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	29C0001057		04/24/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
DIGESTIVE DISEASE CENTER II	2700 CRIMSON CANYON DRIVE LAS VEGAS, NV 89128

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Q 000	INITIAL COMMENTS	Q 000		
	This Statement of Deficiencies was generated as a result of a Medicare recertification survey conducted at your center on April 21, 23, and 24, 2008.			
	The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.			
	Sixteen patient records and 19 employee files were reviewed.			
	The center failed to maintain condition level compliance with the following Conditions of Coverage:			
	42 CFR 416.41 - Governing Body and Management 42 CFR 416.42 - Surgical Services 42 CFR 416.43 - Evaluation of Quality 42 CFR 416.44 - Environment 42 CFR 416.45 - Medical Staff			
	The following regulatory deficiencies were identified:			
Q 003	416.41 GOVERNING BODY AND MANAGEMENT	Q 003		
	The ambulatory surgical center must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the center's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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 003	Continued From page 1 provided through a contract with an outside resource, the center must assure that these services are provided in a safe and effective manner. This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the center failed to ensure the governing body assumed full responsibility for determining, implementing and monitoring the policies governing the center's total operation and for ensuring these policies were administered so as to provide quality health care in a safe environment (Q003); the center failed to ensure surgical procedures must be performed in a safe manner by qualified physician who have been granted clinical privileges by the governing body of the ambulatory surgery center (ASC) in accordance with approved policies and procedures of the ASC (Q005); The ASC, with the active participation of the medical staff, must conduct an on-going, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges (Q009); The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients (Q0010). The cumulative effect of these systemic practices resulted in the failure of the center to deliver statutory mandate care to patients. Based on staff interview and record review, the center's Governing Body failed to assure policies	Q 003		

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Q 003	Continued From page 2 were administered to provide quality health care in a safe environment related to the credentialing of physicians hired by the center or contracted with the center for 9 of 10 physicians (#1, #2, #3, #4, #5, #7, #8, #9, and #10). Findings include: 1. A review of the credentialing files for physicians #1 through #10 were completed on 4/24/08. Credentialing files for 9 of the 10 physicians (#1, #2, #3, #4, #5, #7, #8, #9, and #10) were not complete and/or were outdated based on the requirements of the center's By-laws listed under Article 4 that pertains to Medical Staff Qualifications (Cross Reference Q5). 2. A review of the Quality Assurance meeting minutes dated January 31, 2008 found the minutes documented the credentialing files for all doctors and nurses were current. The minutes did not state whether the files had been reviewed by the Governing Body to assure the physicians credentialing was complete and up to date. A review of the center records and credentialing files on 4/23-24/08 found no evidence the Governing Body had made a review of the physician files on an ongoing basis to assure the physicians practicing in the center were currently credentialed and the physicians met the requirements of the Medical Staff Qualifications listed in Article 4 of the center's By-laws. 3. An interview was conducted with the center's Nurse Manager on 4/24/08 at 4:00 P.M. The Nurse Manager stated she was aware of the fact the credentialing files were not completed and were not updated as required under Medical Staff Qualifications listed in Article 4 of the center's	Q 003		

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Q 003	Continued From page 3 By-laws. The Nurse Manager was unable to provide any evidence the center's Governing Board had made a review of the files.	Q 003		
Q 005	416.42 SURGICAL SERVICES Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ambulatory surgical center in accordance with approved policies and procedures of the center. This CONDITION is not met as evidenced by: The center failed to ensure surgical procedures were performed in a safe manner by qualified physicians who had been granted privileges by the governing body (Q0005). Based on staff interview and record review, the center failed to assure 4 of 4 physicians (#7, #8, #9, and #10) performing procedures in the center and 6 of 10 physicians (#1, #2, #3, #4, #5 and #6) performing anesthesia services in the center were granted privileges by the Governing Body of the center as outlined in the center's By-laws and policy and procedures. Findings include: 1. A review was completed on 4/23/08 and 4/24/08 of the credentialing files for all physicians who, at the time of the survey, were performing procedures at the center. a. The credentialing files for 3 of the 4 physicians (#7, #8, and #9) who performed procedures were outdated and did not have complete files that included a reapplication for privileges, endorsements by qualified physicians, evidence a	Q 005		

