September 8, 2025

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20543

Re: Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program (CMS-1832-P)

Dear Administrator Oz,

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 2026 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1832-P). Together, our societies represent virtually all practicing gastroenterologists in the United States. We thank the Centers for Medicare & Medicaid Services (CMS) for the 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
    - **CY 2026 Proposed Medicare Physician Conversion Factor**
    - **Efficiency Adjustment**
    - **Practice Expense Methodology Update**
    - **Proposed Valuation of Specific Codes for 2026 (4XX04, 91XX1 and 91XX2)**
    - **Digital Mental Health Treatment (DHTM) and Gastrointestinal Care**
    - **Average Sales Price: Units Sold at Maximum Fair Price**
    - **Telemedicine**

- **Artificial Intelligence and Software as a Service (SaaS) Comment Solicitation**

- Quality Payment Program
  - **Maintain the MVP Group Reporting Option for Small Practices**
  - **High Priority Measure Definition**
  - **Core Elements Request for Information (RFI)**
  - **Medicare Procedural Codes RFI**
  - **Well-being and Nutrition Measures RFI**
  - **Gastroenterology Care MVP**
  - **Third Party Intermediaries Support for MVPs**
  - **Toward Digital Quality Measurement in CMS Quality Programs – RFI**
  - **Proposed Removal of Quality Measure 185, Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use**
  - **Proposed Substantive Changes to the Total Per Capita Cost (TPCC) Measure**
  - **Proposals to Update the Improvement Activities Inventory**
  - **Scoring for Topped Out Measures with Limited Measure Choice**
  - **Benchmark Methodology for Scoring Administrative Claims-based Quality Measures in the Quality Performance Category**
  - **Performance Threshold**

Medicare Physician Fee Schedule

CY 2026 Proposed Medicare Physician Conversion Factor

Our societies welcome the first increase in the Medicare PFS conversion factor (CF) in five years. However, we continue to encourage CMS to explore other opportunities to implement a more substantial positive payment update. Physicians continue to face significant increases in practice costs that have persisted over several years. The current proposal does **NOT** adequately account for the impact of increased physician costs which CMS projects will be 2.7% as measured by the Medicare Economic Index (MEI). The +2.5% update as mandated for 2026[1] is temporary and does **NOT** address the long-term sustainability of physician practices. We are also disappointed that the proposed rule does not address any consideration of a cost of living raise as proposed by Medicare Payment Advisory Commission (MedPAC) in its June 2025 Report to Congress[2] or other approaches to ameliorate the annual increased costs physicians face in caring for Medicare beneficiaries.

Beginning in 2026, federal law requires two conversion factors with a +0.25% for most physicians and a +0.75% increase for qualifying alternative payment model (APM) participants. As there are no gastrointestinal (GI)-related Advanced APMs, gastroenterologists will not have the opportunity to earn the higher 0.75% update. Further, for 2026, the positive CF update will be negated by the proposed efficiency adjustment of -2.5% to a significant number of services paid for under the Medicare PFS. Our

[1] Public Law 119-21. https://www.congress.gov/bill/119th-congress/house-bill/1/text
[2] Medicare Payment Advisory Commission June 2025 Report.to Congress. https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_MedPAC_Report_To_Congress_SEC.pdf

societies are also frustrated that CMS continues to use an inaccurate over-projection of utilization for the office visit add-on code, G2211, which contributed to a substantial cut to the 2024 conversion factor. This important correction was not made when calculating budget neutrality for CY 2026. While there are some increases for GI providers, these and other factors limit the potential payment increases for our physicians and their practices. We support the American Medical Association (AMA) RVS Update Committee (RUC) recommendations and urge CMS to correct the utilization assumptions for G2211 for CY 2026, which would provide a positive $1 billion budget neutrality adjustment to the Medicare conversion factor and strengthen support for all services under the Medicare PFS.

Therefore, we urge CMS to collaborate with Congress to develop a long-term solution to the persistent challenges within the PFS, including the absence of a meaningful payment update that reflects actual practice costs.

Efficiency Adjustment

We strongly oppose the efficiency adjustment as proposed. This policy represents a fundamental change that is not supported by evidence, undermines the integrity and relativity of the physician payment system, and threatens patient access to life-saving care.

