September 11, 2017

Submitted electronically via: https://www.regulations.gov

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

Dear Administrator Verma:

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-1676-P), published on July 21, 2017 in the Federal Register, regarding the proposed policy revisions to the CY 2018 Medicare Physician Fee Schedule (PFS). Together, our three societies represent virtually all practicing gastroenterologists in the United States.

There are several provisions in the proposed rule that impact practicing gastroenterologists and the Medicare beneficiaries they treat. Below, we offer comments on these provisions.

* * *

**Determination of Proposed Practice Expense (PE) Relative Value Units (RVUs)**

*Calculation of the Indirect Cost PE RVUs — Expected Specialty for Low-Volume Services*

Under current methods, year-to-year variation in specialty mix can cause practice expense (PE) relative value units (RVUs) to fluctuate — sometimes significantly — for low-volume services. In an attempt to mitigate significant fluctuation for low-volume services, CMS has been relying on three years of claims data to determine specialty mix. Although this approach has helped to decrease year-to-year variability, it has not fully stabilized PE RVUs for low-volume services. As such, CMS is proposing to override the claims-derived specialty mix using a list of expected specialties based largely on a list of specialty overrides submitted by the Relative Value Scale (RVS) Update Committee (RUC). CMS also intended to apply this proposal to the calculation of malpractice (MP) RVUs.
While we support CMS’ proposal to use a list of expected specialties instead of the claim-derived specialty mix to calculate PE and MP RVUs for low-volume services to address concerns about year-to-year variability, we do not support the proposed expected specialty assignment for Current Procedural Terminology (CPT) code 43754 (“Gastric intubation and aspiration, diagnostic; single specimen (e.g., acid analysis”). The proposed expected specialty for CPT code 43754 is gastroenterology. Although, diagnostic gastric intubation is a gastroenterology service, it is not routinely performed by gastroenterologists. Rather, it is a procedure that is most commonly performed in an emergency department by an emergency medicine physician. As such, our societies recommend that the expected specialty for CPT code 43754 be emergency medicine. CMS utilization data also supports emergency medicine as the expected specialty. As illustrated in Table 1, over the past three years more than 50 percent of all services described by CPT code 43754 have been reported by the emergency medicine specialty. Moreover, in each of these years, emergency medicine is by far the dominant provider of diagnostic gastric intubation.

Table 1

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Utilization by Year</th>
<th>Grand Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2014 (^1)</td>
<td>2015 (^2)</td>
<td>2016 (^3)</td>
</tr>
<tr>
<td>Emergency Medicine (93)</td>
<td>42</td>
<td>37</td>
<td>28</td>
</tr>
<tr>
<td>Internal Medicine (11)</td>
<td>7</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Gastroenterology (10)</td>
<td>8</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>General Surgery (02)</td>
<td>5</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Nurse Practitioner (50)</td>
<td>4</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>General Practice (01)</td>
<td>2</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Physician Assistant (97)</td>
<td>1</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Anesthesiology (05)</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Family Practice (08)</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Infectious Disease (44)</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>CRNA (43)</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Undefined (99)</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>67</strong></td>
<td><strong>78</strong></td>
<td><strong>57</strong></td>
</tr>
</tbody>
</table>

\(^1\) CY 2014 Utilization Data Crosswalk to CY 2016
\(^2\) CY 2015 Utilization Data Crosswalk to CY 2017
\(^3\) CY 2016 Utilization Data Crosswalk to CY 2018
We support the CMS’ proposal to use expected specialty to calculate PE and MP RVUs for codes with no or low Medicare volume. For CPT code 43754, we recommend emergency medicine as the expected specialty.

Equipment Recommendations for Scope Systems

For CY 2018, CMS is considering options for standardizing further how scopes are defined in the direct PE database. CMS says, “Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We believe that the variation between these scopes is not significant enough to warrant maintaining these distinctions, and we believe that creating and pricing a single scope equipment code for each category would help provide additional clarity.” To address variation, CMS is seeking feedback on whether to create a single scope equipment code for each of five categories of scopes: (1) a rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope.