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Q 005	Continued From page 4 retrospective review and evaluation had been completed or a review had been completed by the center's Governing Body. The original date of application for physician #7 was 8/13/04; physician #8 was 4/30/04; and physician #9 was 8/3/04. Article 4 "Medical Staff Qualifications" of the center By-laws documented reapplication for all physicians must be made every three years. The lack of a reapplication for the three physicians, endorsement by qualified physicians, evidence of a retrospective review and evaluation, and a review by the center's Governing Body was confirmed by the center's Nurse Manager in an interview on 4/24/08 at 4:00 P.M. b. The credentialing file for 1 of 4 physicians (#10) was not completed and there was no indication the Governing Body had reviewed the file. The file was missing the initial application for privileges and endorsements by qualified physicians. The lack of an application for the physician, physician endorsements and a review by the Governing Body was confirmed by the center's Nurse Manager in an interview on 4/24/08 at 4:00 P.M. c. The credentialing files for 6 of 6 physicians (#1, #2, #3, #4, #5, and #6) performing anesthesia services were not completed and did not contain any evidence of endorsements by qualified physicians and a retrospective review and evaluation. The lack of physician endorsements and a review by the Governing Body was confirmed by the center's Nurse Manager in an interview on 4/24/08 at 4:00 P.M.	Q 005		
Q 009	416.43 EVALUATION OF QUALITY The ambulatory surgical center, with the active participation of the medical staff, must conduct an	Q 009		

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Q 009	Continued From page 5 ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges. This CONDITION is not met as evidenced by: The center failed to ensure with the active participation of the medical staff, the center conducted on-going, comprehensive self assessment of the quality of care provided, which included medical necessity of procedures performed and appropriateness of care, and used these findings, when appropriate, in the revision of the centers policies and consideration of clinical privileges (Q0009). Based on staff interview and record review, the center failed to provide for an evaluation of quality and self assessment in consideration of clinical privileges. Findings include: On 4/24/08 review was made of the minutes for the Joint Quality Improvement Committee meeting held on 1/31/08. As part of the accomplishments and reviews completed by the center the minutes documented all doctors and nurses were credentialed. Record review found no evidence the center had completed the credentialing process that included an evaluation of quality for the physicians as required under the center's By-laws as outlined under Article 4 "Medical Staff Qualifications." A review was made on 4/23/08 and 4/24/08 of the	Q 009		

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Q 009	Continued From page 6 credentialing files for all physicians that practiced in the center. This review found the following: a. The credentialing files for 3 of the 4 physicians (# 7, #8, and #9) who performed procedures were outdated and did not have complete files that included a reapplication for privileges, endorsements by qualified physicians, evidence a retrospective review and evaluation had been completed or a review had been completed by the center's Governing Body. The original date of application for physician #7 was 8/13/04; physician #8 was 4/30/04; and physician #9 was 8/3/04. Article 4 "Medical Staff Qualifications" of the center's By-laws documented reapplication for all physicians must be made every three years. The lack of a reapplication for the three physicians, endorsement by qualified physicians, evidence of a retrospective review and evaluation, and a review by the center's Governing Body was confirmed by the center's Nurse Manager in an interview on 4/24/08 at 4:00 P.M. b. The credentialing file for 1 of 4 physicians (#10) was not completed and there was no indication the Governing Body had reviewed the file. The file was missing the initial application for privileges and endorsements by qualified physicians. The lack of an application for the physician, physician endorsements and a review by the Governing Body was confirmed by the center's Nurse Manager in an interview on 4/24/08 at 4:00 P.M. c. The credentialing files for 6 of 6 physicians (#1, #2, #3, #4, #5, and #6) performing anesthesia services were not completed and did not contain any evidence of endorsements by qualified physicians and a retrospective review and	Q 009		

