



August 24, 2010

Donald Berwick, MD, MPP, FRCP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-P
P.O. Box 8013
Baltimore, MD 21244-8013

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

Dear Dr. Berwick:

The American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) appreciate the opportunity to provide comments on CMS's proposed rule CMS-1503-P, published on July 13, 2010 in the *Federal Register*, regarding the proposed policy revisions to the 2011 Medicare physician fee schedule. Our three societies represent virtually all practicing gastroenterologists in the United States.

The GI societies congratulate you on your new role as CMS administrator. We also appreciate that CMS has accepted the RUC recommendations for direct practice expenses on four codes presented by our societies over the past year, CPT codes 91038 (Esophageal function test, greater than one hour), 91065 (Breath hydrogen test); 91132 (Electrogastrography) and 91133 (Electrogastrography with provocative testing). We ask that these updated practice expense inputs be implemented in the 2011 final rule.

There are a number of provisions in the proposed rule that impact practicing gastroenterologists and the Medicare beneficiaries they treat. Our comments will focus on the following issues:

- Consultation Code Policy
- CY 2011 Identification and Review of Potentially Misvalued Codes
- High-Cost Supplies
- Geographic Practice Cost Indices (GPCIs)
- Rebasement and Revising the Medicare Economic Index (MEI)
- Sec. 3003: Improvements to the Physician Feedback Program and Sec. 3007: Value-Based Payment Modifier Under the Physician Fee Schedule
- MIPPA Sec. 131 Improvements to the Physician Quality Reporting Initiative (PQRI)
- Electronic Prescribing Incentive Program
- Sec. 3401: Productivity Adjustment Regarding the Ambulatory Surgical Center Fee Schedule

- Sec. 4103: Medicare Coverage of an Annual Wellness Visit Providing a Personalized Prevention Plan
- Sec. 6003: Physician Self-Referral for Imaging
- Sec. 6404: Maximum Period for Submission of Medicare Claims

Consultation Code Policy

Because the proposed rule solicits physician comment on new physician fee schedule policies for the purpose of improving future physician fee schedule payment accuracy, we believe it is appropriate for our societies to comment on CMS’s decision to eliminate consultation codes effective Jan. 1, 2010. In April, 340 gastroenterologists participated in a multi-specialty society survey spearheaded by the American Medical Association on the impact of the elimination of consultation codes on physician practices. Nearly all respondents (98 percent) said their total revenue stream has decreased as a result of Medicare’s decision to eliminate the use of consultation codes and instead require physicians to bill using evaluation and management (E/M) codes. About one-third (36 percent) said total revenue has decreased by more than 15 percent. As a result, 29 percent said they have had to modify their practice or services. Of those who have made modifications, 21 percent said they reduced the number of new Medicare patients, and 12 percent said they reduced the amount of time spent with Medicare patients. One of the reasons why this new payment policy is taking a significant financial toll on gastroenterology practices is because 46 percent of gastroenterologists surveyed said that at least a quarter of their patients has a return visit within three years. Many of these return visits are for complex conditions unrelated to the first visit, requiring highly comprehensive evaluations that will not be adequately reimbursed.

Our societies, therefore, request that the definition of a new patient be modified to include a patient who has not received any professional E/M service from the physician or physician group practice (same physician specialty) within the previous three years. This modification would allow a patient to be considered “new” when the patient had been seen within the previous three years for a non-E/M service. Examples of this situation are quite common in gastroenterology and other specialties performing procedures. For example, the physician may have performed a direct-access colonoscopy for colorectal cancer screening without the beneficiary receiving an office visit prior to the visit, and at some future time (within three years), the patient returns for a new complex problem. As Section 1862(a)(1)(A) of the Social Security Act states “that no payment may be made for items or services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member” and Section 1862(a)(7) of the Act prohibits payment for routine physical checkups, taken together these sections prohibit payment for routine screening services or an E/M visit prior to a screening service that is specifically authorized by statute, such as colorectal cancer screening tests covered under 1861(s)(2)(R). Under current rules, the patient who returns to the same physician or physician of the same specialty in a practice for a new complex problem would be considered “established” and the valuation of the outpatient visit service is more than 40 percent lower than it had been before the consultation codes were eliminated.

