



September 2, 2014

Marilyn B. Tavenner, MHA, BSN, RN  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P. O. Box 8013  
Baltimore, MD 21244-8013

**RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015 (CMS-1612-P)**

Dear 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 the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1612-P), published on July 11, 2014 in the *Federal Register*, regarding the proposed policy revisions to the 2015 Medicare physician fee schedule (PFS). Our three societies represent virtually all practicing gastroenterologists in the United States.

There are a number of provisions in the proposed rule that impact practicing gastroenterologists and the Medicare beneficiaries they treat. We offer comments in the following areas:

**Payment Policy**

- Valuing New, Revised and Potentially Misvalued Codes
- Valuing Services that include Moderate Sedation as Inherent to Procedure
- Potentially Misvalued PFS Codes
- Final Recommendations for Upper Endoscopy Codes
- Direct Practice Expense Inputs
- Definition of Colorectal Cancer Screening Tests

- RVS Update Committee (RUC) Recommendations for Migration from Film to Digital Practice Expense Inputs
- Use of Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Rates in Developing Practice Expense (PE) Relative Value Units (RVUs)
- Collection of Data on Services Furnished in Off-Campus Hospital Provider-Based Departments
- Reports of Payments or Other Transfers of Value to Covered Recipients

### **Quality Improvement**

- Physician Quality Reporting Program (PQRS)
- Physician Value-Based Payment (VBP) Modifier Program
- Physician Compare
- Electronic Health Record (EHR) Incentive program

### **VALUING NEW, REVISED AND POTENTIALLY MISVALUED CODES**

#### Fair and Accurate Reimbursement for Upper and Lower Endoscopy - Delay in Valuation is Necessary

Our societies thank CMS for proposing that any changes to work, malpractice RVUs and direct practice inputs for new, revised, and potentially misvalued services would be first published in the annual Medicare PFS proposed rule. CMS is proposing that this new process begin in CY 2016. As our societies have stated in previous comment letters, providers, professional medical societies and other stakeholders must be afforded adequate time to review and comment on all proposed fee schedule changes. Last year, nearly 20,000 gastroenterologists first learned of significant cuts of 3-36 percent to upper gastrointestinal (GI) endoscopy codes in late November because of delayed publication of the Final Rule as a result of the Federal government shutdown. These drastic cuts did not afford physicians, many of whom are small business owners, time to prepare for anticipated reimbursement changes. Under CMS' timeline for implementation of its proposal, the upper endoscopy codes published in November 2013 as interim final values and the lower endoscopy codes currently under review will not be afforded the benefit of increased transparency. Our societies believe that before CMS finalizes value recommendations for clinical procedures currently under consideration, the Agency must make certain that it is fully transparent, as proposed, in its rate-setting process. We still remain deeply concerned about the validity of the methodologies used to determine interim final values for upper endoscopy procedures in the 2014 final rule. Many of these upper endoscopy services preclude higher cost and higher risk surgeries, such as those for biliary and pancreatic diseases, bleeding ulcers and large polyps.

The need for transparency in rate-setting will be even more important this year, as CMS recommends values for colonoscopy services which are key services provided by gastroenterologists. Colonoscopy screening has been widely credited with reducing colorectal cancer (CRC) diagnoses in the United States by 30 percent over the last decade. As our health

system moves more aggressively toward value- and outcomes-based care, it is important that Medicare reimbursement rates accurately reflect the full value of the services provided and that the methodologies used to determine valuation be logical, fair and transparent.

We understand that many members of Congress have also expressed their interest in having all codes currently being reviewed as potentially misvalued benefit from the newly proposed review process. **In fairness, we urge CMS to delay valuing the lower endoscopy codes and finalizing the values for the upper endoscopy codes for one year so they can benefit from transparency in rate-setting.**

#### Valuing Services that Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

In the Proposed Rule, CMS reports that its data clearly indicate that moderate sedation is no longer typical for some of the procedures listed in Appendix G. Specifically, CMS notes that practice patterns for endoscopic procedures are changing, and anesthesia is increasingly being separately reported for these services. CMS is proposing a review of the codes currently listed in Appendix G of the CPT<sup>®</sup> book to ensure that moderate sedation is typical for the procedures listed.

The GI societies support the intention of CMS to establish a uniform approach for valuing Appendix G services for which moderate sedation is no longer inherent. However, we stress that it is important to value moderate sedation accurately when it is furnished. There are several components to the work of moderate sedation, none of which have ever been valued or validated via the AMA RUC survey process, including the induction, administration and monitoring which is currently accounted for in pre-service time, monitoring of the patient and adjustment of sedation dose in intra-service time, and post-procedure monitoring. The RUC has assumed that the work of moderate sedation should be part of the pre-service package at 0.0224 RVW/min, but this has never been valued through the RUC survey process. For perspective, 0.0224 RVW/min is the same intensity as taking history and exam, preparing for the procedure (i.e., check labs, plan, assess risks, and review procedure), communicate with patient and/or family, communicate with other professionals, check the room, supplies and equipment, check/prepare patient readiness (i.e., gown, drape, prep, and mark), prepare/confirm/review the procedure, and position the patient. Endoscopic services should not be inappropriately devalued because of flawed assumptions. Our societies do not understand how the clinical process of sedation induction that brings patients to a level of decreased responsiveness for adequate comfort, analogous to the induction process of anesthesiologist-provided propofol for upper and lower endoscopic procedures (00740, 00810), would carry such a trivial value. Adaption of an unevaluated intensity, which can impact the provision of these services, is unfair to the practice and may have unintended consequences, including changes in access to important procedures.

Finally, the GI societies are concerned with the timeline and process which is required by both the RUC and CMS to change existing policies associated with valuing moderate sedation for Appendix G codes. CMS states it will not change existing policies associated with valuing moderate sedation as inherent in the procedures listed in Appendix G until it has an opportunity to consider overall valuation of these codes. **We request that CMS delay the final review of the upper endoscopy codes and interim final review of lower endoscopy codes until the**

**Agency has established a clear direction on valuing services where moderate sedation is inherent to the procedure, as well as after the public has an opportunity to review reimbursement changes, and the methodologies used, as part of the annual proposed regulations.**

The Survey as the Gold Standard for Determining Time and Intensity

Our societies are encouraged by and agree with CMS' position that the best data available to determine physician work time and intensity for a particular service are derived from the surveys that specialty societies use as part of the AMA RUC process. As CMS noted in the proposed regulation:

“For many codes, the surveys conducted by specialty societies as part of the RUC process are the best data that we have regarding the time and intensity of work. The RUC determines the criteria and the methodology for those surveys. It also reviews the survey results. This process allows for development of survey data that are more reliable and comparable across specialties and services than would be possible without having the RUC at the center of the survey vetting process.”

As noted in the minutes from the January 2014 AMA RUC meeting, our societies voiced our objection to the RUC's work RVU recommendations for the colonoscopy family of services. We believe the RUC failed to follow its own processes when considering the results of the statistically valid survey facilitated by the six surgical and gastroenterological societies whose members provide the majority of colonoscopy services to Medicare beneficiaries. We remain committed to working closely with CMS to share objective data, analysis, and other information that will provide additional context to the physician work RVU recommendations on colonoscopy and the other lower gastrointestinal endoscopy procedures that were recently submitted by the RUC.

When compared to the previous review of the colonoscopy base code in 2005 as part of the Five-Year Review, the 2013 survey data reflected no change in the total procedure time of colonoscopy when the time for administration of moderate sedation is moved from intra-service to pre-service time. The intensity of the work of colonoscopy has not decreased. Intensity has increased since the code was reviewed in the Five-Year review in 2005 for the following reasons:

- the availability of video endoscopic systems with high-definition viewing screens that permit multiple health care professionals to watch the procedure, increasing the focus on adenoma detection, which have become predominant in use since the 1990's and the 2005 Five-Year review survey; and
- new multi-specialty task force recommendations on CRC surveillance put a greater emphasis on examination of the mucosa for detection and removal of smaller and increasingly subtle pre-malignant lesions, such as flat adenomas.

