January 27, 2014

Marilyn Tavenner, MHA, BSN, RN
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1601-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC  20201

Re: CMS-1601-FC – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule and CY 2014 Payment Rates

Dear Administrator Tavenner:

The American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE) welcome the opportunity to provide comments on the Centers for Medicare and Medicaid Services’ (CMS) final rule (CMS-1601-FC), published in the Federal Register on December 10, 2013 regarding final changes to the hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system for CY 2014.

While we continue to be concerned about a number of provisions in the ASC payment system including the inflation factor used to update ASC payment, our societies welcome the opportunity to provide comments on the following areas in the final rule:

• Process for assignment of new Category I and III CPT codes to APCs
• Ambulatory Payment Classification (APC) assignment for GI CPT codes
• Development of a new APC for Gastrointestinal Capsule Procedures
• Inclusion of Endoscopy Surveillance Measures in the ASC Quality Reporting Program

Process for Assignment of New Category I and III CPT Codes to APCs

As has been CMS’ practice in the past, the agency has included in the OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2014. Our societies urge CMS to revise this policy and release the new Category I and III CPT codes in the proposed rule. Doing so will allow the public to provide comment before the final rule is released and affords the opportunity to make any necessary revisions before ambulatory payment classification (APC) assignment of these new procedures is finalized for the following year.
APC Assignment for GI CPT Codes

We agree with CMS that it is necessary to ensure clinical and resource homogeneity when determining code assignment to APCs. During our review of APC assignments for GI procedures, we have identified inconsistencies in APC assignments and are concerned that some codes have been assigned to inappropriate APCs.

GI Procedures with Stents

In the Final Rule, CMS assigned new CPT codes 43274, Endoscopic retrograde cholangiopancreatography (ERCP); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent, and 43276, Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), each stent exchanged, to APC 0151, ERCP. While these codes are part of the ERCP clinical family, our societies believe they should be placed in APC 0384, GI Procedures with Stents, particularly since metal stents are routinely used in these procedures. Codes 43274 and 43276 replaced codes 43268, Endoscopic retrograde cholangiopancreatography (ERCP); with endoscopic retrograde insertion of tube or stent into bile or pancreatic duct, and 43269, Endoscopic retrograde cholangiopancreatography (ERCP); with endoscopic retrograde removal of foreign body and/or change of tube or stent, which were assigned to APC 0384. The new codes also bundle dilation and guide wire placement, which indicates that more resources are involved. In addition, code 43240, Esophagogastroduodenoscopy, flexible, transoral; transmural drainage, pseudocyst, involves the transgastric placement of metal stents into a pancreatic pseudocyst, but has been assigned to APC 0419.

Given that all other GI endoscopic stent placement procedures are assigned to APC 0384, we believe it is inconsistent to assign these three GI procedures involving stent placement to a non-stent APC. We note that codes 43212, Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed), which replaced code 43219, Esophagoscopy, rigid, transoral; with insertion of plastic tube or stent, and code 43266, Esophagogastroduodenoscopy, flexible, transoral; with place of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed), which replaced code 43256, Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with transendoscopic stent placement (includes predilation), were appropriately assigned to APC 0384 in the final rule. Our societies seek further clarification from CMS on its rationale regarding APC assignment for GI procedures with stents and urge CMS to reassign codes 43274, 43276 and 43240 to APC 0384, GI Procedures with Stents.

