September 6, 2013

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 2014. (CMS-1600-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-1600-P), published on July 19, 2013 in the Federal Register, regarding the proposed policy revisions to the 2014 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:

- Medicare Beneficiary Screening Colonoscopy Cost Sharing
- Misvalued Physician Fee Schedule (PFS) Codes
- Physician Quality Reporting Program (PQRS)
- Physician Value-Based Payment (VBP) Program
- Physician Compare
- Complex Chronic Care Management Services
- Data Collection for Off-Campus Hospital Provider-Based Departments
- Investigational Device Exemption Trials
Our societies urge CMS to take action in the CY 2014 physician fee schedule final rule to waive Medicare beneficiary coinsurance when a polyp is removed during a screening colonoscopy. Colorectal cancer screening by colonoscopy is a unique preventive service because it allows removal of potentially precancerous polyps during the preventive exam. The current policy does not reflect the intent of current law, it is confusing to Medicare patients, and the threat of additional patient cost can serve as a deterrent to screening.

Under Sec. 4104 of the Affordable Care Act (ACA), 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.” Parallel language is included under Sec. 2713 of the ACA 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.”

We wish to emphasize that under both Sec. 4104 and Sec. 2713, waiver of coinsurance and cost sharing, respectively, hinge on whether the service has an “A” or “B” grade from the United States Preventive Services Task Force (USPSTF). Colorectal cancer screening by colonoscopy has an “A” grade from the USPSTF.

On February 20, 2013, additional “Frequently Asked Questions” (FAQs) were released regarding implementation of various provisions of the ACA. These FAQs were prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury. Included was an FAQ clarifying 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:

“Based on clinical practice and comments received from the American College of Gastroenterology, American Gastroenterological Association, American Society of Gastrointestinal Endoscopy, and the Society for Gastroenterology Nurses and Associates, polyp removal is an integral part of a colonoscopy. Accordingly, the plan or issuer may not impose cost-sharing with respect to a polyp removal during a colonoscopy performed as a screening procedure. On the other hand, a plan or issuer may impose cost-sharing for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.”

Our organizations seek clarification from CMS as to why it cannot take similar administrative action to eliminate coinsurance for Medicare beneficiaries when polyp removal occurs during a colonoscopy performed as a screening procedure. Inaction to date by CMS to correct current regulations is in conflict with HHS’ position on such cost-sharing obligations for privately insured patients. We do not understand how HHS can
interpret Sec. 2713 and Sec. 4104 of the ACA differently considering there are no distinguishing differences between the language in each section and the underlying intent of the sections are the same, i.e. to remove financial barriers to highly proven preventive services that have the potential to reduce morbidity and mortality from preventable disease. By doing so, CMS is treating Medicare beneficiaries unfairly and imposing added costs compared with privately insured beneficiaries without a rational basis.

**Misvalued PFS Codes**

CMS is statutorily required to periodically identify potentially misvalued services and Congress expanded this authority under the ACA to review codes on an ongoing basis. Our societies appreciate the opportunity to work with the Agency and with the American Medical Association’s Relative Value System Update Committee (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.

We are concerned that recent media reports critical of the RUC have included inaccurate and misleading information based on reviews of a small number of gastroenterologists’ performance of colonoscopy. We fear that media mischaracterizations eclipse the more important public health success story: colonoscopy saves lives and decreases long-term Medicare costs. Of the more than 50,000 people expected to die to from colorectal cancer this year, screening could have saved more than half of them. Our societies commend HHS for its cross-agency efforts to increase colorectal cancer screening rates, as much more needs to be done to achieve HHS’ screening goals, and we look forward to working with CMS and through the AMA RUC to ensure appropriate valuation of gastroenterology services.

As CMS has noted, the AMA RUC has its own process for identifying potentially misvalued codes and making recommendations for adjusting relative value units (RVUs). Our organizations maintain that this process is transparent, well understood by the medical specialty societies, and is sensitive to the federal government’s mandate to improve the valuation of services paid under the Medicare PFS.

Nevertheless, we are concerned about CMS’s 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 the CMS’ concerns, identify potential solutions, and provide meaningful comments in response to CMS’ proposals related to potentially misvalued services. While CMS reviews recommendations by other organizations in making its own final and independent determination on physician-work values, the Agency has a history of waiting until the final rule to disclose changes in the valuation of services. We believe this practice is inconsistent with physician fee schedule rulemaking. In future rulemaking, we urge the Agency to release proposed changes to revised physician work values in the physician fee schedule proposed rule along with other proposed policy changes for the upcoming calendar year. Providers, professional medical societies, and other stakeholders must be afforded adequate time to review and comment on all proposed fee schedule changes. Of equal
importance, physicians, many of whom are small business owners, must be afforded more time to prepare for anticipated reimbursement changes. November publication of the final rule provides less than 60 days notice of often dramatic changes in reimbursement levels, which we argue is fundamentally unfair.

During a comprehensive review of families of codes, as gastroenterology has been doing, when all of a specialty’s codes must be surveyed existing codes cannot be utilized and comparisons must be made using unrelated codes. This is a significant issue because we cannot utilize existing endoscopy services and their work RVUs as comparators and cannot use RUC-approved work RVUs that CMS has not yet released in the PFS final rule as comparators. These restrictions have resulted in gastroenterologists having to compare the GI endoscopy code under review to a service that they do not perform, e.g., a comparison of an upper GI endoscopy service to a bronchoscopy, tracheostomy, etc., rather than relating one GI endoscopy service to another. In conjunction with the AMA RUC, we would welcome more study of suitable options to avoid facing this difficulty with the families of codes yet to be reviewed as this issue is likely to arise more often as the valuation or revaluation of one code will require review of its entire family. We recommend that CMS consider releasing the in the PFS Proposed Rule the new values for the codes under review instead of holding publication until the Final Rule so that societies can use those codes and values as comparator codes for current RUC surveys.

Medicare Contractor Medical Director (CMD)-Identified Potentially Misvalued Codes
CMS explains that it solicited input from Medicare CMDs in developing a list of potentially misvalued codes. CMS contends that CMDs have a unique perspective on the Medicare program given their day-to-day engagement with providers in their jurisdiction. It is not always clear, given the information presented in the rule of the rationale used by the CMDs to identify services as potentially misvalued. For example, in the case of two codes, CMS merely states, “CPT codes….are proposed as potentially misvalued because based on CMD comments, we believe that the codes may be overvalued.” This explanation is wholly unhelpful and offers the medical specialty societies no opportunity to understand why and how the codes are misvalued. If CMDs are going to be used to nominate potentially misvalued codes, they should be required to provide compelling arguments for any nominated codes based on data rather than conjecture.

CMDs should be encouraged, or perhaps even required, to bring such concerns routinely to the Contractor Advisory Committees in their region(s), where attendees are frequently knowledgeable about the services in question, nuances of coding and reimbursement, and typically are participants in the boards of the specialty organizations.

When CMS has concerns about services that may be potentially misvalued, it should broaden its collaboration with the medical specialty societies and the AMA RUC using the established process for addressing potential discrepancies. We note that the AMA RUC has a process in place that medical specialty societies must use to determine if there is compelling evidence to warrant review of a procedure or service. CMS should also consider reaching out to the dominant specialty when CMDs raise concerns about potentially misvalued codes. To the extent that CMDs are including codes on the potentially misvalued list because they have experienced problems with a few “bad actors” that have misused or inappropriately coded services in their
jurisdiction, it may be that a society-led educational effort on the appropriate use of the code or service is warranted, rather than a re-review of the codes.

We maintain that full disclosure and transparency are paramount in the shared effort to identify potentially misvalued codes and adjust their values. We look forward to collaborating with CMS on addressing truly misvalued services.

Services with Higher Total Medicare Payments in the Office vs. Facility

We understand CMS’ attention to potentially anomalous site-of-service payment differentials that may result from inaccurate resource input data used to establish rates under the PFS. We believe that CMS has created a useful screening tool in the CY 2014 PFS proposed rule to identify potential codes where the non-facility payment appears to be higher than the facility payment. However, we disagree with CMS’ reliance upon the identification of codes through this process to adjust automatically the non-facility PE RVUs without providing a mechanism for validating that both the facility and non-facility resource use data that CMS is relying upon may otherwise be accurate.