The issue of where the moderate sedation work fits into these RUC-approved surveys (intra-service vs. pre-service) and whether the work is all in pre-service or whether it spans intra-

service (e.g., reassessment of patient, administration of more medication as necessary) and post-service recovery has not been addressed. These issues are key when comparing the survey time of colonoscopy. However, should CMS decide to move forward with publishing interim final work values for these codes for the 2015 payment year, it is unclear how CMS can accurately determine intensity based on the survey results as CMS has never valued moderate sedation when inherent to the procedure.

Moderate sedation when administered by the same individual performing the procedure has never been valued, and CMS holds the position that the survey is the best available data the Agency has to value time and intensity. Therefore, CMS must determine to either move forward accepting the position of our societies (based on the best data available) that there is no change in time from the previous review of colonoscopy base code 45378 (*Colonoscopy, flexible, proximal to splenic flexure; diagnostic, with or without collection of specimen(s) by brushing or washing, with or without colon decompression (separate procedure)*), or delay valuing the colonoscopy family of codes until CMS can determine (with public input) a proper framework for valuing moderate sedation when considered inherent to the procedure.

We again emphasize to CMS that the RUC application of the ‘standard’ pre-service package subsequent to the 2005 valuation of 45378 created an artificial decrease in the overall and intra-service time of 5 minutes. Those taking the 2013 survey were told that moderate sedation was now pre-service work. The reported intra-service time, 25 minutes, is thus identical to the intra-service time of the 2005 survey.

**We respectfully request that CMS delay the final review of the upper and lower endoscopy codes until the Agency has established a clear direction on valuing services where moderate sedation is inherent to the procedure.**

#### **CMS’ EFFORTS TO IMPROVE TRANSPARENCY**

Our societies applaud CMS for proposing a new process by which stakeholders can review proposed reimbursement changes in the annual proposed rules as opposed to publication of the final rule, which typically occurs less than two months prior to significant reimbursement changes taking effect. However, we believe this proposal can be further improved by including a one-year delay for procedural codes currently under review by CMS. We believe that this delay will allow all specialties the opportunity to benefit from the new transparency process, while also allowing time for CMS to determine how it will value moderate sedation when it is inherent to a procedure, such as colonoscopy. We agree with CMS that the current process provides very little time for medical practices to prepare for upcoming reimbursement changes. The reduction in value for many GI upper endoscopy procedures was significant. In very few specialties are such significant cuts made instantly that impact tens of thousands of physicians without adequate advanced notice. Providers, medical practices of all sizes, medical societies, and other stakeholders must be afforded adequate time to review, comment, and prepare for Medicare fee schedule changes. The current process is not transparent and is counter to the intent of public rulemaking.

Our societies also understand the difficulty of including reimbursement-related changes in the annual proposed rule given the AMA CPT Editorial Panel and RUC meeting schedules. **We continue to urge CMS to revise the current process so it is consistent with the intention of public rulemaking and stakeholder input.** Our societies do recognize and appreciate the difficulty CMS faces in weighing the public's interest of greater transparency through incorporating RVU and PE changes in the annual proposed rules versus the public's interest in adopting new and revised codes in Medicare given the timing of AMA CPT and RUC meeting and schedules.

#### Use of G-Codes

When CMS does not have the opportunity to consider RUC recommendations prior to a proposed rule, the Agency proposes to use Medicare G-codes to resolve conflicts in the implementation of CPT coding changes. We thank the Agency for seeking feedback on its proposal to use G-codes as a temporary solution so that changes to codes can go through a proposed rulemaking and comment process.

We acknowledge that the use of G-codes as the temporary transitional bridge will be an administrative and logistical burden for many medical practices because they will have to keep track of various codes for the same services depending on whether patients are Medicare beneficiaries or have private insurance. This is all in the backdrop of preparing for upcoming ICD-10 changes scheduled to take effect in October 2015.

**As a compromise, our societies recommend that CMS continue the current process of publishing changes as “interim final” for newly-created services in the annual final rule.** For the purposes of this recommendation, we would group an existing code that was significantly revised in the CPT and RUC processes to be a “newly-created service.” This recommendation would follow CMS' rationale under the current regulatory process by deeming RVU and PE changes as “interim final” in order to gauge the impact to providers and Medicare beneficiaries over the course of the calendar year. It also allows new services to be quickly adopted into Medicare when CMS determines it is in the public's interest.

**For existing codes that are reviewed as potentially misvalued or codes for which there is a change in the CPT definition of a service without the value of the code being altered, we believe CMS' new transparency process should apply as proposed. To provide for greater transparency, our societies recommend that CMS include in the annual proposed rule all existing codes that have been targeted by CMS and gone through the RUC review process.** While we understand that CMS must work around potential AMA CPT and RUC meeting conflicts, the fact remains that the misvalued codes initiative is a mandate from Congress and the CPT and RUC panels are not federal advisory committees. Yet, under the current process, CMS announces which codes are under review sometimes two to three years in advance, then remains silent on those codes until the Agency announces changes in an annual final rule just weeks prior to their taking effect. There is little opportunity for the public to be updated or provide feedback in between the time that the misvalued codes are announced and the time final recommendations for these codes are revealed. This is particularly problematic if the surveying societies disagree

with the AMA RUC process during the review as we note above for the colonoscopy family of codes. Clearly this process should be improved. **We urge CMS to rectify this problem by moving forward with its proposal to include RVU and PE changes to codes in the annual proposed rules, but to modify this proposal to include only those existing codes that were part of the misvalued code initiative.**

#### Role of the Refinement Panel

As part of CMS' efforts to revise the process to increase stakeholder review and feedback before Medicare reimbursement rates are finalized, CMS proposes to eliminate the refinement panel process as the Agency believes it may no longer be necessary. CMS' stated rationale for this change is that should the Agency finalize its proposal to include reimbursement changes in the annual PFS proposed rule, these rates will no longer be considered "interim final" rates. Our societies believe CMS can further promote a transparent process by including reimbursement changes in the annual proposed rule as well as keeping the refinement panel process. **We ask CMS to reconsider this proposal and instead incorporate the refinement panel process into the newly finalized process to improve transparency in Medicare rate setting.**

As discussed in the 2011 PFS final rule (75 FR 73306), the refinement panel process provides an opportunity to review and discuss proposed and interim final work RVUs with a clinically diverse group of experts, which then provide informed recommendations to CMS. This process helps CMS balance the interests of those who have made comments on these work value changes together with the redistributive effects that would occur in other specialties should CMS decide to finalize changes to RVUs. Our societies still see value in this process as it allows CMS to review the impact on changes made to medical services and on Medicare beneficiaries with a year's worth of data and in an open forum that includes a diverse group of experts. Our societies are concerned with CMS' recommendation to eliminate the refinement panel due to the proposed increased transparency in the rate-setting process. We believe that discrepancies in the methodology used to determine physician work values will still be inevitable in some circumstances regardless if the recommendation is provided in the proposed or final rule. There would still be a need for a refinement panel if CMS adopts our societies' suggested changes to the review process as outlined above.

#### **POTENTIALLY MISVALUED CODES**

CMS is statutorily required to periodically identify potentially misvalued services and Congress expanded this authority under the Affordable Care Act (ACA) to review codes on an ongoing basis. Our societies appreciate the opportunity to work with the Agency and the AMA RUC to accomplish this task. Our societies have been responsive, forthcoming, and transparent throughout this process. We hope the Agency recognizes these efforts and continues to view our societies as a collaborative partner in forthcoming reviews.

### Process for Identifying Potentially Misvalued Codes

We continue to hold the position that **CMS should work with the AMA RUC to further improve its processes and initiate the use of other data sources for validating and updating RVUs.** The AMA RUC Relativity Assessment Workgroup was created in 2006 to develop objective screens and establish a formal process to identify misvalued services. A process was created to ensure that potentially misvalued services were identified systematically using relevant and objective screening criteria. To date, the result has been 1,500 services identified and an annual redistribution of \$2.5 billion.

