IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RUSSELL S. BARRON– Director

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January 22, 2018

Steven Farro, Administrator
Idaho Endoscopy Center
6259 West Emerald Street
Boise, ID 83704

RE: Idaho Endoscopy Center, Provider #13C0001010

Dear Mr. Farro:

Based on the survey completed at Idaho Endoscopy Center, on January 11, 2018, by our staff, we have determined Idaho Endoscopy Center is out of compliance with the Medicare ASC Condition for Coverage of **Medical Records (42 CFR 416.47)**. To participate as a provider of services in the Medicare Program, an ASC must meet all of the Conditions for Coverage established by the Secretary of Health and Human Services.

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

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

An acceptable Plan of Correction contains the following elements:

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

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

Such corrections must be achieved and compliance verified by this office, before February 25, 2018. 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 February 15, 2018.

Please complete your Allegation of Compliance/Plans of Correction and submit to this office by **February 5, 2018**.

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,

NICOLE WISENOR, Supervisor
Non-Long Term Care

NW/pmt
Enclosures

ec: Debra Ransom, R.N., R.H.I.T., Bureau Chief
Patrick Thrift, Survey & Certification Manager Region X
Julius Bunch, Certification & Enforcement Manager Region X

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	13C0001010	A. BUILDING _____ B. WING _____	01/11/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
IDAHO ENDOSCOPY CENTER	6259 WEST EMERALD STREET BOISE, ID 83704

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 000	INITIAL COMMENTS The following deficiencies were cited during the Medicare recertification survey of your surgery center conducted from 1/08/18 to 1/11/18. Surveyors conducting the recertification were: Laura Thompson, RN, BSN, HFS - Team Leader Teresa Hamblin, RN, MS, HFS Acronyms used in this report include: AER - Automated Endoscope Reprocessor DC and D/C - Discontinue DON - Director of Nursing EGD - Esophagogastroduodenoscopy (a diagnostic procedure that visualizes the upper gastrointestinal tract) EHR - Electronic Health Record FDA - U.S. Food and Drug Administration H&P - History and Physical Examination HIM - Health Information Management HLD - High-level Disinfection IV - Intravenous LOC - Level of Consciousness MA - Medical Assistant MD - Medical Doctor QI - Quality Improvement RN - Registered Nurse	Q 000	*Please reference attached spreadsheet titled "Plan of Correction Detail" outlining the specific elements for the plan of correction. RECEIVED FEB - 6 2018 FACILITY STANDARDS	
Q 002	DEFINITIONS CFR(s): 416.2 As used in this part: Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must	Q 002	Continue to page 2	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: Medical Director | (X6) DATE: 2/5/18

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

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Q 002	Continued From page 1 have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part.The ambulatory surgical center must comply with state licensure requirements. This STANDARD is not met as evidenced by: Based on record review, review of administrative records and staff interview, it was determined the ASC failed to remain a distinct and separate entity from a clinic which was associated with 8 of 8 physicians (A-H). This resulted in shared administrative documentation and programs which caused difficulty in identifying the ASC's activities from the clinic's activities. Findings include: 1. An organizational chart for the ASC was requested during the entrance conference at 8:25 AM on 1/08/18. The Administrator for the ASC presented the organizational chart at 9:15 AM, the same day. The organizational chart had the name of the clinic at the top and included administrative lines of authority for the clinic and the ASC. It was not clear on the chart who had oversight and responsibility of the ASC. During an interview at 10:10 AM on 1/08/18, the Administrator reviewed the organizational chart and acknowledged the name of the ASC was not referenced. He stated the organizational chart represented both the ASC and the clinic associated with the ASC. The Administrator stated the clinic owned the ASC and that was why their name appeared at the top of the chart. The Administrator stated it was difficult to show the areas of the organizational chart which were exclusive to the ASC because many administrative staff oversaw both the clinic and	Q 002	Q 002 1. Company organizational chart updated to indicate distinct separation between ASC and clinic. Every 3 years the organizational chart will be reviewed to ensure ASC and clinic staff roles are delineated appropriately (refer to attached ASC organizational chart to be approved at 02/06/2018 Board meeting). continued on page 3	02/15/2018

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Q 002	Continued From page 2 the ASC. 2. A binder of occurrence reports, grievances, and complaints was reviewed. The information in the binder included occurrence reports, grievances, and complaints mixed together for the ASC and the clinic. This was confirmed during an interview with the DON on 1/08/18 at 3:00 PM. 3. A binder of QAPI information was reviewed. It included data related to the ASC and the clinic. The Director of HIM and QI was interviewed on 1/10/18 at 1:39 PM. She stated they did not separate quality information related to the ASC from the clinic. Administrative documents failed to identify the ASC as a distinct entity from the adjacent clinic.	Q 002	2. Occurrence reports, grievances and complaints are separated into "ASC", "clinic", and "other" sections. 3. QAPI information is separated into ASC and clinic designations. 4. Format of administrative documents updated to reflect the ASC as a distinct entity.	02/15/2018
Q 160	MEDICAL RECORDS CFR(s): 416.47 The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. This CONDITION is not met as evidenced by: Based on record review, policy review, observation, staff interview, patient interview, and physician interview, it was determined the ASC failed to ensure medical records systems allowed for individualization of consent language in procedural reports, failed to ensure a system to time stamp when the physician's physical examination was entered into the medical record, and failed to ensure complete and accurate documentation. These failures resulted in patient records that did not accurately or completely reflect the course of patient care. Findings	Q 160	Continue to page 4	

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Q 160	Continued From page 3 include: 1. Refer to Q 161 as it relates to the failure of the ASC to ensure systems were in place to develop a unique medical record as it relates to documentation of timing of pre-procedural examinations and the failure of the ASC to ensure a system was in place to individualize pre-populated consent language to accurately reflect the consent process. 2. Refer to Q 162 as it relates to the failure of the facility to ensure complete or accurate documentation.	Q 160	Q 160 1. Refer to Q 161 correction plan below. Q 160 2. Refer to Q 162 correction plan below.	
Q 161	ORGANIZATION CFR(s): 416.47(a) The ASC must develop and maintain a system for the proper collection, storage, and use of patient records. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined the ASC failed to ensure systems were in place to develop a unique medical record as it related to documentation of timing of pre-procedural examinations reviewed and that a system was in place to individualize pre-populated consent language to accurately reflect the consent process for 20 of 20 patients (#1-#20) whose records were reviewed. This resulted in documentation that did not accurately reflect the timing of care and consent process. Findings include: 1. The ASC did not have an established system to identify the time the pre-procedural physical	Q 161	Q 161 1 1. A "Pre-procedure History & Physical" form was created to supplement documentation as to when the physical examination was conducted. The form will follow the patient throughout the procedure process and then scanned into the medical record with the consent form to become a permanent record of the procedure. Assessment policy was updated to reflect changes and will be approved at 02/06/2018 Board meeting. (Refer to "Pre-procedure History & Physical" form and Assessment policy.) continued on page 5	02/15/2018

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Q 161	Continued From page 4 examination, as part of the H&P, was entered into the medical record. Patient #1-#20's records were reviewed. They did not include a time as to when the physical examination was entered into the medical records. The DON was interviewed on 1/09/18 at 11:00 AM. She confirmed the medical records did not include a documented time stamp of when the history was reviewed or physical examination was entered into the medical record. The medical record system did not allow for entering a time when the physical examination portion of the H&P was entered into medical records. 2. The ASC did not have an established system to ensure individualization of informed consent information entered by the physician in the Procedural report. Procedural reports in Patient #1-#20's records contained standardized language regarding informed consent. They stated "Consent: Benefits, risks, and alternatives explained, and the patient wished to proceed. Risks include but are not limited to bleeding, perforation, infection, missed lesions, medication/sedation reactions, cardiac and pulmonary complications, and death." Physician B was interviewed on 1/10/18 at 4:10 PM. He confirmed the consent language in the procedural report was standardized, even if the patient was not interested in hearing about the risks of the procedure. The current system did not allow physicians to individualize the information.	Q 161	Q 161 2 a. The "Pre-procedure History & Physical" form (noted in response 1 above) includes an area for the physician to improve documentation of the consent process. b. The electronic medical record template will be updated to allow the physician to select the appropriate consent language that will appear on the procedure report. c. Language on consent form will be modified to include declination of the opportunity to have the form read to the patient. Also, area added for witness to document observation of patient's informed decision. (Refer to "Detailed Consent for Medical/Surgical Procedures" form.)	02/15/2018