Legal Authority to Adjust the Non-Facility PE RVUs Based Solely on Hospital OPPS Data

CMS states that “[g]iven the differences in the validity of the data used to calculate payments under the PFS and OPPS, we believe that the non-facility PFS payment rates for procedures that exceed those for the same procedure when in a facility result from inadequate or inaccurate direct PE inputs, especially in price or time assumptions, as compared to the more accurate OPPS data.” (78FR43296) Accordingly, CMS states that “this proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures” (78FR43297). However, CMS fails to cite to any legal authority in the Social Security Act that would allow CMS to establish “upper payment limits for office-based procedures” by relying solely upon data used to calculate payments under the OPPS, which is a separate payment system under the Medicare Program. The establishment of an upper payment limit can only be done by statute.

We believe that CMS requires specific statutory authority to permit CMS to use payment rates established under one regulatory scheme (hospital OPPS) to create an absolute upper payment limit on payment amounts under another regulatory scheme (the PFS). Something more akin to a rebuttable presumption is required to address the lack of statutory authority for an absolute limit. CMS may use such OPPS payment rates to establish a guideline for determining potential payment limits under the PFS, but then needs to establish reasonable criteria for the presumption to be rebutted.

CMS Assumes that OPPS Data are More Reliable than MPFS PE Resource Inputs

CMS argues that hospital OPPS data is better and more reliable than data used to develop PE payments under the PFS, and therefore the hospital OPPS data should be relied upon in adjusting payments under the PFS. However, other than the fact that the hospital OPPS data is “auditable” and “updated annually,” CMS does not provide any evidence that such data is more accurate for all codes paid for under the PFS in all circumstances.

In the proposed rule, CMS states that: “[w]hen services are furnished in the facility setting, such
as a hospital outpatient department (OPD) or an ambulatory surgical center (ASC), the total Medicare payment (made to the facility and the professional combined) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other nonfacility setting.” (78FR43296). Further, CMS states that: “[w]e believe that this payment difference generally reflects the greater costs that facilities incur than those incurred by practitioners furnishing services in offices and other non-facility settings.” (78FR43296).

However, CMS states that: “for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare payment when the service is furnished in an OPD or an ASC. When this occurs, we believe it is not the result of appropriate payment differentials between the services furnished in different settings. Rather, we believe it is due to anomalies in the data we use under the PFS and in the application of our resource-based PE methodology to the particular services.” (78FR43296). Finally, CMS states that: “this proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures based on relatively more reliable cost information available for the same procedures when furnished in a facility setting where the cost structure would be expected to be somewhat, if not significantly, higher than the office setting.” (78FR43297-98).

We challenge CMS’ assumption that hospital OPPS data are more reliable, for example, when a service is significantly and disproportionately physician office-based. We believe that information from non-facility data resources is more accurate that the facility data that CMS has published in the Supplies Public Use Table. Accordingly, CMS should have a mechanism for excluding codes from the proposal to adjust non-facility PE RVUs for certain codes if CMS is presented with data that is more reliable than the hospital OPPS data.

**CMS Acknowledges that Small Sample Sizes may Distort Resource Use Data But Fails to Provide a Mechanism to Rebut Distortions in the Data if the Code Falls out of the five percent Exception Threshold**

In the proposed rule, CMS states that “[t]he PFS PE RVUs rely heavily on the voluntary submission of information by individuals furnishing the service and who are paid at least in part based on the data provided. Currently, we have little means to validate whether the information is accurate or reflects typical resource costs.” (78FR43296) To circumvent the perceived unreliability of the non-facility data, CMS proposes to use facility data instead to determine PFS PE RVUs for certain codes. However, CMS also acknowledges that data distortions can occur even in the OPPS setting when the relevant volume of data being relied upon is low. Accordingly, CMS proposes to “exclude any service for which 5% percent [sic] or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services.” (78FR43297) However, CMS does not provide a rationale for why the threshold for the exception is five percent, and not some other percent or absolute number. Further, CMS does not contemplate the use of other types of thresholds, such as a unit volume or cost threshold, either in addition to or in lieu of the percent threshold, for circumstances in which the five percent threshold may cause statistical anomalies. CMS’ proposal fails to take into account other circumstances, besides the volume of services furnished in the OPPS setting below five percent, wherein the non-facility data may be more accurate than the OPPS setting facility data. Accordingly, there needs to be a mechanism outside of the five percent threshold to rebut the presumption that the OPPS data will always be more reliable than the non-facility data.

**CMS Assumes that PE RVUs Based Upon Single Price Quotes are Biased or Inaccurate**
CMS states that “[i]n some cases the PE RVUs are based upon single price quotes or one paid invoice… Such incomplete, small sample, potentially biased or inaccurate resource input costs may distort the resources used to develop non-facility PE RVUs used in calculating PFS payment rates for individual services.” (78FR43296) CMS assumes that PE RVUs based upon resource input costs using a single price quote must be distorted, because such information is biased or inaccurate. CMS fails to consider situations where market competition impacts the pricing of a product, even when that product is the only product billed under a particular CPT code and there is only one supplier for the product. In such a situation, the availability of substitutable products creates a competitive marketplace. If there are substitutable products available in the market, the pricing of the single product captured in the CPT code must remain competitive with those other products. CMS should consider that the existence of a competitive market serves as a “checks and balances” system when the resource input costs for certain PE RVUs are based upon a single price quote, and that pricing is not necessarily arbitrary just because a single price quote or one paid invoice is used to establish the PE RVUs.

**CMS Must Provide a Mechanism to Determine if the Non-Facility PE RVUs of Identified Codes Should be Adjusted.**

CMS must provide a mechanism to determine if there are statistical anomalies or other data issues that would create a rationale for excluding a code from the proposal to adjust the non-facility PE RVUs for certain codes. When a code is identified under this proposal, entities should have the opportunity to provide updated resource use data to the agency. Alternatively, the RUC should have the opportunity to evaluate the resource use data associated with the codes identified in this proposal to determine if there are statistical anomalies in the data.

**Gastroenterology Examples**

Several of the GI motility codes were affected by the ASC/HOPD payment cap. If the proposed PE changes are implemented, the PFS payment will no longer cover the costs of the supplies for some of the procedures. The motility procedures are rarely, if ever, performed in the ASC or HOPD setting. Of the four motility codes affected by the cap, codes 91038, 91040, and 91120 are performed in the office setting 99-100 percent of the time and code 91035 is performed in the office setting 95 percent of the time. As noted in the examples below, we disagree with CMS that the OPPS data inputs are more accurate than non-facility PFS payment rates. Please refer to Attachment (A) for recent invoices that capture the typical price of each of the highest cost supply of the codes listed below.

Code 91120, which is paid at $427.67 under the PFS is part of APC 0126 (Level I Urinary and Anal Procedures) and has a payment rate of $81.99 in 2013. Code 91120 is performed in the office 100 percent of the time, and therefore has no impact in the calculation of the APC payment rate which is driven primarily by code(s) 51703 and 90911, and paid at $129.29 and $85.06 respectively in the physician fee schedule. Code 91120 has invoiced priced direct expenses of $251.75, including a rectal barostat catheter at $217.00. The cost of the supplies alone exceeds the APC payment by $169.76. We believe that code 91120, *Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)*, is misplaced in APC 0126 which, aside from 91120, contains only urology procedures; from the standpoint of resource and clinical coherence, code 91120 should be placed in APC 0164.
Code 91040, which is paid at $306.55 in the PFS, is part of APC 0360 (Level I Alimentary Tests) and has a payment rate of $137.27 in 2013. Code 91040 is performed in the office 100 percent of the time, and therefore has no impact in the calculation of the APC payment rate, driven primarily by code 91037 and paid at $172.50 in the physician fee schedule. Code 91040 has invoiced priced direct expenses of $255.22, including an esophageal barostat catheter at $217.00. The cost of the supplies alone exceeds the APC payment by $117.95.

