and training for the ASC, and the steps she performed when reprocessing endoscopes. She stated she did not have formal training when she started work at the ASC on 3/17/16. Reprocessing Technician A stated she had worked for the same Medical Director, and at the same ASC, previously six years ago. She stated she watched 2 procedures and the reprocessing steps by another Technician when she first started. She then watched videos from the endoscope manufacturer on her own to "refresh my memory."</p> <p>During the same observation of Patient #17 on</p>	Q 241		

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Q 241	<p>Continued From page 59</p> <p>7/21/16, beginning at 10:47 AM, Reprocessing Technician A was observed during the reprocessing procedure of the endoscope used and cleaning of the procedure room. Reprocessing Technician A did not demonstrate the competencies necessary to complete reprocessing in accordance with accepted standards of practice, as follows:</p> <p>i. When the Medical Director ended the procedure Reprocessing Technician A placed the far end of the endoscope into a disposable cup which contained water and enzymatic detergent. She then used suction to pull the detergent/water mix into the endoscope and placed the scope inside a plastic bucket. There was no water or detergent in the bucket. Reprocessing Technician A began cleaning up the procedure room, disconnecting tubing, and throwing out trash and linen. After this was completed she then transported the dirty endoscope to the reprocessing room, which was adjacent to the procedure room through a swinging door.</p> <p>SGNA "Standards for Reprocessing Endoscopes," dated 2016, stated "Precogning occurs in the procedure room immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source. Precogning should be performed at point of use, before bioburden has an opportunity to dry and before complete decontamination."</p> <p>The AORN Guidelines for Perioperative Practice 2015 stated "Precogning of flexible endoscopes and accessories should occur at the point of use, before organic material has dried on the surface or in the channels of the endoscope, and before</p>	Q 241		

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Q 241	<p>Continued From page 60</p> <p>transport to the decontamination area." Additionally, the guidelines stated "Organic materials (e.g.. blood and body fluids) that have dried on the flexible endoscope surfaces are difficult to remove and can inhibit sterilization and high-level disinfection." The AORN guidelines stated biofilm formation can begin within minutes of completion of the procedure.</p> <p>ii. Reprocessing Technician A placed the plastic bucket on a designated dirty counter and began filling the first 2 sinks with water. Neither of the sinks were marked to indicate how much water the sink held, or how far the sink was to be filled. When asked how much water was needed Reprocessing Technician A stated she was unsure, but stated she normally filled the sink to the area which was marked by a mineral deposit going around the sink, about halfway up from the bottom of the sink.</p> <p>Reprocessing Technician A placed the scope into the first sink, while it was still filling with water. She hooked up the scope to an air source to perform the leak test. Once she completed the leak test, Reprocessing Technician A squirted 4 pumps of enzymatic detergent into the first sink. There was no mark or indication how much water was in the sink prior to adding the enzymatic detergent. She then used a disposable brush, specified for cleaning endoscopes, to clean the inside of the dirty scope.</p> <p>An ASC policy "Endoscope Reprocessing," revised 1/23/16, stated "Manufacturer's guidelines will be followed for the reprocessing and cleaning of endoscopes. All chemicals will be used in accordance with manufacturer's recommendations."</p>	Q 241		

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Q 241	Continued From page 61 The manufacturer instructions for the enzymatic detergent were reviewed in the presence of Reprocessing Technician A. The manufacturer instructions stated "Manual cleaning: Add 1/2 fluid ounce of concentrate per gallon of water. Soak for 2-3 minutes. Rinse thoroughly." When asked, during the interview on 7/20/16, at 9:10 AM, about the measurements for the enzymatic detergent used for precleaning, Reprocessing Technician A stated "I use one squirt, from the pump on the bottle, in the disposable cup and then fill the cup with water. I think a squirt is about 1/2 an ounce but I'm not sure." Reprocessing Technician A stated she used 4 squirts each time when adding it to the water in the first sink. She stated, regarding how much water the sink was filled with, "I think it's about 5 gallons of water." Reprocessing Technician A stated she was unaware of the manufacturer instructions prior to the review with the surveyors. iii. After using the brush, Reprocessing Technician A attached adapters, used for cleaning, to the scope. She used a 60 ml syringe to flush the cleansing solution through the scope, 2 times. Reprocessing Technician A then hooked up the scope to a suction canister and drew 500 ml of the cleansing solution through the scope and into the canister. Reprocessing Technician A threw away the endoscope brush, into a trash can next to the sink, and used a 1 time use sponge to wipe down the outside of the endoscope. She performed this while keeping the endoscope under the water. Reprocessing Technician A picked up the	Q 241			

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Q 241	<p>Continued From page 62</p> <p>endoscope and transferred it to the second sink, which was already filled with plain water.</p> <p>She used the same syringe from the cleansing sink to flush the plain water through the endoscope. Reprocessing Technician A then filled the syringe with air, 3 times, and flushed that through the endoscope, to remove water. She removed the adapters and placed them in the bottom of the second sink. Reprocessing Technician A removed the endoscope and placed it in the third sink for drying.</p> <p>Reprocessing Technician A dried the endoscope with a lint free cloth, picked up the endoscope and placed it in the DSD for high level disinfection. She went back to the first sink, and cleaned the endoscope pieces which had been removed prior to the leak test. She placed those in the DSD with the endoscope. Reprocessing Technician A did not rinse or dry the pieces prior to placing them in the DSD.</p> <p>iv. Reprocessing Technician A placed the cover over the endoscope and the attachment pieces, entered the endoscope's serial number on a key pad, and started the machine for disinfection.</p> <p>During the reprocessing, Reprocessing Technician A wore the same gown and gloves, as she did during the colonoscopy. She did not change her gown or gloves between steps. After she started the DSD, Reprocessing Technician A removed her gown and gloves then washed her hands with soap and water.</p> <p>v. The closet where the endoscopes were stored after high level disinfection were observed. The scopes were hanging vertically with the distal</p>	Q 241		