Nevertheless, we are concerned about CMS' process for identifying potentially misvalued services and adjusting RVUs. Despite CMS' use of the rulemaking process to carry out much of this activity, CMS has provided little in the way of detail and rationale for several of its proposals, which limits our ability to understand CMS' concerns, identify potential solutions, and provide meaningful comments .

As enacted in the Protecting Access to Medicare Act of 2014, our societies are concerned with the broad discretionary authority provided to the Secretary to collect or obtain data from any eligible professional or other sources to assist in accurate valuation under the fee schedule. We strongly believe that if data is collected, it should be valid, reliable and derived from a statistically appropriate sample of practice sizes and settings. Our societies agree that professionals who submit data to CMS for these purposes should be paid as this process can be very time consuming for providers.

### Misvalued Codes Identified through High Expenditure Specialty Screen

The most recent sustainable growth rate (SGR) patch--the Protecting Access to Medicare Act--included nine new categories of services that the Secretary is directed to examine for the purpose of identifying potentially misvalued codes. One new category is "codes that account for the majority of spending under the physician fee schedule." Under this new category, CMS proposes to review 64 codes across specialties with Medicare allowed charges greater than \$10 million that have not been reviewed since 2009 or earlier. As with the similar review of high expenditure codes in 2012, our societies assert that values assigned in the past should not automatically be viewed as potentially misvalued. The majority of codes have not been reviewed since 2009. Additionally, while the GI societies appreciate Congress' desire to protect the Medicare trust, as it mandated CMS to find 0.5 percent savings from misvalued codes each of the next three years, the emphasis only on codes that cost more the \$10 million demonstrates an agenda to cut spending rather than ensure appropriate payment. We are concerned that CMS has no plan to identify services that are misvalued but simply seeks to nominate the most high dollar value services. We recommend CMS not finalize its proposed list of misvalued codes, but rather develop a more targeted list of codes that are not just potentially misvalued, but likely misvalued.

Our societies have already undertaken the work of preparing action plans for review of those services that are performed by gastroenterologists at the next AMA RUC meeting. We request that CMS clearly describe any disagreements with the RUC's assessment for each of the 64

codes in the final rule, or remove them from further review. It is reasonable for stakeholders to have more information on which to enact a response than a statement of disagreement or a “belief” that the value should be lower.

### **Obesity Behavioral Group Counseling (GXXX2 and GXXX3)**

In 2011, CMS updated the PFS to include, for the first time, a unique code for obesity counseling as a preventive benefit. Since that time, physicians have used HCPCS code G0047 (Intensive Behavioral Therapy for Obesity) for billing and reporting general counseling services for patients classified as obese. We have supported these efforts to ensure that adequate reimbursement is provided in this area as a means of both improving current health status and also managing the potentially serious complications that can arise from obesity. The specialty of gastroenterology is particularly affected by obesity, which worsens outcomes for many gastroenterological disorders and is strongly correlated with higher rates of colorectal cancer.

Obesity counseling is a significant tool that our members use as part of our common fight against chronic diseases and deadly cancers. We support steps taken to improve access to obesity counseling, which improves patient health and satisfaction while also helping to control long-term costs for CMS associated with patients who have co-occurring chronic disorders.

The CY 2015 fee schedule proposed rule would break group behavioral counseling into two separate codes based on group size, while maintaining the existing code for individual face-to-face counseling. While we appreciate that CMS clearly acknowledges the role of group counseling, we are concerned with the work times that have been offered as a basis for calculating reimbursement for counseling provided in groups of 5 to 10. CMS proposes a work time of 3 minutes for new code GXXX3, which is largely inadequate and inappropriate for any but the largest group. We ask that CMS reconsider the decision to assign a work time of 3 minutes, which is appropriate only for the time spent with a patient in a 10-person group and fails to take into account smaller groups.

Groups of 5 to 9 will be reimbursed far below the actual time expended per patient, which will limit access to group counseling in many circumstances. The discrepancy is particularly obvious for groups of 5, where CMS will reimburse based on a standard time (3 minutes) that is half the actual per-patient time being allotted (6 minutes). The change in reimbursement for larger groups will disincentivize weight management efforts and hinders efforts to provide group counseling in any case other than those where a full 10-person group is being treated. Doing so will limit access to critical treatments for patients struggling with obesity and who are at-risk for co-morbidity.

**For these reasons, we ask that CMS reconsider the work time assigned to new code GXXX3 (Face-to-face behavioral counseling for obesity, group (5-10), 30 minutes) in order to more accurately reflect the per-patient time spent in the 5-10 person group setting.**

## **FINAL VALUE RECOMMENDATIONS FOR UPPER ENDOSCOPY CODES**

We appreciate the opportunities the Agency provided us this year to meet with CMS staff and discuss the interim final values for the upper GI endoscopy procedures published in the 2014 Medicare Physician Fee Schedule Final Rule in November 2013. We would like to take this opportunity to review the evidence we have provided during our meetings in support of the RUC physician work recommendations and also provide additional explanation of the intensity and complexity of the procedures. Attachments A and B provide detailed analysis of each of the upper GI endoscopy codes, 43200 - 43278.

### **DIRECT PRACTICE EXPENSE INPUTS**

We thank CMS for acknowledging and accepting the RUC recommendation of 15 minutes of RN time for each one hour of monitoring following administration of moderate sedation. Our societies advocate that continued observation by a well-trained member of the endoscopy team dedicated to monitor patient post-procedure is appropriate to assess patient status.

Additionally, our societies appreciate CMS addressing the issue of stretcher time in the moderate sedation package. ACG, AGA and ASGE participated in several discussions with the AMA RUC regarding the need for a stretcher (EF018) (sometimes refer to as a gurney) for patients receiving moderate sedation. Endoscopy services, both upper and lower, require the stretcher throughout the entire procedure. The patient is wheeled in on the stretcher, remains on the stretcher for the entirety of the procedure and recovers on the stretcher. The stretcher is dedicated to that patient for the entire service and cannot be used by another patient. Therefore, we request that as CMS finalizes inputs on stretcher time based on the use during entire procedure be allocated.

Our societies also thank CMS for accepting the RUC's recommendation to update the prices associated with SA042 (pack, cleaning and disinfecting, endoscope) from \$15.52 to \$17.06 to reflect the addition of supply item SJ009 (basin, irrigation) to the pack, and increase the prices of SA019 (kit, IV starter) from \$1.37 to \$1.60 to reflect the addition of supply item SA044 (pack, moderate sedation).

### **DEFINITION OF COLORECTAL CANCER SCREENING TESTS**

Colorectal cancer is the third leading cause of cancer death among men and women in the United States; yet, this cancer is almost entirely preventable thanks to effective screening tools, particularly colonoscopy.

Congress recognized the public health benefit of colorectal cancer screening by mandating Medicare's colorectal cancer screening coverage under Section 4104 of the Balanced Budget Act of 1997. Subsequent regulation expanded the colorectal cancer screening benefit to include colonoscopies for Medicare beneficiaries at average-risk for developing colorectal cancer. Medicare currently covers: (1) annual fecal occult blood tests (FOBTs); (2) flexible sigmoidoscopy every 4 years; (3) screening colonoscopy for persons at average risk for

colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years; (4) barium enema every 4 years as an alternative to flexible sigmoidoscopy, or every 2 years as an alternative to colonoscopy for persons at high risk for colorectal cancer; and, (5) other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.