Code 91035, which is paid at $525.66 under the PFS is part of APC 0361 (Level II Alimentary Tests) and has a payment rate of $302.60 in 2013. Code 91035 is only performed one percent of the time in the HOPD and four percent of the time in the ASC so it has little impact in the calculation of the APC payment rate, driven primarily by code 99120 and paid at $252.45 in the physician fee schedule. Code 91035 has invoiced priced direct expenses of $277.02, including a pH capsule sensor at $225, which is 92 percent of the total APC payment.

Code 91038, which is paid at $493.33 under the PFS is also part of APC 0361 (Level II Alimentary Tests) which has a payment rate of $302.60 in 2013. Code 91038 is only done 0.02 percent of the time in the HOPD and zero percent of the time in the ASC so it has little impact in the calculation of the APC payment rate driven primarily by 99120, and paid at $252.45 in the physician fee schedule. Code 91038 has invoiced priced direct expenses of $274.27, including an infusion impedance catheter at $95, which is 91 percent of the total APC payment.

Code 43456, which is paid at $632.83 under the PFS, is part of APC 0140 (Esophageal Dilation without Endoscopy) and has a payment rate of $271.06 in 2013. Code 43456 is done 13 percent of the time in the ASC and 64 percent in the HOPD so it has little impact in the calculation of the APC payment rate driven primarily by 43453, and paid at $311.31 in the physician fee schedule. Code 43456 has invoiced priced direct expenses of $313.70, including a ureteral-GI catheter at $166. The cost of the supplies alone exceeds the APC payment by $40.25.

Code 43756, which is paid at $231.36 under the PFS, is part of APC 0272 (Fluoroscopy) and has a payment rate of $64.12 in 2013. Code 43756 is done 29 percent of the time in the ASC and 62 percent in the HOPD so it has little impact in the calculation of the APC payment rate driven primarily by 76000, and paid at $53.08 in the physician fee schedule. Code 43756 has invoiced priced direct expenses of $121.19. The cost of the supplies alone exceeds the APC payment by $57.07.

Code 43757, which is paid at $324.58 under the PFS, is part of APC 0272 (Fluoroscopy) and has a payment rate of $64.12 in 2013. Code 43757 is done two percent of the time in the ASC and 78 percent in the HOPD so it has little impact in the calculation of the APC payment rate driven primarily by 76000, and paid at $53.08 in the physician fee schedule. Code 43756 has invoiced priced direct expenses of $163.56. The cost of the supplies alone exceeds the APC payment by $99.44.

**Physician Quality Reporting System**

The ACA authorizes CMS to provide incentive payments to eligible professionals who successfully participate in PQRS for 2011-2014. However, beginning in 2015, the ACA imposes
payment penalties to eligible professionals who do not meet PQRS reporting requirements. Additionally, PQRS performance data will soon be made available to the public, which makes successful PQRS participation of great importance to our members. Over the years, CMS has made a number of positive improvements to the program; however, we believe that several of CMS’ proposed changes to PQRS for the 2014 performance year do not reflect the current state of PQRS participation.

We believe changes to the program should first and foremost aim to increase PQRS participation and emphasize the quality of the measures reported over the quantity of measures. According to CMS’ 2011 PQRS and Electronic Prescribing (eRx) Incentive Program Experience Report, 29 percent of all eligible professionals participated in PQRS for that year, of which 83 percent earned an incentive payment. While participation rates have steadily improved in recent years, it remains that less than a quarter of all eligible professionals successfully participated in PQRS in 2011 to earn an incentive payment.

Because the Medicare physician VBP modifier is based on PQRS participation, reimbursement to physicians and other eligible professionals is placed at considerable risk for failure to successfully meet PQRS requirements. Given the financial jeopardy associated with PQRS, we believe that CMS should establish program predictability as a priority. Physicians, who must modify medical record systems and practice workflows to accommodate PQRS reporting changes, benefit from consistency and predictability of program parameters. Unanticipated changes to the program also limit opportunities for registry reporting, as the time and cost associated with adding data fields within a registry can be considerable.

We look forward to continuing our collaboration with CMS to improve the PQRS program, including its relevance to and ease of participation by gastroenterologists. We are committed to the development of measures that are meaningful to gastroenterologists and will lead to improved outcomes, as well as to educating our members about the program with the goal of increased participation rates. The following comments and suggestions are offered in the spirit of collaboration with CMS and continued quality improvement.

Proposed PQRS Measures for 2014 and Beyond

**Adenoma Detection Rate** – We thank CMS for using its exception authority to propose for PQRS 2014 and beyond the addition of the Screening Colonoscopy Adenoma Detection Rate measure. Our organizations have repeatedly called for the addition of PQRS measures related to digestive conditions and diseases, particularly endoscopy measures. We are pleased that CMS agrees with our societies that adenoma detection rate is medically significant as a quality measure of colonoscopy as a screening tool to prevent colorectal cancer by polyp identification and removal. This measure, along with other existing colonoscopy PQRS measures, is vital to improving the quality of measure choices for gastroenterologists. However, we are concerned that the number of gastroenterologists who will report this measure will be restricted by CMS’ proposal to only allow the measure to be reported via registry. We strongly encourage CMS to allow claims-based reporting for the adenoma detection rate measure, as well as registry reporting. If quality improvement is the goal of PQRS, restricting the
adenoma detection rate measure only to registry reporting will unnecessarily limit the use of this medically important measure.

Additionally, with the addition of the adenoma detection rate measure, gastroenterologists have for the 2014 performance year an improved complement of colonoscopy measures on which to report:

- Screening Colonoscopy Adenoma Detection Rate – PQRS # TBD
- Preventive Care and Screening: Colorectal Cancer Screening – PQRS #113
- Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use – PQRS #185
- Endoscopy and Polyp Surveillance – Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients – PQRS #320

Our societies strongly support the inclusion of these colonoscopy measures in PQRS for the 2014 reporting period and beyond.

Hepatitis B Vaccination – CMS has proposed removal of PQRS measure #184 Hepatitis C: Hepatitis B Vaccination in Patients with HCV. As rationale for the measure’s removal, CMS states in the proposed rule that the measure lost NQF endorsement/measure owner support. We recommend that CMS retain PQRS measure #184 for 2014 and beyond. It is best practice to vaccinate or ensure immunity to Hepatitis B for Hepatitis C patients. We believe that eliminating this measure from PQRS would be disruptive to those practices that have developed reporting mechanisms for meeting this measure. Additionally, we do not understand why CMS would retain PQRS measure #183 Hepatitis C: Hepatitis A Vaccination in Patients with HCV and remove its paired measure, which is PQRS measure #184. We believe both should be retained.

Clinical Database Registry Participation – We are disappointed that one year after adding PQRS measure #321 (NQF #493) Participation by a Hospital, Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Measures CMS is proposing its removal due to the proposed inclusion of Qualified Clinical Data Registries, which CMS states would make measure #321 redundant. We disagree that the measure would be redundant because the Qualified Clinical Data Registries option as proposed would severely limit the number of registries that could be deemed qualified.

PQRS measure #321 recognizes a physician’s participation in a clinical registry. We believe this measure is consistent with CMS’ previously stated desire to increase the frequency of registry-based reporting, rather than claims-based reporting. The measure is an important bridge to increased registry-based PQRS reporting. By including measure #321 in PQRS, we believe that CMS conveys the importance of establishing and maintaining clinical data registries. Given the uncertainty of how many registries will be able to fulfill the new Qualified Clinical Data Registries option as proposed, we believe that CMS should maintain PQRS measure #321 until it has implemented the new Qualified Clinical Data Registries option and can assess the number of eligible professionals who were able to utilize this new reporting option.
Recommended Core Measures

CMS is proposing to recommend additional core measures for 2014 and beyond. CMS notes that it is proposing to add measures due to its desire to align with recommended measures available under the Electronic Health Record (EHR) Incentive program. Beyond CMS wanting to align measures across quality reporting programs, which we support, it is unclear what CMS’ future intentions are with respect to promoting “core” measures and the implication of using the term “core” in PQRS since the EHR Incentive Program uses the term to refer to mandatory measures. **We wish to remind CMS that the proposed list of core measures would not be applicable to many single specialty physician practices. We encourage CMS to continue in future rulemaking cycles to allow physicians the flexibility to choose measures that are applicable to their scope of practice.** We believe this flexibility will also not interfere with the ultimate goal of aligning the various quality reporting programs, but instead, increase physician participation rates and quality of care.