CMS currently defines a “new” patient as follows:

**30.6.7 - Payment for Office or Other Outpatient Evaluation and Management (E/M) Visits (Codes 99201 - 99215)
(Rev. 731, Issued: 10-28-05, Effective: 01-01-04 Chemotherapy and Non-Chemotherapy drug infusion codes/01-01-05 Therapeutic and Diagnostic injection codes, Implementation: 01-03-06)**

A Definition of New Patient for Selection of E/M Visit Code

Interpret the phrase “new patient” to mean *a patient who has not received any professional services, i.e., E/M service or other face-to-face service (e.g., surgical procedure) from the physician or physician group practice (same physician specialty)* within the previous three years. For example, if a professional component of a previous procedure is billed in a three-year time period, e.g., a lab interpretation is billed and no E/M service or other face-to-face service with the patient is performed, then this patient remains a new patient for the initial visit. An interpretation of a diagnostic test, reading an x-ray or EKG, etc., in the absence of an E/M service or other face-to-face service with the patient does not affect the designation of a new patient.

The “professional component” recognition in the CMS definition allows physicians in some specialties, including cardiology and primary care, to consider the patient “new” after providing an EKG, lab test, blood draw, skin test, etc. prior to providing the first E/M service. We believe that similar recognition is needed for physicians whose initial encounter with a patient may be a non-E/M service, especially as an increasing number of Medicare beneficiaries avail themselves of Medicare-covered colorectal cancer screening colonoscopies.

We ask CMS to amend its definition of new patient to:

a patient who has not received any professional services, i.e., E/M service or other face-to-face service (e.g., surgical procedure) from the physician or physician group practice (same physician specialty) within the previous three years.

A patient who has been seen only for a directly-referred procedure such as colonoscopy (screening or diagnostic) has provided just the basic information required to meet the pre-service component of the endoscopy service as required by the facility and the detail obtained is substantially less than what would normally be required to provide what was previously billed as an outpatient consultation.

A change in the CMS operational definition of new patient to refer only to E/M service, rather than to “other face-to-face service (e.g. surgical procedure),” will more fairly allow for recognition of physician work and resource costs.

The GI societies are one of the specialties that have been most significantly affected by CMS’ action. We are aware that a coding change request will be submitted to the October 2010 CPT Editorial Panel meeting to address the discrepancy between the New and Established Patient definitions in the Evaluation and Management Services Guidelines, and the chart depiction of this definition in the CPT code book. We would be pleased to work with CMS and other affected specialties to address this issue.

CY 2011 Identification and Review of Potentially Misvalued Codes

In the proposed rule, CMS outlines the steps that CMS and the RUC have taken over the past few years to identify potentially misvalued codes. CMS indicated it is especially interested in comments regarding approaches, including the use of time and motion studies, to validate estimates of physician time and intensity that are factored into the work RVUs for services with rapid growth in Medicare expenditures, one of the categories that the statute specifically directs CMS to examine. CMS will provide feedback on this issue in a subsequent proposed rule. **The gastroenterology societies believe that if CMS is going to use existing databases/studies versus surveys to validate time and intensity of work, then it is critical for CMS to assure that these data sources fulfill specific criteria to get accurate assessments.**

The gastroenterology societies also believe that CMS should initially focus its assessment of potentially misvalued codes on those codes with 010 and 090 global periods of service. Evolving models of care with hospitalists and intensivists have changed the dynamics of care where, in many

facility settings, post-operative care and discharge services are provided by those other than the attending surgeon.

We are concerned that CMS seeks a RUC review of codes on the multi-specialty points of comparison (MPC) list. It is unclear why CMS is targeting codes that have been thoroughly vetted by the RUC with substantiated time and work RVUs. The MPC codes are used as a basis for relativity when determining the physician work RVU recommendations for new, revised, and new technology codes evaluated through a look-back procedure.