Despite Medicare's coverage of screening colonoscopy, the number of beneficiaries who are current on recommended colorectal cancer screening is below our shared goal of 80 percent screened. According to the data from the 2012 Behavioral Risk Factor Surveillance System, 76.8 percent of adults age 65-75 are current on their screening, with rates substantially lower in beneficiary populations who face greater cost barriers to receiving important preventive screenings. To increase adherence to preventive services, the ACA eliminates Medicare Part B cost-sharing requirements (coinsurance and deductible) for screening tests that have an "A" or "B" rating from the U.S. Preventive Services Task Force (USPSTF). For adults age 50 to 75, colonoscopy has an "A" rating. In spite of changes made by the ACA, Medicare continues to require beneficiaries to pay coinsurance when the preventive action of removing a polyp, abnormal growth, or suspicious-looking tissue occurs during a screening colonoscopy.

Medicare's current cost-sharing policy is confusing to beneficiaries, and the threat of out-of-pocket costs can serve as a deterrent to screening. In fact, in the current proposed rule, CMS acknowledges that costs associated with colorectal cancer screening present a "significant barrier" to this "essential" preventive service. CMS further notes in the proposed rule that the goal of waiving the Part B deductible and coinsurance was to "eliminate financial barriers so that beneficiaries would not be deterred from receiving them." Given CMS' statements and the intent of the ACA, our societies ask CMS to identify a way under its existing authority to redefine colorectal cancer screening to include screening colonoscopy with removal of polyp, abnormal growth or tissue during the screening encounter – a position that has been supported by as well as patient stakeholder organizations including AARP, the American Cancer Society Cancer Action Network, and Fight Colorectal Cancer.

On May 22, 2014, you met with representatives of our societies, during which you expressed an interest in knowing which diagnostic codes our societies believe should fall into the category of "screening" for the purpose of beneficiary cost-sharing. For coding and reimbursement purposes, a colonoscopy is considered diagnostic or therapeutic, rather than screening, when a polyp or abnormal growth is removed during the procedure, or when suspicious-looking tissue is removed for laboratory analysis. In addition to screening codes (HCPCS codes G0105 and G0121), beneficiaries should not be obligated to pay coinsurance or deductible for the following CPT procedure codes, when billed for diagnoses including colon polyp (211.3) or colon cancer (153.X, 154.X):

- 45380 – Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple;
- 45384 – Colonoscopy, flexible, proximal to splenic flexure; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery;

- 45385 – Colonoscopy, flexible, proximal to splenic flexure; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique; and
- 45342 – Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s)

To identify the specific circumstance where a screening examination becomes diagnostic/therapeutic, CMS instructs the use of modifier PT with the CPT code, and physicians report the ICD-9-CM diagnosis code V76.51 (screening, malignant neoplasm of colon). For commercial payers, CPT adopted an equivalent modifier 33.

By proper utilization of CPT and ICD-9-CM codes (ICD-10-CM has specific counterparts), payers can recognize the intent of the procedure was screening and distinguish the circumstance from non-screening situations.

It has been four years – prior to implementation of Section 4104 of the ACA – since our societies first asked that CMS remove beneficiary coinsurance for screening colonoscopy with removal of polyp or other tissue. Because the ACA explicitly waived the Part B beneficiary deductible for colorectal cancer screening tests that become diagnostic, we do not believe it implies a restriction that requires beneficiaries to pay coinsurance under Part B in cases when polyps are removed. **We urge CMS to include screening colonoscopy with removal of polyp or other tissue in its definition of “colorectal cancer screening tests.”**

By redefining colorectal cancer screening to include separately billable anesthesia services as proposed, CMS is likely to cause additional confusion among Medicare beneficiaries. Many beneficiaries are already surprised to learn they owe coinsurance for a screening colonoscopy with polyp removal. Based on our understanding of the proposal, beneficiaries who choose separately billable anesthesia for their screening colonoscopy under the assumption that it will be covered without cost-sharing will be surprised to learn that they are liable for coinsurance for both the colonoscopy and anesthesia when a polyp is removed. The proposed rule as written is not clear in this regard, nor is it clear how the deductible will be treated for the anesthesia services when a polyp or other tissue is removed during a screening colonoscopy.

We urge CMS to provide guidance as to whether CPT code 00810 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum) would be billed with a modifier to indicate whether the procedure was screening or not. Further, if anesthesia is covered without beneficiary financial responsibility, can Medicare Medical Carrier Directors still issue Local Coverage Determinations regarding the medical necessity of anesthesia services for endoscopic procedures? Noridian and Novitas (Attachments C, D and E) have policies that define medical necessity criteria for anesthesia for patients under age 70 and state that anesthesia is medically necessary for 70 and older. Also, in times when the screening colonoscopy with moderate sedation is performed in the non-facility setting, where is the practice expense for the anesthesia— with the endoscopist or anesthesia provider?

While the Administration purports colorectal cancer screening to be a “free” preventive service, for nearly half of beneficiaries who choose colonoscopy as their method of colorectal cancer

screening, cost-sharing will apply. Based on data collected by our registries, nearly half of all patients who undergo screening colonoscopy have a polyp or other tissue removed. CMS' current policy is not only unfair, but disproportionately affects lower income beneficiaries because they are most likely to lack supplemental insurance coverage to defray the expense of these unexpected out-of-pocket costs. This is also the population which has the lowest current participation in colorectal cancer screening services.

We are disappointed with the lack of parity in the Administration's colonoscopy cost-sharing policy between Medicare and private payers. Section 4104 of the ACA states Medicare beneficiary coinsurance is waived "if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual." Section 2713 of the ACA includes parallel language for commercially insured patients which states, "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost-sharing requirements for – (1) evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force."

Our societies are pleased that on February 20, 2013, the Administration's release of "Frequently Asked Questions" pertaining to implementation of various provisions of the ACA, including Section 2713, clarified that a private health plan or issuer cannot impose cost-sharing when a polyp is removed during a colonoscopy that is performed as a screening. CMS' policy for Medicare beneficiary cost-sharing for screening colonoscopy is in direct conflict with requirements for private payers. Our organizations do not understand how the Administration can have conflicting interpretations of Section 2714 and Section 4104 given that there are no distinguishing differences between the language in each section and the underlying intent of both sections are the same. We urge CMS to correct this inconsistency in the CY 2015 Medicare PFS final rule or to ask Congress to provide the necessary authority to address the issue.

#### **RUC RECOMMENDATIONS FOR MIGRATION FROM FILM TO DIGITAL PRACTICE EXPENSE INPUTS**

The RUC Practice Expense Subcommittee Workgroup on Migration from Film to Digital Imaging completed its work and its recommendations were submitted to CMS by the RUC following the April 2013 RUC meeting. CMS accepted the RUC recommendation to remove the identified supplies and equipment, however they also proposed to remove the supplies and equipment from the CMS direct PE input database entirely, including 50 additional codes purposefully excluded from the RUC recommendation (Table 7 of the 2015 NPRM). CMS noted that they proceeded because digital technology is not yet typical or because the code describes a service that is not imaging, but does require one piece of equipment that is used to view past imaging studies. As a proxy for the PACS equipment recommended by the RUC, CMS proposes to allocate equipment minutes for a desktop computer, ED021.

The GI societies disagree with CMS' proposal to remove individual pieces of equipment from codes that were specifically excluded from the RUC recommendations. GI services listed on

Table 7 of the NPRM were not included in the RUC recommendations. Prior to removal of necessary equipment, we suggest the PE for these services should remain intact until the codes come back to the AMA RUC Practice Expense Subcommittee for review. Additionally, the GI societies strongly endorse greater transparency and accuracy in the practice expense process. We are happy to work with CMS to develop other options to make available the breakdown of clinical labor time in the direct PE input database and devise a more manageable solution.

#### **USE OF HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGERY CENTER RATES IN DEVELOPING PRACTICE EXPENSE RELATIVE VALUE UNITS**

Our societies thank CMS for carefully reviewing comments from stakeholders and withdrawing its proposal introduced in the 2014 proposed rule to use OPPS (or ASC) payment rates for certain procedures to ensure that PFS payment rates are based on accurate cost assumptions.