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Q 161	Continued From page 5 The medical record system did not allow for individualization of the consent process for physicians in the procedural report.	Q 161		
Q 162	FORM AND CONTENT OF RECORD CFR(s): 416.47(b) 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 record review, observation, policy review, patient interview, and staff interview, it was determined the facility failed to ensure complete or accurate documentation in 20 of 20 patients (#1-#20) whose records were reviewed. This resulted in a lack of clarity as to the actual course of patient consent, examination, and care. Findings include: 1. The ASC policy, "CHARTS/MEDICAL	Q 162	Continue to page 7	

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Q 162	Continued From page 6 RECORDS," dated 9/08/15, stated: - "Complete, comprehensive and accurate medical records will be maintained for all patients." - "Records must include ...documentation of properly executed informed patient consent." This ASC policy was not implemented, as follows: Procedural reports contained standardized language regarding consent for Patients #1-#20's records. All of the reports stated "Consent: Benefits, risks, and alternatives explained, and the patient wished to proceed. Risks include but are not limited to bleeding, perforation, infection, missed lesions, medication/sedation reactions, cardiac and pulmonary complications, and death." The information did not accurately reflect each individual patient's consent process or lack thereof, as follows: a. Patient #16 was a 66 year old female scheduled for a screening colonoscopy on 1/09/18. She was accompanied by surveyors from the time of arrival in the facility on 1/09/18 at 8:30 AM until discharge at 10:35 AM. Upon arrival at the facility, at the front desk, the Receptionist was observed to provide Patient #16 with the procedural consent form referenced above. In signing the form, she attested that her physician explained the risks and benefits of the procedure, before talking to a physician. She signed the form and the Receptionist stated she would witness the form. Patient #16 was interviewed at approximately	Q 162	Q 162 1 a 1. Consent form will be given to the patient in the ASC prior to procedure to have the opportunity to read. Physician will provide verbal benefits, risks, and alternatives as well as the opportunity to ask questions to the extent of the patient's comfort level. The patient will then sign the consent form, the physician will sign and ASC staff will witness. 2. Physicians will be re-educated on regulation, Company policy and procedure at 02/06/2018 Board meeting. 3. A "Pre-procedure History & Physical" form has been created which includes an area for the physician to improve documentation of the consent process. In addition, the electronic medical record template will be updated to allow the physician to select the appropriate consent language that will appear on the procedure report.	02/15/2018

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Q 162	Continued From page 7 8:40 AM, after signing the consent and prior to being taken back to the pre-operative area. When asked if a physician had explained the procedure prior to the visit, she stated "No," her primary care doctor just told her she should have a screening colonoscopy. Prior to the procedure at 9:15 AM, Physician C was observed to visit Patient #16 in the pre-operative area. During the visit, Physician C examined Patient #16, asked questions regarding her health history, and educated Patient #16 on the purpose of the procedure. The physician was not observed to explain the risks of the procedure or to ask Patient #16 if she had any questions. The procedure report, "Colonoscopy," dated 1/09/18, stated: "Consent: Benefits, risks, and alternatives explained, and the patient wished to proceed. Risks include but are not limited to bleeding, perforation, infection, missed lesions, medication/sedation reactions, cardiac and pulmonary complications, and death." Physician C was interviewed on 1/10/18 at 5:00 PM. He confirmed he did not explain the risks of the procedure to Patient #16 or give her an opportunity to ask questions. He stated that informed consent was not usually done by the physician, rather by a "MA or Nurse" prior to the procedure but that he usually did give the patient an opportunity to ask questions prior to the procedure. Physician B was interviewed on 1/10/18 at 4:10 PM. He confirmed the consent language in the procedure report was standardized, even if the patient was not interested in hearing about the risks of the procedure.	Q 162	continue to page 9	

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Q 162	Continued From page 8 Standardized consent language included in procedural reports of patient records did not accurately reflect an individualized consent process. b. Patient #17 was a 64 year old blind male who had an EGD on 1/09/18. He was accompanied by a surveyor from the time of arrival at the facility on 1/09/18 at 2:35 PM until discharge at approximately 4:45 PM. At the reception desk at the time of arrival, Patient #17 was asked by the Receptionist to sign his procedural consent. He was blind and could not read the consent. The Receptionist asked him if he wanted to have his spouse read the consent form to him. He declined the offer and signed the consent without knowing what the consent said. There was no documentation on the consent or in Patient #17's medical record that explained Patient #17 declined an opportunity to have the consent read to him and that he elected to sign the consent without knowing what information was included. The DON was interviewed on 1/10/18 at 8:30 AM. She confirmed incomplete documentation for Patient #17's consent process. Documentation of Patient #17's consent process was incomplete. 2. Intra-operative nursing documentation for Patients #1-#20 included standardized language "Physician reviewed patient's H/P at: [relevant time added]." This language did not accurately reflect the course of events as physicians did not review the physical examination. Rather,	Q 162	Q 162 1 b 1. Language on consent form modified to include declination of the opportunity to have the form read to the patient. Also, area added for witness to document observation of patient's informed decision. continued on page 10	02/15/2018

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Q 162	Continued From page 9 physicians conducted the physical examination portion of the H&P prior to the procedure. a. Patients #1-#20's records did not include a date and time which indicated the physical examination was completed and in the patient record prior to their scheduled procedure. The DON was interviewed on 1/09/18 at 11:00 AM and she confirmed the medical records did not include a documented date and time indicating when the history was reviewed and the physical examination was entered into the record. b. Physician A was interviewed on 1/10/18 at 3:30 PM. He stated "The grammar is not ideal. It should say I reviewed the history and entered the physical examination." Physician C was interviewed on 1/10/18 at 5:00 PM. He stated "It is semantics. I review the history and perform the physical exam." The standardized language related to the H&P review did not accurately and clearly reflect the course of care. 3. Discharge nursing documentation for Patients #1-#20 included standardized language "Discharge orders given to nursing staff at [time inserted]." The standardized language lacked clarity as to what discharge orders were given, whether to remove IV, or give a particular medication, or discharge to home with a responsible adult, etc. There were no documented and authenticated physician discharge orders included in Patient #1-#20's records which corresponded to the	Q 162	Q 162 2 a&b 1 A "Pre-procedure History & Physical" form has been created which includes an area for the physician to improve documentation of language, date, and time that the history was reviewed and the physical exam completed prior to the start of procedure. This form will supplement the electronic physician entry and will be scanned into the medical record following the procedure. Assessment policy was updated to reflect changes and will be approved at 02/06/2018 Board meeting (refer to assessment policy). Q 162 3 Nursing discharge documentation will be modified to state "Discharge criteria met [Time]" to reflect current policy language. Language updated to reflect existing protocol (refer to discharge policy and standing orders for discharging patients). continued on page 11	02/15/2018 02/15/2018