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Q 241	<p>Continued From page 63 ends laying on a towel in the bottom of the closet.</p> <p>The AORN Guidelines for Perioperative Practice stated "Flexible endoscopes should be stored in a closed cabinet with...adequate height to allow flexible endoscopes to hang without touching the bottom of the cabinet..."</p> <p>vi. During an interview on 7/20/16 at 9:10 AM, an open, half empty bottle of 70% isopropyl alcohol was observed, which was used in the DSD cleaning cycle. The alcohol expired on 6/2015. Reprocessing Technician A confirmed the opened bottle of isopropyl alcohol was expired. The bottle was then discarded by Reprocessing Technician A.</p> <p>Further, the ASC supply room was observed on 7/21/16 at 8:50 AM. During the observation, a box containing approximately 14 bottles of 70% isopropyl alcohol, expired on 6/2015.</p> <p>The ASC Administrator was interviewed on 7/21/16, at 9:00 AM. He confirmed the bottles of isopropyl alcohol were expired. The bottles were then discarded by ASC staff.</p> <p>The ASC failed to ensure staff were trained and competent with reprocessing of endoscopes. Additionally, ASC staff failed to follow policies, procedures, and nationally recognized standards and guidelines for reprocessing endoscopes.</p> <p>2. A tour of the ASC laundry facilities with the Administrator and designated Maintenance/Staff Support employee was conducted on 7/20/16 at 1:10 PM.</p> <p>An ASC policy "CLEANING LAUNDRY," revised</p>	Q 241			

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Q 241	<p>Continued From page 64</p> <p>12/01/2011, was reviewed. The policy stated "Water temperature must be at least 160 degrees. Wear gloves, gown and goggles to sort laundry and load machines." Additionally, the policy stated "Wear clean gloves and a clean gown to move the laundry from the dryer to folding table."</p> <p>The ASC failed to follow their policy. Examples include:</p> <p>It was observed the ASC had several consumer rated washing machines and dryers in the basement of the facility. The washing machines did not have a means to display water temperature used for laundry loads. A shelf across from the machines held the laundry detergent and bleach solutions. The water heater was located in a separate room. Upon inspection, the water heater did not have a temperature gauge or means to record water temperature.</p> <p>The ASC Administrator and Maintenance/Staff Support employee were interviewed on 7/20/16 at 1:20 PM. The Administrator confirmed the ASC water heater did not have a way to display the internal temperature. Additionally, the Administrator confirmed the water temperature for the laundry was not being monitored or documented. When asked if staff were washing the separation curtains from the patient care areas, the Administrator stated the curtains had not been washed to his knowledge. When asked if the washing machines were routinely cleaned with bleach as part of a scheduled cleaning cycle, the Administrator stated they were not to his knowledge.</p>	Q 241			

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Q 241	Continued From page 65 The Maintenance/Staff Support employee stated he was responsible for the ASC laundry. He stated routine machine cleaning with bleach, as part of a scheduled cleaning cycle, was not performed. He stated temperature logs for laundry water was not monitored or recorded. He stated no logs were kept of laundry loads or contents. The Maintenance/Staff Support employee stated he only donned a PPE disposable gown if he was handling laundry containing bodily fluids or blood. He stated he did not wear PPE when moving laundry from the dryer to the folding table and did not wear gloves, a gown, or goggles to sort laundry when loading the machines. The Maintenance/Staff Support employee stated the separation curtains in the patient areas, the preoperative, and recovery room were not being washed and he was unaware if they were supposed to be. ASC staff failed to follow policies, procedures, and nationally recognized guidelines for Infection Control practices. The ASC failed to document staff were oriented, trained, and educated to perform their duties in line with nationally recognized guidelines.	Q 241		
Q 242	416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.	Q 242		

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Q 242	<p>Continued From page 66</p> <p>This STANDARD is not met as evidenced by: Based on staff interview, ASC policy review, infection control documentation review, and ASC document review, it was determined the ASC failed to ensure that an explicit, ongoing infection control program based on nationally recognized guidelines was developed, implemented and monitored to ensure the health and safety of all patients receiving care in the ASC. This resulted in a lack of direction and training being provided to staff necessary to ensure patient risk of infection and communicable diseases was minimized. The findings include:</p> <p>1. The Medical Director, who was also the Infection Control Officer, was interviewed on 7/28/16, at 2:10 PM. When asked about the development of the ASC's infection control policies and procedures, to ensure they were consistent with national standards and guidelines, the Medical Director stated she followed the guidelines from the ASGE. She stated if there were procedures or areas not covered by the ASGE, then they followed the CDC guidelines.</p> <p>The ASC policy "Infection Control Plan," revised 1/23/16, stated "APIC [Association for Professionals in Infection Control and Epidemiology] has been identified as one excellent resource for training and education, the CDC another."</p> <p>Additionally, an ASC policy "Procedures Performed at HADS," revised 1/06/16, stated "HADS has adopted recommendations from the GI societies (ASGE, ACG, AGA) and from the SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes."</p>	Q 242		