The RUC's process for accepting a code on the MPC list has been established and accepted by CMS for more than a decade. It is unclear why CMS now believes these codes to be misvalued. **We believe it is inappropriate for CMS to use volume as the only trigger for review when compelling evidence does not otherwise exist to suggest that a review is necessary.** Again, we believe that there needs to be a compelling argument by CMS to request that the RUC revisit a code on the MPC list that has been recently surveyed (e.g. during or since the prior five-year review). This is already the standard that specialty societies are held to in order to get a valuation reconsidered.

We suggest that CMS adhere to specific criteria for referring codes to the RUC for review. Those criteria could include:

- **When was the code last surveyed?**
- **Have there been changes since last survey (site of service, specialty, diagnosis codes, etc.)?**
- **What is the rank order within the MPC list?**
- **What is the Intraservice Work per Unit of Time (IWPUT) compared with other codes for the specialty?**

However, it is our understanding that during the coming year, the RUC MPC Workgroup intends to perform a thorough review of the codes on the MPC list to ensure that it reflects appropriate relativity. **We recommend that CMS await the recommendations of this Workgroup before proceeding with any calls for codes on the MPC list to be reviewed by the RUC or resurveyed and also allow specialty society input on any change in process.**

High-Cost Supplies

In the proposed rule, CMS is considering a refined process for updating prices for high-cost supplies using the U.S. General Services Administration (GSA) medical supply schedule. CMS states that the GSA medical supply schedule is a source for pricing information that is public and transparent and reflects the best government contract price for a product.

CMS should use caution in using the GSA database as the sole source of information. CMS acknowledges that only nine of the 62 high cost suppliers could be found within the GSA list. In addition, the GSA reflects government negotiated prices and it is unlikely that individual physicians would have the ability to negotiate prices from vendors at these rates. We urge CMS to publish the analysis that led to the proposed 23 percent reduction, and agree that the pricing of these supplies should be based on a transparent process.

Our major concern is that the GSA schedule does not reflect the actual expense for supplies when purchased by the average physician practice. Many physicians practice in small group settings that do not have the purchasing power of a group purchasing organization. Most physician practices cannot negotiate lower prices and discounts on their own. **If CMS proposes to use the GSA schedule, then CMS needs to guarantee that physicians can purchase supplies at the GSA schedule prices.** Otherwise, under-

reimbursing high-cost supplies translates into lower practice expense reimbursement for these procedures, which is inherently unfair, could ultimately result in patient access issues for medically necessary and beneficial procedures for Medicare beneficiaries.

CMS also asks for comments on its proposal to update high-cost supplies every two years. We believe that this proposal will delay reimbursements for new technologies if companies need to wait for the bi-annual review process to be considered for inclusion. We ask CMS to remain flexible for providing updates on an as-needed basis, **for either new technologies or for existing items which are subject to significant (e.g. 25% or above) price increases from suppliers. A method for CMS to assess such requests—which should be a relatively modest number of supplies-- every six months would be far more responsive to needs than an update every two years.**

Geographic Practice Cost Indices

We understand that CMS is mandated by Congress to analyze the data sources used and cost share weights assigned to the practice expense GPCIs. Knowing the implications that rebasing and revising the Medicare Economic Index (MEI) have on the GPCIs, it is unclear why CMS has completed its required review of the practice expense GPCIs and is implementing changes for 2011 in advance of the MEI technical advisory panel recommendations and one full year prior to the 2012 statutory deadline for implementing any adjustments as a result of the practice expense GPCI analysis.

Our societies request that CMS repeat its analysis of the practice expense GPCIs after the MEI technical advisory panel completes its work because of the impact that changes to the MEI will have on the cost share weights for the GPCIs.

As noted in the proposed rule, among the most significant changes being proposed is revising the weight for the office rent component from the current 12.209 percent to 8.410, which is the weight assigned to the fixed capital category being proposed as part of the MEI rebasing. This new weight for office rent will negatively impact even those localities with GPCIs above 1.0 that are otherwise held harmless from reductions caused by the new statutory requirement that the rent portions of the practice expense GPCI must reflect only one-half of the relative cost differences for each locality compared to the national average.

