



September 8, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20543

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure,

On behalf of the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE), we appreciate the opportunity to provide comments on the CY 2024 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1784-P). Together, our societies represent virtually all practicing gastroenterologists in the United States. We thank the Centers for Medicare & Medicaid Services (CMS) for its ongoing effort to engage with stakeholders to better understand the evolving healthcare environment and believe that the PFS comment solicitation on these issues is a positive step in this ongoing dialogue.

There are several provisions in the proposed rule impacting practicing gastroenterologists and Medicare beneficiaries. In this letter, we offer comments on the following provisions:

- Medicare Physician Fee Schedule
 - Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List
 - Audio-Only Services and Telephone Evaluation and Management Services
 - Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation
 - Request for Comment About Evaluating E/M Services More Regularly and Comprehensively
 - Split (or Shared) Visits
 - Indirect Practice Expense (PE) Methodology
 - Revising and Rebasing the Medicare Economic Index (MEI)

- Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding
- Appropriate Use Criteria Program for Advanced Diagnostic Imaging
- Quality Payment Program
 - Merit-based Incentive Payment System (MIPS) Evolution
 - Promoting Continuous Improvement in MIPS
 - MIPS Quality Performance Category
 - Removal of Two Measures from the Gastroenterology Measure Set
 - Connection to Community Service Provider Proposed Measure
 - Data Completeness Criteria
 - Quality Measures and Associated Benchmarks
 - MIPS Cost Performance Category
 - Cost Performance Category Improvement Scoring
 - Screening/Surveillance Colonoscopy Episode-based Cost Measure
 - MIPS Payment Adjustment / Performance Threshold
 - Improvement Activities Category
 - Promoting Interoperability Category
 - Public Reporting

Medicare Physician Fee Schedule

Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List

Our societies support CMS' proposal to change the way it categorizes services on the Medicare Telehealth List by replacing the Category 1-3 designations and, instead, defining telehealth services as either Permanent or Provisional. We agree that the new proposed categories of “Provisional” and “Permanent” are clearer and more straightforward.

Audio-Only Services and Telephone Evaluation and Management (E/M) Services

In the proposed rule, CMS noted that Section 4113(e) of Division FF, Title IV, Subtitle C of the CAA, 2023 amends section 1834(m)(9) of the Act requires that the Secretary shall continue to provide for coverage and payment of telehealth services via an audio-only communications system during the period beginning on the first day after the end of such emergency period and ending on December 31, 2024.

We thank CMS for this decision. There is a growing body of evidence supporting the need to continue to provide audio-only evaluation and management (E/M) services (99441-99443) to Medicare beneficiaries, especially those living in rural areas. In our comment letters on the 2022 and 2023 PFS proposed rules, our societies provided several studies supporting the continued coverage of telephone E/M codes 99441-99443. Since then, many more studies have demonstrated that seniors, non-English speakers and Black patients are more reliant on telephone than real-time video for care. Continuing coverage for telephone E/M *at payment parity with the physician work of office/outpatient E/M visits* will help address disparities and structural biases.

Our societies continue to believe that the only difference between the physician work of telehealth office visits and telephone E/M is the absence of real-time video. The interactions among the beneficiary and physician (or other practitioner) that take place during a telephone E/M visit are similar to telehealth office visits. In both cases, the physician can assess the patient's condition, make a medical decision, and communicate that decision to the patient via telephone only or a real-time audio/visual telehealth platform. *The absence of video does not change or diminish the time, intensity, or level of medical decision making.* Additionally, no wide-spread evidence of fraud or abuse of telephone E/M has been identified since telephone E/M benefits were expanded in response to the COVID-19 pandemic. Therefore, ***in addition to thanking CMS for continuing coverage of audio-only communications until December 31, 2024, we also urge CMS to continue coverage beyond 2024 at payment parity with the physician work of office/outpatient E/M visits.***

We would also like to thank CMS for covering real-time video telemedicine E/M at the same physician work relative value units (RVUs) as in-person office/outpatient E/M visits until December 31, 2024. This consistency and continuity in coding and coverage between in-person and real-time video E/M visits makes the cognitive load for physicians and office staff (e.g., practice managers, coders and revenue cycle teams) much more manageable. For future rulemaking, we urge CMS to consider the impact that differing coding and coverage for telemedicine E/M and in-person E/M could have on practices. If telemedicine coverage and coding were to diverge from in-person office/outpatient E/M visit coverage and coding, that would impose additional burden and stress on physicians and practices which would have to learn, prepare for, account and plan for different coding and reimbursement models despite the care delivery and patients being the same. ***We thank CMS for continuing to provide continuity for coding and coverage of telemedicine and we urge CMS to consider the impact of future decisions on practices and patients.***

Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation

Our societies appreciate CMS' proposed utilization reassessment of G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*). CMS has lowered the estimated utilization assumption of the add-on code from 90 percent and has proposed 38 percent when it is implemented in 2024, adjusting to 54 percent after the code has been fully adopted. However, we continue to have concerns regarding CMS' utilization estimates.

CMS has not clearly explained how G2211 works within the revised O/O E/M coding framework, and it is still not clear when an add-on code would be a substitute for billing a higher-level E/M visit. For example, can the add-on code be reported when the E/M code level is based on time or medical decision-making, or both? How do physicians ensure that the add-on code does not duplicate work or time already counted for in higher-level E/M codes? Without additional clarification and instructions from CMS on appropriate reporting, it is difficult to accurately predict utilization; some physicians may be reluctant to report the code given the ambiguity of the proposed reporting instructions while others may find it applicable to a majority of office visits. We are particularly concerned about how Medicare contractors,

compliance officers and other stakeholders will audit health care practitioners on the proper reporting of this code without additional clarification from CMS.