Endoscopic Mucosal Resection

Our societies are extremely concerned that codes 43211, Esophagoscopy, flexible, transoral; endoscopic mucosal resection, and 43254, Esophagogastroduodenoscopy, flexible, transoral; endoscopic mucosal resection, were inappropriately placed in APC 0141, Level I Upper GI Procedures. We believe that endoscopic mucosal resection (EMR) procedures are more complex procedures than the CPT codes currently included in APC 0141, Level I Upper GI Procedures. Endoscopic mucosal resection is a procedure to remove cancerous or other abnormal tissues from the digestive tract by a combination of injection-assisted, cap-assisted and ligation-assisted techniques. These procedures involve the identification and demarcation of the lesion, submucosal injection to lift the lesion, placement of bands to create a pseudopolyp, and endoscopic snare resection. Prior to 2014, the only way to report EMR procedures was through the billing of multiple codes that best described the various components of the EMR procedure. For example, before the development of code 43254, an Esophagogastroduodenoscopy EMR would have been billed using codes 43251, Esophagogastroduodenoscopy, flexible, transoral; with
removal of tumor(s), polyp(s), or other lesion(s) by snare technique, and 43236, Esophagostroduodenoscopy, flexible, transoral; directed submucosal injection, an EMR with injection. In the 2014 Final Rule, existing codes that include only part of an EMR procedure are assigned to higher level APCs than the full EMR procedure. For example, CPT code 43251 includes one of the main treatments included in EMR and it has been assigned to APC 0419, Level II Upper GI Procedures.

We do not believe that these assignments for the above mentioned EMR procedures accurately reflect the estimated cost and complexity of these procedures; therefore we urge CMS to reassign these procedures to APC 0419, consistent with the resource and clinical homogeneity principles.

Development of a New APC for Gastrointestinal Capsule Procedures

Our societies consistently believe that code 91112, Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report, has been inappropriately assigned to APC 0361. Performance of gastrointestinal transit and pressure measurement requires the patient to swallow a disposable capsule. CMS received practice expense information when this code was valued in the physician fee schedule, and has established a supply cost of $600 for SD272.

Accordingly, our societies believe that assignment of code 91112 to APC 0361, Level II Alimentary Tests, violates the two times rule which states that “items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than two times greater than the lowest cost for an item or service within the same group.”

The AMA has established code 0355T, Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report, which will become effective on July 1, 2014. Similar to codes 91110, Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report, and code 91111, Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report, the clinical coherence of these tests are identical. The patient swallows a capsule, and wears monitoring equipment which tracks the physiologic and/or image findings from the digestive tract. The resources, primarily the cost of the capsules and the monitoring equipment for performing these procedures, are relatively similar. Our societies request that CMS create a new APC for Gastrointestinal Capsule procedure codes:

- 91110 Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report
- 91111 Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
- 91112 Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
- 0355T Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report

Together, these four codes meet CMS’ clinical and resource homogeneity principals governing APC assignment. We encourage CMS to consider establishing a new APC for these procedures in CY 2015.
January 27, 2014

ASC Quality Reporting Program

As our societies have stated in previous comments, we support quality reporting by ASCs and appreciate that implementation of the ASC Quality Reporting Program is an evolutionary process. However, we are disappointed with CMS’ decision to finalize two endoscopy/polyp surveillance measures for the ASC Quality Reporting Program CY 2016 payment determination and beyond.

- **Endoscopy/Polyp Surveillance**: Appropriate follow-up interval for normal colonoscopy in average risk patients. (NQF #0658 / ASC-9)

- **Endoscopy/Polyp Surveillance**: Colonoscopy interval for patients with history of adenomatous polyps – avoidance of inappropriate use. (NQF #0659 / ASC-10)

Our societies oppose the inclusion of these measures in the ASC Quality Reporting Program because the measures are not appropriate for measuring facility-level performance and because of the potential for significant administrative burden on ASCs for reporting these measures.

Our societies believe it was appropriate for CMS to delay the data collection requirements for these measures until April 1, 2014. We do not believe these measures should be implemented as finalized and ask CMS to reconsider their inclusion in the ASC Quality Reporting Program for the CY 2016 payment determination and beyond.

**Appropriateness of Endoscopy/Polyp Surveillance Measures as Facility-Level Measures**

We believe the ASC Quality Reporting Program measures for the CY 2014 and CY 2015 payment determinations were largely relevant to the types of gastroenterology services provided in the ASC. These measures promote improvement in patient care and safety and reflect the variables within the control of the facility, including quality of care provided by the facility staff, processes of care, and preventive measures. The ASC Quality Reporting Program should focus on conditions and performance aspects within the direct control of the facility and which lead to greater patient safety. Therefore, we are of the strong opinion that the endoscopy/polyp surveillance measures (ASC-9 and ASC-10), which are utilization measures developed and endorsed for analysis at the clinician level, are not appropriate measures for the ASC Quality Reporting Program.