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Q 242	Continued From page 67 The ASC employed an Administrator, a Recovery Room Technician, and 2 Reprocessing Technicians (Reprocessing Technician A and Reprocessing Technician B) who reprocessed the endoscopes and assisted the physician during procedures. The ASC had a CRNA group which were privileged to provide anesthesia services. Documentation of staff training in infection control practices could not be found for any of the ASC's employees. When asked, during an interview on 7/28/16, at 2:10 PM, about staff training and monitoring to ensure the ASC's infection control policies and procedures were being implemented, the Medical Director stated she had staff observe for hand hygiene. However, the last time hand hygiene was observed for compliance she stated it was done by a surveyor from an accrediting agency. The Medical Director stated she asked the surveyor to provide her with information she observed while in the facility on 3/07/16. She stated infection control related training was provided to staff during orientation and when she provided mandatory inservices. The Medical Director confirmed there was no documentation of this education in the staff personnel records. During the interview, the Medical Director was asked about staff training and monitoring for reprocessing endoscopes. The Medical Director stated Technician A had worked for her previously doing reprocessing. She stated she had observed Technician A during reprocessing to ensure she was following national guidelines, but stated she did not document observations. The Medical Director stated Technician B was still	Q 242			

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Q 242	Continued From page 68 being trained by Technician A. The facility failed to ensure an ongoing infection control program was implemented and monitored to prevent the spread of communicable diseases and infection. 2. Refer to Q241 as it relates to the ASC's failure to ensure patients were provided with a functional and sanitary environment in accordance with nationally recognized, acceptable standards of practice.	Q 242		
Q 260	416.52 PATIENT ADMISSION, ASSESSMENT AND DISCHARGE The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed. This CONDITION is not met as evidenced by: Based on record review, ASC policy review, and staff interview, it was determined the ASC failed to ensure each patient had the appropriate post-surgical assessments completed and were discharged by a physician. This resulted in lack of appropriate evaluation of the patient's post-operative condition and increased potential for patients to suffer adverse events following their procedures. Findings include: 1. Refer to Q264 as it relates to the failure of the ASC to ensure the patients' post-surgical condition was assessed and documented in the medical record.	Q 260		

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Q 260	Continued From page 69 2. Refer to Q266 as it relates to the failure of the ASC to ensure each patient had a discharge order signed by the physician who performed the surgery.	Q 260		
Q 264	The cumulative effect of these systemic omissions resulted in the inability of the ASC to ensure each patient's health and safety. 416.52(b) POST-SURGICAL ASSESSMENT (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Post-surgical needs must be addressed and included in the discharge notes. This STANDARD is not met as evidenced by: Based on record review, ASC policy review, ASC document review, and staff interview, it was determined the ASC failed to ensure patients' post-surgical conditions were assessed and documented in the medical record for 16 of 19 patients (#1 - #3, #5 - #13, #15 - #18) whose records were reviewed. This had the potential to result in unmet patient needs and unsafe discharge. Findings include: An ASC policy "Sedation Guidelines," revised 1/06/16, stated "Patients will be discharged when they meet the following criteria: a. Physician's or CRNA clearance for discharge..."	Q 264		

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

PRINTED: 09/01/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 13C0001023	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/28/2016
NAME OF PROVIDER OR SUPPLIER HEALING ARTS DAY SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 222 WEST IOWA AVENUE, SUITE B NAMPA, ID 83686	
(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 264	<p>Continued From page 70</p> <p>An ASC protocol "Discharge Protocol," undated, stated "Physician or CRNA has cleared patient for discharge."</p> <p>Patient #1 - #3, #5 - #13, and #15 - #18's post procedure evaluation and assessment were not documented in their records by the physician, CRNA, or a qualified RN with post-operative experience. The ASC failed to follow their policy and protocol.</p> <p>The medical records included a "PROCEDURE FLOW SHEET," with a section titled "DISPOSITION." This section included the statement "Patient has been assessed by MD/CRNA and has been cleared for discharge." However, there was no physician or CRNA signature next to this statement and no indication of a time when patients were assessed. Additionally, there was no documentation of a discharge assessment by the physician or CRNA in the medical records.</p> <p>During an interview on 7/21/16, at 11:37 AM, the Medical Director confirmed the "PROCEDURE FLOW SHEET" and "ANESTHESIA RECORD" forms were incomplete and did not document who assessed the patients after their procedures and prior to discharging home. She stated she saw each patient prior to their discharge and initialed their discharge instruction sheet. The Medical Director confirmed there was no date and time next to her initials on the discharge instructions.</p> <p>The ASC failed to ensure patients' post-surgical assessments were documented in their medical records.</p>	Q 264		