We are also concerned that patient cost-sharing may be a barrier, as physicians may not want to burden patients with the additional out-of-pocket cost for their office visits that will result from this add-on code. We fear the added out-of-pocket expense will have a disproportionate impact on low-income patients.

Given the barriers to uptake of this code, including reporting and documentation instruction ambiguity and concerns about patient cost-sharing obligations, we urge CMS to reassess its utilization assumptions for G2211.

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

CMS requested feedback on how the Agency can potentially move forward with reforms to the way CMS establishes values for E/M and other services. Several questions were provided. We will not address each question posed, but we would like to offer general comments instead.

Over the years, our societies have voiced frustration at the lack of rationale provided for CMS' decisions when they differ with American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) recommendations. It is difficult to respond when CMS' rationale is only a stated "belief" that a crosswalk to another code is better than either the RUC recommendation or the data from the survey. Without additional substantive rationale, we can only express in our responding comments that just because a CPT code has the same intra-service or total time, or both, does not mean another code should share its exact physician work RVU and restate what the survey data showed. Likewise, CMS often rejects inputs for practice expense (PE) with limited rationale which makes the decisions appear arbitrary. ***Therefore, we urge CMS to consider restoring the Refinement Panel process that served as an appeals process for those commenting on CMS proposed relative values.*** The refinement panel was composed of physicians and contractor medical directors. In 2016, we joined the AMA and 90 other specialty societies to ask for the restoration of the refinement panel.

We understand CMS' desire for feedback on enhancing the current process. However, currently, the RUC is the only major body that provides CMS with physician work and PE data on all new and existing Category I CPT procedures and services. As the AMA states in their materials, the RUC is an independent entity, composed of volunteer physicians and staffed and funded by the AMA, national medical specialty societies and other health care professional organizations.¹ This body, along with participating specialty societies, like ours, and other stakeholders provide feedback under the First Amendment right of individuals and entities to petition the government. While we do not always agree with the RUC's recommendations, the RUC is the only body that develops recommendations for physician time, work relativity, clinical staff time, medical supplies and medical equipment based on data collected by national specialty societies and other health care professional organizations. The clinical input and expertise of such a large body of participating groups is an important resource and one that has not been successfully duplicated so far. We caution CMS to carefully consider any resources that rely

¹ <https://www.ama-assn.org/system/files/2021-04/introduction-to-the-ruc.pdf>

mainly on time data, as they can miss or inappropriately devalue vital components, such as complexity and intensity, which are necessary components when determining the value of services and procedures.

Split (or Shared) Visits

We thank CMS for proposing this continued delay and urge CMS to finalize in the 2024 PFS final rule allowing physicians or qualified health providers (QHPs) to bill split or shared visits based on time or medical decision making.

We support the inclusion of all four elements when determining who should bill for the visit in order to best capture accurate contributions: (1) history, (2) performing a physical examination, (3) making a medical decision, and (4) spending time. We urge CMS to allow the split (or shared) visit policy to continue to allow the physician or QHP who is managing and overseeing the patient's care and course of treatment to bill for the service. Team-based patient care provides patients with high quality treatment and care. Significant variability in mental difficulty exists between different elements of the visit. Time alone is not a proper indication of who contributed the most in a visit. For example, medical decision making, which drives patient care and outcomes, may require less time than other less impactful elements of the visit such as paperwork and documentation. Additionally, there is significant variability in how much time it takes to perform elements of the visit based on the level of training and expertise of the physician and QHP. One final concern is that deciding who can bill solely based on time could also disincentivize the collaboration between physicians and QHPs, which may adversely affect access to care.

We remind CMS of our societies' previous comments on defining "substantive portion" as more than half of the total time spent by the physician and NPP. The previously proposed change of "substantive portion" on time could have significant implications for our members if portions of split (or shared) services that are used to qualify for billing at the physician rate no longer qualify as a result of this change. CMS notes that medical decision-making is not easily attributed or quantifiable to a single physician or NPP when the work is shared, and that time is more precise. However, this proposed change requires monitoring and tracking of physician and NPP time spent on every visit, including when it is spent simultaneously. We believe CMS has previously underestimated the potential burden of tracking time, as well as the perverse incentive for team-based and/or coordinated care if time determines which provider bills for the service. For example, CMS originally proposed nine specific activities that could count toward total time, meaning physicians and NPPs will have to document time spent for each of these categories to determine who provided the substantive portion and therefore bills for the service provided.

Each year that CMS proposes a delay results in facilities and practices spending significant amounts of staff resources and time to prepare for a potential change that may not happen. An enormous amount of money has been spent modifying systems and preparing plans since the proposal was first published in the 2022 PFS proposed rule. *Therefore, we urge CMS to finalize the current rules for split (or shared) visits in the 2024 PFS final rule.*

Indirect Practice Expense (PE) Methodology

We thank CMS for soliciting feedback and suggestions that give an evidentiary basis to shape optimal PE data collection and methodological adjustments. Implemented in 2010, CMS uses data from the AMA's Physician Practice Information Survey to determine PE relative values. This survey utilizes data from

2006. The agency has received public comments expressing concerns regarding the agency's approach to indirect PE allocation and seeks a way to move towards a standardized and routine approach to valuation of indirect PE. We offer the following comments on a survey methodology as well as alternatives.

Our societies support more frequent updates to indirect PE data to reflect current costs associated with running a practice. Market consolidation, shifts in workforce alignment, and the evolution in the type of business entities predominant in healthcare markets all suggest significant transformation in PE. The survey currently used to determine indirect practice costs is extremely dated and significant administrative changes have occurred leading to additional costs.