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Q 162	Continued From page 10 nursing documentation indicating discharge orders had been received at specific times. During an interview on 1/10/18 at 8:30 AM, the DON confirmed discharge orders lacked clarity. She stated "They should say D/C IV and may discharge patient." She also confirmed the discharge orders referenced in the nursing notes were not separately documented by physicians or authenticated. 4. Patient #1-#20's records included a pre-printed form, signed by patients upon admission to the facility. The form included a checkbox next to the words "I have received or have been offered a copy of the patient's rights and responsibilities statement." Patients or their representatives signed acknowledgment on the bottom of the form. Patient #16 was interviewed on 1/09/18 at approximately 8:40 AM, after checking in at the registration desk. She stated she received written copy of her rights in the mail prior to the appointment. Patient #17 was interviewed on 1/09/18 at approximately 2:45 PM, after checking in at the registration desk. He stated he did receive a written copy of his rights in the mail prior to the appointment. There was a lack of clarity in medical records as to whether each patient was provided written notice of patient rights or was offered rights and refused. 5. Refer to Q 184 as it relates to the failure of the ASC to ensure verbal orders for medications	Q 162	Q 162 4 Every patient for each encounter will be given the "Patient Rights and Responsibilities" form or obtain a copy from our website. Reception staff were trained on 01/30/2018 on how to verbally provide patients with notice of rights and responsibilities (refer to 01/30/2018 reception meeting minutes). "Patient Rights and Responsibilities" form has been modified to include an area for reception staff to document that patients' rights were provided in verbal format. Patient Rights and Responsibilities policy update to reflect that patients will be informed of their rights and responsibilities in verbal and written form. If patient declines to sign acknowledgment of rights and responsibilities, this will be documented on form and scanned into patient's medical record (refer to "Patient Rights and Responsibilities" form and policy to be approved at 02/06/2018 Board meeting). Q 162 5 Procedure documents containing verbal orders will be generated to rendering physician's provider approval queue for authentication. Medications policy updated and will be approved at 02/06/2018 Board meeting (refer to Medications policy).	02/15/2018 02/15/2018

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Q 162	Continued From page 11 were signed by the physician.	Q 162	refer to page 11	
Q 184	VERBAL ORDERS CFR(s): 416.48(a)(3) Orders given orally for drugs and biologicals must be followed by a written order signed by the prescribing physician. This STANDARD is not met as evidenced by: Based on record review, policy review, staff interview, and physician interview, it was determined the ASC failed to ensure verbal orders were signed by the physician for 20 of 20 patients (#1-#20) who had verbal orders and whose records were reviewed. This failure resulted in patients receiving medications and treatments without authenticated orders. Findings include: An ASC policy "Medications," revised 8/04/15, stated "III. Ordering Medications A. Verbal orders may be given to the clinical staff, who will record the order in the medical record, to be subsequently documented or co-signed by the provider." This policy was not implemented, as follows: Patient medical records included a section "Intra-Op Medications Given." This section included areas for documentation of the medication, time given, amount, LOC, and name of the staff who administered the medication. The records for Patients #1-#20 included documentation verbal orders were received for medications during their procedures from the physician performing the procedure. However,	Q 184	Q 184 ASC staff received training regarding upcoming medications policy update 1/30/2018. Procedure documents containing verbal orders will be generated to rendering physician's provider approval queue for authentication. Medications policy updated regarding physician sign off. Physicians will be educated regarding medications policy changes on 02/06/2018. (Refer to 01/30/2018 ASC meeting minutes and updated medications policy to be approved at 02/06/2018 Board meeting.)	02/15/2018

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Q 184	Continued From page 12 the medical records did not include physician signatures which authenticated the verbal orders. During an interview beginning at 11:01 AM on 1/09/18, the DON confirmed the medical records did not include physician signatures for the verbal orders received during procedures. During an interview beginning at 3:35 PM on 1/10/18, Physician A confirmed he was not authenticating his verbal orders in the patient's records. During an interview beginning at 4:30 PM on 1/10/18, Physician B confirmed there was not an area for the physician to authenticate, or co-sign, his verbal orders. Verbal orders for medications were not signed or authenticated by physicians.	Q 184	refer to page 12	
Q 221	NOTICE OF RIGHTS CFR(s): 416.50(a) An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman. This STANDARD is not met as evidenced by: Based on observation and staff interview the facility failed to ensure each patient or	Q 221	Q221 Reception staff trained 01/30/2018 to verbally communicate rights and responsibilities to all patients (refer to 01/30/2018 reception meeting minutes).	02/15/2018

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Q 221	Continued From page 13 representative was provided verbal notice of patient's rights for 2 of 2 patients (#16 and #17) whose care was observed. This had the potential to interfere with patient understanding of their rights and the exercise of patient rights. Findings include: 1. Verbal notice of rights was not provided to patients whose care was observed, as follows: a. Patient #16 was a 66 year old female scheduled for a screening colonoscopy on 1/09/18. She was accompanied by surveyors from the time of arrival in the facility on 1/09/18 at 8:30 AM until discharge at 10:35 AM. She was not observed to be verbally informed of her rights by front desk staff or clinical staff. b. Patient #17 was a 64 year old blind male who had an EGD on 1/09/18. He was accompanied by a surveyor from the time of arrival at the facility on 1/09/18 at 2:35 PM until discharge at approximately 4:45 PM. He was not observed to be verbally informed of his rights by front desk staff or clinical staff. The DON was interviewed on 1/11/18 at 10:00 AM. She confirmed there was not a process in place to verbally explain rights to patients. Verbal notice of rights was not provided to patients.	Q 221	refer to page 13	
Q 224	ADVANCED DIRECTIVES CFR(s): 416.50(c)(1)(2)(3) The ASC must comply with the following requirements:	Q 224	continue to page 15	

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Q 224	Continued From page 14 (1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms. (2) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care. (3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive. This STANDARD is not met as evidenced by: Based on record review, observation, staff interview, and patient interview, it was determined the facility failed to ask and document whether patients had advance directives for 20 of 20 patients (#1-#20) whose records were reviewed. This had the potential to interfere with coordination of patient care in the event a patient had to be transferred to an inpatient facility. Findings include: 1. There was not a process in place to ask patients whether they had executed an advance directive and to have the advance directive placed in their medical records. Examples include: a. Patient #16 was a 66 year old female scheduled for a screening colonoscopy on 1/09/18. She was accompanied by surveyors from the time of arrival in the ASC on 1/09/18 at 8:30 AM until discharge at 10:35 AM. She was not observed to be asked by front desk staff or clinical staff whether she had an advance	Q 224	Q 244 1 Patient rights and responsibilities policy "Advance directive" portion updated to reflect changes. Policy to be approved at 02/06/2018 Board meeting (refer to patient rights and responsibilities policy). 2&3 ASC staff received training regarding aforementioned policy update and documentation on 1/30/2018. Advance directive questions will be asked to all patients prior to procedure and documented in a prominent part of patient's medical record (refer to 01/30/2018 ASC staff meeting minutes).	02/15/2018

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Q 224	Continued From page 15 directive. The Receptionist was interviewed on 1/09/18 at 9:25 AM. When asked if it was her responsibility to ask patients if they had an advance directive, she replied "No, they do that in the clinic." During an interview on 1/09/18 at 10:23 AM, Patient #16 was asked if someone from the ASC asked her if she had an advance directive, she replied, "No." b. Patient #17 was a 64 year old blind male who had an EGD on 1/09/18. He was accompanied by a surveyor from the time of arrival at the ASC on 1/09/18 at 2:35 PM until discharge at approximately 4:45 PM. He was not observed to be asked by front desk staff or clinical staff whether he had an advance directive. During an interview on 1/09/18 after signing forms and before pre-operative assessment, Patient #17 was asked if someone from the facility asked him if he had an advance directive, he replied, "No, but it does not matter because I don't have one." Patients were not asked if they had an advance directive and the information was not entered in medical records. 2. The medical records for Patients #1-#20 did not include documentation as to whether they had executed an advance directive. A pre-printed form, signed by patients upon admission to the ASC, had a checkbox next to information regarding advance directives.	Q 224	refer to page 15	

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Q 224	Continued From page 16 A second form "Advance Directive Patient Information" was included in the registration information. It explained the meaning of an advance directive and how patients could obtain forms to execute an advance directive. Neither form included a space to enter whether the patient had executed an advance directive. The DON was interviewed on 1/09/18 at 11:00 AM. When asked if it was part of the ASC's process to ask patients if they had an advance directive and to place any advance directive in the medical record, she explained it was not a part of their process since it was their policy to always resuscitate patients regardless of any advance directive. She stated that was done "on the clinic side" and those electronic medical records could be accessed by the facility. She confirmed not all patients seen for procedures came from the clinic. The facility failed to document in the medical records whether patients had executed an advance directive.	Q 224	refer to page 15	
Q 225	SUBMISSION AND INVESTIGATION OF GRIEVANCES CFR(s): 416.50(d)(4),(5), & (6) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met: (1) The grievance process must specify timeframes for review of the grievance and the provisions of a response.	Q 225	continue to page 18	