Our societies continue to substantiate that many of the practice expense items that support the same endoscopy service have different costs when purchased by a hospital versus non-hospital owned ASC, versus an office facility, and the inputs for one site cannot be assumed to fairly represent other sites.

#### **COLLECTION OF DATA ON SERVICES FURNISHED IN OFF-CAMPUS HOSPITAL PROVIDER-BASED DEPARTMENTS**

Over the last few years, concerns about a “reverse” migration of services that were once provided in the physician office setting but are now shifting back to hospital outpatient departments (HOPD) have arisen, particularly as hospital employment of physicians has increased. There are many contributors to this reverse migration, including reduced payment rates in the ASC setting. The Medicare Payment Advisory Commission (MedPAC) has investigated the issue on multiple occasions and has considered recommendations that would equalize payment across settings for some services. Hospitals are also purchasing physician practices and designating them as off-campus provider-based HOPDs, which allows the same “practice” to bill for the same service at a significantly higher rate. The result is higher program spending and beneficiary cost-sharing without a notable change in patient care or quality.

In the CY 2014 fee schedule proposed rule released last year, CMS stated that to better understand these trends it was considering new steps to collect information that would allow it to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. To achieve this goal, CMS discussed several means by which this information could be collected and suggested either creation of a new place of service (POS) code for off-campus departments or a HCPCS modifier for both CMS-1500 claim forms and the UB-04 form. ACG, AGA, and ASGE recommended the use of a new POS code as the most effective and least burdensome means of retrieving the data sought by CMS.

CMS stated in the CY 2014 fee schedule final rule that most commenters agreed on the need to collect such information, but that no consensus solution was clear other than the importance of avoiding new administrative burdens that might not furnish the type of information sought. The

lack of agreement on whether to endorse a new HCPCS code or POS code caused CMS to defer a decision on the issue while continuing to collect public input.

CMS is proposing the use of a new HCPCS modifier that would be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital. We continue to believe that a new code-based reporting mechanism is superior to other options under consideration over the last year, including proposals that would require hospitals to break out charges for services in their cost reports. However, while we previously stated in our comments to the CY 2014 proposed rule that a code-based approach is the most reliable source of data sought by CMS, we noted that the HCPCS proposal is not ideal because it will require the use of a modifier for each individual service contained in a claim.

**For these reasons, we ask that CMS endorse the use of a new POS code to identify off-campus provider-based outpatient departments, rather than creating a new HCPCS modifier.**

**Additionally, the proposed rule states the data collection would occur for facilities located more than 250 yards from the main hospital building. We ask CMS to clarify in the final rule the rationale for the 250 yards criteria, including why it is limiting the data collection to those facilities, as well as its decision not to require data collection for those facilities within 250 yards. Our societies respectfully request that data collection apply to all such facilities.**

#### **REPORTS OF PAYMENTS OR OTHER TRANSFERS OF VALUE TO COVERED RECIPIENTS**

Throughout the Open Payments rulemaking process, our societies have supported the underlying goal of transparency, while also believing that relationships between physicians and the health care industry can lead to important advancements in technology and improved patient care. However, we object to proposed changes that eliminate existing provisions exempting accredited continuing medical education (CME) activities from public reporting, which provides substantial educational and collaborative benefits to the medical community.

As accredited providers of CME, our organizations are required by the Accreditation Council for Continuing Medical Education (ACCME) to keep a clear separation between developing educational content (including faculty selection) and pursuing and securing industry support. One of the hallmarks of accredited CME activities is that they are developed using evidence-based needs for improvement in physician practice, and not the financial interests of any drug or device industry supporter. The CME provider must control all aspects of the activity, including how all commercial support is utilized. For example, faculty honoraria payments must be made in accordance with the CME provider's policy (i.e., not the commercial supporter).

There is a significant difference between education that is developed and funded by industry for which physicians are paid directly, versus education that is funded through a CME provider. CME is highly regulated, must demonstrate that it is developed based on the needs of

the audience, and creates a clear firewall between faculty and industry supporters. Faculty typically identifies their involvement with CME activities as a service to their society or hospital, and their financial relationship is only with the ACCME-accredited organization for the purposes of the CME activity. To portray a relationship directly between the physician and manufacturer for these activities would be inaccurate and misrepresentative and could reduce the interest of physicians, who are experts in their fields, from participating and teaching in CME programs, which will lead to fewer hours of CME activities.

In the absence of the existing §403.904(g) exclusion, CMS states that the indirect transfer of funds will also be considered in light of the general exclusion found in §403.904(i)(1). However, this language is not identical to the existing exclusion but would exempt the indirect transfer only when the industry donor is unaware of the beneficiary or recipient both before and after funds are transferred: when the manufacturer is unaware of the identity of the covered recipient during the reporting year, *or by the end of the second quarter of the following reporting year*. This is a dramatic change that is impractical given the nature of CME events and will be extremely difficult to enforce. Industry donors could easily learn of speakers before or after a CME event through completely unrelated occurrences, such as media reports or promotional materials in other settings. Additionally, it is not uncommon for our societies to continue to solicit industry support for a CME program after the program course and faculty have been confirmed and publicized. In such cases, **rules that would exempt from reporting the indirect transfer if the industry donor is unaware of the recipient at the time funding or other support is committed for the CME activity is not a practical solution**. Any standard based on the time at which a donor becomes aware of a beneficiary is unreasonable and will act as a roadblock to participation for both industry and physicians. Furthermore, our societies do not see this proposal as practical, as it is unclear how industry donors will attribute their contribution at an individual physician level if they don't know the honorarium or if funding was also provided to the CME organizer by another industry donor.

In an attempt to overcome these concerns, the rule states that the reporting requirement will not apply when the industry donor does not either select or pay the speaker directly, or provide the continuing education provider with an identifiable set of recipients to be considered as speakers. Our societies agree with CMS' discussion in the proposed rule that when the manufacturer conveys "full discretion" to the continuing education provider, these payments should be excluded from reporting requirements. However, we are concerned that these sections may not be interpreted as "duplicative" as CMS notes in the proposed rule but instead, could require reporting of many educational costs that are currently excluded.

**We urge CMS to distinguish CME from other activities by maintaining the existing exclusion contained in §403.904 (g), which provides the most reasonable and workable treatment of CME activities under the Open Payments program.**

#### **PHYSICIAN QUALITY REPORTING SYSTEM**

Over the years, PQRS has evolved, our societies have made significant efforts to educate our members about the importance of quality data reporting and performance improvement. We have

embraced quality data collection through the establishment of clinical data registries and have guided our members through the often confusing maze of PQRS requirements for successful participation. Our societies recognize CMS is proposing modifications to the program for the 2015 performance year with the intent that beneficiary outcomes will be improved when eligible professionals successfully participate in the program. We appreciate that improvements in beneficiary outcomes rely, in part, on the robustness of reporting requirements and measures. While our societies believe that CMS is advancing the program in the appropriate direction, namely with an increased emphasis on registry reporting, it is our assessment that our physician members remain inadequately informed and prepared to meet the rapidly evolving changes in PQRS reporting requirements as proposed. This confusion regarding PQRS, and other Medicare quality reporting programs, has led to excessive amounts of non-reimbursable time spent by our members and their staff in order to avoid future reimbursement cuts. According to our members, many independent physicians list this increasing administrative burden of participating in Medicare quality reporting programs as one of the primary reasons for leaving or selling independent practices and joining a hospital system.

Given the amount of payment at risk for non-successful participation in PQRS during the 2015 performance year (-2 percent for PQRS and -4 for the VBP modifier), we urge greater program predictability and believe CMS' proposals should better reflect the state of PQRS participation based on available data.

The 2012 data tell us that gastroenterologists still rely heavily on claims-based reporting. According to CMS' 2012 Experience Report, of the 5,875 gastroenterologists who participated in PQRS in 2012, 2,544 reported individual measures via claims, an increase over the number of gastroenterologists who reported using claims in 2011 (2,202). Comparatively, the number of gastroenterologists reporting through a traditional registry decreased from 1,008 in 2011 to 727 in 2012. Like most specialties, the number of gastroenterologists reporting via electronic health record (EHR) grew significantly from 2011 to 2012 (7 to 410). These data, as well as feedback from our physician members, serve as the basis of our comments.