The AMA and Mathematica formally launched the Physician Practice Information (PPI) Survey on July 31, 2023. The PPI Survey, supported by 173 healthcare organizations, will provide more than 10,000 physician practices with the opportunity to share their practice cost data and number of direct patient care hours provided by both physicians and qualified healthcare professionals.^{2,3} A coalition of other non-MD/DO organizations is also working with Mathematica to administer a similar study of their respective professions. These physician and QHP surveys will be in the field through April 2024. Data would be shared with CMS in early 2025 for the 2026 Medicare Physician Payment Schedule rulemaking process.

Our societies support the concept of an AMA-led survey to refine the PE methodology, and support CMS collaboration with the AMA on this new data collection effort to ensure consistency and reliability in physician payment. Since 2006, there has been a significant amount of change that would not have been captured, such as widespread electronic health record (EHR) implementation & maintenance costs, impacts of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) & cybersecurity requirements in the digital records environment, and emerging costs of artificial intelligence (AI) technology.

The collection of indirect PE data will be a large, challenging, and complex undertaking. It will also have a significant impact on the allocation of resources in the fee schedule. Every effort must be made to ensure its success. Our societies believe partnership with the AMA will provide the means for the physician community to provide critical expertise and insight on how the current practice environment has evolved since the last survey and how that will impact data collection, survey methodology, and even the best means to field the survey.

Our societies support CMS's interest in developing a roadmap for updates to the PE methodology that accounts for changes in the health care landscape. We urge that any changes the Agency considers should be made carefully to ensure they reflect actual practice costs incurred by all types of physician practices and other service suppliers. All changes that impact physician practices should be phased in to minimize the redistributive impact on payment.

² AMA PPI Survey: <https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf>

³ <https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf>

Revising and Rebasement the Medicare Economic Index (MEI)

The MEI was last updated nearly ten years ago in 2014. In the 2023 MPF final rule, CMS finalized updated MEI weights for the different cost components of the MEI for CY 2023 using a new methodology based primarily on a subset of data from the 2017 US Census Bureau's Service Annual Survey (SAS). However, because the finalized MEI changes are significant and would result in a significant redistribution of PFS spending among specialties, CMS delayed implementation of this policy in CY 2023 to "time uncertain" and solicited comments on when and how best to incorporate these changes for future rulemaking.

In the CY 2024 PFS proposed rule, CMS announced that it will continue to delay implementation of the updated MEI weights. CMS believes continuing to delay implementation of the updated MEI weights is appropriate in light of the AMA's national study to collect representative data on physician PE, the AMA PPI Survey, and because of the significant impacts that implementation of the updated MEI weights would have on PFS payments. Therefore, CMS is not proposing to incorporate the 2017-based MEI in PFS rate setting for CY 2024. If 2017 data were to be implemented in CY 2025, the 2017-based MEI would already be eight years old. Our societies encourage CMS to use data that will best reflect current market conditions and practice costs.

Our societies strongly support CMS for recognizing the PPI Survey effort and postponing implementation of the updated MEI weights for CY 2024. We strongly encourage CMS to continue to postpone implementation of the updated MEI weights until after the AMA completes the PPI Survey update.

Request for Information (RFI): Drugs and Biologicals which are Not Usually Self- Administered by the Patient, and Complex Drug Administration Coding

Our societies support CMS's proposal to conduct a thorough examination of the management of medications and biologicals that are not usually self-administered by the patient, and complex drug administration coding. These issues have presented significant challenges to gastroenterologists and specialists across various medical fields. Physicians who administer drugs and biologicals have an ethical responsibility to ensure the highest standards of care for patients and safeguard the patient-care team relationship to ensure access to quality healthcare for individuals dealing with chronic gastrointestinal (GI) conditions, such as inflammatory bowel disease (IBD).

CMS plays a pivotal role in collaborating with affected medical specialties to find lasting solutions to the current problems related to the "down coding" of services associated with the administration of biologics and the inclusion of drugs on the Self-Administered Drug (SAD) list. *We are concerned that the criteria governing drugs on the SAD list may conflict with the proposed nondiscrimination rules designed for Medicare Fee-for-Service.*

"Down coding"

Our societies, together with the American College of Rheumatology (ACR) and many other specialties, have voiced concern over the practice of "down coding" the billing of biologics for treating non-oncologic conditions. For years, we have tried to fight the flawed billing and coding practices established by Medicare Administrative Contractors (MACs), which have limited reimbursement options for complex

therapies. This limitation has forced specialists, excluding hematologists and oncologists, to bill such services using therapeutic drug administration codes. The advent and evolution of biologics and other immunomodulating therapies have been transformative and life-saving therapies for patients with autoimmune diseases and are cost-effective when used in appropriate patient populations.

The AMA CPT manual specifically acknowledges the applicability of chemotherapy administration codes to a broader range of treatments: Chemotherapy administration codes 96401-96549 apply to parenteral administration of non-radionuclide antineoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as certain monoclonal antibody agents, and other biologic response modifiers. However, MACs continue to rely on unsubstantiated criteria to determine which drugs merit complex administration codes. Given the evolving landscape of biologics and monoclonal antibody treatments in various medical fields, ***our societies urge CMS to reevaluate the definition of the outdated term “chemotherapy” and align it with drug indications and toxicity.***

Language in the CPT manual further states, “The highly complex infusion of chemotherapy or other drug or biologic agents requires physician or other qualified health care professional work and/or clinical staff monitoring well beyond that of therapeutic drug agents (96360-96379) because the incidence of severe adverse patient reactions are typically greater. These services can be provided by any physician or other qualified healthcare professional.” The complexity associated with designing, manufacturing, and storing biologics, coupled with variations over time in their structure, efficacy, and safety, requires specialized supervision by trained physicians and advanced practitioners. We believe it is important for the impacted specialty societies to work within the CPT process and collaborate with key stakeholders to update terminology to reflect the nature of immunomodulatory therapies. While we acknowledge that CMS’ role in the CPT process does not include the Agency bringing proposals directly to the CPT Editorial Panel, CMS does attend CPT meetings and we would encourage CMS to monitor this issue, should the CPT Editorial Panel consider it in the future, and participate meaningfully in the discussions.