We are also concerned that of the nine new cost categories resulting from the disaggregation of the office expense category, only the fixed-cost capital cost component will be adjusted for local area cost differences beginning in 2011. The other eight components of the office expense category will be bundled with the medical equipment, supplies and other miscellaneous expenses cost component of the practice expense GPCIs, which are not adjusted for local area cost differences. As a result, a greater portion of the practice expense GPCI would be set nationally rather than varying by locality, which, when combined with other changes, negatively affects urban localities with high practice expenses. Consequently, specialists tend to bear the brunt of these changes because they predominately practice in urban areas.

Rebasing and Revising the Medicare Economic Index

Our societies are pleased with CMS's proposal to convene a technical advisory panel later this year to review all aspects of MEI and to consider the analysis and recommendations of the panel in future rule making. In light of this proposal, we do not understand why CMS is proposing to rebase and revise the MEI before the panel is convened. **We believe that the better approach is to delay rebasing and revising the MEI because, once implemented, the effects of redistribution are far-reaching – including implications for calculating the GPCIs – and RVUs could be upended again after the technical advisory panel submits its recommendations.** The implications of the delay should be minimal to none since the projection of the proposed rebased MEI for 2011 is an increase of 0.3 percent, which is identical to the projected increase using the 2000-based MEI.

CMS requests comments on specific issues that should be considered by the technical advisory panel, including inputs, input weights, and price-measurement proxies. At the same time, CMS proposes several changes to the expenses that are eligible to be included in the MEI including the expansion of the office expense category into nine detailed components with additional price proxies associated with these components. While CMS states in the proposed rule that it is proposing these new detailed weights for office expenses to derive an increased level of precision, the exact policy rationale for the purposes of calculating MEI remains unclear.

Sec. 3003: Improvements to the Physician Feedback Program and Sec. 3007: Value-Based Payment Modifier Under the Physician Fee Schedule

The proposed rule outlines that Sec. 3003 of the Patient Protection and Affordable Care Act (ACA) requires the Secretary, beginning in 2012, to provide reports that compare patterns of resource use of individual physicians to other physicians. Sec. 3007 also requires the Secretary to apply a separate, budget-neutral payment modifier to the fee-for-service physician fee schedule payment formula that will be phased in beginning Jan. 1, 2015-Jan. 1, 2017.

CMS anticipates that reports in Phase II of the Resource Use Reports (RUR) Program will be distributed in fall 2010. CMS also proposes: 1) to discontinue its use of commercially-available proprietary episode grouping software and develop a Medicare-specific episode grouping software product; 2) to use the Generating Medicare Physician Quality Performance Measurements Results (GEM) project measures instead of PQRI measures in the feedback reports; 3) to distribute resource reports electronically using an electronic portal; and 4) to use both group and individual level reporting in Phase II.

The gastroenterology societies are supportive of CMS's decision to provide the RURs electronically and to use both group and individual reporting. We also believe that GEM measures, which are designed to generate medical group performance information and capture the attributions of multiple providers to care, are better for RUR e than PQRI measures which are generally designed as individual provider measures. However, we are concerned about how CMS plans to use GEM or PQRI measures to adjust payments in the future and request that CMS provide more clarity on that issue in the final rule. **We also seek clarity on how CMS will capture utilization of GEM measures and how reporting these quality measures relate to PQRI measures.** With a finite set of GEM measures, we are also unclear how gastroenterology would be able to participate in the RUR Program as there is only one related GEM measure – colorectal cancer screening. Our concerns are shared by other specialties that may have only one or no measures under the GEM measure set. **Since the number of GEM measures are much more limited than measures in PQRI, CMS needs to provide more details about how GEM measures will be developed and applied to practices in the RUR program in the final rule.**

In the proposed rule, CMS explains why GEM measures will not be risk adjusted. However, it is not stated if exclusions will be allowed for patient refusal or for cases of terminal illness. It is necessary that these exceptions be allowed to ensure accurate and meaningful reports.

It is essential that physicians receive the most accurate and thorough information possible to make the RUR Program useful, effective and educational, especially if these reports will be used in the future to adjust payments and the adjustment is done in a budget neutral manner. It is also essential that physicians have the ability to review and correct any data on these reports that they believe is inaccurate. If quality reporting is used in the future to adjust payments, it is imperative that specialties that do not have adequate measures to report are not penalized.