Proposed PQRS Measure Reporting Requirements

We note that Tables 24, 25, 26 and 27 of the proposed rule provide summaries of proposed criteria for satisfactory reporting of measures for the 2014 incentive and 2016 payment adjustment. **We ask that CMS publish tables in the final rule that include the full compendium of reporting criteria rather than just finalized changes to the reporting criteria.** Because CMS only provided in the proposed rule tables for those criteria to which changes were proposed, understanding the full range of possible reporting criteria for the 2014 incentive and 2016 adjustment was unnecessarily complicated.

Proposed Requirements for Reporting Individual Measures

CMS is proposing for individual eligible professionals to earn a 2014 incentive payment at least nine measures covering at least three of the National Quality Strategy Domains must be reported. CMS is proposing that each measure must be reported for at least 50 percent of the Medicare Part B fee-for-service patients seen during the reporting period to which the measure applies. Furthermore, CMS is proposing to align the reporting criteria for earning the 2014 payment incentive with the criteria for avoiding the 2016 payment adjustment. However, CMS would continue to allow individual eligible professionals to report three measures via claims to avoid the 2016 payment adjustment.

Our societies appreciate that CMS is proposing to increase the number of measures that eligible professionals would be required to report for claims and registry reporting to better capture the picture of beneficiary care, particularly for the purpose of evaluating physician performance under the VBP modifier. However, the significant increase in the number of measures proposed by CMS was unanticipated and could lead to fewer successful PQRS participants and a shift from registry reporting back to claims-based reporting. **We believe CMS should maintain for the 2014 reporting period the three-measure threshold for individual eligible professionals who report measures via claims or registry and should establish a predictable timeline of future changes to criteria for satisfactory reporting.** Such a timeline could be based on specific milestones being met, such as participation rate thresholds among providers.
We acknowledge that CMS is proposing to allow eligible professionals the continued option of reporting three measures via claims to avoid the 2016 payment adjustment. However, we believe it is unfair to raise the measure threshold for eligible professionals to earn the 2014 incentive. In the CY 2013 physician fee schedule final rule, Table 91 (Federal Register, page 69194), CMS summarized the criteria for satisfactory reporting by individual eligible professionals to earn the 2014 incentive payment. Physician practices have prepared for 2014 reporting using criteria finalized in the CY 2013 physician fee schedule final rule; therefore, we believe CMS should maintain the reporting criteria for the 2014 incentive payment as previously finalized.

We reiterate our position that CMS’ focus should be to increase the rate of successful PQRS reporters if the ultimate goal is to improve quality of care. Nearly a quarter of all eligible professionals who submitted measures via claims in 2011 did not earn an incentive payment. CMS notes in the 2011 PQRS experience report that the most common claims-based submission error was reporting a measure-specific Quality Data Code (QDC) on a claim that did not also have the required procedure code. We suggest that even though CMS is proposing to lower the reporting threshold to 50 percent, the addition of six measures for successful PQRS reporting will increase the likelihood of claims submission errors. This is concerning since claims-based reporting remains the most common PQRS participation method for individual eligible professionals.

Many specialties, including gastroenterology, have struggled with the lack of specialty-specific PQRS measures. The focus of PQRS should be the reporting of measures by physicians that can lead to meaningful quality improvement. We believe that CMS’ goal of increasing the number of measures required for successful PQRS reporting is gradually being accomplished through the addition of measure groups, which for the 2013 reporting period are comprised of 4-10 measures. Our societies concede that gastroenterologists would likely be able to identify nine measures encompassing at least three quality domains. However, when physicians are required to report measures to simply meet a threshold rather than choose measures that can have a meaningful impact on beneficiary care, limited resources are unnecessarily diverted from more meaningful quality improvement activities.

Additionally, we believe that CMS’ proposal to increase the number of reported measures to nine will have the unintended effect of stifling progress toward increased registry reporting. In fact, it could lead to a shift from registry reporting back to claims reporting if current qualified registries cannot meet the nine measure threshold. Many registries have been working toward the goal of becoming a qualified PQRS registry, but the unanticipated requirement of additional measures simply pushes the timeline of when those registries can seek qualified status. At a minimum, individuals should also be allowed to report three measures via claims and a qualified registry to avoid the 2016 payment adjustment.

**Proposed Changes to the Group Practice Reporting Option**

CMS is proposing that group practices must report at least nine measures covering three of the National Quality Strategy Domains to earn a 2014 incentive payment and avoid the 2016 payment adjustment. Consistent with our comments regarding reporting criteria for individual eligible professionals, we believe CMS should maintain for the 2014 reporting period the
three-measure threshold for group practices with two or more eligible professionals that report measures via PQRS qualified registry. Furthermore, CMS should establish a predictable timeline of future changes to criteria for satisfactory reporting.

Should CMS finalize its proposal to require group practices to report nine measures across three National Quality Strategy Domains to avoid the 2016 payment adjustment, at a minimum we request CMS maintain the current reporting criteria that allows group practices with two or more eligible professionals to report at least three measures using a PQRS qualified registry to avoid the 2016 adjustment. Regardless of the required number of measures, CMS should adhere to its proposal requiring group practices to report each measure on at least 50 percent of the Medicare Part B fee-for-service patients seen during the reporting period to which the measure applies rather than increasing the reporting threshold to 80 percent for the reasons cited above.

_Proposed Requirements for Reporting Measures Groups_

CMS is proposing two key changes for individual eligible professionals and group practices that report PQRS measures groups to earn an incentive payment or avoid a payment adjustment. CMS is proposing to: 1) eliminate the claims-based reporting option for measures groups; and 2) increase the number of measures to be included in a PQRS measures group.

CMS is proposing to eliminate for individual eligible professionals claims reporting for measures groups because for 2011 only 4,472 eligible professionals reported measures groups via claims, compared to 12,894 via registry. While approximately one-third of eligible professionals reported measures groups via claims, the number of eligible professionals using claims to report measures groups has steadily increased: 1,410 (2008), 3,649 (2009), 4,151 (2010), and 4,472 (2011). We suggest the rate of eligible professionals reporting measures groups is increasing because measures groups have been added to the program since they were introduced in the 2008 program year. Physicians should have access to as many PQRS reporting options as possible. Physician confidence in the system erodes when predictability and stability are lacking. We do not believe that now is the time for CMS to propose the elimination of reporting options. We suggest that more, not fewer, reporting options need to be available until PQRS participation rates increase. Our societies recommend that CMS maintain for individual eligible professionals claims-based reporting for measures groups for the 2014 reporting period. Specifically, we ask CMS to maintain claims and registry reporting for the Hepatitis C measures group.

CMS is proposing to increase the minimum number of measures to be included in a PQRS measures group from four or more to six or more. Consequently, CMS is proposing to add additional measures to groups that previously contained less than six measures. For those practices that have modified their workflow and medical record systems to capture data for measures groups, unanticipated changes can create a tremendous amount of work. Internal information technology changes alone, such as those required to capture the frequency of individual provider compliance, can take many more months than exist between the published proposed rule and new calendar year. When measures are added to PQRS or measures groups are introduced, physicians need to be assured that measures are going to stand for a significant period of time. Volatility in the program inhibits successful PQRS participation and, ultimately,
impedes the overarching goal of quality improvement. For these reasons, we ask CMS to work toward greater program stability, including introducing and maintaining measures groups for an established time period (e.g., three to five years) before modifications can be proposed.