A significant historical point is the 2003 Medicare Modernization Act (MMA), which allowed physicians to use chemotherapy administration codes for non-oncologic medications. The MMA emphasized the need for the same level of supervision and equal costs for administration across specialties, eliminating disparities in reimbursement. However, issues persist regarding the assignment of “chemotherapy” via J-codes versus monoclonal antibodies and biologic therapies through HCPCS, which contradicts the MMA's intent. Additionally, toxicity concerns related to infusions remain consistent across different indications of use.

There has been substantial progress in biologics' usage across various medical disciplines. In the field of Gastroenterology, biologics have become integral in the treatment of Crohn's Disease and Ulcerative Colitis. ***We join ACR in recommending CMS convene stakeholder roundtables or workgroups to explore regulatory and legislative solutions to these policies, ensuring access and coverage for beneficiaries and their healthcare teams.***

Self-Administered Drug (SAD) List

Inadequate reimbursement for certain drugs and biologics listed under the existing Self-Administered Drug (SAD) exclusion policy, along with a lack of transparency in determining self-administration, raises concerns. Beneficiaries unable to self-administer drugs on the SAD list may risk delayed therapeutic benefits and increased severity of symptoms.

Our societies emphasize the ethical responsibility of the healthcare team to prioritize patient welfare and maintain strong patient-care team relationships and to ensure patients' continued access to high-quality care and necessary therapies for their conditions. *We urge CMS to collaborate with the gastroenterology community and other stakeholders to address equitable criteria for the SAD list and complex administration services billing, while considering potential consequences for future medications.*

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

Our societies support CMS' proposals to pause implementation of the AUC Program for reevaluation and to rescind the current AUC program regulations, effectively ending the educational and operations testing period. Program implementation challenges have spanned nearly 10 years since enactment of the *Protecting Access to Medicare Act (PAMA)*. The time has come for a thorough program reevaluation.

We support that CMS has reached the conclusion that the real-time claims-based reporting requirement prescribed by PAMA presents an “insurmountable barrier” for CMS to fully operationalize the AUC program, including because the existing Medicare claims processing system does not have the capacity to fully automate the process for distinguishing between advanced diagnostic imaging claims that would or would not be subject to the AUC program requirement to report AUC consultation information as required.

Additionally, CMS, in previous rule making, noted the “challenging nature of the program because the furnishing professional is subject to an immediate penalty based on the ordering professional’s actions (or lack thereof), whose behavior the furnishing professional is unable to control. CMS reaffirms its concerns in this rule by stating there is a “serious risk to data accuracy and integrity” because of the reliance on manual reporting by one party of information supplied by another party. We agree.

Our societies also concur with CMS that program requirements, as prescribed by *PAMA*, would add to the workload of physicians and other health care professionals who order and furnish advanced diagnostic imaging services. If implemented, CMS had estimated that 579,687 ordering professionals would be subject to the program, crossing almost every medical specialty, including gastroenterology.

Across the house of medicine, physicians are seeking relief from regulations and mandates that drive up the cost of healthcare and impede the delivery of care without measurable benefits to patients. We do not believe the Program, as constructed, would have resulted in measurable benefits to patients because the Program lacked any connection to quality measurement and patient outcomes. As CMS states in the rule, the Program could have exposed beneficiaries to financial risk due to service claims being denied because of the potential for omissions or errors in conveying AUC consultation information on claims. Further, as CMS has appropriately highlighted, there is risk of delayed beneficiary access to imaging services if

information from the ordering professional is not transmitted accurately or in a timely manner to the furnishing provider.

As CMS gives thoughtful reconsideration of the Program and considers recommendations to Congress, *we encourage CMS to consider how existing CMS programs can be leverage including, but not limited to, the Merit-based Incentive Payment System (MIPS), and alternative payment models (APMs) which should be recognized as mechanisms for discouraging inappropriate resource use.*

Quality Payment Program

Merit-based Incentive Payment System (MIPS) Evolution

Our societies appreciate that CMS' proposed changes for participation in MIPS for the 2024 performance year were kept to a minimum. However, we have issues with a number of the proposed modifications and remain deeply concerned with the overall direction of the program, including the current construct of MIPS Value Pathway (MVP).

Our societies, along with the AMA, previously supported a concept whereby MIPS credit would be awarded to clinicians who engage in performance activities that satisfy the requirements of multiple MIPS performance categories ("multi-category credit"). For example, if a clinician reported quality measures electronically through a Qualified Clinical Data Registry (QCDR) that interfaces with their EHR, the clinician would receive full credit for the Promoting Interoperability category. This concept was also envisioned as a steppingstone for clinicians between participation in separate, unrelated MIPS measures and participation in an APM or Advanced APM.