The above noted endoscopy/polyp surveillance measures are very good measures, and our societies have promoted their use as physician quality measures. Both measures are available for reporting under the Physician Quality Reporting System (PQRS) for the 2014 performance year. However, the recommended surveillance intervals for colonoscopy or the documentation of those recommended intervals are not under the control of the facility. Rather, the physicians should be held accountable for their documentation and compliance with recommended surveillance intervals and this is why these measures are appropriate for PQRS.

We believe use of these measures is important to achieving shared accountability between the physician and the ASC, but shared accountability can be achieved without requiring the facility to report on measures that are already being reported by the physicians who provide care in the ASC. We agree with the February 2013 Measure Applications Partnership’s (MAP) Pre-Rulemaking Report which recommended that, for the ASC Quality Reporting Program, the endoscopy/polyp surveillance measures should be tested and National Quality Forum-endorsed at the facility level for analysis. Furthermore, the MAP concluded that it “Supported Direction” for both measures, but they were not ready for
implementation in the ASC Quality Reporting Program because of “concerns regarding feasibility of data collection.”

It is important for CMS to draw a distinction between a measure that is endorsed for use in an ASC and a measure that is endorsed as a facility measure. Both endoscopy/polyp surveillance measures are endorsed for use in the following settings: ASC, Clinician Office/Clinic, Urgent Care, Hospital/Acute Care Facility. However, the level of analysis for which the measures are endorsed is the clinician level: group/practice, individual, and team.

We are also concerned that using the endoscopy/polyp surveillance measure (NQF #0659 / ASC-10) for the ASC Quality Reporting Program could harm the integrity of the measure through overuse of exclusions. For NQF #0659 / ASC-10, among the exclusions is “documentation of system reason(s) for an interval of less than 3 years since the last colonoscopy (e.g., unable to locate previous colonoscopy report).” It is possible that the difficulty the ASC will have in obtaining this information from the physician will lead to overuse of this measure exclusion for ASC reporting, which could lead to skewed performance results or results that are inconsistent with those derived from PQRS or individual clinical quality data registries.

**ASC Reporting Burden for Endoscopy/Polyp Surveillance Measures**

*Obtaining Information not within the Control of the ASC*

As noted above, the endoscopy/polyp surveillance measures are not in direct control of the facility. Typically, decisions about colonoscopy intervals are based on information obtained during an office visit and upon review of a patient’s medical record, which would not be maintained by the ASC unless the ASC was the site of service for the patient’s last colonoscopy. To report the endoscopy/polyp surveillance measures and document any exclusions, the facility will be required to obtain additional clinical history from the physician who performs the colonoscopy.

For ASCs whose physicians report the endoscopy/polyp surveillance measures to a clinical quality data registry, information for reporting the endoscopy/polyp surveillance measures will be more easily attainable. Regardless, the burden remains on the facility to obtain measure exclusion information for accurate reporting through QualityNet.org. We suggest that rather than require ASCs to report physician-level measures that are already being reported by physicians to clinical data registries and CMS through PQRS, CMS should identify ways to link physician quality data reporting and performance to their site-of-service, particularly when providing the public with information for making decisions about where and from whom to receive health care services.

*Questions about Population Sampling*

The OPPS/ASC final rule states, “...we are permitting ASCs to collect information on a sample of eligible patients, with minimal case number requirements, instead of requiring the collection of information on all eligible patients. Sampling is a process of selecting a representative part of a population in order to estimate the ASC’s performance, without collecting data for its entire population. In this way, using a statistically valid sample, an ASC can measure its performance in an effective and efficient manner. Sampling will reduce burden significantly for ASCs with high volume because the number of cases that must have data reported will be significantly reduced. We have provided the option of sampling in other quality reporting programs when we have determined that it would be appropriate, including the Hospital IQR and OQR Programs.”
The above final rule language and ASC Quality Reporting Program Specifications Manual (Version 3.0a) do not provide clear expectations of ASCs for collecting data for endoscopy/polyp surveillance measures. While CMS has minimized the burden of reporting the endoscopy/polyp surveillance measures by requiring ASCs to report on a sample of cases for the CY 2016 payment determination, depending on CMS’ expectations for patient population sampling, reducing the reporting requirements may not necessarily reduce the burden of information collection.