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Q 266 Q 266	Continued From page 71 416.52(c)(2) DISCHARGE - ORDER [The ASC must -] Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy. This STANDARD is not met as evidenced by: Based on record review, ASC policy review, and staff interview, it was determined the ASC failed to ensure patients were discharged with a valid order from the physician who performed their procedures for 19 of 19 patients (#1 - #19) whose records were reviewed. This resulted in patients being discharged without an evidence-based determination they were medically stable. Findings include: 1. An ASC policy "Documenting in the Medical Record," revised 1/06/16, stated documentation in the medical record must be noted with the date and time, using a 24 hour clock." There was no documentation included in Patient #1 - #19's records there was a physician order for discharge. The ASC did not follow their policy. Examples include: a. The "POST PROCEDURE FLOW SHEET" included a section titled "POST PROCEDURE ORDERS." Under this section were 3 items: "1. Monitor per protocol," "2. Treat nausea/pain per protocol," and "3. Discharge per protocol." Under item 3 was a blank physician signature line. Patient #1 - #18's records included a physician signature on this line, but no time was	Q 266 Q 266		

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NAME OF PROVIDER OR SUPPLIER HEALING ARTS DAY SURGERY			STREET ADDRESS, CITY, STATE, ZIP CODE 222 WEST IOWA AVENUE, SUITE B NAMPA, ID 83686	
(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 266	<p>Continued From page 72 documented next to the signature.</p> <p>b. The "COLONOSCOPY PROCEDURE DISCHARGE SUMMARY" was separated into two parts: discharge instructions at the top of the form and a procedure summary at the bottom of the form. The discharge instructions were identical for Patients #1 - #19. The procedure summary varied for each patient depending upon the specifics of the procedure and individualized findings. Next to each procedure summary were the initials of the Medical Director, who performed the procedure. There were no dates or times documented next to the Medical Director's initials in Patient #1 - #19's records.</p> <p>The Medical Director was interviewed on 7/21/16, at 2:05 PM. Patient records, including the "COLONOSCOPY PROCEDURE DISCHARGE SUMMARY" and "PROCEDURE FLOW SHEET" were reviewed in the presence of the Medical Director. She stated her initials on the "COLONOSCOPY PROCEDURE DISCHARGE SUMMARY" acted as the official discharge order. The Medical Director confirmed she did not document dates or times next to her initials on the form. She also confirmed she did not document times next to her signatures on the "PROCEDURE FLOW SHEET" forms under "POST PROCEDURE ORDERS" section. The ASC policy "Documenting in the Medical Record" was reviewed in the presence of the Medical Director. She confirmed all orders should include a physician signature, date, and time.</p> <p>The ASC failed to ensure a signed discharge order by the physician who performed the procedure was documented.</p>	Q 266		

RECEIVED
SEP 01 2016
FACILITY STANDARDS

Q040 - Governing Body failed to provide oversight and supervision necessary to ensure all patients received safe and appropriate care.

- A) Failed to assume responsibility for defining and directing nursing services.
- B) Failed to ensure ASCs employees were appropriately qualified and trained.

Result 1 – The Governing Body of the ASC failed to ensure direct and defining roles for the nursing services. As stated in the interpretive guide, the governing body delegated day-to-day operational responsibilities to other staff that were at employed at the ASC. The governing body had put policies and procedures in place to ensure the safety of the patients and staff at the ASC. Personnel were trained on those policies and procedures, with documentation and continued training including continual monitoring was delegated to the administrator and trained employees. The delegated employee(s) had fallen short of expectation and in part, that is why they are no longer employed at the ASC. The governing body has reassumed the control for the defining and direction of nursing services and has met with the staff both individually, on July 25th, 2016 as well as, September 1st, 2016, in a group to ensure that the ASC policies and procedures are understood and roles of patient care are clearly defined for the safety of all, and will continue to do so by continuing to have and document monthly QAPI meeting with appropriate staff for compliance.

It states in the ASC document, "CRNA JOB DESCRIPTION", under the title of RESPONSIBILITIES and FUNCTIONS it states....."Provide such other services as many be determined by the responsible physician...Provide on- site direction of any non-physician who participates in the delivery of care to the patient" ...The CRNAs are, W-2 type employees of the ASC and are NOT contracted employees, so in reference to the 2567, "documentation of legal relationship....to provide nursing services" is not a valid deficiency. The ASC has met with most of our currently employed CRNAs to review, train and get a signed and dated document to ensure that they clearly understand their roles within the ASC, specifically in reference to the CRNA JOB DESCRIPTION. The CRNA that we have not met with to review and train for a clear understanding will be met with prior to their next day of providing patient care for the ASC, but no later than 09/01/2016. With one exception who has been out of state but will be met with and trained prior to his next scheduled shift at the ASC. This will be completed by Jared Silvis, the administrator of the ASC. Refer to Q100, Q140, Q160, Q219, Q240 and Q260.

Q100 –Refer to Q105 and Q106

Q105 - ASC failed to ensure staff was trained to ensure emergency medical equipment was operational prior to providing patient care.

A) Failed to ensure staff properly and routinely checked operational status of emergency medical equipment prior to patients being seen.