While we support CMS’ desire to standardize direct PE inputs for scope systems, systems are not always directly comparable. For example, a rigid endoscope used by a gastroenterologist as compared to an otolaryngologist may vary in price significantly. Therefore, we urge CMS not to create a single equipment code for each scope category. Instead, we support the American Medical Association (AMA) recommendation that CMS establish a set of equipment codes for each scope category and anatomical application (or specialty). Establishing scope equipment codes for each scope category and anatomical application will allow CMS to achieve its goal of limiting variation and standardizing how scopes are defined in the direct PE database, while allowing meaningful price differences to be accounted for in the calculation of PE RVUs.

With respect to proposed changes to PE inputs related to scopes, our societies support CMS’ proposals to (1) add an LED light source into the cost of the scope video system (ES031) and (2) increase the price of the scope video system (ES031) to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.).

Calculation of MP RVUs

In the proposed rule, CMS is proposing to update CY 2018 MP RVUs using MP premium data collected for the CY 2018 update of the MP geographic practice cost indices (GPCIs). CMS is further proposing to align future updates of MP premium data, MP RVUs and MP GPCIs to once every three years. Currently, MP RVUs are updated every five years and the last review and update of MP RVUs was implemented by CMS in the CY 2015 Medicare PFS final rule. The next update is not required until CY 2020. While, our societies appreciate and generally support CMS’ efforts to align updates of MP RVUs and MP GPCIs, we have significant concerns with the data collected.

The last update of the MP RVUs resulted in non-surgical and surgical risk factors of 2.09 and 3.83, respectively, for gastroenterology in CY 2017. In contrast, a single risk factor, 2.40, is proposed for
gastroenterology for CY 2018. This change reflects flaws in the premium data collected by a CMS contractor for the MP GPCI update. Specifically, available data did not reliably report premium class (i.e., surgical vs. non-surgical) for gastroenterologists and CMS is proposing to address this flaw by calculating a single, blended risk factor for gastroenterology. We are concerned with CMS’ proposal to apply a single, blended risk factor to both surgical and non-surgical services performed by gastroenterologists, especially when the update is not required until CY 2020 and CMS acknowledges that the new data is flawed. Practicing physicians should not see payment reduced because of an administrative shortcoming. Our societies urge CMS not to implement the proposed CY 2018 risk factors. Instead, we recommend that CMS maintain the CY 2017 risk factors, which include unique non-surgical and surgical risk factors. Our societies also urge CMS and its contractor to work with ACG, AGA and ASGE to better understand the data collected and to identify new sources that may be useful in improving this flawed dataset.

PROPOSED VALUATION OF SPECIFIC CODES FOR CY 2018

Anesthesia Services for Gastrointestinal (GI) Procedures (CPT codes 007X1, 007X2, 008X1, 008X2 and 008X3)

For CY 2018, the CPT Editorial Panel is implementing new codes for anesthesia services furnished in conjunction with and in support of gastrointestinal endoscopic procedures, including two codes for upper GI procedures (007X1 and 007X2), two codes for lower GI procedures (008X1 and 008X2) and one code for upper and lower GI procedures (008X3). CMS is also proposing to adopt, without refinement, the RUC-recommended base units (Table 2). We support CMS’ proposal to adopt the RUC-recommended base units for anesthesia services for GI procedures without refinement.

Table 2

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Descriptor</th>
<th>Proposed Base Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>007X1</td>
<td>Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified</td>
<td>5</td>
</tr>
<tr>
<td>007X2</td>
<td>Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ERCP)</td>
<td>6</td>
</tr>
<tr>
<td>008X1</td>
<td>Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified</td>
<td>4</td>
</tr>
</tbody>
</table>
Gastroenterology
Health Cancer, 2006

4.00

Typically, CMS is requesting feedback on whether 3.00 base units (the 25th percentile survey result) is more appropriate for CPT code 008X2. This alternative proposal is based on CMS’ comparison of the surveyed post-induction anesthesia intensity allocation for CPT code 008X2 to codes with similar allocations (e.g., CPT code 01382 (Anesthesia for diagnostic arthroscopic procedures of knee joint)). **We do not support the alternative proposal of 3.00 base units for CPT Code 008X2.**

Although RUC-recommended base units were proposed for CY 2018, in the proposed rule CMS is seeking feedback on alternative base units for CPT code 008X2 (Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy).

