September 4, 2012

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1589-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: CMS-1589-P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2013 Payment Rates

Dear Acting Administrator Tavenner:

The American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE) appreciate the opportunity to provide comments on CMS’ proposed rule (CMS-1589-P), published on July 30, 2012 in the Federal Register, regarding proposed changes to the hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system for CY 2013. Our three societies represent virtually all practicing gastroenterologists in the United States.

The 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, such as colorectal cancer screening, for patients of all ages. The majority of ASCs in which gastroenterologists practice are single specialty centers. According to a 2009 study prepared by KNG Health Consulting, LLC, of the more than 5,000 ASCs in the United States, 24 percent specialize in just gastrointestinal (GI) procedures. Because of their single specialty structure, GI ASCs are particularly sensitive to changes in Medicare payments.

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There are a number of provisions in the proposed rule that impact the practice of gastroenterology, particularly in the ASC setting. Our comments focus on the following issues:

**PAYMENT POLICY**
- ASC Inflation Update
- Multifactor Productivity Adjustment
- Process for Assignment of New Category I and III CPT Codes to Ambulatory Payment Classifications (APCs)
- Expiration of Transitional Pass-Through Payment for HCPCS Code C1749

**QUALITY IMPROVEMENT**
- ASC Quality Reporting Program

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**PAYMENT POLICY**

**ASC Inflation Update**

CMS has the discretion to use an alternative update factor to the default adjustment based on estimates of the Consumer Price Index for All Urban Consumers (CPI-U). We have repeatedly called upon CMS to use an alternative update factor. Specifically, we have recommended that ASC payments be updated annually using the hospital market basket. The continued use of what amounts to an arbitrary metric chosen more for its availability than is applicability creates an errant trajectory that varies further and further from true cost with each year it continues to be applied.

In the proposed rule, CMS provides a three percent upward adjustment of the OPPS market basket. After accounting for the 0.8 percent reduction for productivity, less an additional adjustment of 0.1 percent, the OPPS update will be 2.1 percent. Comparatively, the ASC update for calendar year (CY) 2013 will be 1.3 percent (2.2 percent CPI-U projection minus a projected productivity adjustment of 0.9 percent).

Our organizations support the comments offered by the Ambulatory Surgery Center Association (ASCA) on the ASC inflation update and productivity adjustment and offer the following supporting comments.

CMS states in the proposed rule that the CPI-U is “highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services.” Yet, CMS argues that the hospital market basket does not align with the cost structures of ASCs, nor does CMS believe that using the physician’s practice expense component of the Medicare

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2 Since publication of the proposed rule, CMS has issued the FY 2013 Hospital Inpatient PPS final rule which sets the market basket update at 2.6 percent, which is then reduced by a multi-factor productivity adjustment of 0.7 percent and an additional 0.1 percent reduction for an update of 1.8 percent.
Economic Index (MEI) is a better proxy for cost inputs of ASCs than the CPI-U. Therefore, CMS is proposing a continuation of the established policy of basing the ASC update on the CPI-U. In addition, CMS is seeking comment on the type of cost information that would be feasible to collect from ASCs to determine if either the hospital market basket, MEI, or an ASC-specific market basket would be a better proxy for ASC cost inflation than the CPI-U.

For most Medicare-covered surgical procedures provided in the ASC, the relative weight is based on the procedure’s relative weight under the OPPS. The payment rate is the product of the procedure’s relative weight and a conversion factor. For 2013, the OPPS conversion factor is $71.537. In contrast, the ASC conversion factor is proposed at $43.190, making payment rates lower for ASCs than for hospital outpatient departments (HOPDs). Under the revised ASC payment system, the ASC conversion factor, which is budget neutral, is intended to reflect the relative costliness of services between the ASC and HOPD. However, the use of different conversion factors for ASCs and HOPDs has resulted in a growing divergence between their Medicare rates. For example, the CY 2013 proposed ASC facility rate for a diagnostic colonoscopy (43578) is $389.60. Comparatively, the facility fee for diagnostic colonoscopy (43578) in the HOPD is $691.78. This represents a 56 percent difference in facility fee for performing the exact same procedure.