Result 4 – On July 28th, 2016 the ASC failed to ensure all emergency medical equipment was operational prior to providing patient care. The ASC had a policy and process in place to check emergency medical equipment, but that process did not include the facilities supplemental oxygen supply. The ASC had begun intake of a patient for a procedure, and the ASCs supplemental oxygen was not turned on, this resulted in an Immediate Jeopardy situation. As a result, the ASC immediately revised its policy and its pre procedure emergency equipment checklist to include the facilities supplemental oxygen to ensure that it as well as the rest of the facilities emergency medical equipment was fully operational prior to the start of any procedure. By doing these actions, the Immediate Jeopardy was removed from the ASC. This “emergency medical equipment” checklist will be maintained and bi-weekly “spot checks” will be performed for continual completeness and accuracy, as well as it will be added for review to a monthly review in the ASCs QAPI report; addition training if needed will be given and documented by the administrator and the Governing Body of the ASC at the monthly QAPI meetings. This will be completed by 09/01/2016.

Q106 – ASC failed to ensure staff was trained in emergency medical equipment and cardiopulmonary resuscitation.

- A) Failed to ensure recovery room staff was assessed and documented for appropriate management of any life-threatening situations, as well as having current documentation of the individual’s knowledge and skills to perform all BLS duties.
- B) Failed to ensure recovery room technician was proven competent and documented in the use of emergency equipment, specifically the facilities’ AED.

Result 3 – On July 25th, 2016 we held a six-hour training for the staff at Healing Arts Day Surgery Center. ASC staff was in attendance and participated in the training. Topics of this training included but were not limited to, basic life support responsibilities, AED use and operations, emergency medical equipment and its use. Training was performed and competencies were documented for each staff member of the ASC. ASC employee files were also updated with current and appropriate documentation for their individual job responsibilities. New employees will have a documented training prior to providing patient care, as well as having their employee training files current. This will be monitored by “second tier” review of new employee files to include by not limited to training and competency documentation by the governing body of the ASC. This meeting was conducted by Jared Silvis, ASC administrator and was attended and overseen by Dr. Croitoru. This will be completed by 09/01/2016.

Q140 – Refer to Q141

Q141 - ASC failed to ensure nursing staff were present and provided sufficient direction and supervision for all patients receiving care.

- A) Failed to ensure nursing staff were provided sufficient direction and supervision for all patients receiving care.
- B) Failed to ensure nursing services were clearly delineated to meet patients' needs.

Result 5 - On July 25th, 2016 we held a six-hour training for the staff at Healing Arts Day Surgery Center. ASC staff was in attendance and participated in the training. Topics of this training included but were not limited to responsibilities, criteria and delineation of nursing services as it pertains to our recovery room technicians as well as our currently employed CRNAs' and their job description. Some of the ASCs CRNAs were not able to attend this meeting; for all CRNAs training concerning the duties and responsibilities including nursing services and responsibilities will be reviewed and documented; a signed and dated, "CRNA Job Description" will be placed in their employee files. With the exception on one CRNA who is out of state, his will be completed prior to his next scheduled shift at the ASC. This will be completed by 09/01/2016 and it will be done and documented under the direction of Jared Silvis, ASC administrator and overseen by Dr. Croitoru. This will be monitored by "second tier" review of new employee files to include by not limited to training and competency documentation by the governing body of the ASC.

Q160 – Refer to Q162

Q162 - ASC failed ensure complete, comprehensive and accurate medical records system had be developed and implemented.

- A) Failed to ensure medical records were complete and comprehensive on both the "Procedure Flow Sheet" as well as the "Anesthesia Records"
- B) Failed to ensure ACS's policy, "Documenting in The Medical Record" was followed.

Result 6 – The ASC "Procedure Flow Sheet 2016" has been modified to ensure an accurate representation of what is occurring is documented for the patients' medical record, specifically focused on completeness and accuracy. Training has been done with the ASC staff to teach proper documentation in medical records. This includes all records for completeness and accuracy. Currently 100% of patients charts that are receiving procedures in the ASC are being reviewed for competency has been done and will continue to be done until the point that the ASC reaches 95% accuracy for three consecutive weeks, at which point in will drop to 50% of patient charts to ensure we maintain compliance, after an addition three weeks of compliance,

chart reviews will be done on a “spot check” bases. This monitoring and training will be overseen by the Jared Silvis, ASC administrator and the Governing Body of the ASC, and the results will be submitted to the governing body for review at the monthly QAPI meetings.

The ASC “Anesthesia Record” will be modified specifically in reference the box titled “Recovery” to Emergency Recovery to more accurately reflect its intend use for emergency recovery only. This will be completed by 09/01/2016 by the administrator of the ASC.

The ACSs’ policy, “Documenting in the Medical Record”, is under review and will be modified to reflected a more accurate documentation practice. The revised policy will be implemented and documented by 09/01/2016, and review for compliance will be done by the ASCs Governing Body. Refer to Q264, Q266.

Q181 - ASC failed to ensure a developed and comprehensive system was in place to ensure drugs disposed of in accordance with accepted standards of practice.

A) Failed to ensure expired drugs were removed out of patient care areas.

Result 7 – The ASC has a process and procedures in place to ensure the removal and disposal of expired drugs from the ASC. Due to the recent transition of new staff at the ASC, the policies were not followed which allowed the failure of the policy. The administrator of the ASC on 07/25/2016 was trained in the policy of removal of expired drugs in compliance with the ASC. The monthly QAPI reports also reflect documenting and monitoring of medication and narcotics for expiration and compliance to ASC policy. This policy will be maintained by the ASC administrator and overseen by the governing body in the monthly QAPI meeting. The topic of expired medications was also discussed in an ASC staff meeting on 09/01/2016 as documented.

