



June 22, 2010

The Honorable Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3217-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Medicare Program; Ambulatory Surgical Centers, Conditions for Coverage; CMS-3217-P,  
Proposed Rule

Dear Acting Administrator Tavenner:

The American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) appreciate the opportunity to provide comments on CMS's proposed rule on ambulatory surgical centers that would modify the current conditions for coverage (CFC) for patient rights to include an exception that would allow a patient to receive care in an ASC setting on the same day he or she receives a physician referral for the ASC service(s) and when a delay in providing the service(s) would adversely affect the patient's health. Our three societies represent virtually all practicing gastroenterologists in the United States.

The AGA, ACG and ASGE appreciate CMS's recognition that patients may need to receive care in an ASC setting on the same date as being evaluated by a specialist with little notice in order to protect a patient's health. We are, however, extremely concerned about CMS's proposed language on page 21209 that states . . . "(1) The written referral was signed and dated by the physician on the date the patient was presented at the ASC for the service(s): . . ."

The requirement that a patient obtain a written referral is an unrealistic expectation to meet when a patient is presenting to the ASC for an immediate procedure. There is also no proof that a written referral contributes to improved patient care. In addition, the requirement for a referral may cause an unnecessary delay in care. It would also serve no purpose to require a

written referral after the procedure is performed in order to meet the requirements in the regulation.

We believe that the physician deeming the procedure in the ASC setting as medically necessary, urgent and safe to be performed in the ASC setting, should be sufficient without requiring the additional burden of requiring the patient to obtain a written physician referral.

We have several examples below on why a written referral is not workable for gastroenterologists:

1. Open access colonoscopy is the process whereby a patient can obtain a screening colonoscopy in an ASC setting. Patients can self-refer for a screening colonoscopy without a referral from a physician. A screening colonoscopy may identify a polyp, which is removed during the procedure. If the patient is discharged from the ASC and post-procedure has a GI bleed, it is appropriate to have the patient return to the ASC for colonoscopy and management of the bleed. However, the patient who self-referred and did not have a primary physician would have no one to provide a written referral. Therefore, item (1) above would not be able to be met under the CFC regulations but the patient would still have an urgent situation that would require the ability to be treated at the ASC.
2. An existing patient with a known history of an esophageal stricture contacts the gastroenterologist with complaints of inability to swallow from a potential food bolus obstruction. The gastroenterologist determines that the patient needs to have an urgent upper endoscopy that same day, and that it can be safely performed in the ASC. Since the patient is already under care of that gastroenterologist, a physician would not provide a referral to himself/herself to provide to the patient; therefore, the referral requirement could not be met.

**Recommendation: Since there is no evidence that a written referral improves care quality, the GI societies request that CMS strike the text from (1) above in the final rule and not require a written referral for a same day procedure in an ASC setting.**

We are also concerned with language on page 21209 of the proposed rule that states ... “2) a physician in the ASC or the referring physician communicates in writing and the ASC documents in the medical record that the procedure must be performed as soon as possible to safeguard the health of the patient.”

We believe the language should be broadened to allow same-day procedures in cases that are not necessarily related to safeguard the health of the patient. For example, in rural and frontier areas, and with referrals to academic or tertiary centers, patients may drive long distances to receive care. Often, a patient will be referred for non-emergent service that can be performed in an ASC on the same day. For these patients in rural areas, it would inconvenience the patient and their transportation/caregiver or may impose a hardship on a patient to return at a later date. The physician may be concerned that a patient will decide to delay care if they are required to return at a later date, resulting in adverse health outcomes. In circumstances that

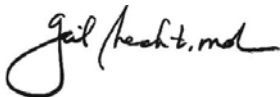
allow a patient to schedule a procedure in an ASC on the same date, there is no reason for CMS to make that patient wait until a later date to receive care. CMS has stated that the goal of this proposed regulation is to further protect patients' rights in the ASC setting. However, by broadening this exception and by requiring written referral, CMS will limit a patient's right to receive expeditious, medically necessary care which is in the best interest of the patient.

Allowing this exception would enable appropriate access to care for the patient and also benefit the Medicare program. In addition, this may help to preserve the Medicare trust funds as it reduces the potential for the patient's care being shifted to the emergency department or more costly hospital outpatient setting for the same procedure.

**Recommendation: The GI societies recommend that the above language in (2) be amended as follows: (2) a physician in the ASC or the referring physician communicates in writing and documents in the ASC medical record that the procedure must be performed as soon as possible to safeguard the health of the patient or to serve the best interest of patient care.**

Our societies appreciate the opportunity to provide comments on the proposed changes to the ASC conditions for coverage. If we may provide any additional information, please contact Anne Marie Bicha, Director of Regulatory Affairs, AGA, at 240-482-3223, or [abicha@gastro2.org](mailto:abicha@gastro2.org); Brad Conway, Vice President of Public Affairs, ACG, at 301-263-9000, or [bconway@acg.gi.org](mailto:bconway@acg.gi.org); or Camille Bonta, consultant to ASGE at 202-320-3658.

Sincerely:



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