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Descriptor</th>
<th>Proposed Base Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>008X2</td>
<td>Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy</td>
<td>4</td>
</tr>
<tr>
<td>008X3</td>
<td>Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum</td>
<td>5</td>
</tr>
</tbody>
</table>

Typically, there is no difference in the endoscopist’s work for screening and diagnostic colonoscopy. This is demonstrated by the physician work RVUs for Healthcare Common Procedure Coding System (HCPCS) codes G0105 and G0121 and CPT code 45378. Each of these codes share the same physician work RVUs (3.26). Moreover, studies show that polyp removal, which increases the work of the endoscopist and anesthesia professional, occurs in nearly half of all screening colonoscopies in patients who are at average risk of developing colorectal cancer. These data also support the notion that the typical screening colonoscopy is, on average, the same as the typical diagnostic colonoscopy. If the endoscopist’s work is the same for both screening and diagnostic colonoscopy, the work of the anesthesia professional is also the same. Therefore, **we support CMS’ proposal to adopt 4.00 base units for 008X2, equal to 008X1.**

---


5 GI Quality Improvement Consortium Ltd. GIQuIC data registry: A joint initiative of the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) In; 2012.
POTENTIALLY MISVALUED SERVICES UNDER THE MEDICARE PFS — TARGET RECAPTURE AMOUNT

The file — “CY 2018 PFS Proposed Rule HCPCS Defined as Misvalued for Target” — posted in the downloads section includes colorectal cancer screening codes G0104 (“Colorectal cancer screening; flexible sigmoidoscopy”), G0105 (“Colorectal cancer screening; colonoscopy on individual at high risk”) and G0121 (“Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk”) under the “RVUs for Target by HCPCS” worksheet, but the corresponding family, “Cancer Screening”, does not appear in the “RVUs for Target by Family” worksheet. We ask CMS to clarify why G0104, G0105 and G0121 are included in the worksheet “RVUs for Target by HCPCS”.

PROPOSED PAYMENT RATES UNDER THE MEDICARE PFS FOR NONEXCEPTED ITEMS AND SERVICES FURNISHED BY NONEXCEPTED OFF-CAMPUS PROVIDER-BASED HOSPITAL DEPARTMENTS

Section 603 of the Bipartisan Budget Act of 2015 requires that items and services furnished in off-campus provider-based hospital departments (PBDs) not be covered under the Hospital Outpatient Prospective Payment System (OPPS) beginning January 1, 2017 and that those items and services be paid under an “applicable payment system.” The impetus for the law was concern with the trend toward hospital acquisition of physician practices as payments to PBDs are higher than payments to physician offices for the same service.

CMS identified the PFS as the applicable payment system and, for CY 2017, established new PFS payment rates for services provided in PBDs. Specifically, CMS set PBD-specific PFS payment rates equal to 50 percent of the OPPS payment amount. As such, for CY 2017, nonexcepted off-campus PBDs were reimbursed 50 percent of the OPPS payment amount for the technical component of a broad range of nonexcepted items and services. The 50 percent PFS relativity adjuster for CY 2017 was determined based on an analysis of the relative relationship between PFS and OPPS payments for services provided in PBDs. Although payment for the technical component is reduced for PBDs, the professional component of these services is reimbursed at the usual rate.

For CY 2018, we suggest that CMS, at a minimum, maintain the PFS relativity adjuster at 50 percent. CMS has stated that more precise data is needed to establish a relativity adjuster in future payment years and that it is disadvantaged by the lack of data now. CMS should not implement a lower PFS relativity adjuster without adequate data and without considering the unique costs associated with providing care based on site of service. Moreover, although we support the overall objective of the Bipartisan Budget Act, it fails to consider the root cause for changes in physician practice ownership, including drastic reimbursement cuts for services provided under the PFS and increasing administrative and regulatory burdens imposed upon physicians as a stipulation of payment.

