September 27, 2019

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

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

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-1715-P), published on August 14, 2019 in the *Federal Register*, regarding the proposed policy revisions to the CY 2020 Medicare Physician Fee Schedule (PFS). Together, our three societies represent virtually all practicing gastroenterologists in the United States.

Our societies also submitted comments to the proposed rule on August 30, 2019 regarding proposals specifically impacting gastroenterology.

There are other several provisions in the proposed rule that impact practicing gastroenterologists and the Medicare beneficiaries they treat. In this letter, we offer comments on the following provisions.

- Medicare Physician Fee Schedule
    - E/M Office Visit Services
    - Physician Supervision for Physician Assistant (PA) Services
    - Care Management Services
- Quality Payment Program

- Quality Performance Category
- Cost Performance Category: Episodes in Gastroenterology
- Improvement Activities Category
- MIPS Value Pathways

Medicare Physician Fee Schedule

E/M Office Visit Services

In the CY 2019 final rule, CMS finalized several coding, payment, and documentation changes for office/outpatient E/M visits (CPT codes 99201-99205 (new patient) and 99211-99215 (established patient)). In response to these finalized policies, the AMA/CPT established a Joint AMA CPT Workgroup on E/M to develop an alternative solution. The CPT Editorial Panel adopted revisions to the E/M code descriptors and revised the CPT prefatory language and interpretive guidelines that instruct practitioners on how to bill these codes. **Our societies appreciate CMS' proposal to align its E/M office visit coding changes with the framework adopted by the CPT Editorial Panel**. Our societies participated in the CPT workgroup as well as the Specialty Society Relative-Value Services Update Committee **(**RUC) survey. Although the surgical specialties participated in the RUC survey and their data were similar to other specialties, CMS proposes not to apply the office visit increases to the visits bundled into global surgery packages.

During this process, our societies expressed concern over the negative impact our specialty would experience as a result of these changes. Gastrointestinal procedural codes are expected to face reimbursement cuts due to this redistribution. While many services in gastroenterology are procedural, we are a subspecialty of internal medicine. Gastroenterology is one of 20 specialties under the umbrella of the American Board of Internal Medicine (ABIM).Yet, according to CMS estimates, gastroenterology will experience a combined impact of -4% due to these changes while other internal medicine specialties (endocrinology [+16%], cardiology [+3%], hematology/oncology [+16%], and rheumatology [15%]) are expected to see positive increases. **We request CMS to reclassify gastroenterology from a surgical specialty to a cognitive specialty**. Our members do not bill surgery codes (i.e.,10- and 90-day global codes). Thus, gastroenterology should experience a similar impact as other sub-specialties of internal medicine.

Revised Inherent Complexity Code GPC1X

In addition to the CPT and RUC recommended changes, CMS proposes to implement a Medicare-specific add-on code for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical care or for ongoing care related to a patient's single, serious, or complex chronic condition. We thank CMS for listening to comments we submitted regarding CMS' original proposal in the 2019 MPFS proposed rule by removing the specialty-specific language within the HCPCS code descriptor that prevented its use by specialties not listed in the code descriptor, like gastroenterologists and hepatologists. **We support implementation of HCPCS code GPCIX as proposed; however, we also encourage CMS to provide guidance to providers regarding appropriate use of the code to ensure it is used as the Agency intended and to protect physicians should they be audited. Like AMA and other groups, we encourage CMS to work with the relevant specialty societies to submit this service for consideration by the AMA CPT Editorial Panel and the AMA/RUC.**

Physician Supervision for Physician Assistant (PA) Services

Review and Verification of Medical Record Documentation

CMS proposed to "establish a general principle to allow the physician, the PA, or the APRN who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team." CMS' proposal would apply to all Medicare-covered services paid under the Medicare PFS. CMS added that this includes notes documenting the practitioner's presence and participation in services and clarified that it does not modify the scope of or standards for documentation that is needed in the medical record to demonstrate medical necessity of services. Additionally, CMS also proposed conforming amendments to the regulations specific to teaching physicians to allow "physicians, residents, nurses, students, or other members of the medical team" to enter information in medical record that can be "reviewed and verified" by the teaching physician.