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Q 009	Continued From page 7 evaluation. The lack of physician endorsements, a retrospective review and evaluation, and a review by the Governing Body was confirmed by the center's Nurse Manager in an interview on 4/24/08 at 4:00 P.M. 2. During an interview with the Nurse Manager on 4/24/08 at 4:00 P.M., the Nurse Manager stated she was aware the credentialing files for the physicians were not complete and further work was needed to get all of the files up to date. The Nurse Manager stated a previous manager had not completed the process and did not know why the Governing Body had not reviewed the files to assure they were complete and up to date.	Q 009		
Q 010	416.44 ENVIRONMENT The ambulatory surgical center 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: The center failed to ensure a sanitary environment to protect the health and safety of patients (Q10), provide a sanitary environment for the provision of surgical services (Q11), and ensure emergency equipment including a ventilator was available for the procedure room (Q16). Based on observation and interview, the center failed to maintain a sanitary environment to protect the health and safety of patients. Observation 1. On 4/21/08 in the afternoon, the center did not maintain a sanitary environment in the recovery room area. The following observations were	Q 010		

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Q 010	Continued From page 8 made: a. The cabinet doors facing the recovery room area were discolored with streaks of an unknown substance. During the observation, one cabinet door was wiped with a germicidal wipe and the wipe was discolored with an unknown yellow-brown substance. b. The cut-outs in the countertops directly behind the gurneys in the recovery room area had small amounts of trash (glove, piece of paper) and gray-black dirt and dust on the floors underneath the countertops. 2. On 4/23/08 at 1:30 PM during a tour with the Nurse Manager, the center did not maintain a sanitary environment in the recovery room area and a storage closet for trash and linen. The following observations were made: a. The recovery room area floor was discolored with gray-black dirt accumulated near the floor and wall junction. b. The countertop cut-outs directly behind the gurneys in the recovery room area had gray-black dirt and dust on the floors (underneath the countertops). c. The recovery room curtains were discolored with streaks and spots from unknown substances. d. A storage closet was full of trash and linen as well as a ceiling tile and a rolled up rug. Interview	Q 010		

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Q 010	Continued From page 9 On 4/23/08 in the afternoon following the tour of the center, the Nurse Manager indicated she would have the center cleaned, but needed to learn how to say it in Spanish. The Nurse Manager indicated she had spoken to the center staff on 4/21/08 about the sanitary conditions of the center and stated "I didn't think it was that bad."	Q 010		
Q 011	416.44(a) PHYSICAL ENVIRONMENT The ambulatory surgical center must provide a functional and sanitary environment for the provision of surgical services. This STANDARD is not met as evidenced by: Based on observation and interview, the center failed to provide a sanitary environment for the provision of surgical services. Observation 1. On 4/21/08 in the afternoon, the center did not provide a sanitary environment for the provision of surgical services in the procedure room. The following observations were made: a. The floors in the procedure room had gray-black dirt and dust that were easily dislodged behind the anesthesia cart, the television/monitor on a cart, and behind the gastrointestinal procedure cart. b. The tiled wall directly behind the gastrointestinal procedure cart had yellowed streaks of an unknown substance extending down from just above the cart to just above the floor. 2. On 4/23/08 at 1:30 PM during a tour with the Nurse Manager, the center did not provide a	Q 011		

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Q 011	Continued From page 10 sanitary environment for the provision of surgical services in the procedure room and cleaning/decontamination room. The following observations were made: a. The floors in the procedure room had gray-black dirt and dust that was easily dislodged behind the anesthesia cart, the television/monitor on a cart, and behind the gastrointestinal procedure cart. b. The tiled wall directly behind the gastrointestinal procedure cart had yellowed streaks of an unknown substance that extended from the floor to 6 tiles up the wall. c. The cleaning/decontamination room had 2 flush tubing sets (used in the cleaning of the gastrointestinal scopes) hung from the faucet and into the sink to dry. A large fan on a stand was positioned close to the doorway of the cleaning/decontamination room oscillating back and forth near the counter where cleaned equipment was drying and the sink where scopes were cleaned. Interview On 4/23/08 at 1:55 PM during a tour of the cleaning/decontamination room, a GI (gastrointestinal) technician revealed the fan was in place for added ventilation of the room. On 4/23/08 in the afternoon following the tour of the center, the Nurse Manager indicated she would have the procedure room cleaned. On 4/24/08 in the afternoon following the tour of the center, a physician stated the fan was in the	Q 011		