6 CY 2018 PFS Proposed Rule HCPCS Defined as Misvalued for Target
EVALUATION & MANAGEMENT GUIDELINES AND CARE MANAGEMENT SERVICES

In the proposed rule, CMS seeks comment on changes to update current Evaluation and Management (E/M) documentation guidelines to reduce physician burden and to better align E/M documentation with the current practice of medicine. CMS acknowledges that E/M documentation reform will be a multi-year, multi-stakeholder process and proposes to focus initial changes on simplifying documentation requirements specific to the past family social history (PFSH) and physician exam portions of the E/M guidelines to allow medical decision making (MDM) and time to serve as the key determinants of level of E/M service. Our societies support CMS’ efforts to reduce the burden associated with current E/M documentation guidelines. We disagree, however, with other stakeholders that have suggested that the E/M code set is outdated and should be revised. CMS should not focus its efforts on revising the existing E/M code set.

Complexity of MDM and time should determine the level of service for each E/M encounter. We support CMS’ proposal to reducing documentation requirements related to history of present illness (e.g., review of systems, non-pertinent aspects of the PFSH) and the physical exam. CMS should focus E/M documentation requirements on the nature of the presenting problem, MDM and time to serve. Although the PFSH and physical exam provide valuable information and may continue to be components of the patient visit, they should not determine level of E/M service. Moreover, our societies urge CMS to eliminate the PFSH and physical exam from auditing requirements for E/M services. Eliminating these elements from auditing requirements will allow physicians to focus on documenting what is necessary for MDM. It will also provide immediate administrative relief to clinicians so they can focus on providing high-value care to patients while CMS works with stakeholders to further restructure and improve E/M documentation.

PAYMENT POLICY FOR BIOSIMILARS

In the CY 2016 PFS final rule, CMS finalized a proposal to assign a single HCPCS code and payment amount to all biosimilar biological products for a given reference product. As CMS notes, stakeholder perspectives on the policy varied widely. As biosimilar development increases and more products enter the market, our concerns with the current policy grow. We thank CMS for seeking additional feedback on current policy.

Biologic products are primarily used by gastroenterologists to treat inflammatory bowel disease, such as Crohn’s disease and ulcerative colitis. To date, there are multiple U.S. Food and Drug Administration (FDA) approved biosimilar products licensed for these indications. Our societies support the development of biosimilar products as use of biologics can be a significant cost burden to patients. However, payment policy for biosimilar products, including those approved as interchangeable, should reflect the clinical and scientific differences among products. A biosimilar product, by its nature, is not a generic drug. A biosimilar must be “highly similar” to a reference product, not identical like a generic, small molecule drug. Moreover, the similarity is only between the biosimilar and the reference product. The FDA does not compare biosimilar products to other biosimilars when reviewing safety and efficacy. An approved biosimilar may or may not be highly similar to other biosimilars of the same
reference product. Likewise, an interchangeable biosimilar, when approved, will only be interchangeable with the reference product. It may not be interchangeable with biosimilar products for the same reference product. These distinctions are important not only for monitoring the safety and efficacy of biosimilars, but also for coding and payment. Coding and payment policy should not suggest that biosimilar and interchangeable products are highly similar to or interchangeable with each other. Instead, **coding and payment policy should reflect important clinical and scientific differences through unique HCPCS codes and payment rates.**

Failing to recognize clinical and scientific differences among biosimilar and interchangeable products through coding and payment policy, will also harm physician ability to prescribe individualized therapy. Gastroenterologists will have many biologic and biosimilar products from which to choose when treating patients with Crohn’s disease and ulcerative colitis. Which therapeutic agent to choose, should be based on clinical appropriateness and shared decision making. **Assigning a single HCPCS code and payment amount to all biosimilar biological products for a given reference product may interfere with a physician’s ability to consider fully all therapeutic options.** We can illustrate this point through an example: Inflectra and Renflexis — two biosimilars for the branded biologic Remicade — are therapeutic options for the treatment of Crohn’s disease and ulcerative colitis. If the cost of Inflectra is greater than the shared payment amount, gastroenterologists may be required to prescribe Renflexis even if Inflectra may be more clinically appropriate for the patient.