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Q 225	Continued From page 17 (2) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished. (3) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed. This STANDARD is not met as evidenced by: Based on policy review, grievance documentation, and staff interview, it was determined the ASC failed to ensure written notice was provided in response to grievances for 3 of 4 patients (#3, #5, and #21) whose grievance documentation was reviewed. This resulted in an incomplete grievance process and interfered with patient rights. Findings include: The ASC policy "GRIEVANCE AND COMPLAINT REPORTS," dated 8/24/16, stated: - "The Company must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished." - "The completion of the Company's review of the grievance allegations and to provide a written response will be no later than 30 days from the receipt of the grievance." - "Document how grievance is addressed, as well	Q 225	Q 225 1 Grievance policy updated to reflect 60 day time frame to respond to patient's grievances via letter addressing the results of the grievance process (refer to grievance policy). 2&3 All staff and management staff will be educated 02/07/2018 via Company newsletter regarding grievance definition, documented how grievance will be address, and that all grievances will be documented.	02/15/2018

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Q 225	Continued From page 18 as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. a. The decision must contain the name of the Company's contact person. b. The steps taken to investigate the grievance. c. The result of the grievance process. d. The date the grievance process was completed." This policy was not implemented, as follows: 1. A grievance was received on 4/12/17 from Patient #3 related to bleeding complications from a procedure on 3/24/17. There was documentation of investigation and in-person follow-up with an ASC physician on 5/03/17. There was no documentation the ASC sent a letter of response to Patient #3 addressing the results of the grievance process. During an interview with the DON on 1/10/18 at 11:25 AM, she confirmed a letter of response was not sent to Patient #3. She stated she thought it was not necessary since the physician saw her in person. 2. A grievance was received on 4/26/17 from Patient #21 related to care received on 4/24/17. There was evidence of investigation and follow-up with Patient #21, including a phone call to Patient #21 from an ASC physician on 5/23/17. There was no documentation the ASC sent a letter of response to Patient #21 addressing the results of the grievance process. During an interview with the DON on 1/10/18 at 11:30 AM, she confirmed a letter of response was not sent to Patient #21.	Q 225	refer to page 18	

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Q 225	Continued From page 19 3. A grievance was received on 7/11/17 on behalf of Patient #5, related to care and treatment received on 7/05/17. There was evidence of investigation and follow-up staff education. There was no documentation the ASC sent a letter of response to Patient #5 addressing the results of the grievance process. During an interview with the DON on 1/10/18 at 11:37 AM, she confirmed a letter of response was not sent to Patient #5 addressing the grievance. The ASC failed to ensure letters of response to grievances were sent to Patient #3, Patient #5 and Patient #21.	Q 225	refer to page 18	
Q 229	EXERCISE OF RIGHTS - INFORMED CONSENT CFR(s): 416.50(e)(1)(iii) [(1) The patient has the right to the following:] (iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed. This STANDARD is not met as evidenced by: Based on record review, policy review, observation, staff interview and patient interview, it was determined the ASC failed to ensure patients were fully informed about a procedure for 1 of 2 patients (#16) whose care was observed. This resulted in a procedure being conducted without a patient being fully informed. Findings include: The undated procedural consent form, "DETAILED CONSENT FOR MEDICAL/SURGICAL PROCEDURES," included	Q 229	Q229 1 Physicians have been re-educated on regulation, Company policy and procedure. 2 Consent form will be given to the patient in the ASC prior to the procedure. Physician will provide verbal benefits, risks, and alternatives as well as the opportunity to ask questions to the extent of the patient's comfort level. The patient will then sign the consent form, the physician will sign and ASC staff will witness. 3 A "Pre-procedure History and Physical" form has been created which includes an area for the physician to improve documentation of the consent process. In addition, the electronic medical record template will be updated to allow the physician to select the appropriate consent language that will appear on the procedure report.	02/15/18

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Q 229	Continued From page 20 the following pre-printed information: - "My physician has explained the risks and benefits of the recommended procedure to me. I have been given the opportunity to ask questions about my condition, alternative forms of sedation and treatment, risks of non-treatment, the procedures to be used, and the risks and hazards involved. My questions have been answered to my satisfaction, and I believe that I have sufficient information to give this informed consent." - "I certify that I have read this form or have had it read to me, that the blank spaces have been filled in, that I understand its contents, and that I consent to the procedure and sedation referenced above." The ASC policy "CHARTS/MEDICAL RECORDS," dated 9/08/19, stated "Records must include at least the following: ...documentation of properly executed informed patient consent." 1. Patient #16 was a 66 year old female scheduled for a screening colonoscopy on 1/09/18. She was accompanied by surveyors from the time of arrival in the ASC on 1/09/18 at 8:30 AM until discharge at 10:35 AM. Upon arrival at the ASC, at the front desk, the Receptionist was observed to provide Patient #16 with the procedural consent form referenced above. In signing the form, she attested her physician explained the risks and benefits of the procedure, before talking to a physician. She signed the form and the Receptionist stated she would witness the form. Patient #16 was interviewed at approximately	Q 229	refer to page 20	

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Q 229	Continued From page 21 8:40 AM, after signing the consent and prior to being taken back to the pre-operative area. When asked if a physician had explained the procedure prior to the visit, she stated "No," her primary care doctor just told her she should have a screening colonoscopy. Prior to the procedure at 9:15 AM, Physician C was observed to visit Patient #16 in the pre-operative area. During the visit, Physician C examined Patient #16, asked questions regarding her health history, and educated Patient #16 on the purpose of the procedure. The physician was not observed to explain the risks of the procedure or to ask Patient #16 if she had any questions. The Receptionist was interviewed on 1/09/18 at 9:25 AM. She stated they routinely have patients sign the procedural consent upon arrival "unless the patient refuses and wants to talk to the doctor first." She stated, in that case, they send the consent form back with the RN and MD to get a signature. Physician C was interviewed on 1/10/18 at 5:00 PM. He confirmed he did not explain the risks of the procedure to Patient #16 or give her an opportunity to ask questions. He stated that informed consent was not usually done by the physician, rather by a "MA or Nurse" prior to the procedure but that he usually did give the patient an opportunity to ask questions prior to the procedure. Patient #16 did not give informed consent and was not consented in accordance with agency policy and consent forms.	Q 229	refer to page 20	
Q 241	SANITARY ENVIRONMENT	Q 241	continue to page 24	

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Q 241	Continued From page 22 CFR(s): 416.51(a) The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, policy review, manufacture instruction review, and staff interview, it was determined the ASC failed to ensure a sanitary environment for patients receiving care at the ASC and failed to follow nationally recognized guidelines and manufacturer instructions for reprocessing of endoscopes. This directly impacted 2 of 2 patients (#16 and #17) whose procedures were 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 Prevention," revised 4/04/17, stated "The purpose of this policy is to meet the standards of a sanitary environment by adhering to professionally acceptable standards of practice of the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) and/or Association for Professionals in Infection Control and Epidemiology (APIC) and to maintain an ongoing infection prevention program." The "Equipment/Medical Devices" section of the policy stated: "1. All reusable equipment that comes in contact with patients will be cleaned and disinfected according to manufacturers' recommendations or nationally-recognized guidelines, whichever is	Q 241	continue to page 24	

