



# AMERICAN COLLEGE OF GASTROENTEROLOGY

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May 23, 2011

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## Clarifications to the Ambulatory Surgical Center Interpretive Guidelines- Comprehensive Medical and History & Physical (H&P) Assessment

Dear Mr. Hamilton,

The American College of Gastroenterology (College) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers over 12,000 physicians among its membership of health care providers of gastroenterology specialty care. The College focuses its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, promoting evidence-based medicine and optimizing quality care.

The ambulatory surgical center (ASC) is an important part of the practice of gastroenterology, providing a safe, patient friendly and cost effective environment for the provision of medical services for patients of all ages. According to a 2011 U.S. Department of Health & Human Services report to Congress, of the more than 5,000 Medicare-certified ASCs in the United States, 33 percent of total CY 2009 Medicare ASC claims came from gastrointestinal procedures.<sup>1</sup> The majority of ASCs in which gastroenterologists practice are single specialty centers. In many rural areas, an ASC is the only setting by which Medicare beneficiaries can receive care without traveling great distances to a hospital. Because of their single-specialty structure and ability to create access to care for many patients, gastrointestinal ASCs are particularly sensitive to Medicare coverage policies and guidelines.

## Background

On December 17, 2010, the Centers for Medicare and Medicaid Services (CMS) released a set of clarification guidelines regarding comprehensive medical history and physical (H&P) assessments in the ASC setting. These guidelines state that “it is not acceptable to conduct the H&P after the patient has been prepped and brought into the operating or procedure room.”<sup>2</sup> Also, “if the H&P is conducted after admission to the ASC and on the date of the surgery, some elements of the pre-surgical assessment may be incorporated in the H&P. This does not apply to the anesthetic/procedure risk assessment required under 42 CFR 41642 (a)(1); this assessment must be performed by a physician immediately before surgery and after the H & P.”<sup>3</sup>

The College agrees that a comprehensive H&P and anesthesia risk assessment prior to surgery is crucial to assessing the patient's overall condition and to determine whether a particular procedure should be performed on a patient at that time. The College also agrees with CMS that for many services performed in the ASC setting, such as colorectal cancer screening, an H&P directly before the procedure does not raise any issue of patient care or place the patient at risk of harm.

However, many ASCs around the country and in rural areas are very small and do not have additional office space to perform an H&P outside of the operating or procedure room without significant threats to patient confidentiality and facility efficiency. In those ASCs with limited space, our members have expressed concern with the current interpretive guidelines as drafted because it requires the H&P to be performed in the waiting area or pre-operating area, both areas where other patients are present. The College fears that the clarifications as drafted requires our membership to weigh violating the patient confidentiality provisions set forth in the Health Insurance Portability and Accountability Act (HIPAA) versus violating these condition of coverage guidelines. Also, any waiting line to the an office in the facility (if available) or pre-operating bed occupied for an H&P disrupts the ability to see more patients in a workday and therefore impacts patient access to services.

The H&P and pre-surgical assessment guidelines allow certain pre-surgical assessment to be incorporated into the H&P if the procedure is performed on the same day but the assessment of the patient's anesthesia risk must be performed immediately prior to surgery.<sup>4</sup> We urge CMS to allow ASC facilities to operate more efficiently and in a manner that does not threaten patient safety or quality of care. The guidelines require physicians to perform the H&P outside the operating room but the pre-surgical assessment must be performed immediately prior to surgery in the operating room. The College believes that if CMS allows certain pre-surgical assessments to be incorporated into the H&P then the H&P should also be allowed in the operating room as well. It is unlikely there will be a change in the patient's overall condition as the patient is being transferred from the pre-operating room to the operating room. CMS notes in these guidelines that the rationale for requiring H&Ps outside the procedure room is to determine whether there is something in the patient's overall condition that might affect the procedure, or even require cancellation of the procedure. The College believes this is also the purpose of the pre-surgical anesthesia assessment, which again, is allowed in the operating room.

### **ACG Recommendations**

The College encourages CMS to consider two recommendations that we believe would maintain the importance of assessing the patient prior to a procedure while allowing ASCs to operate more efficiently.

### **Amended Language**

CMS notes that these guidelines may be amended.<sup>5</sup> The College requests CMS to revise this language clarifying the regulation on the H&P and pre-surgical assessment in the ASC setting.