Such a scenario may be of little consequence in a patient’s first initiating therapy. However, for patients established on a therapy, it may cause harm. Study results indicate that for at least one biological treatment (infliximab), antibodies cross-react with the biosimilar, which may lead to a loss of clinical response suggesting that antibody-positive infliximab users should not be switched to a biosimilar. Although this example is specific to a biologic and a biosimilar, the effect is likely to be true for biosimilars that share the same reference product. If biosimilar and interchangeable products share a single billing code and payment rate, clinical harm may result. As such, **we urge CMS to reconsider its policy of assigning a single HCPCS code and payment amount to all biosimilar biological products for a given reference product.**

**Appropriate Use Criteria for Advanced Diagnostic Imaging Services**

The “Protecting Access to Medicare Act of 2014” (PAMA) created a complex program to drive clinicians toward consultation of appropriate use criteria (AUC) for advanced diagnostic imaging tests. While we support the overall objectives of the program, ensuring patients get the most clinically appropriate diagnostic imaging test in a timely manner should not mean complicated, cumbersome and costly regulatory-imposed burdens on physician practices or on the hospitals and ambulatory surgery centers in which they practice. In gastroenterology, there are many clinical situations in which advanced diagnostic imaging services are necessary and appropriate, and we are concerned about the requirements imposed by the Medicare AUC Program. **Our societies**

---

appreciate and recognize that the proposed implementation date — January 1, 2019 — substantially lags the statutorily required implementation date of January 1, 2017; however, we urge CMS to delay implementation further.

The law defines the applicable imaging services for which AUC consultation is required as those for which there is at least one free mechanism available for AUC consultation. CMS has acknowledged it is more likely that qualified clinical decision support mechanisms (CDSMs) available free of charge may initially begin as web-based tools. A free tool is an impractical solution for those practices unable to afford acquisition of a DSM that integrates with an electronic health record (EHR) system. The Government Accountability Office (GAO) notes in a 2015 report that providers participating in the AUC imaging demonstration and who used web-based or stand-alone software applications experienced frustration with the lack of integration between the DSM and their EHR system and experienced workflow inefficiencies.

For AUC consultation by the ordering professional to be least burdensome, CMS has acknowledged that ideally, multiple qualified DSMs will be available that can integrate directly into, or be seamlessly interoperable with, existing health information technology systems. Although several DSMs have received full or preliminary qualification from CMS, most do not integrate with the broad range of EHR systems used by physicians. As such, participating in the AUC Program will require use of web-based or stand-alone software applications, which create workflow inefficiencies and increase burden. Moreover, use of such web-based and standalone tools are likely to require additional financial investment by physician practices at a time when physicians, with already scarce resources, are focused on investing in upgrading to certified 2015 Edition EHR technology.

The law, establishing the AUC Program, while perhaps well-intended by lawmakers, creates an expensive, box-checking mandate for clinicians. Furthermore, the program lacks important patient outcomes or quality components. Our societies support delaying the program until at least 2019 during which time we urge CMS to examine whether the intent of the AUC Program may be achieved through clinician participation in the Quality Payment Program rather than through the complex, stand-alone AUC Program. We further support CMS’ proposed period of “educational and operations testing.” CMS should extend to two years the educational and operations testing period, during which clinicians could receive credit for AUC consultation through both the Merit-based Incentive Payment System (MIPS) quality and improvement activities performance categories.

Our societies offer the following comments on the other AUC-related proposals:

1. Use of G Codes

CMS proposes to establish a series of HCPCS level 3 codes. These G-codes would describe the specific DSM that was used by the ordering professional. CMS also proposes to establish a G-code to identify circumstances where there was no AUC consultation through a qualified DSM. The
description of this code would indicate that a qualified CDSM was not consulted by the ordering professional.