In the proposed rule, CMS specifically states that the grouper software currently in use does not work well to create episodes for beneficiaries with multiple chronic conditions, which is a significant portion of Medicare beneficiaries. Since CMS is developing and testing its own Medicare grouper software, it is essential that CMS continue to test the validity of this software to ensure accurate resource use for physicians and to be assured that proper episodes are determined for patients with chronic conditions, such as a beneficiary who has diabetes and hepatitis C. **The gastroenterology societies recommend that CMS releases the methodology behind the CMS grouper software for public review in order to address questions relating to attribution, fairness and transparency.** This is important, as physicians want to know that quality and cost information are being calculated accurately.

CMS indicated that it intends to perform extensive data analysis and research, and to seek stakeholder input on issues related to cost and quality measures so that the agency can be prepared to publish, by Jan. 1, 2012, those measures CMS intends to use for the payment modifier. Again, we stress that the measures chosen for use in the payment modifier will need to incorporate all specialties fairly. We support CMS's intentions to seek stakeholder input on various aspects of program design, including cost and quality measures, methodologies for compositing measures, and feedback report content and delivery. We encourage CMS to use both the rulemaking and open door forums processes to gather this input.

The gastroenterology societies believe that CMS's proposed attribution method, outlined in the proposed rule, to use the "plurality-minimum" method with a minimum percentage threshold of E/M services of 20 percent for individual physicians and a minimum percentage threshold of E/M services of 30 percent of the E/M services for physician group level reports is acceptable. However, we strongly suggest that CMS continue to analyze whether this attribution methodology results in fair and accurate reports. Among our primary concerns are statistical issues relating to attribution and risk adjustment. We are skeptical that attribution by proportion of E/M services accurately reflects physician decision making, especially in patients with chronic or multiple conditions. **We remain to be convinced that the Hierarchical Condition Categories (HCC) model is the appropriate risk adjustment in fee-for-service Medicare.** As CMS continues to scale up the program, we encourage CMS to use different models for attribution and risk adjustment and to conduct appropriate statistical analysis to determine the variability among approaches. Extensive sensitivity analysis should be performed, with results made public for review, to examine, for example, factors such as the differing methods of physician attribution, populations with chronic conditions and different methods of taking into account roles of hospitalists (which sometimes take the roles of primary care; sometimes are simultaneously managing care).

We concur with CMS's plan to provide reports only to those physicians that have 30 or more patients for each of the cost measures. However, for the quality measures, we disagree that 11 beneficiaries is a sufficient sample size, and believe that there must be a minimum of 30 beneficiaries to have any statistical validity. It is also critical that physicians lacking a sufficient statistical base for RUR data should be held harmless from budget-neutrality cuts in reimbursement if this program results in payment shifting within categories.

MIPPA Sec. 131 Improvements to the Physician Quality Reporting Initiative (PQRI)

The ACA authorizes CMS to provide incentive payments to eligible professionals who successfully participate in PQRI for 2011-2014. However, beginning in 2015, ACA imposes payment penalties to providers who do not meet PQRI reporting requirements. As CMS notes, only 50 percent of providers using the claims-based reporting mechanism successfully report data and qualify for a PQRI incentive payment. Also noted in the proposed regulation, PQRI data will be used for public consumption when the "Physician Compare" website is launched beginning 2013. These sections in the ACA and forthcoming regulations implementing the legislation make successful participation in PQRI crucial to our members.

It is important that CMS help encourage and facilitate participation in PQRI, and we believe that modifications made to PQRI for 2011 will in fact serve to not only boost participation rates, but also to increase the number of participants who qualify for the incentive payment. One such modification is the proposal to lower the claims-based reporting threshold from 80 percent to 50 percent. Our societies support lowering this threshold in order to help more providers successfully report PQRI data via claims-based reporting.

Our societies have long urged CMS to incorporate more gastroenterology-related measures in the PQRI program. We specifically request that CMS add for PQRI reporting the following measures, which are AQA adopted. Those measures are: 1) Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; and 2) Comprehensive Colonoscopy Documentation. If these measures were added to PQRI, we believe that PQRI participation by gastroenterologists would significantly increase.