Q219 - Refer to Q229, Q232.

Q229 - ASC failed to ensure patients were provided with accurate, comprehensive information prior to their scheduled appointments.

- A) ASC failed to ensure patients full “Informed Consent” was signed and dated prior to the patient receiving services at the ASC.
- B) In the ASC informed consent, it states the consent to use blood and blood product/components or derivatives as deemed necessary as well as the associated risks.

Result 9 – Most patients of the ASC are seen in the office by the physician prior to the day of the scheduled procedure. On that visit, with the patient, the physician obtains an “Informed Consent” for the procedure that was discussed, and documents it in the H+P, as well as the informed consent form. On few occasions, the physician will not meet with the patient until the day of their procedure. At that point, prior to the procedure or medications being given, the physician will obtain an “Informed Consent” on the day of the scheduled procedure, and documents it in the H+P as well as the informed consent form. To clarify that the consent was obtained prior to the procedure when the patient is seen by the physician for the first time that day and it is obtained the day of the procedure, or when the office obtained consent form did not make it to the facility, a time will be added next to the date. This document will be updated and staff will be trained on it by 09/01/2016.

The ASCs informed consent has information that reads as the following; “I consent to the use of blood and blood products/components/derivatives as deemed necessary. Risks and hazards associated with the administration of blood components may include.....”. The ASCs legal counsel was consulted and the following was advised; *...“regarding the consent for treatment form and having the information included for blood transfusions. (Legal) felt since this is a risk the patient could encounter during the surgery and they may need to be transferred, it is definitely appropriate to include this information in the consent form. You should request the reviewers to provide the regulation that doesn’t allow the blood transfusion statement to be included in the consent form. Whether or not you do the blood transfusions or transfer the patient, this is a risk the patient could encounter during the procedure you plan to perform”*. So with that being advised to the ASC, we are electing to NOT change or modify our informed consent. Currently 100% of patients charts that are receiving procedures in the ASC are being reviewed for competency has been done and will continue to be done until the point that the ASC reaches 95% accuracy for three consecutive weeks, at which point it will drop to 50% of patient charts to ensure we maintain compliance, after an additional three weeks of compliance, chart reviews will be done on a “spot check” bases. This monitoring and training will be overseen by the Jared Silvis, ASC administrator and the Governing Body of the ASC, and the results will be submitted to the governing body for review at the monthly QAPI meetings.

Q232 - ASC failed to ensure patients received care in a safe setting.

- A) The ACS’s CRNA’s were not consistently aware of their responsibilities as a result, the lack of direction and delineation of nursing services.

Result 10 - On July 25th, 2016 we held a six-hour training for the staff at Healing Arts Day Surgery Center. ASC staff was in attendance and participated in the training. Topics of this training included but were not limited to responsibilities, criteria and delineation of nursing services as it pertains to our recovery room technicians as well as our CRNAs’. Some of the ASCs

CRNAs were not able to attend this meeting, but by 9/01/16, the duties and responsibilities including nursing services and responsibilities will be trained on and documented. With the exception on one CRNA who is out of state, his will be completed prior to his next scheduled shift at the ASC. This will be done and documented under the direction of Jared Silvis, ASC administrator and overseen by Dr. Croitoru. This will be monitored by “second tier” review of new employee files to include by not limited to training and competency documentation by the governing body of the ASC and reported to the governing body through the ASCs monthly QAPI meetings.

Q240 - Refer to Q241, Q242.

Q241 - ASC failed to ensure a sanitary and functional environment for patients receiving care.

A) ASC failed to provide adequate personnel records for the documentation of training and education in infection control. The lack of education and training related to infection control practices, standards and ASC policies directly impacted the care of patients.

- Lack of hand hygiene performed by ASC staff
- Lack of documented training of the reprocessing technician for endoscopes
- Failure to follow ASCs’ policy “Cleaning Laundry” as it pertains to staff PPE and cleaning of the washers.

Result 12 – The ASC held training for its entire new staff on 07/25/2016 as well as 09/01/2016, which included the ASCs policies for infection control as well as hand hygiene and standards of care when it comes to patient area. We reviewed, and trained on the policies that the ASC currently have in place, and included additional training information via video format from the CDC on related topics of hand hygiene, needle sticks, proper PPE and blood borne pathogens. This training was documented. Validation of continued compliance will be monitored with internal audits to ensure proper policies and procedures are being followed. This continual monitoring and training will be overseen by the administrator, Jared Silvis and the Governing Body of the ASC.

The ASC has been in contact with the endoscope manufacture to ensure that reprocessing is completed to manufactures recommendations as well that the reprocessing is done under ASGE guidelines. On 09/01/2016, we are ensuring our reprocessing technician(s) is/are competent and documented those procedures as well as continuing monitoring and documentation under the supervision of the physician. This continual monitoring and training will be overseen by the Administrator and the Governing Body of the ASC.

The ASC policy titled, "Cleaning Laundry" had been reviewed and modified as of 09/01/2016. We have implemented and trained on 09/01/2016 a new check list that includes documenting and monitoring of specific loads of laundry as well as the cleaning of the machines for disinfecting as well as infection control. We have validated and verified that the water temperature is at a minimum standard of 140 degree Fahrenheit and will be monitored and validated on a quarterly basis. This continual monitoring and training will be overseen by the Administrator and the Governing Body of the ASC, and reported through the monthly QAPI meetings.