The ASC and HOPD compete in the labor market for exactly the same clinical staff and compete in the economic market for exactly the same medical supplies, although the ASC does not have the purchasing power of a hospital. The ASC and the HOPD must each comply with aspects of the Life Safety Code, and changes to and costs associated with accreditation requirements, as they pertain to the “bricks and mortar” of ASCs, increasingly mirror those of the HOPD. While ASCs may not have precisely the same cost structure as HOPDs, the hospital market basket more closely reflects the cost structure of ASCs than CPI-U and is, therefore, a more accurate inflation factor for ASCs.

We do not believe that an ASC-specific market basket will lead to better alignment between the ASC and HOPD. The difference between the ASC and HOPD conversion factor should be consistent from year-to-year. Consistency cannot be achieved through the continued use of the CPI-U for updating ASCs, nor can it be achieved by an ASC-specific market basket. Rather, consistency requires that both ASC and HOPD payments be updated using a single inflation factor.

There is great diversity among ASCs. As mentioned previously, it is estimated that at least a quarter of all ASCs specialize in GI endoscopic procedures only. This diversity does not lend itself well to an ASC-specific market basket. Because the hospital outpatient mix of services most closely resembles services provided across ASCs, we again request that CMS use the hospital market basket index for updating ASCs beginning CY 2013.

Furthermore, CPI-U is highly volatile and incorporates the changes in process for many goods and services unrelated to the costs in providing medical care, making it difficult for the government to accurately forecast. The hospital market basket has demonstrated predictability, while CPI-U varies among government and private sector forecasters, and wide swings from one
year to the next are more likely. For example, CPI-U in 2010 was 1.2 percent and jumped to 2.7 percent in 2012. In addition to the unpredictable nature of CPI-U, ASCs must also contend with an expected across-the-board two percent payment cut, or “sequester,” that will be effective January 2013 under current law.

In its March 2012 report, the Medicare Payment Advisory Commission (MedPAC) raised concern that the CPI-U may not reflect ASCs’ cost structure:

“Although CMS has historically used the CPI-U as the basis for Medicare’s annual updates to ASC payments, the mix of goods and services in this price index probably does not reflect ASC inputs. The CPI-U is based on a sample of prices for a broad mix of goods and services, including food, housing, apparel, transportation, medical care recreation, personal care, education, and energy (IHS Global Insight 2011). The weight of each item is based on spending for that item by a sample of urban consumers during the survey period. Although ASCs probably use some of these items, their share of spending on each item is likely very different from the CPI-U weight. For example, housing accounts for 43.4 percent of the entire CPI-U (Bureau of Labor Statistics 2009).”

We are disappointed that instead of trying to align the update factors for ASCs and HOPDs, CMS has chosen again to continue the use of an update factor that is not reflective of ASC costs. We believe that growing divergence between ASC and HOPD Medicare rates is a significant contributor to ASCs being acquired by hospitals or closing their doors entirely. While our evidence of GI ASC-hospital consolidation is anecdotal at this time, we assure you that it is occurring. Additionally, we know that hospitals that operate ASCs are choosing to close those ASCs and move the services into the HOPD at a greater cost to Medicare. As an August 27, 2012 Wall Street Journal article pointed out, these hospital acquisitions also place a strain on privately insured patients and businesses.

We believe that continued use of CPI-U is unreasonable and that in the absence of a compelling reason for why ASCs should continue to be updated using the CPI-U, we ask that CMS instead use the hospital market basket for updating ASC payments beginning CY 2013, thereby creating better alignment between ASC and HOPD Medicare payment rates.