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Q 011	Continued From page 11 cleaning/decontamination room because of heat.	Q 011		
Q 016	416.44(c) EMERGENCY EQUIPMENT Emergency equipment available to the operating rooms must include at least the following: o Emergency call system. o Oxygen. o Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator. o Cardiac defibrillator. o Cardiac monitoring equipment. o Tracheostomy set. o Laryngoscopes and endotracheal tubes. o Suction equipment. o Emergency medical equipment and supplies specified by the medical staff. This STANDARD is not met as evidenced by: Based on observation and interview, the center failed to ensure emergency equipment including a ventilator was available for the procedure room. Findings include: Observation On 4/21/08, 4/23/08, and 4/24/08 in the late afternoon, a medium, blue, box-like piece of equipment was observed in the corner on a counter in the recovery room area. Interview On 4/21/08 in the late afternoon, a staff member indicated the equipment was a ventilator that was not "set up yet."	Q 016		

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Q 016	Continued From page 12 On 4/24/09 in the late afternoon, the Nurse Manager stated she was making arrangements to have the ventilator "serviced." The Nurse Manager acknowledged a ventilator was required but had experienced difficulty getting it serviced and ready for use.	Q 016		
Q 019	416.45 MEDICAL STAFF The medical staff of the ASC must be accountable to the governing body. This CONDITION is not met as evidenced by: The center failed to ensure all physicians had periodic appraisals had been completed for 3 of 10 practicing physicians (#7, #8, and #9) and failed to assure the credentialing process for these physicians was completed as outlined in the center's By-laws under Article 4 (Q0020). The cumulative effect of these systemic practices resulted in the failure of the center to deliver statutory mandated accountability to the governing body by the medical staff.	Q 019		
Q 020	416.45(a) MEMBERSHIP AND CLINICAL PRIVILEGES Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges in accordance with recommendations from qualified medical personnel. This STANDARD is not met as evidenced by: Based on staff interview and record review, the center failed to assure periodic appraisals had been completed for 3 of 10 practicing physicians who perform clinical procedures (#7, #8, and #9).	Q 020		

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Q 020	Continued From page 13 Findings include: On 4/23/08 and 4/24/08 a record review was made of the center's By-laws. Article 4 of the center's By-laws provided the requirement for "Medical Staff Qualifications." Included in this Article were the provisions for current staff under Section 4.02 "Ongoing Requirements" and Section 4.04 "Medical Staff Recommendations." These provisions included each physician to maintain standards, as outlined by the By-laws under Section 4.02. The provisions of Section 4.04 provided the Governing Body would request the medical staff fully investigate and evaluate all matters relating to medical staff membership status and clinical privileges. Article 4 Section 4.04 stated in part, "The medical staff shall adopt and forward written recommendations to the Board of Directors. The Board of Directors shall act in such matter only after considering the recommendations of the medical staff..." Section 4.06, paragraph (a) outlined the "Reapplication of Privileges" and stated all physicians must reapply every three years or privileges with the center. Review of the credentialing files for physicians #7, #8, and #9 found no evidence the center had conducted a review of the physicians related to the standards set forth under Article 4, Section 4.02 or the Board of Directors had reviewed any reapplications for privileges as set forth under Article 4, Section 4.04. The center did not provide any other records that contained information related to the reapplication and review privileges for current medical staff. An interview was conducted with the Nurse Manager on 4/24/08 at 4:00 P.M. The Nurse Manager confirmed the credentialing files were	Q 020		