Proposed Qualified Clinical Data Registry Reporting Option
In response to CMS’ proposals for defining a qualified clinical data registry and the requirements that such registries will be required to meet for the purpose of implementing Section 601(b) of the American Taxpayer Relief Act of 2012, our organizations will submit separate comment letters. However, we uniformly are disappointed with the initial approach that CMS has proposed to implement the new mandate. We were hopeful that the new qualified clinical data registry reporting option would create more opportunities for physicians to earn PQRS “credit” through participation in clinical data registries that collect uniform, clinically significant, and actionable data and which provide timely feedback to participants to facilitate quality improvement and quality reporting. By doing so CMS would reduce the administrative burden on physicians who are trying to meet PQRS reporting requirements to avoid payment penalties and who are also participating in clinical data registries, often at considerable cost, as a means for improving quality of care.

Proposed Reporting Thresholds for Individual Eligible Professionals and Group Practices
CMS is proposing that eligible professionals and group practices using claims and qualified PQRS registries must report each measure on at least 50 percent of the Medicare Part B fee-for-service patients seen during the reporting period to which the measure applies. While the 50 percent threshold is consistent with the 2013 reporting criteria for individual measures reported via claims, it lowers the threshold (from 80 to 50 percent) for reporting individual measures via a qualified PQRS registry.

We understand that CMS is proposing to lower the reporting threshold to 50 percent because it is proposing to increase the number of measures; we support this rationale. As stated above, we do not believe that the number of measures required for successful PQRS participation should be increased to nine for physicians to earn the 2014 payment incentive or avoid the 2016 payment adjustment. However, even if CMS accepts our recommendation to maintain the three-measure threshold, the reporting threshold should be 50 percent for claims and registry reporting on the basis that an 80 percent threshold could prove difficult to meet as a result of the ICD-10 conversion. We are concerned the ICD-10 conversion could interfere with PQRS reporting accuracy, particularly for physician practices that use claims-based reporting. A reporting threshold of 50 percent would mean that most physicians could meet reporting requirements well before October 1 when the ICD-10 conversion is scheduled to occur. However, a reporting threshold of 80 percent would be much more difficult for practices to meet prior to October 1.

PQRS for the 2017 Payment Adjustment and Beyond
In the proposed rule, CMS seeks comment on several aspects of future PQRS reporting. We appreciate CMS solicitation of stakeholder input on the future aspects of the program and offer the following comments in response.
Should CMS consider establishing a reporting period that occurs closer to the adjustment year for certain PQRS reporting mechanisms, such as the registry, EHR, and GPRO web interface mechanisms?

We continue to oppose CMS’ back-dating proposals for quality programs. The two-year delay in payment adjustments makes it very difficult for physicians to adjust their fiscal obligations, thus impacting a practice’s bottom line. We appreciate it may not be technically feasible for the agency to calculate payment adjustments in less than two years for quality data submitted via claims; however, we believe that other reporting mechanisms, specifically participation in a qualified clinical data registry, makes it entirely feasible to close the two-year gap between the performance and payment periods. We encourage CMS to continue to explore establishing reporting periods that occur close to the payment adjustment year. However, we are not proponents of shortening the reporting period. We believe the shorter reporting periods would result in less data, which could decrease its reliability.

Should CMS modify the current definition of a group practice to account for multiple taxpayer identification numbers (TINs)?

As we have commented to CMS previously, we believe the requirement that physicians reassign their billing rights to a single TIN for purposes of participating in the GPRO is unnecessarily limiting. It is not uncommon for physicians who work in a group practice setting to continue billing Medicare on their own behalf rather than reassigning their billing rights to a group practice TIN. Because these physicians function as a group and use the same data systems, they should be allowed to exercise the GPRO reporting option. For PQRS and the e-Rx Program, as well as for other reporting programs, we propose that CMS create a unique group identifier for the purpose of identifying a group practice in instances where billing reassignment by individual physicians to a single TIN is not practical.

Physicians who wish to be identified as a group practice could then be recognized accordingly by either: 1) reassigning their billing rights to the group practice TIN; or 2) by having their NPI associated with a unique group identifier. For physicians who associate their NPI with a unique group identifier, incentive payments or penalties would still be applied at the individual physician level, but success or failure of participation in PQRS would be determined at the aggregate group level, as would public reporting of participation and performance.

Should CMS eliminate the claims-based reporting mechanism beginning with the 2017 reporting period?

As stated above, we believe the stability and predictability of the PQRS is critical to increasing participation and success rates. We suggest that prior to any decision to eliminate claims reporting, CMS should undertake a survey of Medicare-participating physicians to ascertain why physicians continue to utilize claims-based reporting rather than moving to other reporting mechanisms. Eliminating claims-based reporting will be significantly dependent on adoption of EHRs and availability of registry reporting.
CMS is proposing to include measures available under the Hospital Inpatient Quality Reporting (IQR) Program that have been retooled to be reported under PQRS during the 12-month 2014 PQRS incentive and 12-month 2016 PQRS payment adjustment reporting periods via the registry-based reporting mechanisms. CMS seeks comment on whether it should attribute the reporting periods and performance results from the Hospital IQR Program to individual eligible professionals or group practices that elect to have their hospital’s performance scores attributed to them.

Our societies do not wish to comment specifically on the topic of attributing the Hospital IQR Program to physicians for the purpose of PQRS. However, since the ambulatory surgery center (ASC) is a predominant site of service for many gastroenterologists, we are very interested in the concept of allowing physicians the opportunity to elect to have their ASC performance scores attributed to them for the purpose of PQRS. The ASC Quality Reporting Program and its compendium of measures are in their infancy; however, in future years, it may be important for CMS to identify ways to streamline reporting programs to avoid duplication or unnecessary burden of reporting on physicians.

VALUE-BASED PAYMENT MODIFIER

Our societies appreciate 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 little risk of payment penalties until the following can occur: CMS has gained greater experience with the program; PQRS participation and success rates have improved among physicians; and more physicians receive, understand and can apply the information contained in their Quality and Resource Use Reports (QRURs).

We offer the following comments on CMS’ proposed changes to the VBP modifier in the spirit of working with CMS to transform Medicare from a passive payer to an active purchaser of higher quality, more efficient health care.

Proposed Expansion of the VBP Modifier

CMS proposes to expand the group size threshold for the CY 2016 payment adjustments to include group practices with 10 or more eligible professionals. In the proposed rule CMS estimates that by lowering the threshold to groups with 10 or more eligible professionals it would cause approximately 17,000 groups and nearly 60 percent of physicians to be affected by the VBP modifier in 2016. We appreciate that CMS is required by law to fully phase-in application of the VBP modifier by 2017. However, we have concerns with the increased risk of payment penalty to which groups with 10-99 eligible professionals will be exposed under the VBP modifier largely as a result of proposed PQRS program changes. Therefore, and as discussed below, if CMS does not further mitigate the risk of a negative VBP modifier for groups of 10-99 eligible professionals, the VBP modifier group size threshold should be increased to 50 or more eligible professionals for the 2016 payment adjustment.
Setting the VBP Adjustment Based on PQRS Participation

We commend CMS for continued alignment between PQRS and the VBP modifier. In particular, we believe it is important that physicians continue to have the option to select the clinical quality measures via PQRS that will be used for calculation of the VBP modifier.

**We generally support CMS’ proposed continuance of its policy to categorize groups of physicians into two categories:** Category 1 – Groups of physicians that self-nominate as a group practice and satisfactorily report data on PQRS quality measures to avoid the payment adjustment in 2016; and Category 2 – Groups of physicians that do not fall within Category 1. Additionally, CMS is proposing to expand Category 1 to include physicians who do not self-nominate to participate in the PQRS as a group practice but have at least 70 percent of the group’s eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the 2016 payment adjustment, or, in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry.

We strongly support CMS’ proposal to expand Category 1 to include the 70 percent threshold option which allows eligible professionals to report on any of the measures available to individual eligible professionals via claims, CMS qualified registries, EHRs, or the newly proposed qualified clinical data registry option. While 2012 participation data is not publicly available, we suspect that the GPRO participation rate among small group practices remains low, making the 70 percent threshold option particularly important for small practices. According to CMS’ reporting experience report, in 2011 only 38 group practices participated in GPRO II. We suspect that GPRO participation will remain low for small, single specialty practices because the only proposed GPRO reporting options for groups of 2-24 eligible professionals are qualified registries and EHRs, not claims which remains the most popular data submission mechanism for PQRS.