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 241	Continued From page 23 more stringent. 2. High level disinfection is accomplished utilizing a washer/sterilizer with the high level disinfecting agent recommended for that equipment according to manufacturer's directions. 3. Equipment is pre-cleaned using an enzyme solution prior to placing in the washer sterilizer. 4. Reusable accessories and equipment are cleaned per manufacturer's guidelines or nationally-recognized guidelines, whichever is more stringent." This policy was not followed. Examples include: 1. Cleaning and high-level disinfection of endoscopes was observed during the survey. During the observations, the Lead RN was present in the procedure room and reprocessing area. Staff did not follow ASC policy, manufacture instructions, or nationally recognized guidelines for the cleaning and high-level disinfection of endoscopes. Examples include: The SGNA guidelines for "Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes," 2016, stated "It is imperative that reprocessing personnel be intimately familiar with the manufacturer's instructions for each endoscope that they are responsible for reprocessing and follow the instructions exactly. They must also know which AERs, high-level disinfectants, etc. are compatible with a particular endoscope and use the equipment and products according to the manufacturer's instructions (SGNA, 2013)."	Q 241	Q 241 1 ASC technicians trained 01/30/2018 regarding the following: a. Only using lint-free cloths to wipe down endoscopes. Lint-free cloths subsequently ordered. Reprocessing endoscopes according to manufacturer's guidelines. (Refer to 01/30/2018 ASC meeting minutes.) b. Enzymatic cleaner will be used per manufacturer's guidelines. c. Scratch will be created in stainless steel sink in gallon increments to indicate and ensure proper water level filling. continued on page 25	02/15/2018

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	13C0001010	A. BUILDING _____ B. WING _____	01/11/2018

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Q 241	Continued From page 24 Additionally, the guidelines stated "Manual cleaning of endoscopes is necessary prior to automated/manual high-level disinfection or sterilization. This is the most important step in removing the microbial burden from an endoscope. Retained debris contributes to biofilm development (Fang et al., 2010) and interferes with the HLD capability to effectively kill and/or inactivate microorganisms (Roberts, 2013). Manual cleaning and thorough brushing of channels are required even when AER manufacturers claim that manual cleaning is unnecessary (FDA, 2009)." a. Patient #16 was admitted to the ASC on 1/09/18, for a colonoscopy. Her procedure was observed beginning at 9:10 AM on 1/09/18. The procedure ended at 9:45 AM, and Physician C was observed suctioning a clear liquid through the endoscope, then wiped it down with a sponge. Physician C exited the procedure room, with the dirty endoscope, through a door which led directly to the reprocessing area. He laid the scope on a counter, next to a sink, removed his gown and gloves and went back into the procedure room. Technician A was observed wiping out the stainless-steel sink with a disposable disinfecting wipe. She then began to fill the sink with water. While the sink was filling with water, Technician A picked up 2 paper towels and wet them with water from the sink and proceeded to wipe down the endoscope with them. She then attached the endoscope to an automatic leak tester. Technician A then squirted 3 pumps of the enzymatic cleaner directly into the sink with water, and shut the water off.	Q 241	refer to page 24	02/15/2018

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Q 241	Continued From page 25 The manufacturer instructions for the endoscope stated when manually cleaning the endoscope and accessories use a clean lint free cloth, brushes, or sponge. Paper towels were not included for use with the endoscope. When Technician A was asked how much enzymatic cleaner was needed per each gallon of water she stated it was half an ounce. Technician A was asked how much water was in the sink and how much enzymatic cleaner was in the 3 pumps. She stated "About 3.5 fluid ounces of cleaner and 7 gallons of water." When asked how she knew it was 7 gallons of water, as there were no markers, Technician A stated "There is a line around the sink from the cleaner and I fill it up to that line." Technician A next grabbed a small plastic denture cup and squirted 1 pump of enzymatic cleaner into the cup. She set the cup next to the sink, on the left side, and began to unwrap her cleaning brushes from their packages. Technician A stated the brushes and denture cup were 1 time use only. When asked why there was enzymatic cleaner, undiluted, in the denture cup, Technician A stated she used it to dip her cleaning brushes in when cleaning the endoscopes. Technician A dipped one of the cleaning brushes into the concentrated enzymatic cleaner in the denture cup, and proceeded to brush the inside of the endoscope. She then dipped a toothbrush into the denture cup and cleaned the camera lens, valve ports, and knobs with it. Technician A next grabbed a disposable sponge, squirted enzymatic cleaner onto the sponge, and cleaned the endoscope with the sponge in the water with enzymatic cleaner. Next, she squirted some	Q 241	refer to page 24	

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Q 241	Continued From page 26 more enzymatic cleaner onto the sponge and proceeded to wipe down the outside of the endoscope. The enzymatic cleaner instructions for use stated, when manually cleaning, "Add ½ fluid ounce of concentrate per gallon of water. Soak for 2-3 minutes. Rinse thoroughly." There were no instructions for using the enzymatic cleaner as a concentrate or undiluted. Additionally, the endoscope was not soaked in the enzymatic cleaner for 2 to 3 minutes. Technician A then threw away the cleaning brushes, sponge, and denture cup and began draining the sink. Once the sink was empty she rinsed the endoscope under running water. After rinsing the endoscope, Technician A carried it to the AER for high level disinfection. b. Patient #17 was admitted to the ASC on 1/09/18, for an EGD. His procedure was observed beginning at 2:40 PM on 1/09/18. Patient #17 was taken to the procedure room at 3:47 PM. Once the procedure was completed, Physician A was observed suctioning clear liquid through the endoscope then wiping it down with a sponge. Physician A then exited the procedure room, with the dirty endoscope, through a door which led directly to the reprocessing area. He laid the scope on a counter, next to a sink, removed his gown and gloves and went back into the procedure room. Technician B was at the sink, cleaning it with a disposable disinfecting wipe. She then began filling the sink with water, retrieved the disposable brushes and removed them from their wrapping.	Q 241	refer to page 24	

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Q 241	Continued From page 27 Technician B picked up 2 paper towels, wet them with water from the sink and proceeded to wipe down the endoscope with them. Next, she squirted enzymatic cleaner in a clean denture cup, undiluted, and squirted 2 pumps of enzymatic cleaner into the sink. When asked how much water was in the sink, Technician B stated "7 gallons." When asked how she knew it was 7 gallons of water, Technician B stated "There is a line marked by a stain around the sink from previously marking the sink." When she was asked how much enzymatic cleaner was added to the water she stated "3.5 ounces." Technician B then dipped the endoscope brush into the undiluted enzymatic cleaner in the denture cup and proceeded to brush the inside of the endoscope. She completed this action twice, then used a toothbrush, dipped in the undiluted enzymatic cleaner, to clean the camera lens, valve ports, and knobs. Technician B then used a sponge to wipe down the endoscope while in the water. She drained the water from the sink and then rinsed the endoscope with running water. Technician B then carried the endoscope to the AER for high level disinfection. During an interview at 4:20 PM on 1/09/18, the Lead RN confirmed there was no mark in the sink or way to determine how many gallons of water were used during both observations. She also confirmed Technician A and Technician B did not follow the manufacturer's instructions for the enzymatic cleaner. The Lead RN confirmed nationally-recognized guidelines and ASC policies were not followed.	Q 241	refer to page 24	

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Q 241	Continued From page 28 Staff did not follow ASC policy, manufacturer instructions, or nationally recognized guidelines for the cleaning and high-level disinfection of endoscopes. 2. A tour was conducted of the ASC beginning at 10:50 AM on 1/08/18, with the DON, Director of HIM and QI, and the QI Lead. The medication room of the ASC was observed. In the medication room on the counter was a glucometer device inside a black bag. The Charge RN stated the glucometer was used for patients diagnosed with diabetes, and was cleaned after each patient use. The glucometer was manufactured by McKesson. On a shelf above the counter was the box for the glucometer and on the outside of the box it was labeled "Single patient use only." The DON was shown the box with the labeling and she confirmed the label stated it was for single patient use. She immediately removed the glucometer from the medication room and stated to the Charge RN it was not to be used. The ASC did not follow the manufacturer instructions for the glucometer.	Q 241	refer to pages 24 for Q 241 1 Q 241 2 d. Multi-patient glucometer purchased and is currently in use in the ASC. Single patient use glucometer destroyed. ASC staff trained on 01/30/2018 to recognize difference between single patient use vs multi patient use devices (refer to 01/30/2018 ASC meeting minutes).	02/15/2018
Q 263	ADMISSION ASSESSMENT - RECORD CFR(s): 416.52(a)(3) The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure. This STANDARD is not met as evidenced by: Based on record review, observation, policy review, and staff interview, it was determined the	Q 263	continue to page 30	