We support CMS' proposal to further clarify and build upon the policies CMS has put in place to reduce documentation burden for teaching physicians. We believe the changes will lessen documentation burden while still maintaining safeguards to ensure that medical records include necessary information to demonstrate medical necessity and accurately document clinical findings, treatments, and ongoing care planning, as applicable.

Care Management Services

Transitional Care Management (TCM)

Our societies applaud CMS for seeking to increase the utilization of TCM services. As CMS noted in the proposed rules, studies conclude that patients who receive TCM services have lower hospital readmission rates, lower mortality, and incur lower costs. Thus, our societies support CMS' proposal to incentivize additional utilization and modifying billing requirements to allow TCM codes to be reported concurrently with other codes.

CMS lists fourteen codes that are paid separately under the PFS that may not substantially overlap with TCM services, and thus proposes these codes can be separately payable along with TCM services. **Our societies agree that these codes, when medically necessary, may complement TCM services rather than overlap or be considered duplicative services. We also agree that removing the provider billing restrictions associated with these codes may increase utilization of TCM services, especially if different providers were able to report claims for services related to TCM.** For example, gastroenterologists often end up treating the primary problem of a Medicare beneficiary, but may be the second-line provider in the patient's transition of care. Thus, they are unable to bill for these services, as only one individual may report these services and only once per patient within 30 days of discharge.

Chronic Care Management (CCM)

CMS is also proposing to adopt new add-on codes for CCM which will allow providers to bill incrementally to reflect additional time resources that are required in certain cases. CMS also proposes to clarify the language describing the comprehensive care plan required for CCM codes. **Our societies support these CMS proposals and appreciate the agency's efforts to increase treating Medicare beneficiaries with multiple chronic conditions while reducing the administrative burden in meeting compliance requirements**.

As CMS notes in the proposed rule, CCM services continue to be underutilized. Our societies agree that refinements are necessary to improve payment accuracy and reduce unnecessary administrative burden. Medicare beneficiaries with multiple chronic conditions are more complex than other patients, naturally requiring more time and resources. However, certain requirements related to care planning are unclear. The estimated time spent with these patients are underestimated as well. Treatment requires complex and multidisciplinary care modalities that involve, among other things, regular physician development and/or revision of care plans and integration of new information into the care plan. **Thus, our societies also support CMS' consideration of making improvement to the typical care plan to reduce provider burden and confusion.**

Principal Care Management (PCM)

CMS proposes to create two new codes for PCM services, which would pay physicians for providing care management to patients with a single serious and high-risk condition. **Our societies support CMS' proposal as the current CCM codes require patients to have two or more chronic conditions**. Our members are also cognitive care specialists in managing chronic conditions of the gastrointestinal tract. For example, inflammatory bowel disease and Hepatitis C are GI conditions that require routine follow-up and care management. Yet, our members managing a Medicare beneficiary are unable to utilize CCM services if the beneficiary does not have another chronic condition. **We agree with CMS there is a gap in coding and payment for care management services, specifically care management is currently for patients with only one chronic condition.** There can be significant resources involved in care management for a single high-risk disease or complex chronic condition that are not well accounted for in existing coding. Our societies believe that adding PCM services would promote better care integration and coordination, as the primary care practitioner would still oversee the overall care for the patient while the specialist would bill PCM services for a specific complex chronic condition. Should the Medicare beneficiary have two or more chronic conditions, the primary care provider responsible for the overall care of the beneficiary may be bill for CCM services, thus increasing CCM code utilization.

Quality Payment Program

Merit-based Incentive Payment System (MIPS)

Our societies welcome the opportunity to comment on specific changes to the MIPS for the 2020 performance year.

Quality

Measure Removal

Please refer to comments submitted on August 30 by our societies that detail our objection to the removal of the following measures:

Measure 343: Screening Colonoscopy Adenoma Detection Rate
Measure 185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

The CMS Meaningful Measures Framework was launched in 2017 to identify high-priority areas for quality measurement and improvement. The proposed removal of these measures appears to contradict this initiative. Both these measures are designated by CMS as high-priority measures and measure 343

is the only gastroenterology-specific outcome measure available for reporting in the MIPS program. Furthermore, these measures are integrated in multiple programs, such as the Core Quality Measures Collaborative, and measure 343 establishes the framework for the Screening/Surveillance Colonoscopy episode-based cost measure such that, if removed, its absence would have unintended consequences across multiple programs. For these reasons and the detailed reasons articulated in our August 30 letter, we urge CMS to maintain these measures for the MIPS 2020 performance year.