**Multifactor Productivity (MFP) Adjustment**

As required by the Affordable Care Act, CMS proposes to reduce ASC rates by a measure of economy-wide productivity gains (a 10-year rolling average calculated by the Bureau of Labor Statistics). The proposed “productivity adjustment” is 0.9 percent. CMS proposes to use a separate estimate of productivity for the HOPD and ASC settings, meaning that the assumption of productivity gains for the ASC setting is higher than the assumed productivity gains for

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HOPDs. While recognizing that CMS is mandated to apply a productivity adjustment, we continue to have a number of concerns regarding CMS’ method for making this application. We maintain that the ASC productivity adjustment should be consistent with that of the HOPD. However, due to CMS’ proposed decision to calculate the productivity adjustments for the ASC and HOPD using different timeframes, the rule describes a 0.1 percent disparity between the two. We urge CMS to employ consistency in which the timeframe for the productivity adjustment is calculated for both the ASC and HOPD, which would eliminate the disparity of the MFP between the two settings, which also contributes to the divergence between the ASC and HOPD updates.

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

As has been CMS’ practice in the past, the agency is proposing to include in the OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013. Our societies urge CMS to revise this policy and release the new Category I and III CPT codes for the subsequent calendar year as part of 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 APC assignment of these new procedures is finalized for the following year. Our societies routinely go through great efforts, and at significant expense, to submit coding proposals before the CPT Editorial Panel and to provide input on physician work and practice expense to the Relative Value Update Committee (RUC). These efforts include a thorough vetting of the medical literature and discussions with the relevant experts before submitting proposals before the CPT Editorial Panel, and subsequently surveying our members to provide the RUC with accurate information regarding the physician work and time, supplies and equipment necessary to perform these services. Due to the current process of publishing codes in the final rule, our societies are left waiting for clarity until the Final Rule is published, which leaves no opportunity to comment prospectively on APC assignment for the subsequent calendar year.

**Expiration of Transitional Pass-Through Payment for HCPCS Code C1749**

Under the OPPS, a category of devices can be eligible for transitional pass-through payment for at least two, but not more than three years. The pass-through expiration date for a device category is the date on which pass-through payment is effective. Once the device is no longer eligible for pass-through payment, the cost of the device is packaged into the cost of the procedure with which the device is reported in the claims data used to set the payment rates.

Devices that are eligible for pass-through under the Medicare OPPS are also separately paid under the ASC payment system, which currently includes four devices, one of which is HCPCS code C1749 (endoscope, retrograde imaging/illumination colonoscope device (implantable)). As CMS notes in the proposed rule, effective December 31, 2012, CMS will package C1749 device costs into the cost of colonoscopy.

Our societies do not agree with CMS’ proposal to package the device into the cost of the colonoscopy. In February 2012, our societies supported a category I CPT code application to
establish a new code for the procedure, which the CPT Editorial Panel ultimately denied as they did not believe the procedure is separate from that of standard colonoscopy. The societies were disappointed by that decision as we believe the physician work and time and practice expense associated with the use of this device is additional to when a standard colonoscopy procedure is performed.

Additionally, data from a recently published clinical evaluation study indicates that the use of the device is more effective with therapeutic/diagnostic colonoscopies as opposed to screening colonoscopies. This distinguishes that it would not be appropriate to use the device for every colonoscopy procedure or for screening colonoscopies, thereby supporting the claim that the cost of the device should not be part of the standard cost of a colonoscopy. Packaging the cost of the device into the APC will preclude CMS from tracking the usage of this device, which is essential for the agency and others to better understand how the retrograde imaging device is being used and to assess its overall clinical efficacy as to whether it improves the adenoma detection rate for Medicare beneficiaries.