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Q 263	Continued From page 29 ASC failed to ensure the patient's physical assessment was placed in the medical record prior to the surgical procedure for 1 of 1 patient (Patient #17) whose EHR was viewed immediately following the procedure. This had the potential to result in negative outcomes for the patient as a result of the procedure or from sedation. Findings include: The ASC policy, "PATIENT ASSESSMENT," dated 8/23/16, included a section "Provider Assessment" which stated "The assessment must be documented by the provider in the EHR prior to the start of the procedure." Patient #17 was a 64 year old blind male who had an EGD on 1/09/18. He was accompanied by a surveyor from the time of arrival at the ASC on 1/09/18 at 2:35 PM until discharge at approximately 4:45 PM. Physician A was observed to conduct a physical examination of Patient #17 in the pre-operative room prior to the procedure. Physician A was not observed to document the physical examination prior to the procedure. After the EGD was complete at 4:09 PM, Physician A was asked to show where the physical examination was documented in Patient #17's medical record. Physician A went to his computer and pulled up a blank form. He stated the form on the computer screen was where he would be documenting Patient #17's physical examination. Physician A was interviewed on 1/10/18 at 3:30 PM. He confirmed he did not enter the physical examination portion of the H&P in Patient #17's	Q 263	Q263 A "Pre-procedure History and Physical" form has been created which includes an area for the physician to improve documentation of language, date, and time that the history was reviewed and the physical exam completed prior to the start of procedure. This form will supplement the electronic physician entry and will be scanned into the medical record following the procedure. Assessment policy was updated to reflect changes and will be approved at 02/06/2018 Board meeting (refer to assessment policy and "Pre-procedure History and Physical" form).	02/15/2018

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Q 263	Continued From page 30 medical record prior to the procedure. Patient #17's physical assessment was not in the medical record prior to the procedure.	Q 263	refer to page 30	

PLAN OF CORRECTION DETAIL

Page Number	Tag #	Deficiency	The plan correcting the specific deficiency (corrective action taken to correct specified deficiency)	How the actions taken will improve the processes that led to deficiency	The procedure for implementing the acceptable plan of correction for the specific deficiency cited	The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements	The title of the person responsible for implementing the acceptable plan of correction	Dates when corrective action will be completed
Page 2	Q002	Organizational chart not separated to indicate clinic and ASC staff positions.	1. Company organizational chart updated to indicate distinct separation between ASC and clinic. Every 3 years the organizational chart will be reviewed to ensure ASC and clinic staff roles are delineated aopropriately (refer to attached ASC organizational chart to be approved at 2/6/2018 Board meeting).	By having the organizational chart reflect the ASC and clinic as distinct entities, it will clearly identify administrative lines of authority for the clinic and the ASC. This update will also clearly reflect who has oversight and responsibility of the ASC.	Administrator updated organizational chart to indicate separation of clinic and ASC.	To remain consistent with policy review, every 3 years the organizational chart will be reviewed by the Governing Body to ensure clinic and ASC staff roles are delineated appropriately.	Administrator	2/15/2018
Page 3	Q002	Binder of clinic and ASC occurrence reports, grievances, and complaints were mixed together.	2. Occurrence reports, grievances and complaints are separated into "ASC", "clinic", and "other" sections.	Separation of ASC and clinic occurrence reports, grievances, and complaints will accurately reflect the ASC as a discreet entity from the clinic as well as keep information organized appropriately.	Director of Quality separated occurrence reports, grievances, and complaints into "ASC", "clinic", and "other" sections.	The binder of occurrence reports, grievances, and complaints will be reviewed prior to every quarterly combined meeting to ensure these documents are filed accurately in the "ASC", "clinic", and "other" sections of the binder.	Director of HIM & QI	2/15/2018
Page 3	Q002	Binder of QAPI information were mixed between clinic and ASC.	3. QAPI information is separated into ASC and clinic designations.	Separation of ASC and clinic QAPI information will accurately reflect the ASC as a discreet entity from the clinic as well as keep information organized appropriately.	Director of Quality separated QAPI information into clinic and ASC sections.	The binder of QAPI information will be reviewed prior to every quarterly combined meeting to ensure information is filed accurately in the ASC and clinic section.	Director of HIM & QI	2/15/2018
Page 3	Q002	Administrative documents failed to identify the ASC as a distinct entity from the adjacent clinic.	4. Format of administrative documents updated to reflect the ASC as a distinct entity.	Updated administrative documents separating ASC and clinic sections will accurately reflect the ASC as a discreet entity from the clinic as well as keep information organized appropriately.	Director of Quality updated administrative documents to clearly identify ASC and clinic as distinct entities.	Every 3 years administrative documents will be reviewed to ensure documents accurately depict the ASC and clinic as distinct entities.	Administrator	2/15/2018
Page 3	Q160	1. Refer to Q 161 as it relates to the failure of the ASC to ensure systems were in place to develop a unique medical record as it relates to documentation of timing of the pre-procedural examinations and the failure of the ASC to ensure a system was in place to individualize pre-populated consent language to accurately reflect the consent process. Q 161 STANDARD is not met - ASC failed to ensure systems were in place to develop a unique medial record as it related to the documentation of timing of pre-procedural examinations reviewed and that a system was in place to individualize pre-populated consent language to accuracy reflect the consent process. Documentation did not accuracy reflect the timing of care and consent. 2. Refer to Q 162 as it relates to failure of the facility to ensure complete and accurate documentation.	Below	Below	Below	Below	Below	Below

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Page 4 & 5	Q 161	1. Identify the time the pre-procedural physical examination as part of the H&P was entered into the medical record. Record review did not include a time as to when the physical examination was ended into the medical record. 2. ASC did not have an established system to ensure individualization of informed consent information entered by the physician in the procedural report. Physician confirmed the procedural report was standardized, even if the patient was not interested in hearing risks. the current system did not allow physicians to individualize the information.	1. A "Pre-procedure History & Physical" form was created to supplement documentation as to when the physical examination was conducted. The form will follow the patient throughout the procedure process and then scanned into the medical record with the consent form to become a permanent record of the procedure. Assessment policy was updated to reflect changes and will be approved at 2/6/2018 Board meeting. (Refer to "Pre-procedure History & Physical" form and Assessment policy.) 2. a. The "Pre-procedure History & Physical" form (noted in response 1 above) includes an area for the physician to improve documentation of the consent process. b. The electronic medical record template will be updated to allow the physician to select the appropriate consent language that will appear on the procedure report. c. Language on consent form will be modified to include declination of the opportunity to have the form read to the patient. Also, area added for witness to document observation of patient's informed decision. (Refer to "Detailed Consent for Medical/Surgical Procedures" form.)	1. The addition of the "Pre-procedure History & Physical" form will enable the physician to document the time of the history and physical exam. 2. a. The addition of the "Pre-procedure History & Physical" form will enable the physician to document the consent process, specific to the patient, prior to the start of the procedure, supplement to the procedure report. b. The IT department will modify the electronic medical record templates and documents to improve documentation of consent. c. The consent form will be updated to modify the language of to accurately reflect the patient's actions of reading, being read to, or declining to have read.	1. The supplementary "Pre-procedure History & Physical" form will be created for each procedure patient. The physician will complete the form during pre-op. The form will be scanned into the medical record after the procedure. 2. a. The "Pre-procedure History & Physical" form will be created for each procedure patient. b. The IT department will modify the electronic medical record templates and documents to improve documentation of consent. c. Consent form will be given to the patient in the ASC prior to procedure to have the opportunity to read. Physician will provide verbal benefits, risks, and alternatives as well as the opportunity to ask questions to the extent of the patient's comfort level. The patient will then sign the consent form, the physician will sign and ASC staff will witness.	The monthly ASC chart audit form was updated to ensure compliance.	Medical Director	2/15/2018
Page 5 & 7	Q152	The ASC Policy Charts/Medical Records - complete, comprehensive and accurate medical records Record must include...documentation of properly executed informed patient consent. 1. Consent given to pt in reception & signed which attested that her physician explained risks and benefits before talking to the physician, receptionist witnessed. 2. Physician did not discuss risks, benefits, alternatives, or give opportunity to ask questions. Stated that it was usually done by MA or nurse. 3. Consent language on the procedure report is standardized, even if the patient was not interested in hearing about risks.	1. Consent form will be given to the patient in the ASC prior to procedure to have the opportunity to read. Physician will provide verbal benefits, risks, and alternatives as well as the opportunity to ask questions to the extent of the patient's comfort level. The patient will then sign the consent form, the physician will sign and ASC staff will witness. 2. Physicians will be re-educated on regulation, Company policy and procedure at 2/6/2018 Board meeting. 3. A "Pre-procedure History & Physical" form has been created which includes an area for the physician to improve documentation of the consent process. In addition, the electronic medical record template will be updated to allow the physician to select the appropriate consent language that will appear on the procedure report.	Changing the workflow between reception and ASC staff will eliminate the opportunity for patient to sign the consent, before the consent process is complete with the physician. Physician re-education will help ensure the proper informed consent process is carried out in a manner that is fitting to the patients. The addition of the "Pre-procedure History & Physical" form will enable the physician to document the consent process, specific to the patient, prior to the start of the procedure, supplement to the procedure report.	The workflow for the consent process has changed. The consent form will be given to the patient in the ASC prior to procedure to have the opportunity to read. Physician will provide verbal benefits, risks, and alternatives as well as the opportunity to ask questions to the extent of the patient's comfort level. The patient will then sign the consent form, the physician will sign and ASC staff will witness. The ASC staff will document and witness patient's actions (read, read to patient, patient declined to read) on the consent form. After the procedure, the form will be scanned into the medical record. The physicians will be re-educated at the 2/6/2018 Board meeting regarding the consent process. The supplementary "Pre-procedure History & Physical" form will be created for each procedure patient. The physician will complete the form prior to procedure. The form will be scanned into the medical record after the procedure. The supplementary "Pre-procedure History & Physical" form will be created for each procedure patient in the reception area. The form will be given to ASC staff, along with the consent form. The physician will complete the form prior to the procedure. The form will be scanned into the medical record after the procedure. The IT department will modify the electronic medical record templates and documents to allow the provider to document the consent process in language that is	The monthly ASC chart audit form was updated to ensure compliance.	Medical Director	2/15/2018