**Proposed Changes to the Quality Tiering Methodology**

For the 2015 payment adjustment, group practices had the option to elect quality tiering. CMS is proposing for the 2016 payment adjustment that groups in Category I would no longer have the option to elect quality tiering. **Our societies support CMS’ proposal to subject physician groups with 10-99 eligible professionals only to upward or neutral adjustments derived under quality tiering.**

To be placed in Category I, PQRS reporters must avoid the 2016 payment adjustment. Therefore, even though physician groups with 10-99 eligible professionals are not subject to negative adjustments under quality tiering, they are still at risk of a -2 percent payment adjustment if they fail to successfully participate in PQRS to avoid the 2016 adjustment. We believe an extra step is needed to help physician groups with 10-99 eligible professionals avoid a negative VBP modifier given proposed changes to PQRS participation requirements and low PQRS participation and success rates overall. **We suggest that CMS consider the following options:**

- modify its proposal to classify groups of 10-99 eligible professionals under a quality composite score of “average” under the quality tiering methodology if the group
practice attempts to participate in PQRS (either as a GPRO or under the 70 percent threshold option) but fails to successfully report to avoid the payment adjustment. Average should be defined as medium quality/average cost for a neutral (+0.0 percent) adjustment; or

- modify its proposal to maintain the administrative claims default for group practices of 10-99 eligible professionals that attempt to participate in PQRS (either as a GPRO or under the 70 percent threshold option) but fail to successfully report to avoid the payment adjustment.

CMS, however, proposes that groups of 100 or more eligible professionals will be subject to upward, neutral, or downward adjustments. In the proposed rule, CMS states that it is appropriate to mandate for groups of 100 or more eligible professionals both upward and downward payment adjustments under the quality tiering methodology for the 2016 payment adjustment because large groups should already be focused on quality improvement and should have ample ability to do so. We agree. However, we believe that the amount of payment at risk should continue to be low as PQRS reporting requirements continue to evolve and as CMS modifies other quality and cost measures for calculating the VBP modifier.

Proposed Changes to Payment Adjustment Amounts

CMS is proposing to modify VBP modifier adjustments for the 2016 payment year. First, CMS is increasing the payment adjustment from -1 percent to -2 percent for group practices in Category 2. Second, CMS is increasing the payment adjustment amounts under quality tiering in the following categories: medium quality/high cost (-1 percent), low quality/average cost (-1 percent), and low quality/high cost (-2 percent). We appreciate CMS’ challenge to limit payment adjustment for those practices that fall into Category 2 and under the quality tiering, while also creating the opportunity for upward payment adjustments for practices in Category 1 under the quality tiering methodology, as the VBP modifier must be implemented in a budget neutral manner.

CMS has previously stated that as it gains experience with its VBP modifier methodologies, it is likely to consider ways to increase the amount of physician payment at risk. Because the VBP modifier is still in its first year of implementation and because CMS continues to make adjustments to program and methodologies, we offer the following recommendations regarding payment adjustment amounts:

- **CMS should maintain the Category 2 adjustment at -1 percent until PQRS success rates have substantially increased.** Practices that fall into Category 2 are likely to be smaller practices that are either uninformed about PQRS requirements or simply lack the staffing resources for participation. By increasing the adjustment to -2 percent under Category 2, practices that fall into that category will receive a -4 percent adjustment in the 2016 payment year from the VBP modifier and PQRS adjustment combined.
• CMS should maintain current adjustment levels under the quality tiering methodology, at least through the VBP modifier transition and until CMS has had ample opportunity to evaluate its methodologies.

**VBP Modifier Quality Measures**

We support CMS’ continued alignment of the VBP modifier and PQRS. We believe that this alignment helps to minimize administrative burden to physician practices. However, as previously discussed in this letter, because changes to PQRS requirements impact physicians under the VBP modifier, we believe that CMS should either refrain from implementing further substantial changes to PQRS during the early years of the VBP modifier, or in the event that changes are made to PQRS that could potentially make it more difficult for physicians to meet participation requirements, the risk of a downward adjustment to physicians under the VBP modifier should be none to minimal.

**Core Measures**

We agree with CMS that it is premature to require physician reporting, for the purposes of calculating the VBP modifier, on a limited set of core measures. The VBP modifier should be calculated using measures determined by physicians to be meaningful to their practice. We ask that CMS continue to afford physicians and group practices this measure flexibility for the foreseeable future.

**Outcome Measures**

CMS proposes to maintain the three outcomes measures it finalized in the CY 2013 physician fee schedule final rule for the 2015 payment adjustment: 1) All-Cause Readmission; 2) Composite of Acute Prevention Quality Indicators; and 3) Composite of Chronic Prevention Quality indicators. Our societies expressed concern in our CY 2013 physician fee schedule proposed rule comment letter that it may be difficult to measure physician practices using these measures since they were developed to be applied at the community level. We believe the objective of a VBP modifier should be to calculate quality scores using measures that are specific to physicians and their scope of practice. **We encourage CMS to continue evaluation of these outcome measures and to consider more optimal outcomes measures for future VBP modifier calculations.**

**Clinical Data Registry Option**

For those groups of physicians subject to the VBP modifier whose eligible professionals participate in PQRS as individuals rather than a group practice under the GPRO, if those eligible professionals satisfactorily participate in a PQRS qualified clinical data registry and CMS is unable to receive quality performance data for those eligible professionals, we support CMS’ proposal to classify the group’s quality composite score as “average” under the quality-tiering methodology. **We ask that CMS define “average” as medium quality/average cost for neutral (+0.0 percent) adjustment.**

**Application of the VBP Modifier to All Physicians**
CMS notes in the proposed rule that when the VBP modifier applies to all physicians, it anticipates continuing its policy to align with the PQRS group reporting for all groups of physicians with two or more eligible professionals. CMS further anticipates permitting physicians who are solo practitioners to use any of the PQRS reporting mechanisms available to them under PQRS for purposes of the VBP modifier. Our societies support this approach.

Refinements to Cost Measure Composite Methodology

CMS is proposing that if it cannot attribute a sufficient number of beneficiaries to a group of physicians subject to the VBP modifier and thus is unable to calculate any of the cost measures with at least 20 cases, the group of physicians’ cost composite score would be classified as “average” under the quality-tiering methodology. CMS states in the proposed rule that it has observed that groups of physicians that do not provide primary care services, which would include many gastroenterology practices, are not attributed beneficiaries or are attributed fewer than 20 beneficiaries, which does not allow for calculation of a reliable cost measure. We support CMS’ proposed modification that groups of physicians in Category 1 for which it attributes fewer than 20 cases to calculate any cost measure would have their cost composite classified as “average” cost. We ask that CMS define “average” as medium quality/average cost for a neutral (+0.0 percent) adjustment.

CMS is also proposing to modify the methodology used to calculate cost benchmarks for each cost measure. Currently, CMS calculates the cost benchmark as the national mean of the performance rates among all groups of physicians. CMS has found that this peer grouping methodology can have varied impacts on groups of physicians that are comprised of different physician specialties, especially as the VBP modifier is applied to smaller groups. We appreciate CMS’ ongoing evaluation of its methodologies and support the proposed specialty adjustment method. For the reasons discussed in the proposed rule we believe that using this benchmark is likely to result in more precise attribution. However, we encourage CMS to undertake an ongoing analysis of this and other VBP methodologies so the impact on different specialties, geographic regions, and types of practice can be ascertained.

Proposed Medicare Spending per Beneficiary Measure

CMS is proposing the addition of a new cost measure for calculation of the 2016 payment adjustment – Medicare spending per beneficiary (MSPB) measure. According to the proposed rule, CMS is proposing to add this measure, which has been used for the Hospital Inpatient Quality Reporting (IQR) Program, because spending post-hospital discharge is a significant source of variation on Medicare spending per beneficiary. We appreciate the need for hospitals and physicians to work together to reduce delivery system fragmentation through improved care coordination. We suggest that until electronic health records are interoperable, continued care coordination challenges will persist. As mentioned above, we believe the objective of a VBP modifier should be to calculate quality scores using measures that are specific to physicians and their scope of practice. We have concern with the inclusion of the proposed MSPB measure for the 2016 VBP payment adjustment. Even though the measure has not yet been endorsed by the NQF, it is being reviewed and has been tested as a facility measure. While it may be
appropriate to use the MSPB measure for the hospital IQR program, we do not believe it is appropriate to use the MSBP measure for the physician VBP program until the measure has been appropriately tested for application to individual clinicians and group practices.