The law states payment for an advanced imaging service may only be made if the claim for the service includes the following:

- Information about which qualified CDSM was consulted by the ordering professional for the service.
- Information regarding: whether the service ordered would adhere to the applicable AUC; whether the service ordered would not adhere to such criteria; or whether such criteria was not applicable to the service ordered.
- The national provider identifier of the ordering professional (if different from the furnishing professional).

We are seeking clarification in the final rule of whether CMS is proposing that the furnishing professional could report a G-code describing that a qualified CDSM was not consulted by the ordering professional and still receive payment for the service. We believe this policy, if the interpretation is correct, is appropriate and fair.

2. Significant Hardship Exceptions to Consulting and Reporting Requirements

We appreciate that CMS is attempting to align the AUC hardship exemptions with the MIPS exclusions for the advancing care information performance category. However, we question whether radiologists who meet the “lack of face-to-face patient interaction” threshold should be exempt from the AUC Program if, at any time, they constitute the ordering professional. As our societies have previously commented, we also request that CMS consider exempting ordering physicians based on a low-volume threshold of advanced imaging test ordering and for those who participate in alternative payment models (APMs). We believe the incentive to order only appropriate imaging tests is inherent in APMs, as well as in MIPS.

PQRS Criteria for Satisfactory Reporting for the 2018 Payment Adjustment

In the proposed rule, CMS is proposing to modify Physician Quality Reporting System (PQRS) reporting requirements for the CY 2016 reporting period. Specifically, CMS proposes to consider an individual eligible professional (EP) or group practice to satisfy CY 2016 reporting requirements if they report at least six measures and report each measure for at least 50 percent of the EPs Medicare Part B fee-for-service (FFS) patients seen during the reporting to which each measure applies. This proposal reduces 2016 reporting period criteria, which required EPs to report nine measures across at least three national quality strategy (NQS) domains and included a requirement to report at least one cross-cutting measure for certain reporting mechanisms. In addition to reducing quality measure reporting requirements, CMS also proposes to make participation in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey voluntary. Our societies support, CMS’ proposal to modify PQRS reporting requirements for the CY 2016 reporting period, but we urge CMS to do more.
Although CMS' proposals significantly reduce the reporting requirements necessary to avoid a negative 2018 PQRS payment adjustment, the requirements are still substantially more than those required under MIPS for the CY 2017 reporting period. To satisfy reporting requirements for the MIPS CY 2017 reporting period, eligible clinicians must report only one measure for one patient. Compared to MIPS CY 2017 reporting requirements, PQRS CY 2016 reporting requirements are still substantial. To smooth the transition to MIPS, we urge CMS to modify further the CY 2016 reporting requirements for EPs and group practices, and to allow reporting of a single quality measure to satisfy requirements for the CY 2016 reporting period to avoid a negative payment adjustment. Moreover, satisfactory PQRS reporting is required to avoid penalties under the Value-based Payment Modifier (VM). Without further modifications to the PQRS CY 2016 reporting requirements, a significant number of EPs and group practices are likely to face maximum penalties.

**Medicare EHR Incentive Program Reporting for the 2018 Payment Adjustment**

For the 2018 EHR Incentive Program, CMS has already finalized revisions that allow use of technology certified to the 2014 Edition OR the 2015 Edition for the 2016 program reporting period. We appreciate these changes as allowing both 2014 Edition and 2015 Edition certified EHR technology (CEHRT) provides flexibility to our members, many of whom have been unable to transition to 2015 Edition CEHRT.