As currently designed, MVPs are not much more than a rebranding of MIPS. The silos between the four MIPS performance categories must be eliminated to reduce the complexity and administrative burden associated with the current MIPS program and to create better alignment with APMs which allow physicians to gain familiarity with value-based care. Removing the performance category silos may also help to address many of the methodological issues that plague the program, including the lack of alignment between quality and cost measures. Removing category silos may also allow for the creation of additional MVPs where cost episodes are not yet available. *Until there is a fundamental restructuring of MIPS, MVPs should remain a voluntary option for MIPS participation.*

In the proposed rule, CMS aims to incentivize the reporting of specialty MVPs by proposing an improvement activity (Practice-wide quality improvement in the MIPS Value Pathways Program) and is soliciting feedback on how specialists in Shared Savings Program ACOs could be encouraged to voluntarily participate in MVPs. We support the use of incentives versus mandates that may lead to the reporting of MVPs and more specialty specific quality measures. However, the decisions made by physicians and other clinicians about how to participate in MIPS and the selection of quality measures has not been because of a lack of interest in specialty-specific measures — many of which have been developed by medical specialty societies in collaboration with their physician members. Rather, *scoring methodologies, low statistical reliability of quality measures, lack of confidence in measure benchmarks, lack of timely, actionable feedback, program burden and the marginalization of clinical data registries have all contributed to MIPS participants avoiding selection specialty-specific measures.* Recently it

became known the Total Per Capita Cost (TPCC) measure's benchmark is being calculated monthly. CMS was not transparent about this change which raises additional questions about the measure's validity and usefulness and is further evidence of why confidence in the MIPS program is lacking among medical societies and their clinician members.

Further, physician practices making investments to participate in MIPS are doing so in an environment of growing regulatory practice burden, staffing shortages and declining Medicare reimbursement and climbing practice cost inflation. A recent study on the costs for physician practices to participate in MIPS found physicians, clinical staff, and administrative staff together spent 201.7 hours annually on MIPS-related activities at a per-physician, per-year cost of \$12,811.⁴ According to a survey conducted by the Medical Group Management Association, 90 percent of physician practice respondents said positive payment adjustments did not cover the costs of time and resources spent preparing for and reporting under MIPS.⁵

Furthermore, a disproportionate burden of MIPS participation falls on small practices. CMS estimates that, based on its proposed MIPS policies for 2024, eligible clinicians in groups smaller than 100 clinicians are more than 60 percent likely to face a MIPS penalty in 2026. While CMS estimates the size of dollars available to distribute to high MIPS performers from those who receive a negative adjustment will increase under its proposed policies, those increases will come at the expense of small and rural practices. This fundamental unfairness of the program must be corrected, and ***CMS should avoid MIPS policy changes, such as increasing the performance threshold, that results in greater redistribution of Medicare dollars.***

Our societies appreciate the ongoing engagement with CMS and its contractors regarding an MVP for gastroenterology; however, we remained concerned with the direction of a gastroenterology-specific MVP that is a repackaging MIPS measures rather than a meaningful shift away from MIPS that reduces reporting and administrative burden and meaningfully aligns quality, cost, health information technology, and improvement metrics. As CMS continues to pursue MVP development, we strongly urge the Agency to look toward APMs as a guidepost, not MIPS, and to continue to work with national medical societies in their development and in a manner that is focused on condition, episodes of care and clinical priority areas.

In the rule, CMS states it developed MVPs, “with the intention to support clinicians in their journey of continuous performance improvement and to reduce barriers to APM participation as clinicians and practices prepare to take on, and successfully manage financial risk.” As stated above, MVPs are not materially different from the traditional MIPS program and do not prepare clinicians to take on financial risk under APMs.

⁴ Khullar D, Bond AM, O'Donnell EM, Qian Y, Gans DN, Casalino LP. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. JAMA Health Forum. 2021;2(5):e210527. doi:10.1001/jamahealthforum.2021.0527

⁵ MGMA Annual Regulatory Burden Report - 2022. <https://www.mgma.com/practice-resources/government-programs/mgma-annual-regulatory-burden-report-2022>

Promoting Continuous Improvement in MIPS

In response to the request for feedback on how CMS can foster clinicians' continuous performance improvement, we encourage CMS to focus on efforts to support quality of care which may include supporting efforts to maintain achievement of high-quality care *or* improving it. The message of the request for information (RFI) seems to convey that CMS' emphasis on "continuous performance" is more about points and scoring than it is about continuity or improvement in quality of care, which has been the fundamental problem with the program.

Our societies support continuous improvement in the quality of care for patients throughout their lifetime and this is why our organizations developed and support clinical data registries — the full potential of which has not been leveraged due to the resources required by medical societies to maintain QCDR status. Maintaining and supporting QCDR status is a tremendous effort throughout the three-year cycle of a performance year - from self-nomination through reporting - which is exacerbated by overlapping performance year cycles as well as QCDR measures continuously revised to satisfy the purposes of MIPS rather than to ensure they make clinical sense to the providers who rely on them for improvement. We continue to encourage CMS to work with QCDRs as partners, not simply vendors, in the implementation of the program. QCDRs are arms of professional societies that share CMS' vision for high-quality care based on data of the strongest integrity. The work of QCDRs is so much greater than serving as third party intermediaries for public reporting and yet, this function requires copious resources, which tend to be in limited supply among nonprofits.

Regarding data integrity, our societies support CMS' proposal to eliminate the health IT vendor category beginning with the 2025 performance year and appreciate the Agency recognizing the lack of data validation requirements for these third-party intermediaries has led to submission of data that undercuts the integrity of the MIPS program. By requiring these vendors to self-nominate as a qualified registry or QCDR, the latter of which would require meeting the definition of a QCDR and ensuring consistent data validation and audit requirements for all third-party intermediaries, CMS is taking positive steps toward establishing a program in which all eligible clinicians are assessed fairly and equitably. Further, we would recommend CMS devise data validation standards of equal measure for the sign in and upload and sign in and attest submission types. Without data validation standards for direct reporting and by allowing health IT vendors known to have facilitated the submission of data lacking integrity to facilitate data collection for direct reporting, the Agency leaves open a significant loophole to be exploited which would allow for inaccurate and unusable data to continue to enter the program, impacting the foundations on which the program functions (e.g., performance thresholds, measure benchmarks, topping out measures).