Should CMS proceed with inclusion of the MSPB measure in the physician VBP modifier program for the 2016 adjustment, we do not agree with the chosen attribution method. CMS proposes to attribute a MSPB episode to a group of physicians when any eligible professional in the group submits a Part B Medicare claim under the group’s TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period. CMS proposes that the same index admission and MSPB episode could be attributed to more than one group of physicians. CMS estimates using this attribution method will enable about 11,419 groups with at least 10 eligible professionals to have an MSPB measure score included in their cost composite. By using this attribution method, a single service by one physician of a group practice can expose the group to expensive practice patterns that they may have no potential to influence. We do not believe that incidental involvement in a patient’s care should be the defining aspect of attribution. Rather, attribution should rest with physicians and group practices that are responsible for a substantial level of services provided to the patient. Therefore, we suggest that either of the other two attribution methods considered by CMS be used: 1) attribute the patient to the group that provided the plurality (highest total dollar amount paid by Medicare) of Part B services either during the entire MSPB episode, or during the index hospitalization only; or 2) attribute MSPB episodes to all TINs from which an eligible professional provided services representing at least 35 percent of the total Medicare Part B payments made either: 1) during the MSPB episode; or 2) during the index hospitalization. We suggest that using the plurality attribution method would be consistent with CMS attribution methodology for the other cost measures. Regardless of attribution methodology chosen, ongoing analysis will be required to determine methodology reliability.

CMS is also proposing that a group of physicians would have to be attributed a minimum of 20 MSPB episodes during the performance period to have their performance on this measure included in the VBP modifier cost composite. We believe that a minimum of 20 MSPB episodes is sensible for a methodology that is attempting to capture most large practices.

**Physician Compare Website**

Our societies are encouraged by certain proposals pertaining to Physician Compare, specifically opportunities for providers to review their data before it is made public. We also thank CMS for its interest in including on Physician Compare measures developed by specialty societies. Furthermore, we thank CMS for its outreach to physician organizations in making recent modifications to improve its functionality. However, additional improvements are still needed to ensure the accuracy of the search function and the underlying demographics of the data. These efforts must be undertaken before incorporating any additional performance information.

Posting Patient-Based Survey Measures for Individual Physicians Beginning 2015
CMS seeks comment on posting patient-based survey measures for individual physicians beginning in 2015. While patient survey data may capture important information, these measures are subjective and there may be differences in what the patient deems important when undergoing colorectal cancer screening, for example, and what the medical literature deems important.

We urge CMS to take a careful evaluation of this approach and recommend first evaluating the posting of data on group practices prior to implementing this policy at the individual physician level. We also ask CMS to offer more detailed guidance on how the agency would collect this sample of patient experience data in order for us to better educate our members.

Specialty Society Developed Measures

While we understand CMS is soliciting comment on incorporating measures developed by specialty societies into Physician Compare, we believe that CMS should formally adopt this idea in future rulemaking. CMS solicited the same request in previous rulemaking and our societies recommended that CMS include society-developed measures into Physician Compare. By adding this data, we believe it will provide Medicare beneficiaries with more useful data. For example, Medicare beneficiaries should be able to use Physician Compare to compare performance of a certain procedure or service such as screening colonoscopy. Many of our members participate in independent quality improvement registries at their own expense that measure physician performance on specific quality metrics developed by our societies. We believe the registry should be viewed as the bridge between measure-development and measure-adherence. Medicare beneficiaries should have the knowledge of physician participation in these voluntary quality initiatives and quality metrics.

Recently, our societies formed a multi-society work group to develop, update, and construct measures relevant to our scope of practice, and thus, produce data that are more meaningful for our members. Some measures have been, and will hopefully soon be, endorsed by independent quality improvement organizations, such as the NQF. This workgroup adheres to a rigorous measure development process that includes a thorough review of the current medical literature and medical science by the subject matter experts, a peer review process, an opportunity for all members to provide comment in order to account for regional or other variations in care, approval from the respective workgroup members, and another round of review and approval by each society’s respective leadership before any measure is officially “endorsed” by the society. The product of this workgroup will compliment the goals of the Physician Compare Website as our members’ performance will be assessed by metrics developed by the subject matter experts in our specialty. As a result, Medicare beneficiaries will have pertinent information by which to help compare/select a quality physician with a higher degree of confidence.

As CMS notes in the proposed rule, beginning in 2015, CMS will post individual physician PQRS performance on the Physician Compare website. It is important for CMS to consider incorporating voluntary quality improvement efforts and measures developed by societies as the Medicare beneficiary may be unable to accurately assess physician performance (or find a physician) without these components. For example, a large, multi-specialty group practice, that includes a gastroenterologist, may decide to participate in PQRS by using the GPRO Web
interface, which does not include colonoscopy measures. By including that gastroenterologist’s involvement in other voluntary quality improvement efforts, it provides an opportunity for a Medicare beneficiary to know something about the gastroenterologist in that group practice—information that wouldn’t otherwise be readily available to the patient. To be most useful, we believe it is important for Physician Compare a wide range of information including PQRS participation/performance, specialty-led quality improvement initiatives, and patient experience/satisfaction measures.

Review Period Prior to Publicly Posting Data

Our physicians continue to find, with concerning frequency, inaccuracies with their most basic information. We suggest that before CMS begins posting information that could have a significant effect on a physician practice, CMS must establish confidence among physicians by improving the accuracy of currently posted information.

We support CMS’ proposal for a 30-day preview period prior to public posting of any data on Physician Compare. This review period should also include a process for physicians, group practices, and accountable care organizations to challenge the accuracy or validity of any publicly available information. This is especially important as CMS moves to include patient experience/satisfaction data on the Website. However, we question whether a 30-day period will be adequate for physicians to review their information, identify errors and gather evidence that may be necessary to refute any errors. At a minimum, CMS should considering allowing a 45-day review period, which would be consistent with the physician review period in the newly implemented National Physician Payment Transparency Program.

COMPLEX CHRONIC CARE MANAGEMENT SERVICES

CMS is proposing to establish a separate payment under the PFS for complex chronic care management (CCCM) services furnished to patients with multiple complex chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We appreciate CMS continuing to explore potential refinements to the PFS that would appropriately value care management services and the recognition that resources required furnishing complex chronic care management services to beneficiaries with multiple chronic conditions are not adequately reflected in the existing E/M codes. Further, we believe that gastroenterologists should be able to report care coordination since we manage patients with chronic conditions such as pancreatitis, hepatitis, malnutrition and inflammatory bowel disease (IBD).

CPT created the Complex Chronic Care Coordination Codes (CPT 99487, 99488 and 99489) to describe the services of clinical staff with oversight and participation by physicians and qualified non-physician professionals to a small subset of patients who have multiple chronic conditions and other factors that put them at high risk for death, acute illness exacerbation or functional decline. We strongly recommend that CMS not finalize the G codes but instead recognize the existing non-face-to-face CPT codes. Use of CPT codes will allow use of CPT Guidelines and more likely adoption by other payers.
CMS recognizes that not all physicians and practices will be capable of meeting the requirements without making investments in technology, staff training, and maintenance of systems and processes. We agree and believe that the proposed standards may burden smaller practices. In fact, it seems as though the proposal is geared toward large group practices or integrated groups with primary care. For example, 24-hour access to a full electronic medical record may be difficult for many small practices as it requires interoperability of ALL providers to the patient. While we believe that interoperability is important and agree that the practice should have timely access to records, we are concerned complete interoperability is not attainable by a plurality of physicians that could potentially report complex chronic care management services. As many otherwise qualified physician practices would not be able to ensure 24 hour electronic access to the FULL medical record by January 1, 2015, we do not believe this is feasible at this time. It will be difficult for physicians to access full EMRs in closed hospital networks with restricted internet access. We encourage CMS to consider a phase-in of EMR capabilities to ensure the care coordination team has 24-hour access to the medical record, such as contact via email or telephone to other physician offices.