In this proposed rule, CMS is proposing to modify further the 2018 EHR Incentive Program, by reducing 2016 Clinical Quality Measure (CQM) reporting requirements for EPs and group practices who choose to report CQMs through the PQRS portal. To align with proposed changes to PQRS, CMS is proposing to change the reporting criteria from nine CQMs across three NQS domains to six CQMs with no domain requirement. Our societies support, CMS' proposal to modify EHR Incentive Program CQM reporting requirements for the CY 2016 reporting period, but we urge CMS to do more. CMS' proposals significantly reduce the reporting requirements necessary to avoid a negative 2018 payment adjustment, but the requirements are substantially more than those required under MIPS for the CY 2017 reporting period. Under MIPS, eligible clinicians are not required to demonstrate meaningful use of EHR technology in the CY 2017 reporting period. However, if they choose to report on the advancing care information performance category, satisfactory reporting may be achieved by reporting on only four or five base score measures. The number of base score measures depends on whether the eligible clinician uses 2014 Edition or 2015 Edition CEHRT. Compared to MIPS CY 2017 reporting requirements, EHR Incentive Program CY 2016 reporting requirements are still substantial. We urge CMS to modify further the CY 2016 reporting requirements for EPs and group practices, and to allow reporting of a single CQM to satisfy requirements for the CY 2016 reporting period to avoid a negative payment adjustment under the 2018 EHR Incentive Program.
VALUE-BASED PAYMENT MODIFIER AND PHYSICIAN FEEDBACK PROGRAM

To provide a smoother transition to MIPS, CMS is proposing modifications to payment adjustments under the VM and Physician Feedback Program. Proposed changes eliminate negative payment adjustments for all EPs and group practices that satisfy PQRS reporting requirements and reduce penalties for those EPs and group practices that do not. **We support eliminating negative payment adjustments for all EPs and group practices that satisfy PQRS reporting requirements. Our societies also support reduced penalties for EPs and group practices that do not satisfy PQRS reporting requirement.**

Additional changes proposed by CMS reduce positive payment adjustments available to physicians, nurse practitioners (NPs), physician assistants (PAs), clinical nurse specialists (CNSs) and certified registered nurse anesthetists (CRNAs) in group practices with 10 or more EPs. Changes to positive payment adjustments for these EPs align incentives across the VM program and we support them.

MACRA PATIENT RELATIONSHIP CATEGORIES AND CODES

To facilitate the attribution of patients and episodes to one or more clinicians, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. As a step toward fulfilling this statutory requirement, CMS previously finalized an operational list of patient relationship categories (PRCs):

- Continuous/Broad Services.
- Continuous/Focused Services.
- Episodic/Broad services.
- Episodic/Focused Services.
- Only as Ordered by Another Clinician.

We support the patient relationship categories on the operational list and our societies appreciate that CMS listened to stakeholders and further delineated the relationship categories after posting its draft list in April 2016. Our societies also agree that the best way to operationalize the reporting of PRCs is through CPT Modifiers, and **we support CMS’ plan to resubmit patient relationship modifiers to AMA for future consideration into the CPT modifier code set.**

For CY 2018, CMS proposes voluntary reporting of the HCPCS modifiers on Medicare claims and indicates that use and selection of modifiers will not be a condition of payment. Our societies appreciate this approach, especially since, as CMS notes, use of these codes is not necessary for measuring quality and resource use under MIPS. **Before reporting of PRCs becomes mandatory, we urge CMS to implement more formal pilot testing.** It is likely that even with implementation of PRCs patient attribution will remain challenging for episodes that involve multiple providers and multiple sites of service and these challenges are unlikely to be identified through voluntary reporting. **A more formal pilot testing will allow CMS to identify challenges and develop methods and guidance on how to navigate these situations.** To be successful, pilot testing must
require submission of PRCs, a period of stakeholder feedback, and an evaluation of the effect of PRCs in the calculation of resource use or episode costs.

In conclusion, our societies support voluntary reporting of the proposed HCPCS modifiers on claims submitted for items and services furnished by a physician or applicable practitioner and we urge CMS to extend voluntary reporting beyond 2018 and to consider a more formal testing of PRCs, including their impact on resource use measures, in the future.

REQUEST FOR INFORMATION ON CMS FLEXIBILITIES AND EFFICIENCIES

Medicare Cost Sharing for Colorectal Cancer (CRC) Screening

Per the Affordable Care Act (ACA), Medicare waives cost-sharing for preventive services with an "A" or "B" rating from the U.S. Preventive Services Task Force (USPSTF). The USPSTF recommends screening for colorectal cancer in adults beginning at age 50 and continuing until age 75 years. To achieve further declines in incidence and death from colorectal cancer, it is important that policies promote access to all covered colorectal cancer screening tests, and for those with an "A" or "B" USPSTF rating, without beneficiary cost-sharing. Our societies strongly believe that CMS policies should foster colorectal cancer screening.