Q242 - ASC failed to ensure that an explicit, ongoing infection control program was developed, implemented and monitored.

- A) ASC failed to provide documented direction and training to staff necessary to ensure patients' risk of infection and communicable diseases was minimized.

Result 13 –Refer to Q241.

Q260 - ASC failed to ensure each patient had the appropriate post-surgical assessments completed and were discharged by a physician.

Result 14 –Refer to Q264, Q266.

Q264 - ASC failed to ensure patients' post-surgical conditions were assessed and documented in the medical record.

Result 15 – The ASC "Procedure Flow Sheet 2016" has been modified on 07/25/2016, to ensure an accurate representation of the patients' pre and post procedure conditions are documented for the patients' medical record. Specifically, in reference to the patients post procedure, additional areas have been added to appropriately record patients post procedural vital signs, pain assessment and additional area for narrative dictation from staff. The "Procedure Flow Sheet 2016", has been modified and trained to the current ASC staff on 07/25/2016 as well as 09/01/2016, for competency and compliance. Currently 100% of patients charts that are receiving procedures in the ASC are being reviewed for competency has been done and will continue to be done until the point that the ASC reaches 95% accuracy for three consecutive weeks, at which point in will drop to 50% of patient charts to ensure we maintain compliance, after an addition three weeks of compliance, chart reviews will be done on a "spot check" bases. This monitoring and training will be overseen by the Jared Silvis, ASC administrator and the Governing Body of the ASC, and the results will be submitted to the governing body for review at the monthly QAPI meetings.

Q266 - ASC failed to ensure patients were discharged with a valid order from the physician who performed their procedures.

Result 16 – The ASC “Procedure Flow Sheet 2016” has been modified on 07/25/2016, to ensure an accurate representation of the patients’ pre and post procedure conditions are documented for the patients’ medical record. Specifically, in reference to the patients discharge order, additional areas have been added to appropriately record the actual time the physician or CRNA discharged the patient from the care of the physician and/or CRNA. The “Procedure Flow Sheet 2016”, has been modified and trained to the current ASC staff on 07/25/2016 as well as 09/01/2016, for compliance and competency. Currently 100% of patients charts that are receiving procedures in the ASC are being reviewed for competency has been done and will continue to be done until the point that the ASC reaches 95% accuracy for three consecutive weeks, at which point it will drop to 50% of patient charts to ensure we maintain compliance, after an additional three weeks of compliance, chart reviews will be done on a “spot check” bases. This monitoring and training will be overseen by the Jared Silvis, ASC administrator and the Governing Body of the ASC, and the results will be submitted to the governing body for review at the monthly QAPI meetings.



IDAHO DEPARTMENT OF
HEALTH & WELFARE

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September 14, 2016

Jared Silvis, Administrator
Healing Arts Day Surgery
222 West Iowa Avenue, Suite B
Nampa, ID 83686

Provider #13C0001023

Dear Mr. Silvis:

An unannounced on-site complaint investigation was conducted from July 18, 2016 to July 28, 2016 at Healing Arts Day Surgery. The complaint allegations, findings and conclusions are as follows:

Complaint #ID00007300

Allegation #1: The Ambulatory Surgical Center (ASC) did not keep personnel files for employees and did not orient or train employees responsible for reprocessing the endoscopes.

Findings #1: An unannounced survey visit was conducted at the ASC from 7/18/16 to 7/28/16. During the survey 19 patient records were reviewed, 2 procedures were observed, patients and staff were interviewed, policies and procedures were reviewed, and administrative documents were reviewed.

The ASC's personnel included an Administrator, 3 CRNAs, a Recovery Room Technician, and 2 Reprocessing Technicians, who reprocessed the endoscopes and assisted the physician during procedures.

Personnel records for the ASC staff were reviewed. The Administrator, CRNAs, and Recovery Room Technician's personnel records did not include documentation of orientation, training, competencies, or education and instruction regarding their responsibilities.

Additionally, on 7/20/16 at 11:30 AM, the Administrator stated he did not have personnel files for the 2 Reprocessing Technicians working at the ASC.

A Reprocessing Technician was interviewed on 7/20/16 at 9:10 AM regarding her orientation and training for the ASC, and the steps she performed when reprocessing endoscopes. She stated she did not have formal training when she started work at the ASC on 3/17/16. The Reprocessing Technician stated she had worked for the same Medical Director, and at the same ASC, six years ago. She stated she watched 2 procedures and the reprocessing steps by another Technician when she first started. She stated she then watched videos from the endoscope manufacturer on her own to "refresh my memory."

An observation of a colonoscopy was conducted on 7/21/16 beginning at 9:50 AM. The Reprocessing Technician did not demonstrate the competencies necessary to complete reprocessing in accordance with accepted standards of practice.

The Medical Director was interviewed on 7/28/16 at 2:10 PM. During the interview, the Medical Director was asked about staff training and monitoring for reprocessing endoscopes. The Medical Director stated Reprocessing Technician A had worked for her previously doing reprocessing. She stated she had observed Reprocessing Technician A during reprocessing to ensure she was following national guidelines, but stated she did not document observations.