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	29C0001057		04/24/2008

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Q 020	Continued From page 14 not complete. The Nurse Manager stated the reapplication process for the three current physicians performing procedures at the center had not been started and were late. The original date of application for physician #7 was 8/13/04; physician #8 was 4/30/04; and physician #9 was 8/3/04.	Q 020		
Q 026	416.47(a) ORGANIZATION The ambulatory surgical center 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 observation and interview, the center failed to maintain a secure system for the storage of patient records. Observation 1. On 4/21/08 in the afternoon during a tour of the center, medical records were observed in a small room near the receptionist's office; the small room also housed electrical and computer equipment. Observation of the small room included: a. Two large bookcases with locking lids were filled with patient records. b. The patient records extended beyond the edge of the bookcase shelves and the locking lids could not be closed. c. The door to the small room containing the patient records was open to an interior hallway. d. No one was present in the small room. 2. On 4/21/08 in the afternoon during a tour of the center, medical records were observed in the receptionist's office. Observation of the	Q 026		

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Q 026	Continued From page 15 receptionist's office included: a. One large bookcase with a locking lid was filled with patient records. b. The patient records extended beyond the edge of the bookcase shelves and the locking lids could not be closed. c. The door to the receptionist's office was propped open. 3. On 4/23/08 in the afternoon during a tour of the center, medical records were observed in both the small room near the receptionist's office and in the receptionist's office. In both locations, the patient records extended beyond the edge of the bookcase shelves and the locking lids could not be closed. The doors leading out of both the small room and receptionist's office were open to an interior hallway. There was no one present in the small room near the receptionist's office. Interview On 4/23/08 at 2:05 PM, the Nurse Manager stated the patient records extended beyond the edge of the bookcase shelves and closing/locking the bookcase lids did not occur routinely.	Q 026		
Q 027	416.47(b) FORM AND CONTENT OF RECORD The ambulatory surgical center 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: o Patient identification o Significant medical history and results of physical examination o Pre-operative diagnostic studies (entered before surgery), if performed	Q 027		

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Q 027	Continued From page 16 o Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body. o Any allergies and abnormal drug reactions o Entries related to anesthesia administration o Documentation of properly executed informed patient consent o Discharge diagnosis. This STANDARD is not met as evidenced by: Based on interview and record review, the center failed to maintain a properly completed medical record for 8 out of 16 patients (#1, #2, #3, #4, #5, #6, #7, and #8.) Record Review 1. The medical records for patients #1, #2, #3, #4, #5, #6, and #8 contained a form titled "Anesthesia Record." The back of the "Anesthesia Record" had a section titled "Post Anesthesia Care Unit Orders" with spaces for the following 4 entries: a. Entry #1 stated"O2 (oxygen)_____L/M (liters per minute) to maintain SAO2 (saturation of arterial blood with oxygen)_>_____%, b. Entry #2 _____, c. Entry #3_____, and d. Entry #4 "Transfer to unit when anesthesia discharge criteria is satisfied." The "Post Anesthesia Care Unit Orders" were not completed by the anesthesiologist for patients #1, #2, #3, #4, #5, #6, and #8. Entries #1, #2, and #3	Q 027		

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Q 027	Continued From page 17 were not completed. A registered nurse signed off the orders with the first initial, last name, and the date. 2. Patient #6 had a colonoscopy and polypectomy performed on 4/22/08 in the morning. The patient's pre-procedure BP (blood pressure) was 139/86 and pulse was 80. At 9:14 AM the patient arrived in the recovery room with a BP of 88/58 and pulse of 66. At 9:17 AM the BP was 78/58, pulse was 65, and the patient was "placed in Trendelenberg" (head down) position and "IVF's (intravenous fluids) wide open." At 9:32 AM the last BP was recorded as 117/72. The patient was discharged with his father "in stable condition." There was no documentation of orders received from the anesthesiologist while the patient was in the recovery room. 4. The medical record for patient #7 contained a consent for "endoscopy, administration of conscious sedation by a licensed anesthesiologist, and/or the rendering of other medical services." The consent was signed by the patient but was not dated and did not have a witness signature or time listed. Interview 1. On 4/23/08 in the afternoon, the Nurse Manager indicated the recovery room nurse assessed the patient's status and then made decisions regarding the need for oxygen and intravenous fluids based on the patient's status. The Nurse Manager confirmed the "Post Anesthesia Care Unit Orders" were not completed for patients #1, #2, #3, #4, #5, #6, and #8. The Nurse Manager confirmed the consent for patient #7 was not complete.	Q 027		

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