According to the Hospital Outpatient Quality Reporting Program Specification Manual for 2014, “Hospitals that choose to sample must ensure that the sampled data represent their outpatient population by using either the simple random sampling or systematic random sampling method and that the sampling techniques are applied consistently within a quarter.”

For ASCs to conduct sampling, it appears it will require ASCs to ensure that the medical records for each case include measure data elements, which from a sample population will be extracted and reported. In effect, reporting on a sample of patients for the endoscopy/polyp surveillance measures does not necessarily mitigate the burden on ASCs. ASCs will need to establish systems by which to collect this information on all cases from physicians and input this data into the ASC patient medical record. We believe, as stated above, this burden on ASCs should be avoided because an increasing number of gastroenterologists are reporting the endoscopy/polyp surveillance measures to CMS via the various reporting mechanisms available to eligible professionals for participation in PQRS.

**Endoscopy/Polyp Surveillance Measure Reporting Alternatives**

Facility-based ASC Quality Reporting Program measures should complement clinician-level measures. If CMS is interested in increasing the number of measures for the ASC Quality Reporting Program, CMS should give priority to the development, testing and use of facility measures. Our societies have previously suggested measure topics for the ASC Quality Reporting Program, as well as modifications to existing measures. We look forward to working with CMS to identify and develop appropriate facility-level measures.

We believe the endoscopy/polyp surveillance measures (ASC-9 and ASC-10) should not be implemented as finalized. If CMS is unwilling to remove these measures from the ASC Quality Reporting Program, we recommend the following reporting options to minimize the burden of measure data collection, as well as reporting duplication:

- ASCs could fulfill reporting requirements by attesting they require their physicians to participate in a data registry that collects all-patient data on the two proposed endoscopy/polyp surveillance measures.

  and/or

- ASCs could attest that a majority (or choose a number such as 70%) of the physicians who perform colonoscopy screening and surveillance procedures in the ASC to report these measures through PQRS using any of the reporting mechanisms available to eligible professionals.

Under each alternative, the ASC could be required to obtain registry or PQRS reports from their physicians. For example, if a physician participates in a CMS-certified qualified clinical data registry (QCDR), the physician would submit a report to the ASC generated by the QCDR showing his/her
compliance with the measures. We believe these alternatives would greatly reduce the burden on ASCs and accomplish CMS’ objectives.

Another, and least burdensome, alternative would require an ASC to provide documentation to CMS that it has a system of review and education of practice standards and guidelines in place for its physicians.

We support the ASC Quality Reporting Program and look forward to working with CMS to make sure that the reporting requirements on ASCs are feasible and understandable, and the measures reflect variables within the control of the facility and promote improvements in patient care and safety.

Conclusion

The ACG, AGA, and ASGE appreciate the opportunity to provide comments on the 2014 hospital outpatient prospective payment and ambulatory surgical center payment systems final rule. If we may provide any additional information, please contact Brad Conway, Vice President of Public Policy, ACG, at 301-263-9000 or bconway@gi.org; Elizabeth Wolf, Director of Regulatory Affairs, AGA, at 240-482-3223 or ewolf@gastro.org; or Camille Bonta, consultant to ASGE, at 202-320-3658 or cbonta@summithealthconsulting.com.

Sincerely,

Harry Sarles, Jr., MD, FACP
President
American College of Gastroenterology

Loren Laine, MD, AGAF
Chair
American Gastroenterological Association

Kenneth K. Wang, MD, FASGE
President
American Society for Gastrointestinal Endoscopy