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Page 9		Consent given to patient in reception. Patient was blind and reception offered that spouse could read the consent form to him. Patient declined and signed without knowing what the consent said, which attested that his physician explained risks and benefits before talking to the physician. There was no documentation on the consent or in the medical record that explained that patient declined an opportunity to have the consent read to him and that he elected to sign the consent without knowing what information was included.	Language on consent form modified to include declination of the opportunity to have the form read to the patient. Also, area added for witness to document observation of patient's informed decision.	The consent form will be updated, modifying the language to more accurately reflect the patient's actions.	The supplementary "Pre-procedure History & Physical" form will be created for each procedure patient in the reception area. The form will be given to ASC staff, along with the consent form. The physician will complete the History & Physical form prior to the procedure, including the consent process (on the H&P form), physician signature, date and time. The workflow for the consent form will be changed. The consent form will be initiated in reception and given to ASC staff to take to the ASC with the patient. The consent process will take place prior to the procedure. The ASC staff will document patient's actions (read, read to patient, patient declined to read) on the consent form and witness. After the procedure, the form will be scanned into the medical record. The IT department will modify the electronic medical record templates and procedure documents to allow the provider to document the consent process in language that is customized to the individual patient on the procedure report.	The monthly ASC chart audit form was updated to ensure compliance.		
Page 9	Q 162	Intra-operative nursing documentation included standardized language "Physician reviewed Patients H/P at [time added]. This language did not accurately reflect the course of events as the physician did not review the physical examination. Rather, physician conducted the physical examination portion of the H&P prior to the procedure. a. Records did not include a date and time which indicated the physical examination was completed and in the patient record prior to the scheduled procedure. b. Standard language related to the H&P did not accurately and clearly reflect the course of care.	1 A "Pre-procedure History & Physical" form has been created which includes an area for the physician to improve documentation of language, date, and time that the history was reviewed and the physical exam completed prior to the start of procedure. This form will supplement the electronic physician entry and will be scanned into the medical record following the procedure. Assessment policy was updated to reflect changes and will be approved at 2/6/2018 Board meeting (refer to assessment policy).	The addition of the "Pre-procedure History & Physical" form will enable the physician to document the time of the history and physical exam, completed prior to procedure.	The supplementary "Pre-procedure History & Physical" form will be created for each procedure patient in the reception area. The form will be given to ASC staff, along with the consent form. The physician will complete the History & Physical form prior to the procedure, including the consent process (on the H&P form), physician signature, date and time. The IT department will modify the electronic medical record templates and procedure documents to allow the provider to document the history and physical exam process.	The monthly ASC chart audit form was updated to ensure compliance.	Director of Nursing	2/15/2018

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Page 10	Q152	Discharge nursing documentation for patients included standardized language "discharge orders given to nursing staff at [time inserted]. The standard language laced clarity as to what discharge orders were given, whether to remove IV, or give particular medication, or discharged to home with adult, etc.. No documented authenticated physician discharged orders included in chart to correspond to the nursing documentation. DON stated they should say D/C IV and may discharge patient. Also confirmed the orders referenced in nursing notes were not separately documented by a physician or authenticated.	Nursing discharge documentation will be modified to state "Discharge criteria met [Time]" to reflect current policy language. Language updated to reflect existing protocol (refer to discharge policy and standing orders for discharging patients).	Changing the documentation will more clearly reflect the course of treatment. Patient will be discharged when criteria is met.	IT department will modify the nursing post op template and procedure document to enable ability to document the core of treatment.	The monthly ASC chart audit form was updated to ensure compliance.	Director of Nursing	2/15/2018
Page 11	Q162	Pre-printed form - I have received or have been offered a copy of the patients rights and responsibilities. Lack of clarity in medical records as to whether each patient was provided written notice of patients rights or was offered rights and refused.	Every patient for each encounter will be given the "Patient Rights and Responsibilities" form or obtain a copy from our website. Reception staff were trained on 1/30/2018 on how to verbally provide patients with notice of rights and responsibilities (refer to 1/30/2018 reception meeting minutes). "Patient Rights and Responsibilities" form has been modified to include an area for reception staff to document that patients' rights were provided in verbal format. Patient Rights and Responsibilities policy update to reflect that patients will be informed of their rights and responsibilities in verbal and written form. If patient declines to sign acknowledgment of rights and responsibilities, this will be documented on form and scanned into patient's medical record (refer to "Patient Rights and Responsibilities" form and policy to be approved at 2/6/2018 Board meeting).	The changes made to the workflow and form will clearly document that each patient either received written and verbal patient rights and responsibilities refused.	The Director of Quality Improvement will modify the patient rights and responsibility forms. Reception staff has developed language to review the Patient Rights and Responsibilities verbally. If patient refuses to sign the acknowledgment, reception will write the patients name on the form, write refused and scan the form into the medical record. Patient Rights and Responsibilities policy updated.	The monthly ASC chart audit form was updated to ensure compliance.	Director of Billing & Reception	2/15/2018
Page 11	Q162	Refer to Q184 as it relates to the failure of the ASC to ensure verbal orders for medications were signed by the physician.	Procedure documents containing verbal orders will be generated to rendering physician's provider approval queue for authentication. Medications policy updated and will be approved at 2/6/2018 Board meeting (refer to Medications policy).	Modifying the electronic medical record to allow the ASC procedure document, to be routed to the providers to co-sign verbal orders. Adding a timeframe for co-sign to the medication policy will create a protocol, which can be used to monitor compliance	IT staff will enable the ability to send the ASC document to the Providers Approval Queue for co-sign of all orders.	The monthly ASC chart audit form was updated to ensure compliance.	Director of Nursing	2/15/2018
Page 12	Q184	Orders given verbally for drugs must be followed by a written order signed by the prescribing physician.	ASC staff received training regarding upcoming medications policy update 1/30/2018. Procedure documents containing verbal orders will be generated to rendering physician's provider approval queue for authentication. Medications policy updated regarding physician sign off. Physicians will be educated regarding medications policy changes on 2/6/2018. (Refer to 1/30/2018 ASC meeting minutes and updated medications policy to be approved at 2/6/2018 Board meeting.)	Requiring ordering physician's signature on all verbal orders ensures that all patients receiving medications and treatments have authenticated orders.	ASC procedure documents will be generated to rendering physician's Provider Approval Queue in the EHR for sign-off.	Monthly ASC chart audit worksheet updated with addition of "all verbal orders signed by ordering physician within 5 days of original verbal order" (refer to updated ASC chart audit form).	Director of Nursing	2/15/2018
Page 13	Q221	ASC did not provide verbal notice of rights to patients.	Reception staff trained 1/30/2018 to verbally communicate rights and responsibilities to all patients (refer to 1/30/2018 reception meeting minutes).	By providing patients with verbal notice of rights in addition to written notice, helps solidify patient understanding of these rights.	1. Policy updated to reflect that notice will be provided both verbally and in writing. 2. Patient Rights & Responsibilities form updated. 3. Reception staff trained on 1/30/2018 on how to verbally provide patients with notice of rights.	Director of Billing & Reception will observe reception staff to ensure they are providing patient rights in verbal and written form. This will be performed on a monthly basis.	Director of Billing & Reception	2/15/2018