Our societies agree with CMS that registry-based reporting will not only increase the PQRI success rates, but it also allows physicians to report clinical quality data that is meaningful, actionable, and that can be appropriately risk adjusted. We believe that as a growing number of physician specialty societies create data registries it will allow for greater specialty participation in PQRI. We therefore support CMS's commitment to expanding the number of qualified registries for PQRI reporting.

CMS should continue to support registries as a PQRI reporting option. Our societies have devoted substantial resources in the development of data registries and look forward to working with CMS to ensure that these registries are viable PQRI reporting mechanisms.

While our societies support the ability of physicians to report on measures groups and the establishment of the Group Practice Reporting Option (GPRO) II, few gastroenterologists will be able to avail themselves of these reporting options because the only measure group related to gastroenterology is the Hepatitis C Measures Group.

While we believe that lack of a measures group that is broadly applicable to gastroenterologists will inhibit participation in GPRO II, we nonetheless ask that CMS maintain flexibility and allow a practice to choose the measures on which it will report rather than creating a core measure set for primary and specialty care. Since CMS is only allowing 500 GPRO II groups to participate in 2011, we recommend that CMS strive for diversity of specialty representation rather than just a first-come, first-served approach.

Additionally, we believe that for the GPRO, the requirement that physicians reassign their billing rights to the taxpayer identification number (TIN) could be problematic for some practices where individual physicians continue billing Medicare on their behalf rather than reassigning to the group practice. Yet, these practices still function as a group and use the same data systems. If CMS wants to make the GPRO a more viable and attractive option for physicians, it should reconsider the reassignment requirement, as well as continue to add more specialty-specific measures groups.

Electronic Prescribing Incentive Program

Physicians and other eligible professionals who are successful electronic prescribers in 2011 will be eligible for a 1.0 percent incentive payment. We support CMS's proposal to allow both individuals and group practices to continue reporting the electronic prescribing measure through claims, registry and electronic health record reporting. However, we strongly disagree with CMS's proposed approach for determining the 2012 and 2013 payment penalty. Specifically, we believe it is illogical, unfair, and overly punitive to tie the 2012 and 2013 payment penalties to whether an eligible professional is a successful

electronic prescriber in 2011, especially at a time when physicians are attempting to integrate EHR systems into their practices. As such, we propose the following modifications:

- 1.) For 2012, we request a nine-month reporting period of Jan. 1, 2011-Sept. 30, 2011. By allowing a reporting period of nine months versus six, it will give physicians a longer period of time to integrate electronic prescribing systems into their practices and still meet the reporting thresholds.
- 2.) For 2013, we request a nine-month reporting period of Jan. 1, 2012-Sept. 30, 2012. We believe this approach is fair, reasonable, and constitutes rational policy making.

Sec. 3401: Productivity Adjustment regarding the Ambulatory Surgical Center Fee Schedule

In applying the multifactor productivity (MFP) adjustment to the ambulatory surgical center (ASC) annual payment update, we are pleased that CMS proposes to hold the consumer price index for urban consumers (CPI-U) update factor to zero in the instance where the percentage change in the CPI-U for a year is negative. While our societies believe it is unfair to use CPI-U as the update factor for ASCs, **we believe that CMS is correct in its interpretation that the “percentage increase” in the CPI-U, which must be determined before applying the MFP adjustment, cannot be a negative number.**

As required by statute, the productivity adjustment must be equal to the 10-year moving average of changes in annual economy-wide, private, non-farm business MFP, as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period. As specified in the proposed rule, the end of the 10-year moving average of changes in the MFP would coincide with the end of the CPI-U timeframe (beginning with July 1 of the previous year and ending with June 30 of the current year). We believe that the proposed 10-year moving average window could result in an MFP adjustment for ASCs that is different from the MFP adjustment for providers paid on a fiscal year basis (hospitals). We believe that this difference could become yet another factor that causes further divergence in ASC and hospital outpatient department (HOPD) payment rates. **We request that CMS develop one MFP adjustment for providers for which the 10-year moving average window would not vary by calendar or fiscal year.**