Over the years, our societies have enjoyed significant cooperation with CMS toward inclusion of new measures specific to the field of gastroenterology, as well as receptivity by CMS to our program suggestions. We offer the following comments in the spirit of ongoing collaboration and with a shared goal of true health care quality improvement.

### PQRS Measures

CMS is proposing a number of measure modifications for CY 2015, which are detailed in Tables 21, 22, 23, 24 and 25 of the proposed rule. It would, however, be of value to eligible professionals if CMS would publish, as an addendum to the proposed rule, a complete list of PQRS measures, as proposed. In doing so, eligible professionals would be able to review a comprehensive list of proposed measures for the next performance period, rather than cross referencing the tables with measure modifications to the current measure list. For example, the "preferred" specialty measure sets currently on the CMS website include measures that reflect

the proposed changes for the 2015 performance year. These preferred measure sets are useful tools that allow for earlier reporting preparation. While CMS should continue to offer and expand upon and refine these preferred lists, they should remain voluntary lists and should be in addition to a comprehensive measure table that reflects all proposed measure modifications. Because there has been little measure variation between the proposed and final rules, creating this resource would help eligible professionals and practices better prepare for the new performance year.

We understand measures must continually evolve, and we share CMS' desire to include measures that address performance gaps and lead to improved outcomes. However, as we have commented previously, we respectfully ask CMS to create greater program predictability, rather than the current practice of often unanticipated year-to-year changes in PQRS measures and reporting requirements. Physician practices, which must modify medical record systems and practice workflows to accommodate PQRS reporting changes, benefit from consistency and predictability of program parameters.

CMS is proposing, effective 2015, to change the National Quality Strategy domain for 24 measures, remove 73 measures, and modify allowable reporting mechanisms for 56 measures. These significant changes are accompanied by increased reporting requirements to avoid the 2017 PQRS payment penalty.

**We specifically oppose CMS' proposal to eliminate claims reporting for the following measures:**

- NQF #113: Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer. This measure is important to specialty physicians and was the second leading measure reported by gastroenterologists in 2012. This is an important measure for primary care providers as well.
- NQF #185: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with History of Adenomatous Polyps – Avoidance of Inappropriate Use.
- NQF #320: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.

We share CMS' desire to gradually move away from claims reporting as the predominant reporting mechanism and toward greater use of registry and EHR reporting, especially given the continued high error rate for claims reporting. However, we believe CMS' primary goal should remain increasing successful PQRS participation and to maintain specialty-specific measures across all reporting mechanisms. Currently, physicians have limited capacity to assure that their EHR vendors will add specialty-specific and alternative reporting options into their EHR software.

**To improve program predictability, we suggest that CMS institute a policy that allows a phase-out period when measures are to be eliminated or their reporting mechanisms**

**significantly altered (e.g., a reporting mechanism eliminated)**, with an exception for measures that, if retained, could have a detrimental effect on patient health and outcomes. A transition period provides adequate time for practices to make necessary adjustments in their reporting practices, which is especially important given that physicians will increasingly rely on PQRS measure performance data in their Quality and Resource Use Reports (QRURs) to make practice improvements and adjustments in the context of the VBP modifier. As more eligible professionals choose Qualified Clinical Data Registries (QCDRs) as their mode of PQRS reporting, fewer eligible professionals will be negatively affected by changes in PQRS measures. However, in the interim, physicians are acutely impacted by sudden changes in PQRS measures and reporting requirements.

Finally, our societies appreciate that CMS has instituted, beginning this year, a continuous “Call for Measures” with the recognition that measure development is a costly and timely endeavor. We appreciate that CMS’ aim is to provide timely feedback to measure submitters, including on whether a proposed measure meets the needs of PQRS. Additionally, we believe that medical societies could benefit greatly from additional resources for developing EHR measure specifications.

#### Proposed PQRS Reporting Requirements

Consistent with our request for predictability with PQRS measures, **eligible professionals and medical societies that maintain clinical registries would greatly benefit from a period of PQRS program stability during which no significant changes to the program are made. In addition, we ask CMS to publish each year, as part of the proposed rule, a two- or three-year timeline of anticipated PQRS changes.** Such a timeline would allow eligible professionals to engage in more predictable planning and would still give CMS the flexibility to make modifications through rulemaking based on program experience.

***Proposed Requirements for Satisfactory Claims Reporting by Individual Eligible Professionals***  
Eligible professionals participating as individuals and reporting on individual measures must report on at least nine measures covering at least three of the quality domains to avoid a 2017 payment adjustment. These two requirements are uniform across all reporting mechanisms (claims, traditional registry, EHR, or QCDR).

Our societies appreciate that CMS is proposing to increase the number of measures reported by eligible professionals to better capture the picture of beneficiary care, particularly for the purpose of evaluating physician performance under the VBP modifier. However, we are concerned the leap from three to nine measures may result in a greater number of unsuccessful PQRS participants. These increased reporting requirements are proposed at the same time CMS is proposing to set the VBP modifier at -4 percent for unsuccessful PQRS participation.

According to the 2012 Experience Report, 83 percent of individual eligible professionals reported using claims. Of those using claims to report individual measures, 72 percent received an incentive payment. Because the reporting threshold in 2012 was only three measures and was accompanied by a significant number of unsuccessful participants, we are concerned that a

requirement of nine measures will result in an even higher PQRS failure rate, especially if the majority of PQRS participants continue to use claims reporting.

**We ask CMS to hold PQRS requirements steady from at least the 2014 to 2015 performance years, which would include not increasing the measure reporting threshold from three to nine.**

Alternatively, CMS could explore ways to reduce the risk of payment penalties in 2017 for eligible professionals. For example, and particularly for eligible professionals who choose claims reporting, CMS could deem an eligible professional a successful PQRS participant, if he/she *demonstrates* an attempt to report on nine PQRS measures but only fulfills reporting requirements for three PQRS measures. The Measures Application Validation (MAV) process would apply. CMS would need to establish what would constitute a reporting “attempt,” (e.g., a quality data code that does not match the diagnosis code on the claim form would be considered an “attempt.”) CMS could also look at ways to limit VBP modifier penalties if an eligible professional attempts but fails to meet proposed nine-measure reporting threshold.

***Proposed Requirements for Satisfactory QCDR Reporting by Individual Eligible Professionals***

Our societies maintain registries selected as QCDRs for the 2014 performance year and will provide comments separate from this letter on proposed QCDR requirements.

**Per our comments above, our societies respectfully ask for a period of PQRS program stability as well as a timeline of anticipated QCDR changes so our societies can plan and adjust in a timely manner so as to not leave our physicians who rely on QCDR reporting in the unexpected position of having to find an alternative reporting mechanism if our QCDRs cannot meet new requirements.**

***Cross-Cutting Measures in Table 21***

For claims and traditional registry reporting, should CMS finalize its nine-measure requirement, we do not object to CMS’ proposed requirement that of the nine measures, two should be among the broadly applicable cross-cutting measures found on Table 21 of the proposed rule. In fact, according to the 2012 Experience Report, among the top five measures reported by gastroenterologists, three are among those proposed on Table 21: #130 – Documentation of Current Medications in the Medical Record; #226 – Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention; and #111 – Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.

**We believe clarification is needed in the proposed rule on what would happen if an eligible professional cannot identify applicable measures on Table 21 for reporting and such lack of measures is confirmed through the MAV process.** Our assumption is that the eligible professional would still need to report on nine measures. We believe this scenario is not adequately addressed in the proposed rule.

We also strongly encourage CMS to increase the number of national provider calls, and to promote them accordingly, because our experience tells us that practices are very confused about

PQRS reporting requirements and that many practices still do not understand the intersection between PQRS and the VBP modifier, and others do not understand that PQRS and the ASC Quality Reporting Program are distinct quality programs.