Given the flaws in the existing MIPS program, our societies are concerned with CMS' efforts to increase reporting requirements or change scoring parameters for clinicians whom CMS identifies as "high performers." CMS states in the proposed rule that it is presented with two challenges: 1) after a clinician has achieved high performance scores on the same measures and activities year over year, there may be little or no room for the clinician to improve their performance; and 2) some MIPS eligible clinicians choose measures and activities on which they are already performing well, rather than measures and activities where they would be required to implement changes in their workflow, clinical care, or practices in order to achieve a positive payment adjustment. Again, we do not believe these are challenges from a quality-of-care standpoint; rather, they appear to be MIPS scoring concerns.

First, to reiterate our earlier point, there is value in continuous quality of care delivery instead of looking for ways in which clinicians must be challenged to improve their performance in ways that may not necessarily be meaningful to patients.

Second, CMS should not diminish the cost and staffing time required to make changes to a practice's workflow for the purpose of reporting on different measures and activities for a program for which positive payment adjustments oftentimes do not cover the costs of time and resources spent to successfully participate in MIPS. Therefore, clinicians and group practices select measures that create the greatest odds of receiving a positive performance score and recouping staffing costs, or even in the hopes of a neutral payment adjustment. Unfortunately, a zero-sum program has necessitated careful and calculated selection of measures. This is not meaningful by any standard and underscores the need for a fundamental restructuring of the MIPS Program, not increased requirements for a subgroup of eligible clinicians.

We encourage CMS to fix the flaws in the existing MIPS program and to focus on a MVP construct that is meaningfully different from MIPS rather than pursue efforts to increase reporting requirements or change scoring parameters for clinicians whom CMS identifies as "high performers." ***Our societies oppose any efforts at this time to increase reporting requirements or change scoring parameters for clinicians whom CMS identifies as "high performers" while significant concerns persist with the MIPS program.***

MIPS Quality Performance Category

Removal of Two Measures from the Gastroenterology Measure Set

Our societies do not support the removal of measures 113 and 128 from individual reporting in 2024 MIPS. Although these measures have been combined into a new preventative care composite measure option geared toward primary care providers, these measures continue to hold value for quality improvement across multiple specialties and should continue to be available and accessible for individual reporting across multiple specialties. We are also concerned about the loss of transparency on important gaps in the quality of care delivered since the composite will produce a single score and based on the current design of this new composite, performance on the individual indicators will not be available.

Connection to Community Service Provider Proposed Measure

While our societies support the intent of this measure, we do not believe that the implementation of this process measure at the individual clinician or group level in MIPS is appropriate, particularly due to the absence of any resources or tools that would be widely and readily available to clinicians and practices. Measures must be evidence-based and facilitate improvements in patient care. Unfortunately, the developer does not provide any evidence to support the five social needs, nor did they sufficiently justify the requirement to connect a patient with a community services provider on at least one need within 60 days. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). In addition, the measure itself is not yet tested to demonstrate reliability and validity since only data for two screening tools (which

are not required) were provided and most of the information outlined is based on the Center for Medicare and Medicaid Innovation's (CMMI) Accountable Health Communities project, which involved community health centers/CMMI health systems and, therefore, does not provide sufficient information on how this measure would perform at the individual clinician level. Furthermore, we believe that it is imperative that this process measure has demonstrated links to directly improving patient outcomes without any unintended consequence of creating patient harm. ***Because we do not believe that this measure will result in effective change, we do not support its inclusion in MIPS nor do we support its inclusion in the Gastroenterology specialty set.***

Data Completeness Criteria

We oppose CMS's ongoing efforts to increase the data completeness threshold. We do not believe that the concerns that we as well as others continue to raise have been adequately addressed.

Percentage requirements of 75 percent or higher do not account for physicians who provide care beyond a single site and wrongly assume that data are easily shared across sites. Some specialties, including gastroenterology, provide services across multiple locations using the same National Provider Identifier (NPI) / Tax Identification Number (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. In addition, practices report that they often encounter barriers such as the lack of agreed upon semantic and syntactic standards, data privacy concerns, and patient misidentification. 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 the MIPS data completeness requirement.

We continue to urge CMS to adopt requirements that are based on a set number of eligible patients or case minimums per measure, rather than an arbitrary percentage, which will make it easier for physicians and practices to track while also ensuring reliability of the performance scores used for MIPS benchmarking. If CMS continues to use the current approach for data completeness, we believe that CMS must validate its assumptions that it is possible to continually increase the percentage when interoperability and seamless transfer of data are not yet universally available. For example, CMS could compare the patients and data that are reported by practices to registries against who can be identified for the practice via administrative claims. This type of analysis would need to be completed across multiple specialties such as gastroenterology, radiology, internal medicine, and family practice. This type of analysis would provide additional information on the extent to which challenges such as data interoperability or site of service differences impact the feasibility of practices, registries, and others to meet the data completeness thresholds.

Quality Measures and Associated Benchmarks

Our societies remain concerned about the lack of stability in quality measures and quality measure benchmarks. Moving forward and failing to account for the impact of the pandemic over multiple performance years with many eligible clinicians applying for or having applied automatically the CMS Extreme and Uncontrollable Circumstances Exception for multiple performance years sets eligible clinicians up for failure and likely a negative payment adjustment. Many eligible clinicians are returning to MIPS reporting learning that meaningful measures to their practice have been eliminated or altered to

make less clinical sense, fitting the program but not necessarily actionable quality improvement, forcing them to create new workflows to collect data on altered or new measures in a time of continued staff shortages. Gastroenterologists, in particular, have been challenged over the years in being able to meaningfully report across a broad array of QPP and QCDR specialty-specific quality measures with available measures changing each performance year.