The College recommends CMS modify these interpretive guidelines to read:

*If the H&P required under §416.52(a)(1) is performed on the same day of the surgical procedure in the ASC, a comprehensive H&P and the assessment of the patient's risk for the procedure and anesthesia required under §416.42(a)(1) must be conducted by a physician immediately prior to surgery.*

### Pre-Operative Visit

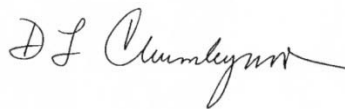
The College continues to urge CMS to provide Medicare coverage for a pre-operative visit for services such as screening colonoscopy.<sup>6</sup> Although adverse events are rare, both diagnostic/therapeutic and screening colonoscopies involve risk to the patient. While Medicare provides coverage for a pre-operative office visit prior to a diagnostic colonoscopy, the identical service for a screening colonoscopy remains uncovered. It has long been the standard of care for a gastroenterologist to ascertain a patient's medical history and health status prior to sedating the patient for purposes of a colorectal cancer screening procedure. However, Medicare does not provide coverage for a pre-operative visit for asymptomatic Medicare beneficiaries undergoing routine screening. From a clinical perspective, a screening colonoscopy and a diagnostic colonoscopy are the same procedure, thus making the pre-operative visit just as important for a screening colonoscopy.

This coverage discrepancy may contribute to the situation CMS is seeking to avoid with these H&P guidelines. However, for physicians performing procedures in ASCs there is little choice for a private conversation *except* in the procedure room. Medicare coverage for a pre-operative visit for services such as screening colonoscopy allows our membership to more easily follow to these guidelines as it gives patients the option to see physicians in a comfortable and private setting -- the physician's office -- prior to the date of the procedure and also allows the facility to continue to operate in an efficient manner.

The lack of an opportunity to sit and discuss a screening colonoscopy is a demonstrated barrier to increasing colorectal cancer screening utilization rates.<sup>7</sup> A pre-operative visit will also help foster a physician-patient relationship, in order to assess gastrointestinal issues the patient may be experiencing or to help any questions the patient may have regarding the screening. This is important because under Medicare coding rules, any patient undergoing screening colonoscopy is now an "established patient" with that physician performing the procedure even though there is *no established relationship* with the patient. This situation happens frequently and College believes that this is not good medicine and does not promote the quality of care Medicare beneficiaries deserve. The College believes that if CMS would like the H&P and pre-surgical assessment to be performed separately, this pre-operative visit should be covered under Medicare.

The College appreciates the opportunity to comment on these conditions of coverage guidelines and welcomes the opportunity to further discuss this proposal with CMS. Please contact Brad Conway, Vice President of Public Policy, at 301.263.9000 or [bconway@acg.gi.org](mailto:bconway@acg.gi.org) with any question or for more information relating to the impact of this regulation.

Sincerely,



Delbert L. Chumley, MD, FACC  
President, American College of Gastroenterology



March E. Seabrook, MD, FACC  
Chair, ACG National Affairs  
Committee

1. U.S. Department of Health & Human Services Report to Congress: Medicare Ambulatory Surgical Center Value-Based Purchasing Implementation Plan; April 2011.
2. CMS letter to State Survey Agency Directors: Clarifications to the Ambulatory Surgical Center Interpretive Guidelines- Comprehensive Medical History & Physical Assessment.; December 17, 2010. S&C-11-06-ASC.
3. CMS letter to State Survey Agency Directors: Clarifications to the Ambulatory Surgical Center Interpretive Guidelines- Comprehensive Medical History & Physical Assessment.; December 17, 2010. S&C-11-06-ASC.
4. CMS letter to State Survey Agency Directors: Clarifications to the Ambulatory Surgical Center Interpretive Guidelines- Comprehensive Medical History & Physical Assessment; December 17, 2010. S&C-11-06-ASC.
5. CMS letter to State Survey Agency Directors: Clarifications to the Ambulatory Surgical Center Interpretive Guidelines- Comprehensive Medical History & Physical Assessment; December 17, 2010. S&C-11-06-ASC.
6. American College of Gastroenterology Letter to Health & Human Services Secretary Kathleen Sebelius; September 15, 2010.
7. NIH State of the Science Conference: Colorectal Cancer Screening; February 2010. "Colon Cancer Alliance" Survey on Barriers to Colorectal Screening; March 2011.