1. Screening Colonoscopy That Becomes Therapeutic

If during a screening colonoscopy a potentially precancerous polyp is removed, the screening service is "reclassified" as a diagnostic service for Medicare billing purposes. Thus, beneficiary coinsurance is no longer waived for the service. However, there is no way of knowing in advance whether a polyp will be removed during a screening colonoscopy. Moreover, polyp removal occurs in nearly half of all screening colonoscopies in patients who are at average risk of developing colorectal cancer.8,9 Therefore, a significant number of Medicare beneficiaries are surprised to find out after their screening that they must pay a coinsurance. Medicare beneficiary cost-sharing should be waived for screening colonoscopy reclassified as diagnostic because polyps are removed. A colonoscopy performed in the absence of signs or symptoms is a screening colonoscopy regardless of what is identified and removed during the procedure. CMS may implement this change by directing providers to use the Medicare screening colonoscopy code “G0121” for these procedures or by waiving cost-sharing for procedures billed with the PT modifier.


9 GI Quality Improvement Consortium Ltd. GIQuIC data registry: A joint initiative of the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) In; 2012.
2. Colonoscopy Following a Positive FOBT or FIT

Currently, asymptomatic patients who have a positive fecal occult blood test (FOBT) or fecal immunochemical test (FIT) test and thus require a screening colonoscopy are subject to cost-sharing for the colonoscopy. These screening tests are integral to increasing overall colorectal cancer screening rates. After a positive FOBT or FIT, the subsequent colonoscopy examination is necessary to properly examine the entire colon and remove tissue/polyp(s) found during the procedure. This process is still part of the “screening” and completes the continuum of care in colorectal cancer screening. **Medicare beneficiary cost-sharing should be waived for the subsequent colonoscopy.**

In the absence of a national policy, payors have interpreted this scenario differently, which leads to confusion among providers and patients. It would be helpful if CMS could provide clarification on this policy and define “colorectal cancer screening” to address the continuum of care for screening colonoscopy and include those scenarios where patients who have a positive FOBT/FIT and require a subsequent colonoscopy. **CMS may achieve this by using the Medicare screening colonoscopy code “G0121” to stipulate that the follow-up colonoscopy is still part of the “screening” for certain Medicare beneficiaries.** This should also apply to other stool-based screening tests that may be approved by CMS in the future and have an “A” or “B” rating by the USPSTF. Given that some commercial payors are implementing population management strategies where they mail FOBT/FIT tests directly to their patients, **clarifying this policy could have an enormous impact on our ability to screen more Americans for colorectal cancer, especially Americans from lower socioeconomic and minority populations who may not have initial access to screening colonoscopy.**

**Stark and Anti-Kickback Restrictions**

Physicians are barred from participating in innovative and cost-saving care models due to outdated regulations, including Anti-kickback and complicated Stark prohibitions. While safe harbors exist in this area, they are temporary and limited in scope. **Our societies recommend that CMS create new exceptions or safe harbors for Stark and Anti-Kickbacks to facilitate coordinated care and promote cost reductions including extending existing waivers from the Medicare Shared Savings Program’s accountable care organizations (ACOs) to other individuals and entities implementing alternative payment models outside of this program.**

* * *
The ACG, AGA and ASGE appreciate the opportunity to provide comments on the CY 2018 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; Jessica Roth, Director of Regulatory Affairs, AGA, at 240-482-3230 or jroth@gastro.org; or Lakitia Mayo, Senior Director of Health Policy, Quality and Practice Operations at l mayo@asge.org or (630) 570-5641.

Sincerely,

Carol A. Burke, MD FACG
President
American College of Gastroenterology

Timothy C. Wang, MD, AGAF
Chair
American Gastroenterological Association

Karen L. Woods, MD, FASGE
President
American Society for Gastrointestinal Endoscopy