Measure Reporting Threshold

We do not support the proposal to increase the data completeness threshold when reporting on a quality measure from 60 to 70 percent of denominator eligible patients. For the 2020 performance year, we ask that the data completeness threshold be no more than 60 percent, and that over time CMS move to establishing a threshold based on a set number of eligible patients by measure rather than a percentage, which will make it easier for physicians and practices to track.

Importantly, setting the threshold at a high level of 70 percent assumes physicians provide care at a single site and data is fluid between sites, which is not the case. Some specialties, including gastroenterology provide services across multiple sites using the same NPI/TIN; however, not all sites (including across sites of service) may: (1) participate in MIPS; or (2) use the same registry or EHR that the physician uses for MIPS reporting. For example, the GI Quality Improvement Consortium (GIQuIC) has been trying to pilot data pull – seamless, hands-free transition of data between EHRs into the registry – and it is next to impossible, costly and extremely burdensome. Each vendor has a different approach to pulling data including the need to map each practice individually because there is a lack of standardized data elements and how data is captured across EHRs and endowriters. Therefore, until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings and providers, it is premature to continue to increase data completeness and encourage reporting through a registry or EHR.

Cost

Our societies encourage CMS to carefully consider the impact of both the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures in MIPS in light of the growing number of specialty-specific episodes of care. Many of the same Medicare beneficiaries captured in the GI episode-based cost measures will also be included in one or both of the broader population measures (TPCC or MSPB). This "double counting" could lead to several potentially negative unintended consequences, such as attributing costs to a physician for one beneficiary that will likely differ between a GI episode-based measure versus TPCC for the same episode. These results will reflect differences in how each measure is constructed and not differences in performance. In addition, it is unclear what the impact of attributing of the same beneficiary for multiple episodes will have on the overall MIPS' Cost performance category. It is also unclear what impact will be when applied within an MVP. One outcome is that the results will be inconsistent across physicians. **We ask that CMS evaluate whether all the measures, and specifically the TPCC, should be included in future MIPS program years, particularly as an increasing number of specialty-specific episode-based measures are finalized. If the TPCC and/or the MSPB remain, we suggest that CMS explore whether there are methods by which the broader population measures would not be applied when one or more episode-based measures also are attributed.**

Episodes of Care Measures-Gastroenterology

Our societies appreciate the collaborative process used by CMS to develop the episode-based cost measures. **Given the low reliability results when applied to individual physicians, our societies support including the Gastrointestinal Hemorrhage measure, as appropriate, for group level reporting. We encourage CMS to consider setting the minimum threshold to a level that is higher than 0.4, such as greater than 0.7, as it is important that these measures provide the most reliable and consistent information on cost**. If the reported costs are understood and trusted by physicians, it will encourage greater use of this information and potentially assist in any movement toward better cost-management. Increasing the minimum reliability threshold plays a crucial role in this effort. **We also encourage CMS to exclude from the Screening/Surveillance Colonoscopy episode the pathology costs associated with performing the procedure. These costs are related to removing polyps during the procedure, which is the intended purpose of the screening/surveillance colonoscopy in helping to prevent colorectal cancer. Instead, we request that CMS provide data for review related to pathology bottle per case by individual provider (based on the provider's NPI).**

Our societies are extremely concerned that the proposed rule did not provide any information or discussion on the validity of the proposed cost measures, particularly for those that are episode-based. We believe that evaluating the validity of the cost measures within the context of related quality measures is critical to ensure that physicians and practices are attributed costs appropriately and in a meaningful way. Given the move toward the MIPS Value Pathways, understanding the correlation of cost with quality is imperative and must be answered before transitioning to a "value indicator." **Assessing cost without understanding the quality of care provided to patients will lead to inaccurate and potentially harmful conclusions to patient care. Our societies believe that this will occur with the Screening/Surveillance Colonoscopy due to the proposed removal of MIPS #343: Adenoma Detection Rate as it is the only measure that directly assesses an outcome of this procedure**. Patients will now be provided with information on the costs with no assessment of the quality of the colonoscopy. These unintended consequences could be mitigated in part based on this type of analysis. Our societies would like to reiterate our ongoing concern with the removal of relevant quality measures paired with the lack of adequate assessments to understand the relationship between cost and quality.