The ASC failed to keep personnel files for employees and failed to maintain documentation of orientation and training for employees responsible for reprocessing the endoscopes. Therefore, the allegation was substantiated and deficient practice was identified at Code of Federal Regulations (CFR) 42 CFR 416.41 for its failure to ensure the Governing Body provided oversight and supervision necessary to ensure all patients of the ASC received safe and appropriate care. Deficient practice was also identified at 42 CFR 416.51, 416.51(a) and 416.51(b), for its failure to ensure patients were provided with a functional and sanitary environment in accordance with acceptable standards of practice, and that an ongoing infection control program was developed, implemented and monitored to ensure the health and safety of all patients.

Conclusion #1: Substantiated. Federal deficiencies related to the allegation are cited.

Allegation #2: Sterilization equipment does not function properly and is not maintained by qualified personnel. Further, the ASC does not have a plan or method of notifying patients when they are exposed to infectious agents.

Findings #2: During an unannounced survey observations were conducted, infection control policies, procedures, and administrative documents were reviewed and staff were interviewed. The facility's infection control policies were reviewed.

The policy "Infection Control Plan," dated 1/23/16, stated the purpose of the plan was to "Identify and reduce the risks of acquiring and transmitting infections among patients, staff and visitors including unprotected exposure to pathogens throughout the organization, enhancing hand hygiene, and minimizing the risk of transmitting infections associated with procedures, medical equipment and medical devices."

A separate "Rules and Regulations," policy, dated 1/09/16, stated "Each member of the Staff shall also be responsible for informing (the facility), per our infection control policy, of any infection that could be associated with a patient's procedure performed at our facility." The policy stated "Patients identified as having infections, or communicable diseases that may require isolation, will be isolated and transferred (as applicable) or referred to the hospital for care."

The Medical Director was interviewed on 7/19/16 at 4:00 PM, regarding monitoring and tracking of possible patient infections after procedures. She stated the majority of patients who had procedures performed at the facility were seen and evaluated in her office after their procedure. The Medical Director stated she had not had any patient infections documented after a procedure in the last 5 years. The Medical Director stated, in the case of reportable diseases, she would contact the local health department and follow their guidelines if she believed a patient had been exposed or possibly infected.

A Reprocessing Technician was interviewed on 7/20/16 at 9:10 AM. She stated she was responsible for not only reprocessing, but also setting up the procedure room and assisting during procedures. The Reprocessing Technician took the surveyors on a tour of the procedure room and reprocessing area. The Reprocessing Technician stated the facility had 2 DSDs (automated endoscope reprocessors) but one was not used. The Reprocessing Technician showed the surveyors where the DSD, which was not used, was stored in a separate area. The DSD, which was in the reprocessing area, had dual basins for disinfection of 2 endoscopes at a time. The Reprocessing Technician stated after each procedure the endoscope was reprocessed and she currently used only the right side of the DSD machine.

The Reprocessing Technician was asked how endoscopes were tracked for the purpose of infection control. She stated there was a log for endoscope use, which documented the serial number for the endoscope used, and the medical record number of the patient the endoscope was used on. The Reprocessing Technician stated after manual cleaning and rinsing, she placed the endoscope in the machine, with the removable parts, for high level disinfection. She stated she closed the machine lid and entered the serial number for the endoscope on the keypad. The Reprocessing Technician stated the automated machine required the serial number for the endoscope to be entered on the keypad prior to starting the machine and at the end of the day she would print out a report from the automated machine and kept the reports in a log.

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The Reprocessing Technician also stated that prior to starting the DSD, she checked the level of disinfectant in the machine and tested its efficacy. She stated this was documented in a log prior to each load. The Reprocessing Technician stated the disinfectant in the DSD was also changed once a month, per the manufacturer's instructions.

The logs for the automatic reprocessing machine and the endoscopes were reviewed. There were no discrepancies noted on either log.

When asked about maintenance and if DSD had any problems or repairs since she began working at the facility, the Reprocessing Technician stated there had been no problems or repairs since she began working at the facility in March of 2016.

Further, Governing Body meeting minutes, dated 1/15/16, documented the facility maintained a contract with an outside agency for biomedical and electrical equipment maintenance and repair. On 7/19/16 at 3:40 PM, the Medical Director and Administrator were interviewed regarding the Governing Body meeting minutes. The Medical Director stated the agency would come out semi-annually to check equipment for any needed repairs, calibration, and to ensure proper functioning.

It could not be determined that sterilization equipment did not function properly or that it was not maintained by qualified personnel. Further, it could not be determined that the facility did not have a plan or method of notifying patients after potential exposure to infectious agents. Therefore, due to a lack of sufficient evidence, the allegation was unsubstantiated.

Conclusion #2: Unsubstantiated. Lack of sufficient evidence.

Based on the findings of the complaint investigation, deficiencies were cited and included on the survey report. No response is necessary to this complaint report, as it will be addressed in the Plan of Correction.

Thank you for the courtesies extended to us during the survey. If you have any questions, comments or concerns, please contact Dennis Kelly, RN or Nicole Wisenor, Co-Supervisors, Non-Long Term Care at (208) 334-6626, option 4.

Sincerely,



NICOLE WISENOR, Supervisor
Non-Long Term Care

NW/pmt