The proposed rule states that the projection of MFP will be produced by IHS Global Insight. IHS will forecast the underlying proxy components such as Gross Domestic Product, capital, and labor inputs required to estimate MFP and will combine those projections according to the Bureau of Labor Statistics methodology for the measure of MFP. **We are concerned that there is no look-back mechanism for the purpose of determining forecast error that would allow for any necessary adjustments. We ask that CMS incorporate such a mechanism into its proposal for the final rule publication.**

Sec. 4103: Medicare Coverage of an Annual Wellness Visit Providing a Personalized Prevention Plan

We believe that Medicare coverage of an annual wellness visit and personalized prevention plan, as required by the ACA, provides the opportunity for physicians to inform Medicare patients about the importance of availing themselves of preventive care services, such as colorectal cancer screening. However, with this opportunity also comes the responsibility of physicians to fully counsel patients about colorectal cancer screening options since the U.S. Preventive Services Task Force (USPSTF) has assigned an “A” rating to three methods of colorectal cancer screening. Colonoscopy, sigmoidoscopy, and fecal occult blood tests (FOBT) are all recommended for adults beginning at age 50 and continuing until age 75.

A Centers for Disease Control and Prevention study published this year in the *Journal of General Internal Medicine* found that three-quarters of primary care physicians who recommend FOBT make use of in-office tests. We want to underscore that FOBT is an important screening option; however, the study noted that “in-office FOBT may be worse than no screening at all because it misses 95 percent of cases with advanced neoplasia, giving many patients a false sense of reassurance.” Furthermore, the primary goal of colorectal cancer screening should be prevention. FOBT is not a test for detecting precancerous polyps; it is a test for detecting cancer. **Accordingly, we believe that this wellness benefit must be accompanied by continued efforts to educate providers about evidence-based recommendations for colorectal cancer screening and by monitoring adherence to guidelines through performance measurement.**

Sec. 4104: Removal of Barriers to Preventive Services in Medicare

Our societies are pleased that certain cost barriers to colorectal cancer screening for Medicare beneficiaries have been lifted due to efforts by Congress. We hope that relieving beneficiaries of the financial responsibility of obtaining a colorectal cancer screening test will result in increased utilization beyond the current screening rate of 52 percent for this patient population. We also realize that to increase colorectal cancer screening rates, continued efforts are needed to educate providers about screening options and how they can increase patient compliance, such as through patient reminder systems.

Sec. 4104 of the ACA requires that effective Jan. 1, 2011, the deductible for colorectal cancer screenings be waived for Medicare patients regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test. However, as CMS notes in the proposed rule, “coinsurance would continue to apply to the diagnostic test and to other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test.” The continued coinsurance requirement will impact a substantial number of Medicare beneficiaries who will be subjected to a post-procedure “shock” of learning that they must pay a coinsurance simply because they were responsible in getting screened and had a precancerous polyp removed.

We are frustrated with the inconsistent cost-sharing requirements for colorectal cancer screenings that become diagnostic or therapeutic. We believe it is confusing to Medicare beneficiaries and continues to serve as a deterrent to screening colonoscopy.

Sec. 4104 also waives the beneficiary coinsurance for covered preventive services that have a grade “A” or “B” from the USPSTF. Colorectal cancer screening by colonoscopy or flexible sigmoidoscopy, which have a grade “A” from the USPSTF, are unique preventive services because when pre-cancerous polyps are detected they are removed at the same time, thus *preventing* colorectal cancer as opposed to detecting cancer at an early stage. **We believe that CMS should seek authority under Sec. 4104 of the ACA to waive coinsurance for a colorectal cancer screening regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test.**

At a minimum, we believe that CMS should reduce the financial burden on Medicare beneficiaries by waiving the coinsurance requirement for the increment of the procedure that is screening in nature. As a result, coinsurance would only apply to the diagnostic test and to other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

Sec. 6003: Physician Self-Referral for Imaging

The ancillary services exception of the Stark Law prohibiting self-referrals allows referring physicians to provide health services in the same office under certain conditions. ACA amends these conditions by creating a new disclosure requirement when performing magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET) and other imaging services.