Improvement Activities

CMS is proposing to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent for the improvement activities performance category beginning with the 2020 performance year and future years. In the rule, CMS states that a group should be able to find applicable and meaningful activities to complete that would apply to at least 50 percent of individual MIPS eligible clinicians in a group, and that increasing the group reporting threshold from at least one clinician to at least 50 percent of the group will not present additional complexity and burden for the group. We disagree.

The change would discourage the use of specialty-oriented improvement activities within a multi-specialty practice. For example, if 20 percent of a group's NPIs are gastroenterologists, then it would not be feasible for that practice to report on any improvement activity other than one that applies generically to the entire practice. The result will be practices choosing improvement activities that can meet the 50 percent threshold rather than choosing improvement activities that focus on areas within the practice that would benefit from practice improvement. CMS has set the threshold too high, and we encourage a significantly lower threshold and that CMS maintain the 90-day performance period as proposed.

Proposed MIPS Value Pathways (MVPs)

When Congress passed the Medicare Access and CHIP Reauthorization Act (MACRA), it gave CMS significant flexibility when implementing MIPS, including flexibility for the implementation of the Cost component and setting the performance threshold. This flexibility was needed to give physicians the opportunity to succeed within MIPS. Like the legacy quality programs before MIPS, there was also an expectation that refinements would be necessary as experience was gained with the program. We believe Congress made a very prudent decision when it gave, as part of the Bipartisan Budget Act of 2018, CMS three additional years of flexibility for the implementation of the Cost category and setting the performance threshold. CMS has also used its administrative authority to make it easier for small practices to participate in MIPS and to provide exclusions for practices for which Medicare patients or services constitute a small proportion of their practice.

While CMS has sought to provide the greatest flexibility and opportunity for MIPS success, a complaint that we hear frequently from our members is that the Quality Payment Program (QPP), and MIPS specifically, is complex and confusing. The MIPS scoring system is complex and learning how to piece together points through the selection of measures, activities and actions as well as bonus points where available from year to year is administratively time-consuming for physicians and a deterrent to MIPS participation.

CMS seeks to address concerns voiced relative to program complexity by proposing the introduction of MIPS Value Pathways (MVP). Our societies offer some guiding thoughts on the MVP construct below.

MVP Timeline, Participation and Assignment

We strongly suggest that the first few years of MVP implementation should be viewed as a pilot period, allowing time to develop, refine, and educate physicians on this new QPP track. As such, selection of the MVP track should be voluntary, allowing features of an MVP to be improved and refined as physicians gain experience. Many practices, particularly small and rural practices, are still lacking in the

infrastructure to realize real time MIPS data and feedback on either quality or cost information, making the MVP a less beneficial option.

Choice has and should continue to be an important hallmark of MIPS. At the same time, we recognize the physician administrative burden associated with having to piece together measures and possible points, which the MVP has the potential to alleviate. Rather than assigning an MVP to a physician, CMS should adopt an opt-in policy, which allows physicians to opt-in to CMS' suggested MVP, choose an alternative MVP, or continue to report measures through the traditional MIPS pathway. CMS should base its suggested MVP on a combination of the past MIPS reporting data by a clinician or group, specialty designation and claims history. We appreciate that giving clinicians too many choices dilutes reporting and benchmarking. However, if MVPs are well-structured, and if useful and timely feedback is provided by CMS and clinician administrative burden in minimized, over time more clinicians will be inclined to choose MVPs for their participation pathway.

MVP Structure

MVPs may create a better glide path for clinicians to alternative payment model (APM) participation. MVPs also have the potential to fill a void in the lack of availability of physician-led APMs by making MIPS participation more cohesive and, ideally, more meaningful. While the proposed MVP framework groups measures together into bundles in a specific clinical area, it would still require physicians to report in each performance category and maintains the status quo with Promoting Interoperability (PI) and Improvement Activities (IA) categories. To make MVPs a more desirable MIPS pathway, MVPs should eliminate the need for physicians to report in four separate performance categories.

Quality Measures

We strongly support advancing MIPS to a program where clinicians are not required to report on a specific number of measures, but instead are asked to report on measures that best assess the quality and value of care within a particular specialty or condition. We envision the number quality measures in an MVP would vary based on the MVP, but that the overarching goal should be to make the MVP as meaningful and cohesive as possible. For some MVPs, it may take four quality measures to make an MVP meaningful, while for others it may be fewer. Most importantly, CMS should rely on specialty societies to identify the most meaningful measures, with an emphasis on outcomes and high-priority measures, that best correlate with cost measures and improvement activities.