Under this proposal, CMS would apply an automatic 2.5% reduction to all work relative value units (RVUs) for all codes, excluding time-based codes, for 2026, based on the assumption that physicians continually become more efficient in delivering care. This assumption is not grounded in empirical data, or at least any data shared in the proposed rule. Rather, the rationale represents a theoretical construct applied uniformly across all specialties and services, regardless of clinical complexity, patient comorbidities, GI endoscopy quality metrics, or advances in medical technology. The policy ignores the reality that for many services— particularly complex, procedure-based interventions — efficiency does not increase over time. In fact, many gastroenterology services require greater physician work and decision-making due to an aging Medicare population, rising acuity, and the introduction of new technologies that, while clinically beneficial, often add steps and complexity to the procedure.

CMS cites as part of the basis for this proposal the 2014 study by Merrell, Schur, Oberlander, et al. ("Analysis of Physician Time Use Patterns Under Medicare"). That analysis concluded that "research over time has demonstrated that the time assumptions built into the valuation of many PFS services are, as a result, likely overinflated." However, this finding does not support the application of a uniform efficiency adjustment to nearly all work RVUs. First, the study was conducted more than a decade ago, and since that time, all endoscopic gastroenterology codes—including colonoscopy, upper endoscopy, and therapeutic endoscopic procedures— as well as diagnostic testing services have been revalued through the RUC process. These revaluations incorporated updated time and intensity data, meaning that GI services have already undergone scrutiny and correction after the publication of the Merrell study. Applying a new across-the-board efficiency reduction therefore "double counts" adjustments that have already been made.

Moreover, the RUC process was explicitly designed to capture relativity, efficiency, and changes in time use patterns through specialty-driven surveys and peer-reviewed deliberations. To apply a formulaic cut

every three years outside of this process undermines the very mechanism CMS has relied upon to ensure accuracy and fairness in physician work valuation. It also assumes that all services follow the same efficiency trajectory, when in reality, the complexity of patients, the rise of chronic disease, and the increasing use of advanced technologies often make procedures longer and *more* resource-intensive, not less.

The consequence of this policy has profound implications. Over time, an automatic reduction every three years would compound, resulting in a significant and permanent erosion of physician reimbursement. For example, within a decade, cumulative cuts, based on the 2026 2.5% reduction, could reduce the value of many gastroenterology codes by more than 7.5% on top of existing downward pressures from budget neutrality adjustments. This level of reduction is simply unsustainable. It would accelerate the financial strain on physician practices — particularly independent and community-based practices — that are already facing rising labor, supply, and technology costs. Ultimately, this will drive further consolidation into hospital systems, reduce competition, and increase overall costs to the Medicare program.

Most importantly, patient access will be directly at risk. Gastroenterologists provide front-line, high-value services such as colonoscopy for cancer prevention, endoscopic resection for early cancer, and life-saving intervention for acute GI bleeding. These procedures are time-intensive, technically demanding, and require continuous physician presence and judgment. Reducing the work RVUs for these services on the unsupported assumption of efficiency gains devalues the physician's role and jeopardizes the ability of practices to continue offering these critical services—particularly in rural and underserved communities where independent practices are the only point of access.

Equally concerning is the lack of transparency in this proposal. The agency has not disclosed the data sources, analytic methodology, or specialty-specific assumptions used to justify the efficiency adjustment. Without transparency, stakeholders cannot evaluate whether the adjustment is valid, whether it reflects real-world clinical practice, or whether it unfairly penalizes certain specialties. Policies of this magnitude must be grounded in evidence, not untested assumptions.

Rather than applying across-the-board cuts, CMS should work with the RUC to address their concerns through transparent, data-driven methods.

Applying an automatic reduction to all work RVUs every three years is not supported by current evidence and appears inconsistent with CMS' goals of payment accuracy, transparency, and patient access. We encourage CMS to pursue alternative, evidence-based approaches that build established processes rather than imposing arbitrary across-the-board reductions. Rather than applying across-the-board cuts, CMS should work with the RUC to address their concerns through transparent, data-driven methods. Incorporating data from sources such as the AMA RUC survey process gives physicians a critical voice in capturing the real-world time, intensity, and complexity of care. This provider-driven approach ensures fair, accurate, and transparent valuations—unlike arbitrary efficiency adjustments—and is essential to preserving patient access and appropriate recognition of physician work.

On behalf of the nation's gastroenterologists, our societies respectfully urge CMS to reconsider this proposal and instead collaborate with the physician community on evidence-based approaches that preserve relativity while ensuring continued access to high-quality patient care. We urge CMS to continue engaging directly with the providers who perform these services to ensure relativity is accurately maintained.