Our societies encourage CMS to support continuity in available quality measures and their associated benchmarks year over year, and especially as we slowly emerge from the ongoing effects of the pandemic. We would expect quality measure benchmarks to become more realistic, allowing CMS to make more informed decisions on benchmarking and retaining or removing measures from future MIPS reporting.

MIPS Cost Performance Category

Cost Performance Category Improvement Scoring

While our societies maintain MIPS and its evolution to MVPs should be reconsidered fundamentally, we support CMS' proposal to determine each MIPS eligible clinician's cost improvement score at the category level, instead of the cost measure level. The Agency outlines various issues relative to its current policy and we agree changes are required for operational feasibility and fairness of improvement scoring for eligible clinicians.

Screening/Surveillance Colonoscopy Episode-based Cost Measure

Our societies continue to applaud CMS for expanding the regulatory definition of "colorectal cancer screening tests" and waiving cost sharing for a necessary follow-up colonoscopy after a Medicare covered noninvasive stool-based colorectal cancer (CRC) screening test (fecal test) returns a positive result. Recognizing this continuum aligns Medicare policy with requirements for commercial plans, reduces confusion among patients, closes the remaining coverage loopholes that often result in surprise bills, and should help increase CRC screening rates.

Our societies wish to point out data that may call into question the validity of the Screening/Surveillance Colonoscopy episode-based cost measure, as the measure does not account for this innovation in practice and the variability in which it has been adopted. Studies show that adenoma detection rate (ADR), which is the quality measure that balances this cost measure as identified by the clinical experts who worked with Acumen on its development, consistently runs at least an absolute 15 percent higher in patients with

positive fecal tests.^{6,7,8,9,10} Because the use of fecal testing varies regionally and across health practices, screening colonoscopies performed for positive fecal tests are excluded from the calculation of ADR. ***We urge CMS to consider excluding from the denominator of the Screening/Surveillance Colonoscopy episode-based cost measure screening colonoscopies performed following positive fecal tests given the variability in which this innovation has been adopted into practice.***

MIPS Payment Adjustment / Performance Threshold

Our societies oppose CMS' proposal to establish the performance threshold for the CY 2024 performance period/2026 MIPS payment year as 82 points, using the CY 2017-CY 2019 performance years as the prior period. While CMS' proposal to rely on a three-year-average attempts to recognize the impact of the pandemic on the MIPS program and other year-to-year fluctuations, it fails to recognize that reporting requirements and standards for the program were significantly different in the early years of MIPS. First, CY 2017 should be excluded from consideration entirely because "Pick Your Pace" reporting was a 'free for all' in concept and execution. Additionally, many quality measures available for reporting CY 2017-CY 2019 have been removed as they were deemed 'standard of care' or topped out, the latter of which begs the question of the integrity of the data submitted by health IT vendors which may have led to measures topping out prematurely, as noted above. So, too, have the inventories of measures and activities for the Promoting Interoperability and Improvement Activities performance categories evolved. Importantly, the Cost performance category was weighted at 15 percent in CY 2019 and is now weighted at 30 percent. Little is understood about Cost by CMS and eligible clinicians due to the pandemic, even for those who continued to participate in the program. This proposal also fails to recognize that 2024 will be a unique year as many clinicians re-enter the program following the pandemic and continue to face challenges related to residual effects of the pandemic. Here again, our societies recommend CMS consider greater program stability as many eligible clinicians are now returning to reporting while continuing to grapple with staff turnover and shortages. ***We urge CMS to maintain a performance threshold of 75 points.***

Improvement Activities Category

CMS has proposed the improvement activity "Practice-wide quality improvement in the MIPS Value Pathways Program" to encourage participation and incentivize voluntary participation in MVPs. Although we agree that participation in MVPs should continue to be voluntary, the current incentives are

⁶ Cubiella J, Digby J, Rodriguez-Alonso L, et al. The fecal hemoglobin concentration, age and sex test score: Development and external validation of a simple prediction tool for colorectal cancer detection in symptomatic patients. *Int J Cancer* 2017;140:2201-2211.

⁷ Anderson JC, Robinson CM, Hisey W, et al. Colonoscopy findings in FIT+ and mt-sDNA+ patients versus in colonoscopy-only patients: New Hampshire Colonoscopy Registry data. *Cancer Prev Res (Phila)* 2022;15:455-464.

⁸ Hilsden RJ, Bridges R, Dube C, et al. Defining benchmarks for adenoma detection rate and adenomas per colonoscopy in patients undergoing colonoscopy due to a positive fecal immunochemical test. *Am J Gastroenterol* 2016;111:1743-1749.

⁹ Kligman E, Li W, Eckert GJ, et al. Adenoma detection rate in asymptomatic patients with positive fecal immunochemical tests. *Dig Dis Sci* 2018;63:1167-1172.

¹⁰ Robertson DJ, Lee JK, Boland CR, et al. Recommendations on fecal immunochemical testing to screen for colorectal neoplasia: a consensus statement by the US Multi-Society Task Force on colorectal cancer. *Gastroenterology* 2017;152:1217-1237.e3.

insufficient to fully transition from traditional MIPS to MVPs and should be increased to meet the goals that CMS is attempting to achieve with the full-scale adoption of MVPs.