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Page 14	Q224	Advance Directives 1. ASC did not have a process in place to ask patients whether they had executed an advance directive and to have the advance directive placed in their medical record. 2. The medical records reviewed did not include documentation as to whether patients had executed an advance directive.	1. Patient rights and responsibilities policy "Advance directive" portion updated to reflect changes. Policy to be approved at 2/6/2018 Board meeting (refer to patient rights and responsibilities policy). 2&3. ASC staff received training regarding aforementioned policy update and documentation on 1/30/2018. Advance directive questions will be asked to all patients prior to procedure and documented in a prominent part of patient's medical record (refer to 1/30/2018 ASC staff meeting minutes).	1. By inquiring about advance directives and adding these to the medical record, if the patient with an advance directive were transferred from the ASC to a hospital the hospital will understand the patient's wishes regarding execution of their advance directive. 2&3. By documenting advance directive it will be readily noticeable by any staff providing clinical services to the patient.	1. ASC staff trained regarding importance and necessity of asking patients whether they have executed an advance directive and subsequently that advance directive filed in the patient's chart. 2. ASC EHR pre-op template will be updated to be a "red required" meaning staff must first obtain and document patient's advance directive information prior to moving on in the template.	Monthly ASC chart audit worksheet updated with addition of: 1. Advance directive information documented in prominent portion of EHR. 2. If patient has advance directive, this is filed in the patient chart (refer to updated chart audit form).	Director of Nursing	2/15/2018
Page 17	Q225	Grievance process did not specify timeframes for review of the grievance and the provisions of a written response	1. Grievance policy updated to reflect 60 day time frame to respond to patient's grievances via letter addressing the results of the grievance process (refer to grievance policy). 2&3. All staff and management staff will be educated 2/7/2018 via Company newsletter regarding grievance definition, documented how grievance will be address, and that all grievances will be documented.	By providing patients with written notice of its decision regarding how a grievance was addressed, the ASC helps ensure closed-loop communication to the patient regarding grievance.	Policy will be updated to include a 60 day timeframe for ASC to respond to all grievances in writing.	All grievances will be audited to ensure written response was given within 60 day timeframe	Director of Nursing & Director of HIM & QI	2/15/2018
Page 20	Q229	Exercise of Rights-Informed consent: The ASC failed to ensure patients were fully informed about a procedure. This resulted in a procedure being conducted without a patient being fully informed.	1. Physicians have been re-educated on regulation, Company policy and procedure. 2. Consent form will be given to the patient in the ASC prior to the procedure. Physician will provide verbal benefits, risks, and alternatives as well as the opportunity to ask questions to the extent of the patient's comfort level. The patient will then sign the consent form, the physician will sign and ASC staff will witness. 3. A "Pre-procedure History & Physical" form has been created which includes an area for the physician to improve documentation of the consent process. In addition, the electronic medical record template will be updated to allow the physician to select the appropriate consent language that will appear on the procedure report.	It will ensure that patients are fully informed about their procedure prior to the start of procedure.	1. Physician re-education will help ensure the proper informed consent process is carried out in a manner that is customized to the individual patient. 2. Language on consent form modified to include declination of the opportunity to have the form read to the patient. Also added area for witness to document observation of patients choice.	To remain consistent with existing monitoring activities physicians will be observed monthly. Re-education will be performed as needed based on monitoring results.	Medical Director	2/15/2018
Page 29	Q241	The ASC failed to ensure a sanitary environment for patients receiving care at the ASC and failed to follow nationally recognized guidelines and manufacturer instructions for reprocessing of endoscopes: Techs were observed 1. Using a paper towel to wipe down endoscope 2. Using enzymatic cleaner not diluted per manufacturer's guidelines 3. Sink not filled exact amount of water 4. Glucometer used not specific to multiple patients	ASC technicians trained 1/30/2018 regarding the following: 1. Only using lint-free cloths to wipe down endoscopes. Lint-free cloths subsequently ordered. Reprocessing endoscopes according to manufacturer's guidelines. (Refer to 1/30/2018 ASC meeting minutes.) 2. Enzymatic cleaner will be used per manufacturer's guidelines. 3. Scratch will be created in stainless steel sink in gallon increments to indicate and ensure proper water level filling. 4. Multi-patient glucometer purchased and is currently in use in the ASC. Single patient use glucometer destroyed. ASC staff trained on 1/30/2018 to recognize difference between single patient use vs multi patient use devices (refer to 1/30/2018 ASC meeting minutes).	By following manufacturer's guidelines as well as strictly follow ASC Infection Prevention policy, the ASC is strongly reducing the infection risk for patients.	Endoscopy technicians trained on 1/30/2018 regarding the following: 1. Only using lint-free cloths to wipe down endoscopes. Lint-free cloths subsequently ordered. 2. Enzymatic cleaner not used undiluted and denture cup step removed from cleaning process per manufacturer's guidelines. 3. Scratch created in stainless steel sink in gallon increments to indicate and promote proper water level filling. 4. Single use glucometer destroyed and multi-patient glucometer purchased and in use	The following expectations were added to the endoscopy technician's annual clinical competencies: 1. Endoscopes wiped down with lint-free wipes only 2. Enzymatic cleaner is used only diluted per manufacturer's guidelines 3. Technicians fill water in sink to accurate fill level per manufacturer's guidelines 4. Nursing supervisor and endoscopy nurse lead trained on recognition of ordering multi-use glucometers when current one needs to be replaced.	Director of Nursing	2/15/2018

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Page 29	Q262	Admission assessment: The patient's medical history and physical assessment was not placed in the patient's medical record prior to the procedure.	A "Pre-procedure History & Physical" form has been created which includes an area for the physician to improve documentation of language, date, and time that the history was reviewed and the physical exam completed prior to the start of procedure. This form will supplement the electronic physician entry and will be scanned into the medical record following the procedure. Assessment policy was updated to reflect changes and will be approved at 2/6/2018 Board meeting (refer to assessment policy and "Pre-procedure History & Physical" form).	By ensuring a physical exam is performed and documented in the patient's record prior to the procedure decreases the likelihood of a potential for a negative outcome to occur.	The supplementary "Pre-procedure History & Physical" form will be created for each procedure patient. The form will be given to ASC staff, along with the consent form. The physician will complete the "Pre-procedure History & Physical" form prior to the procedure, including the consent process (on the "Pre-procedure History & Physical" form), physician signature, date and time.	Monthly ASC chart audit worksheet updated with addition of "time physical assessment performed was prior to procedure start time" (refer to updated ASC chart audit form).	Medical Director	2/15/2018