CMS assigned C1749 as pass-through status effective October 1, 2010, which was the first pass-through code the agency had issued in several years. We understand that there were significant implementation issues and confusion related to the code by various Medicare Administrative Contractors (MACs). In fact, our societies received numerous requests for assistance from members who wanted to use the device and felt it could benefit their patients, but they were experiencing significant problems with their local MACs who either claimed they did not understand how to process the code, assigned it such a low payment that ASCs or HOPDs could not cover the cost of the device, or refused to cover the device, and therefore, the ASC or HOPD would not permit its use. Ultimately, while the data for the ability of the retrograde imaging device to detect additional pre-malignant lesions in individuals with an existing history of polyps is promising, more data is needed to determine the clinical utility and appropriate role of the test. Extending the pass-through status of C1749 through 2013 will help to support additional data collection and will also ensure access for gastroenterologists and other endoscopists who believe it could improve their adenoma detection rates in patients who have a history of polyps or other significant findings. The code is still within the three-year window; therefore, we request that CMS enact its authority to extend the pass-through status for C1749, which will support further data collection and analysis.

Our societies ask CMS to extend the pass through status for C1749 in order to track utilization and better assess the clinical evidence to determine if the use of the retrograde imaging device not only leads to significant clinical improvement but also to improved patient care and outcomes.

QUALITY IMPROVEMENT

ASC Quality Reporting Program

ASC Education and Outreach
Our societies are educating members about the ASC Quality Reporting Program and are planning the third in a series of webinars for gastroenterologists, nursing personnel and practice administrators on the quality reporting program. GI ASCs were encouraged to begin practice reporting prior to the start of the 2012 reporting period (Oct. 1, 2012 – Dec. 31, 2012). We are asking GI ASCs to report any difficulties in having their claims with quality data codes received and processed by carriers and contractors. While we will continue with these outreach and education initiatives, we encourage CMS to develop and make available additional educational materials that will facilitate successful ASC participation in the new Quality Reporting Program. We greatly appreciate the responsiveness of CMS staff to our questions and their involvement in our educational webinars, and we are pleased that CMS will be holding an educational webinar on September 26, 2012. However, we do believe that ASCs would have benefited from the availability of CMS-developed educational materials earlier in the year. While we have been pleased with the number of GI ASCs that have participated in our webinars, we suspect that there are still a number of GI ASCs that are unaware of the program and reporting requirements.

Future ASC Quality Reporting Program Measures
We recognize that CMS is not proposing to delete or add any quality measures for the ASC Quality Reporting Program for the CYs 2014, 2015 and 2016 payment determinations or to adopt quality measures for subsequent payment determination years. We appreciate, however, that CMS is inviting comment on the inclusion of procedure-specific measures for colonoscopy, endoscopy and anesthesia-related complications.

We support process and outcomes measures that are both actionable and meaningful to GI ASCs, and our organizations want to lead the development of those measures in collaboration with ASCA. We believe that ASC Quality Reporting Program measures should be facility-based measures, and that measures associated with physician performance should be included in the Physician Quality Reporting Program (PQRS).

Measure topics we offer for consideration include:

- **Equipment Reprocessing** – High-level disinfection and sterilization, with a particular emphasis on endoscope reprocessing. We welcome an opportunity to work with CMS on the development of measures to ensure that appropriate cleaning and disinfection/sterilization processes are followed during endoscopy reprocessing, promoting patient safety. We believe that such measures should be derived from multi-society endorsed endoscope reprocessing guidelines.

- **Sedation Safety** – A possible anesthesia-related measure could include the use of reversal agents.
• Post-Discharge Emergency Department Visit within 72 Hours of ASC Procedure.

Additionally, we suggest that CMS consider for future ASC Quality Reporting Program years modifying the current hospital transfer/admission measure into a hospital transfer/admission measure for various immediate complications such as cardiovascular/pulmonary (arrhythmia, aspiration, chest pain), bowel perforation, bleeding, pain, etc. By making this measure more granular, it will be easier to determine whether a hospital transfer/admission is a result of a procedure complication or for an underlying or co-morbid condition.

CMS has previously noted its interest in patient experience of care measures for future payment determinations. We agree that patient experience/satisfaction measurement is important in assessing the overall quality of care delivered in the ASC setting. However, we believe that patient experience/satisfaction should be compared with patient experience/satisfaction of care in other settings, including the HOPD. When presented in this manner, the information will be most useful to Medicare beneficiaries when deciding where to receive outpatient endoscopic services.