Promoting Interoperability Category

We believe that Promoting Interoperability should only require attestation if an individual clinician or practice is using a certified EHR. The growing complexity in the number of measures and duration of reporting continues to increase the burden to participate in this category with little to no added value. In addition, the fact that CMS has added exceptions for reporting to this performance category signals the limited usefulness of the performance category or its requirements. ***We urge CMS to identify alternative ways to capture and report on this important area rather than continuing down this path.***

Public Reporting

CMS proposes modifications to its existing policy to publicly report utilization data, including expanding it to include Medicare Advantage data in addition to fee-for-service (FFS) as well as cost measure public reporting. We are concerned that public access to performance data will have unintended consequences for providers and will be used by commercial payers to diminish physician payment contracts rather than the intended use to inform plan beneficiaries. Furthermore, there has not been enough analysis on how the data will be represented in a meaningful manner to reduce the potential misuse and improper characterization of provider performance. The lack of transparency and reliance on claims-based data could also potentially confuse the end user. ***We would like CMS to conduct a full analysis to mitigate any unintended consequences of this policy prior to adopting nationally.***

Conclusion

Thank you for the opportunity to comment on the CY 2024 PFS proposed rule and issues concerning gastroenterology. Our societies:

- Support CMS' proposal to change the way services on the Medicare Telehealth List are categorized.
- Thank CMS for continuing coverage of audio-only communications until December 31, 2024, and urge CMS to continue coverage beyond 2024 at payment parity with the physician work of office/outpatient E/M visits.
- Thank CMS for continuing to provide continuity for coding and coverage of telemedicine and urge CMS to consider the impact of future decisions on practices and patients.
- Urge CMS to reassess its utilization assumptions for G2211 given the barriers to uptake of this code, including reporting and documentation instruction ambiguity and concerns about patient cost-sharing obligations.
- Urge CMS to consider restoring the Refinement Panel process that served as an appeals process for those commenting on CMS proposed relative values.
- Urge CMS to finalize the current rules for split/shared visits in the 2024 PFS final rule.
- Support more frequent updates to indirect PE data to reflect current costs associated with running a practice.
- Support the concept of an AMA-led survey to refine the PE methodology.

- Support CMS collaboration with the AMA on the new PE data collection effort to ensure consistency and reliability in physician payment.
- Support CMS’s interest in developing a roadmap for updates to the PE methodology that accounts for changes in the health care landscape.
- Urge that any PE changes the Agency considers should be made carefully to ensure they reflect actual practice costs incurred by all types of physician practices and other service suppliers and should be phased in to minimize the redistributive impact on payment.
- Thank CMS for recognizing the PPI Survey effort and postponing implementation of the updated MEI weights for CY 2024.
- Encourage CMS to continue to postpone implementation of the updated MEI weights until after the AMA completes the PPI Survey update.
- Urge CMS to reevaluate the definition of the outdated term “chemotherapy” and align it with drug indications and toxicity.
- Recommend CMS convene stakeholder roundtables or workgroups to explore regulatory and legislative solutions to management of medications and biologicals that are not usually self-administered by the patient and complex drug administration coding policies, ensuring access and coverage for beneficiaries and their healthcare teams.
- Urge CMS to collaborate with the gastroenterology community and other stakeholders to address equitable criteria for the SAD list and complex administration services billing, while considering potential consequences for future medications.
- Support CMS’ proposals to pause implementation of the AUC Program for reevaluation, and rescind the current AUC program regulations, effectively ending the educational and operations testing period.
- Encourage CMS to consider how existing CMS programs can be leverage including, but not limited to, the MIPS, and APMs which should be recognized as mechanisms for discouraging inappropriate resource use.

Quality Payment Program

- Urge CMS to consider maintaining MVPs as a voluntary option for MIPS participation, until there is a fundamental restructuring of MIPS.
- Urge CMS to avoid MIPS policy changes, such as increasing the performance threshold, that result in greater redistribution of Medicare dollars.
- Support the CMS proposal to eliminate the health IT vendor category beginning with the 2025 performance year.
- Urge CMS to devise data validation standards of equal measure for the sign in and upload and sign in and attest submission types to close another loophole that undermines the integrity of data submitted to MIPS.
- Urge CMS to reconsider any efforts at this time to increase reporting requirements or change scoring parameters for clinicians whom CMS identifies as “high performers” while significant concerns persist with the MIPS program.
- Urge CMS to maintain measures 113 and 128 in the gastroenterology specialty measure set and for individual reporting in 2024 MIPS.
- Urge CMS to reconsider inclusion of the Connection to Community Service Provider Proposed measure in the Gastroenterology specialty set and in MIPS.
- Urge CMS to reconsider increasing the data completeness threshold for the MIPS Quality performance category and instead adopt requirements that are based on a set number of eligible patients or case minimums per measure.

- Urge CMS to support continuity in available quality measures in MIPS and their associated benchmarks year over year.
- Support CMS' proposal to determine each MIPS eligible clinician's Cost improvement score at the category level, instead of the cost measure level.
- Urge CMS to consider excluding from the denominator of the Screening/Surveillance Colonoscopy episode-based cost measure screening colonoscopies performed following positive fecal tests given the variability in which this innovation has been adopted into practice.
- Urge CMS to maintain a MIPS performance threshold of 75 points.
- Urge CMS to consider incentives for voluntary participation in MVPs beyond the proposed improvement activity "Practice-wide quality improvement in the MIPS Value Pathways Program."
- Urge CMS to find alternative ways to capture and report measures to advance the goals of the MIPS Promoting Interoperability performance category.
- Urge CMS to conduct a full analysis to mitigate any unintended consequences of modifications to its existing policy to publicly report utilization data, including expanding it to include Medicare Advantage data in addition to FFS as well as cost measure public reporting prior to adopting nationally.

We appreciate the ongoing dialogue concerning these important issues, as well as CMS' significant effort in the proposed rule. If you have any questions about our request or if we may provide any additional information, please contact Brad Conway, ACG, at 301-263-9000 or bconway@gi.org; Leslie Narramore, AGA, at 410-349-7455 or Lnarramore@gastro.org; and Lakitia Mayo, ASGE, at 630-570-5641 or lmayo@asge.org.

Sincerely,



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