#### **VALUE BASED PAYMENT MODIFIER PROGRAM**

Our societies acknowledge that CMS is under a mandate to transition to a VBP modifier for all physicians by January 1, 2017. Given the short transition period, we appreciate that CMS has, to date, put physicians at minimal risk of payment penalties. We are, however, very concerned with the proposed level of payment at risk under the VBP modifier to which group practices and solo practitioners will be exposed as a result of more stringent PQRS participation requirements. We, therefore, respectfully request CMS' consideration of the following comments and recommendations.

#### Proposed Expansion of the VBP Modifier

Consistent with CMS' mandate, the proposed rule expands the application of the VBP modifier to group practices with two or more eligible professionals and to solo practitioners in CY 2017, which will be tied to CY 2015 physician performance. Using its administrative authority, CMS further proposes to expand the VBP modifier in CY 2017 to non-physician eligible professionals. From a practical standpoint, because PQRS applies to non-physician eligible professionals and because the VBP modifier hinges on a group's participation in PQRS, it seems logical that the next step would be to apply the VBP modifier to non-physician eligible professionals. If non-physician practitioners deliver and bill for Medicare services, they should also be held accountable for their performance and resource use.

**If CMS is going to expand application of the VBP modifier to all eligible professionals, then it is critical that CMS continue to allow the classification of groups into Category 1 for both those self-nominating to participate in the group practice reporting option (GPRO) or when 50 percent of eligible professionals in a practice meet PQRS criteria as individual reporters.**

The 50 percent threshold option is important because non-physician eligible professionals may not report the same measures or use the same reporting mechanisms as physician members of a practice. Consequently, if all eligible professionals in a practice do not use the same reporting mechanism, participating as a GPRO is not an option because all eligible professionals under a GPRO must use the same reporting mechanism. For example, a physician may want to participate in a QCDR that does not collect measures applicable to the services provided by a non-physician provider. We believe that CMS should be cautious in making modifications to the VBP modifier program so as not to inadvertently drive physicians away from QCDRs for their PQRS participation.

#### VBP Categorization of Group Practices and Solo Practitioners Based on PQRS Participation

We generally support CMS' proposed continuance of its policy to place groups of physicians, and now also non-physician eligible professionals, into one of two categories: Category 1 –

Group reporters, individual reporters within a group, and solo practitioners who meet the criteria to avoid the 2017 payment adjustment; and Category 2 – Groups of eligible professionals that do not fall within Category 1.

As stated above, **we strongly support the continued policy of including in Category 1 those physicians who do not self-nominate to participate in the PQRS GPRO but have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory PQRS reporting.** This policy allows eligible professionals to use the full range of reporting mechanisms available, including QCDRs.

#### Proposed Changes to the Quality Tiering Methodology

For the 2016 payment adjustment, group practices had the option to elect quality tiering. CMS is proposing for the 2017 payment adjustment that all groups and solo practitioners in Category 1 would be subject to quality tiering. **Our societies strongly support CMS' proposal to subject groups with 2-9 eligible professionals and solo practitioners to only upward or neutral adjustments derived under quality tiering.**

Even though groups of 2-9 eligible professionals and solo practitioners are not subject to downward adjustments under quality tiering, they are still at risk of a proposed -4 percent adjustment if they fail to successfully participate in PQRS. **We believe an extra step is needed to help physician groups with 2-9 eligible professionals and solo practitioners avoid a negative VBP modifier in 2017.** For example, we recommend CMS reinstitute the administrative claims default for calculating a quality score in instances when a group practice or solo practitioner attempts to participate in PQRS but fails to successfully meet reporting requirements and avoid the payment adjustment.

#### Proposed Changes to Payment Adjustment Amounts

CMS is proposing to modify VBP modifier adjustments for the 2017 payment year. First, CMS is increasing the payment adjustment from -2 percent to -4 percent for Category 2. Second, for Category 1, CMS is increasing the payment adjustment amounts under quality tiering in the following categories: medium quality/high cost (-2%), low quality/average cost (-2%), and low quality/high cost (-4%). We fully appreciate CMS' challenges in a budget neutral scheme. However, **we object to CMS doubling the Category 2 VBP modifier adjustment during the same year in which the modifier will be applied to all eligible professionals and at the same time CMS is proposing to make the PQRS reporting requirements more stringent. Alternatively, or in combination, CMS should reduce the potential of a group practice or solo practitioner from being placed in Category 2 and receiving a downward adjustment by maintaining current PQRS requirements and/or by giving credit for attempts at successful PQRS participation.**

For eligible professionals and group practices placed in Category 1, we do not understand why CMS continues to propose putting physicians and other eligible professionals who did and did not fulfill PQRS requirements at the same level of downward payment risk.

**Given that CMS continues to make methodological refinements to the VBP modifier program and because eligible professionals in Category 1 have demonstrated a desire to improve health quality and outcomes through their successful participation in PQRS, we ask CMS to maintain the current Category 1 maximum downward adjustment at -2 percent in CY 2017.**

#### VBP Modifier Quality Measures

##### *PQRS Measures*

Our societies support the continued alignment between PQRS and the VBP modifier. In particular, we support CMS' proposal to continue to include all of the PQRS GPRO reporting mechanisms available for the CY 2015 PQRS reporting period and all of the PQRS reporting mechanisms available to individual eligible professionals. We also support CMS' proposal to use all of the quality measures that are available to be reported under these various reporting mechanisms to calculate a group or solo practitioner's VBP modifier in 2017.

##### *Outcome Measures*

CMS proposes to maintain the three outcome measures as finalized in the CY 2014 physician fee schedule final rule for the 2016 payment adjustment: 1) all-cause readmission; 2) composite of acute prevention quality indicators; and 3) composite of chronic prevention quality indicators. It is CMS' policy to calculate a group's (and now solo practitioner's) composite score for a quality or cost measure based on claims only if there are 20 or more cases for the measure. If a group or solo practitioner has fewer than 20 cases, then the measure is excluded from its domain and the remaining measures in the quality domain are given equal weight. CMS is proposing for the 2017 payment year to increase the minimum case threshold from 20 to 200 for the all-cause hospital readmissions measure. CMS states that it is making this proposal after examining the reliability of the measure data for 2012. Our societies have previously commented that it may be difficult to measure physician practices using these outcome measures since they were developed to be applied at the community level. **We support changing the case threshold for the all-cause readmission measure to a minimum of 200 and appreciate and encourage CMS' ongoing review and revision of the outcome measures.**

#### Beneficiary Attribution Methodology for Cost and Outcomes Measures

CMS is proposing to refine its two-step methodology for assigning beneficiaries to a group for the purposes of calculating the five total per capita cost measures, as well as the claims-based quality measures in the VBP modifier. Under Step 1, beneficiaries would be assigned to a group that had a plurality of primary care services rendered by primary care physicians, nurse practitioners (NPs), physician assistants (PAs), or certified nurse specialists (CNSs) during the performance year. If a beneficiary is non-assigned under this step, then, under Step 2, a beneficiary would be assigned to the group practice whose affiliated non-primary care physicians provided the plurality of primary care services. Under the current attribution methodology, NPs, PAs and CNSs are only in Step 2 of the attribution process, not Step 1. Additionally, to help streamline the attribution process, CMS is going to eliminate the pre-step for attribution, which was to identify a pool of assignable beneficiaries that have had at least one primary care service

furnished by a physician in the group. CMS notes in the proposed rule that these modifications would only apply for groups and solo practitioners who are not participating in the Shared Savings Program, which we believe is an important exception. This approach disregards the large percentage of NPs, PAs, and CNSs who are not actually providing primary care, but instead work in various specialty practices and areas. Consequently, under this attribution approach, specialty practices that include non-physician practitioners would be expected to show lower costs than those that did not include the non-physicians, potentially discouraging team-based practices that include both specialists and non-physician practitioners. **We request that CMS withdraw this proposal until the agency has studied its impact on group benchmarks and other unintended consequences.**

CMS further proposes to include certain part-year Medicare fee-for-service beneficiaries in the methodology for use for calculating the total per capita cost measure. CMS states that this change would provide a more complete assessment of end-of-life costs associated with patients a physician group sees during the year. CMS is also proposing to include Medicare fee-for-service beneficiaries who are newly enrolled to Medicare during the performance period and enrolled in both Part A and Part B while in Medicare fee for service. Our societies suggest that this attribution change unfairly penalizes physicians treating the sickest patients. For gastroenterology, this would include liver failure patients. We urge an abundance of caution in implementing policies that could result in provider avoidance of high-cost terminally ill or end-of-life patients.