For PQRS reporting in 2013 and beyond, CMS is proposing the following patient satisfaction measure: Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS): Getting timely care, appointments and information; How well your doctors communicate; Patients rating of doctor; Access to specialists; Health promotion and education; Shared decision making; Courteous and helpful office staff; Care coordination; Between visit communication; Educating patients about medication adherences; and stewardship of patient resources. CMS has stated that it intends to administer the survey on behalf of the group practices participating in the 2013 PQRS Group Practice Reporting Option for the CY2013 reporting period.

As we have commented to CMS with respect to the inclusion of this measure in PQRS, we suggest that if CMS considers this measure for the ASC Quality Reporting Program that it establish a minimum number of survey responses per physician or group practice for accuracy.

Public Availability of Quality Data
CMS is proposing that any and all quality measure data submitted by an ASC while participating in the ASC Quality Reporting Program could be made publicly available. Our organizations support increased transparency as it relates to ASC quality and look forward to working with CMS to ensure that information made available to the public is meaningful.

As we have commented previously, our societies believe that the real value to patients will not only be the ability to make meaningful quality comparisons across ASCs, but across all settings where endoscopic care is provided, including HOPDs. We believe that public reporting should be multi-dimensional. Along with reporting quality data, we believe that CMS should make publicly available the Medicare rates and patients’ out-of-pocket costs for services provided in both the HOPD and the ASC settings.
A period of confidential feedback and public reporting of participation should be the first steps of any ASC quality public reporting program. Similar to the initial phases of the physician and hospital quality reporting initiatives, the only information made publicly available during the first years of the program should be whether the ASC successfully participated in the ASC Quality Reporting Program. At the same time, CMS should provide confidential feedback to ASCs on their quality data. It is critically important that the quality data made publicly available be accurate. Many endoscopic centers are small businesses and the public posting of inaccurate information could have devastating consequences, including loss of referrals and contracting arrangements.

We believe the process for reconsideration and appeal of payment determination should be initiated before any information or data becomes publicly available. Furthermore, if an ASC has requested reconsideration or an appeal, then the ASC’s information or data should not be made publicly available until CMS has responded in writing to the reconsideration request or appeal.

CONCLUSION

Many of the issues raised in these comments have been stated by our societies and other organizations since the beginning of the new ASC payment system. In the case of the gastrointestinal single specialty ASC, we fear there may be misconceptions about the structure, function and regulation. In the past, it has been suggested that ASCs experiencing a decline in revenue in one area could simply expand services in another area. This may be an option for multispecialty centers, but this statement ignores the reality that state licensure and certificate of need regulations often define a limit on the services that a GI ASC can provide. In fact, despite significant reductions in ASC payments, a number of GI procedures have actually experienced a decline in volume. We believe policies of this proposed rule will foster the migration of Medicare patients back into the HOPD, increase costs to patients and the Medicare program, decrease patient satisfaction, and delay or deny needed medical services, including life-saving colorectal cancer screening. These results are unnecessary since CMS has ample authority to make decisions that will continue to make GI ASCs viable and a choice for Medicare beneficiaries.

The ASC has been one of the most positive developments in the cost-effective delivery of services to Medicare beneficiaries in the last 20 years. We are deeply concerned that CMS continues to make policy choices that clearly undermine the ability of ASCs to serve Medicare beneficiaries, particularly given strong patient preference for these centers and the compelling need to manage Medicare expenses more effectively. Congress granted CMS broad authority to establish a new and better payment system for all services provided in the ASC. We hope that CMS will utilize its authority in a way that enhances the ability of ASCs to provide services to Medicare beneficiaries.

The ACG, AGA, and ASGE appreciate the opportunity to offer these comments. If we may provide any additional information, please contact Brad Conway, Vice President of Public
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Sincerely,

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