For example, CMS has proposed the removal of the only outcome measure specific to gastroenterology currently available for public reporting, measure 343: Screening Colonoscopy Adenoma Detection Rate. The adenoma detection rate is the best-established colorectal neoplasia-related quality indicator, and is defined as the proportion of patients undergoing colonoscopy in whom an adenoma or colorectal cancer is found. Studies show that high adenoma detection rates are associated with a significant reduction in colorectal cancer risk. CMS is proposing removal of this measure a year after introducing the Screening/Surveillance Colonoscopy episode-based cost measure into MIPS. Removing measure 343 will effectively reduce assessment of a physician's performance on screening colonoscopy to cost alone and provides a patient with no assessment of a gastroenterologist's performance of screening colonoscopy relative to value. If CMS is going to proceed with an MVP pathway, it is no longer sufficient for the Agency to review quality measures in isolation. Instead, we ask that CMS review how each measure would interact others in an MVP. Furthermore, without a change in the scoring system for quality measures, the MVP concept will fail. Specifically, CMS' current scoring system creates a disincentive for clinicians to report on new measures or measures without benchmarks and instead report on measures that are not relevant to their specialty. This issue with scoring must be addressed and clinicians need to

be assured that MVP measures will not change from one year to the next. MVP measure predictability will be important not only to clinicians but to MVP developers as well.

QCDR Measures and Data Collection

We strongly believe that QCDR measures should be integrated into MVPs along with MIPS measures. CMS' efforts to better harmonize measures should allow for the creation of MVPs that give clinicians a choice of measures by reporting mechanism. For example, a colonoscopy MVP might include measures from two different registries. A physician reporting on that MVP would then have the opportunity to choose which measures to report based on the data collection mechanism chosen.

Population Health Measures

We recognize that using population health measures that utilize administrative claims data while reducing the number of required condition and specialty specific measures can reduce the burden associated with quality reporting. Also, we appreciate that CMS recognizes the tradeoffs of using administrative claims-based quality measures. However, our position is that measures that should be included in MVPs are those that have been developed by physician-led organizations, including specialty societies, to ensure they are meaningful to physicians, and, most importantly, measure things that physicians can control.

That said, what physicians do within their specialty has an impact on population health; how and whether that should be measured is the question. Broad population health measures such as readmission rates, mortality rates and avoidable admissions present challenges of attribution, risk adjustment and holding physicians accountable for things they cannot control. Instead, CMS should focus on developing MVPs or APMs that have the potential to improve patient health at the individual and population health levels rather than focusing on population health measures. For example, an episode or MVP on screening colonoscopy has the potential to improve value to patients, to the Medicare program overall and reduce the incidence and mortality of colorectal cancer at the population level. This is where we suggest CMS should make an investment, not on assessing individual physician performance based on retrospective analysis of claims that does not provide granular information for physicians to make improvements in practice.

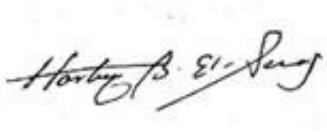
Multi-Specialty Practices

We thank CMS for acknowledging the interest by physicians who belong to multi-specialty groups to report on measures and activities that are specific to their specialty and be scored accordingly based on the performance of their specialty subgroup. We agree the MVP approach could be used as an alternative to sub-group reporting to more comprehensively capture the range of items and services furnished by multi-specialty group practices. Alternatively, multi-specialty groups could select to report on multiple MVPs at the group level. If multi-specialty groups were expected to report multiple MVPs, incentives would need to exist, such as keeping the reporting thresholds low, to offset administrative burden.

Conclusion

The ACG, AGA and ASGE appreciate the opportunity to provide comments on the CY 2019 Physician Fee Schedule proposed rule. If we may provide any additional information, please contact Brad Conway, ACG, at 301.263.9000 or bconway@gi.org; Kathleen Teixeira, AGA, at 240.482.3222 or kteixeira@gastro.org; or Lakitia Mayo, ASGE, at 630.570.5641 or lmayo@asge.org.

Sincerely,



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