CMS proposes that this disclosure must indicate that the patient may go elsewhere for imaging services. CMS also states that the notice should be written in a manner reasonably understood by all patients, be given to the patient at the time of referral, and must include a list of other imaging providers. The notification should include 10 suppliers within a 25-mile radius to the physician's office at the time of referral (same standard for both rural and urban providers). This list must include the name, address, phone number and distance from the referring physician's office. The completed disclosure form must be included in the patient's record. This provision is effective January 2011.

While our societies recognize a disclosure requirement is mandated by law, we urge CMS to require the same disclosure for hospitals to avoid the perception of conflict of interest in all settings.

Our societies are concerned about the message that this new disclosure requirement sends to our patients. This requirement may have the unintended consequence of creating the perception that physicians are endorsing other imaging service providers. A physician should not be potentially liable for any malpractice claim stemming from imaging services provided at another site solely because the physician provided a patient with a list of alternative providers.

Our societies recommend that language be included in this disclosure notice stating that a provider is required by law to provide a list of other imaging service providers and that this list is in no way an endorsement or recommendation of those providers of imaging services.

Although regulations under this section are statutory, our societies want to go on record to indicate our view that these are unnecessarily burdensome requirements and will have no meaningful benefit to patients nor any meaningful impact on utilization of imaging services

Sec. 6404: Maximum Period for Submission of Medicare Claims

The proposed rule specifies that as required by ACA, all Medicare claims for services furnished on or after Jan. 1, 2010 must be filed within one calendar year after the date of service. Claims for services furnished before Jan. 1, 2010 must be filed on or before Dec. 31, 2010. The practical effect of this change is that any claims for services furnished before Oct. 1, 2009 will follow the current existing regulations. For any services furnished during the last three months of 2009, those claims must be filed no later than Dec. 31, 2010. For services furnished between Oct. 1, 2009-Dec. 31, 2009, providers and suppliers will only have 12-15 months to file a claim.

The gastroenterology societies are supportive of CMS's language that the deadlines do not apply when the failure to file "...was caused by error or misrepresentation of an employee, intermediary, carrier, or agent of the Department that was performing Medicare functions and acting within the scope of its authority." We are also supportive of CMS's proposal to create the following two new exceptions and request that these be finalized in the final rule:

- For those situations where a beneficiary becomes retroactively entitled to Medicare benefits, but was not entitled at the time the services were furnished.

- When providers and suppliers file claims after the time limit in limited dual eligible Medicare/Medicaid beneficiary situations.

CMS notes that in no instance, except due to misrepresentation by CMS or contractors/agents, will an extension of time will be granted beyond four years from the date of service. **We feel that four years is an acceptable timeframe and support CMS's implementation of four years in the final rule.**

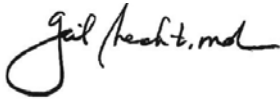
CMS should carefully consider specific instructions to contractors to clarify definitions of claim submission and receipt dates, both for mailed/paper as well as electronically filed claims, to avoid ambiguity in how claims submitted at or beyond deadline are handled. It is our observation that contractors currently lack consistent clear instructions, not uncommonly deny appropriately submitted claims, and have no answers for us about definitions we seek.

Lastly, the gastroenterology societies will educate its members of the changes in timely filing limits; however, we recommend that CMS provide adequate education to physician practices as well so that physicians do not have claims rejected due to missing the new filing time-limits.

Conclusion

The American College of Gastroenterology, the American Gastroenterological Association and the American Society for Gastrointestinal Endoscopy appreciate the opportunity to provide comments on the 2011 physician proposed rule. If we may provide any additional information, please contact Anne Marie Bicha, Director of Regulatory Affairs, AGA, at 240-482-3223, or abicha@gastro2.org; Brad Conway, Vice President of Public Policy, ACG, at 301-263-9000, or bconway@acg.gi.org; or Camille Bonta, consultant to ASGE at 202-320-3658 or cbonta@asge.org.

Sincerely:



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