CMS currently excludes drugs under Medicare Part D in the VBP cost metrics. However, drugs administered by physicians under Medicare Part B are included in the VBP modifier cost calculations. CMS has previously conceded that the cost of drugs in Medicare Part B are outside the control of the physician, thus in 2007 CMS determined that the costs of administering these drugs should not be included in updating the annual SGR formula. We urge CMS to also exclude drugs under Medicare Part B from the VPB calculation and treat all drugs in Medicare Part B and D equally.

### **Specialty Physician Participation in an Accountable Care Organization**

Our societies still remain concerned about PQRS reporting for a specialist who provides services to an Accountable Care Organization (ACO). Specialists who opt to “participate” in an ACO unknowingly lose their ability to report PQRS through their own individual or group’s data and instead become part of the ACO’s quality data reporting. Physicians who work with ACOs in the capacity of “other provider” maintain their ability to submit their own (individual or group) PQRS data. A majority of physicians and ACOs are unaware of the provision. This specification has caused consternation for physicians who have entered into agreements with no knowledge of this obscure element of ACO regulations. We propose that as part of the process of registering to participate in PQRS, there should be a clear option that allows a physician providing services to a shared savings program to opt in to the shared saving program’s quality reporting or opt out and provide their own individual/group data to CMS.

CMS is proposing to apply the VBP modifier beginning with the CY 2017 payment adjustment to physicians and non-physician eligible professionals who are participating in the Shared Savings Program, Pioneer ACO Model, the Comprehensive Primary Care Initiative, and other similar Innovation Center models or CMS initiatives. CMS justifies the expanded application of the VBP modifier based on its interpretation of the law that requires the modifier be applied to all physicians and groups of physicians by CY 2017. **We suggest that applying VBP modifier to these physicians and groups of physicians is duplicative, unnecessary, and counterproductive to encouraging physicians and other eligible professionals to participate in alternative payment models. We suggest that if CMS requires additional authority to continue the current VBP modifier exemption for new payment and care delivery models of care, the Administration should seek that authority from Congress.**

#### PHYSICIAN COMPARE WEBSITE

Our societies remain encouraged with CMS' improvements to the Physician Compare website to ensure that the information contained in each provider's profile is accurate and current. We are also encouraged by CMS' decision to only publish on Physician Compare those measures that are statistically valid and reliable, and, therefore, will be most likely to help consumers make informed decisions about the Medicare professionals they choose to oversee their health care needs. As stated in previous proposed rules, our societies believe it is paramount that PQRS and other quality reporting programs better incorporate meaningful metrics for services provided by specialty medicine. Toward this goal, we appreciate CMS' proposal to only include measures that are deemed valid, reliable, and have a minimum sample size of 20 patients. We also appreciate the 30-day review process prior to posting updated quality information on each provider's profile. **We respectfully request that CMS outline in the final rule the process a provider may take when he/she disagrees with the substantive quality information on his/her profile after this 30-day review period.** While there is a process where a provider may update demographics, CMS does not appear to have a process in place to refute certain information as part of this 30-day preview.

Our societies agree with CMS that it is important to include measures and quality information deemed important to the patient. Therefore, we applaud CMS for undergoing concept testing to gauge how well consumers understand each measure under consideration. **We recommend CMS use concept-testing for the information currently on the Physician Compare as well.** If a measure is not considered helpful and/or if consumers do not understand the relevance of the measure to their health care decision making process, we agree that CMS should not include the measure on the Physician Compare profile page. Inclusion of those types of measures will not aid informed decision-making. Our societies have, in the past, urged CMS to incorporate patient-friendly and meaningful information on Physician Compare such as participation in a quality improvement registry for certain services, fellowship status in a specialty society, or other voluntary quality improvement initiatives offered by one of our societies. We thank the Agency for considering including links to measures developed by, and hosted on, the medical societies' websites and agree that the CMS should move forward with this proposal. **We further recommend that CMS also include links to other patient-friendly educational materials on our societies' websites.**

Our organizations' websites have a robust catalog of patient-friendly educational materials that are popular among patients wishing to learn more about a disease or procedure. These materials also help our members better communicate with and educate patients during office visits. CMS has a unique opportunity to link this information to any provider's profile (per the request of the provider) on Physician Compare. We believe the Medicare beneficiary would find this information helpful in making an informed decision.

We thank CMS for seeking comment on whether to compile and post composite scores for both groups and individual providers on Physician Compare. As proposed, and if technically feasible, CMS would compile composite scores based on a group or provider's reporting of a PQRS measures group. CMS also seeks comment on developing benchmarks at the group level, using GPRO data. The intended goal is to see how groups perform on each measure or measure group, as well as how the groups compare to other practices. CMS would use the benchmark process as designed in the Medicare Shared Savings Program which states that performance below the minimum attainment level (the 30th percentile) for a measure would receive zero points for that measure; performance at or above the 90th percentile of the performance benchmark would earn the maximum points available for the measure. The total points earned for measures in each measure group would be summed and divided by the total points available for that measure group to produce an overall measure group score of the percentage of points earned versus points available. The percentage score for each measure group would be averaged together to generate a final overall quality score for each group practice.

While CMS notes that some consumer groups believe this would be a good indicator of quality, our societies caution that this approach leads to an incomplete, and potentially misleading, indicator of quality. For example, there are groups and individuals participating in PQRS via one of the PQRS individual measure reporting options. There are also providers that will be subject to the MAV process. **CMS must ensure that consumers do not make a presumption of quality based on information on Physician Compare that is in one provider's profile but not in another's simply because providers chose different ways to participate in PQRS.**

#### **ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM**

Our societies applaud CMS for proposing that, beginning in CY 2015, eligible professionals would not be required to ensure that their health IT products are recertified to the most recent version of the electronic specifications for clinical quality measures. This proposal changes CMS' policy as outlined in the 2014 PFS final rule, where eligible professionals are currently required to use the most recent version of electronic specifications for quality measures as well as the health IT certified for these specifications.

Our societies agree with this proposal and appreciate CMS' efforts for easing financial and practice management burdens associated with meeting the Electronic Health Records Incentive Program's mandates.

Ms. Marilyn Tavenner  
Page 27 of 27  
September 2, 2014

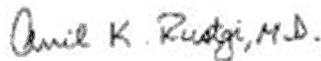
## CONCLUSION

The ACG, AGA, and ASGE appreciate the opportunity to provide comments on the 2014 physician fee schedule proposed 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](mailto:bconway@gi.org); Joshua Keepes, Director of Regulatory Affairs, AGA, at 240-482-3223 or [jkeepes@gastro.org](mailto:jkeepes@gastro.org); or Camille Bonta, consultant to ASGE, at 202-320-3658 or [cbonta@summithealthconsulting.com](mailto:cbonta@summithealthconsulting.com).

Sincerely,



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### Attachments

- Attachment A: Upper GI Endoscopy Code Comments Intensity-Complexity
- Attachment B: 43200 Harvard Phase3
- Attachment C: Novitas LCD L27489 MAC 082114
- Attachment D: Novitas LCD L32628 MAC 082114
- Attachment E: Noridian LCD L24332 - MAC