The agency is also considering the scope of complex chronic care management services. Clearly CCCM is being performed pursuant to a care plan ordered by the treating physician. The physician is regularly involved in implementing and updating the plan and is kept informed as to the patient’s condition. We anticipate that some CCCM activities may be performed by clinical staff while the physician is not in the office - or after office hours, nights, weekends and holidays. CMS is proposing that practices must “employ at least one advanced practice nurse or physician assistant” whose written job descriptions indicate that their job roles include and are appropriately scaled to meet the needs for beneficiaries receiving services in the practice who require complex chronic care management services provided by the practice. We are concerned that this would be problematic for practices that would otherwise be well qualified to provide care management. Complex chronic care management can be performed by a variety of licensed / credentialed clinical staff in addition to an advanced practice nurse or physician assistant. By reporting the code, the practice/signatory is attesting that the practice is capable of - and is - executing/coordinating the original care plan and the revised care plan. Further, the practice is attesting that a care plan is being implemented by appropriately licensed/credentialed clinical staff. Only time spent in activities performed by appropriately trained, licensed and, when applicable, credentialed clinical staff who are a cost to the practice reporting the code should be counted towards care coordination time. In the absence of documentation showing that there is an improvement in health outcomes when complex chronic care management is performed solely by an advanced practice nurse or physician assistant, we urge CMS to relax this requirement and to recognize that such services can be performed by appropriately trained, licensed and, when applicable, credentialed clinical staff. Under certain circumstances, we also believe that independently contracted (but not necessarily employed) personnel could participate in provision of these services under the general supervision of the physician or non-physician practitioner.

We are also concerned with the proposal that patient communication with the provider should not only include telephone but secure messaging, internet, or other same-time consultation methods. Many patients or families of patients may not be capable of this type of communication, even if the practice is equipped to provide this level of communication.
CMS also proposes that beneficiaries must receive either a Welcome to Medicare visit (HCPCS code G0402) or an Annual Wellness Visit (AWV) (HCPCS code G0438 or G0439) within the 12 months prior to receiving complex chronic care management services. Although the annual wellness visit may not be directly related to the needs of chronically ill patients, we appreciate that it could be a mechanism for CMS to identify the physician the patient would most likely use to provide the care coordination services. However, we are concerned that the AWV may not be the best indicator of who provides chronic care management services. The AWV has many characteristics that allow it to be performed by practices that are not the beneficiary’s chosen primary source of care for their complex chronic care management needs, or even a primary care practice. Additionally, the prevention focus of the AWV is inconsistent with the care needs of the typical complex chronic care management patient and performing an AWV may not be appropriate. Similarly, the patient condition at the time the AWV was furnished may have substantially changed and it is possible complex chronic care management services may need to commence before being able to perform the AWV. We believe that the requirement to perform or obtain the AWV serves as an administrative barrier to the performance of complex chronic care management and could actually serve to require performance of services that are not medically necessary for the sole purpose of being able to perform and report the medically necessary complex chronic care management services.

Lastly, CMS also is considering whether to require practices to be recognized as a patient-centered medical home (PCMH) by a national accrediting body to provide and report CCCM services. We do not support this requirement. In general, medical societies have been reluctant to accept proposals that would require medical homes or patient-centered practices to obtain accreditation/recognition by external entities. We suggest that CMS work with the medical community to develop an alternative to accreditation as a path for providing CCCM services.

**Collecting Data on Services Furnished in Off-Campus Hospital Provider-Based Departments**

Over the course of the last few years, concerns about a “reverse” migration of services that were once provided in the physician office setting but are shifting back to hospital outpatient departments (HOPD) have arisen, particularly as hospital employment of physicians has increased. The Medicare Payment Advisory Commission (MedPAC) has made recommendations that would equalize payments across settings for evaluation and management (E/M) services, and has considered additional recommendations that would equalize payment across settings for other services. Hospitals are also purchasing physician practices and redesignating 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.

To better understand these trends, CMS is considering collecting information that would allow it to analyze the frequency, type, and payment for services furnished in off campus provider-based hospital departments. CMS discusses several means by which the data could be collected. Under one option, a new place of service (POS) would be created for use on claim forms when these
departments bill Medicare for health care services. Under another option, CMS would require hospitals to break out charges for services in these departments in their cost reports.

As noted above, we do not believe that hospital cost reports are the most reliable source of data, therefore, we do not support a data collection activity that would emphasize the use of such reports. We do, however, support the development of a new POS code to identify off-campus provider-based outpatient departments, which we believe will help CMS and others identify when physician offices, for example, have been re-designated as OPDs.

**Coverage of Items/Services in FDA Investigational Device Exemption Trials**

CMS proposes to revise its regulations specific to Medicare coverage of investigational devices and routine items and services furnished to beneficiaries during the clinical studies or trials conducted under the Food and Drug Administration (FDA) IDE regulations. Specifically, CMS proposes new standards for coverage of certain investigational devices and routine items and services incurred by Medicare beneficiaries participating in FDA-approved IDE studies, as well as a centralized review process to govern these activities, previously managed by local Medicare administrative contractors (MACs). CMS maintains that the new standards and centralized review process will promote transparency and consistency in coverage decisions, as well as enhance administrative efficiencies.

We appreciate CMS’ rationale for making this proposal and agree that consistency and administrative efficiencies are important. Nonetheless, we are concerned that the proposal could limit beneficiary access and participation in national clinical trials by disallowing coverage for routine care items and services beyond those that may be associated with the trial. Specifically, beneficiaries could be at risk of losing coverage for medical emergencies and other health care items and services that would otherwise be available to beneficiaries outside of the clinical trial. We urge CMS to clarify that such coverage would continue to be available to seniors.

We are also concerned that CMS did not include a timetable that shows a planned order or sequence of action leading to a coverage decision. Despite noting that beneficiary appeals rights would not be modified, CMS failed to include an appeals mechanism as part of its proposed centralized review process. **We urge CMS to collaborate with the medical professional societies and manufacturers to devise an appropriate timetable for when coverage decision activities would take place, so that manufacturers, clinicians and beneficiaries may better understand the coverage decision process.**

Furthermore, we are concerned about the structure and make-up of the group that will be responsible for making coverage decisions. CMS does not provide detail as to the type or level of expertise it will commission to engage in the development of the coverage decisions. Under the current process, MACs work with their contractor advisory committee (CAC) representatives in an open, public and transparent process. CAC representatives are well equipped to provide important perspectives in the development of such decisions, and we urge CMS to ensure that physicians remain active in the process. **We urge CMS to establish a federal advisory committee that would include physician representatives to assist as it carries out this activity.**
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; Elizabeth Wolf, Director of Regulatory Affairs, AGA, at 240-482-3223 or ewolf@gastro.org; or Camille Bonta, consultant to ASGE, at 202-320-3658 or cbonta@summithealthconsulting.com.

Sincerely,

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Chair
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ATTACHMENT A

"Given invoices_CPT 91035-91038.pdf"
91035 - G-esoph reflx tst w/electrod
CMS supply code SD204, sensor, pH capsule (Bravo) - $225
Given Bravo pH capsule (FGS-0312 Bravo pH capsule), $1,125/pack
5 capsules/pack = $225/capsule

91038 - esoph imped funct tst >1hr
CMS supply code SD230, impedance catheter, infusion - $95
Given Veraflex-Z catheter (900003 cath, Versaflex-Z), $1,170/pack
10 catheters/pack = $117/catheter

"MUI scientific invoice - 91120.pdf"
91120 - rectal sensation test
91040 - esophageal balloon distention test
CMS supply code SD216, catheter, balloon, esophageal or rectal (graded distention test) - $217
MUI supply code C7-CB-1077, $950/catheter
4 uses/catheter = $237.50