Updates to Practice Expense Methodology – Site of Service Payment Differential

We appreciate the opportunity to comment on CMS' proposal to significantly refine the current practice expense (PE) methodology to better reflect trends in physician practice settings. While we support CMS' ongoing efforts to ensure accuracy in PE methodology, we are concerned this proposal represents a fundamental relativity change that will reduce PE RVUs for GI endoscopy procedures (43200-43291, 44360-44408, 45330-45350, 45378-45398) performed in ambulatory surgery centers (ASCs) and hospital outpatient departments (HOPDs) by an average of 25% and total payments by an average of 7%. The proposed reductions are destabilizing and reflect a fundamental misunderstanding of how independent GI practices provide services to patients and incur practice expenses.

CMS cites studies from AMA and MedPAC that document a trend of physicians leaving private practice to become employees of hospitals and health systems. The agency asserts that because employed physicians do not bear the same overhead costs as independent practices, the current payment system is outdated and results in "duplicative payments." We will demonstrate how these assumptions are flawed and how implementing such a policy increases the risks of accelerated practice consolidation, reduced competition, and jeopardizes patient access, particularly in rural and underserved communities.

We have the following concerns about the proposed PE methodology changes:

Erroneous assumptions about how physicians incur indirect costs in facilities – While data show that there has been a trend of declining private practice and increasing physician employment by larger health systems, CMS' assumptions about employed physician costs are flawed. CMS itself acknowledges that physicians providing care in facilities still incur administrative and overhead costs (e.g., coding, billing, scheduling). AMA's PPI survey quantified these indirect costs at approximately $57/hour for hospital-based medicine and $62/hour for surgery. A flat 50% reduction to the work RVU allocator misrepresents this reality. Further, the selection of 50% is arbitrary and without supporting rationale. Additionally, while CMS assumes hospital-employed physicians have overhead absorbed by their institution, this does not reflect the numerous arrangements facilities have with gastroenterology departments. Practice expense costs are often charged to the GI department by the hospital. This can take the form of contracts that include paying rent or leasing space in the hospital based on square footage used, paying for scheduling, staffing, billing staff, etc.

Independent gastroenterologists must maintain offices, staff, and billing infrastructure even when performing procedures in hospitals or ASCs.

CMS' across-the-board proposed solution ignores the complexity of how practice expense is borne by physicians in the real world. Gastroenterologists who are in private practice and perform procedures in hospitals as well as hospital-based gastroenterologists with arrangements that include paying for their own practice expense costs will be hurt by this proposal.

Risk of destabilization - By shifting payment in this way, CMS will destabilize practices across the country. Private equity, which already has an outsized impact in gastroenterology, may respond by adjusting models to reap maximum benefits from the new payment system.

CMS' proposal creates a site-of-service differential to incentivize performance of procedures in the office setting in a way that will financially destabilize practices and negatively impact patient safety. We note that CMS does not value all procedures in the office setting, and neither are all procedures safely performed in the office setting. For example, medically fragile patients may require care in the facility setting for procedures that are covered in the office setting. Conversely, some complex procedures cannot be safely performed in the office setting, and which CMS only covers in a facility setting. Patient safety and lack of CMS coverage in the office setting for all procedures do not appear to have been considered in developing the current proposal. It penalizes both facility-based physicians and independent practitioners who must perform some procedures in the facility setting either for patient safety for medically fragile patients or because CMS does not cover all procedures in the office setting. Office-based endoscopy is rare and almost exclusively limited to New York due to the state's rules regulating ASCs. Attempting to incentivize an increase in procedure volume in the office-setting will inevitably lengthen wait times and reduce access for patients requiring care in the facility-as physicians shift their focus to office-based cases. Furthermore, the time between the release of the final rule in November 2025 and the implementation of the policy on January 1, 2026, is not adequate for physicians to prepare for the performance of these procedures in the office setting.

Magnitude of impact warrants delay - CMS declined to adopt the 2024 AMA PPI survey data for CY 2026 rate-setting due to representativeness concerns yet simultaneously proposes a sweeping methodological change that also has not been validated. More time is needed and more work with the impacted specialties must be done to identify and adjust for unintended consequences before finalizing a permanent adjustment.

CMS' impact tables indicate that facility-based physician payments fall by 7% on average while non-facility payments rise by 4%. For gastroenterology, the average PE RVU cut for endoscopic procedures is 25%, and total reductions average 7% for endoscopic procedures performed in ASCs and hospital outpatient departments (HOPD). This magnitude of redistribution has historically justified phase-ins (e.g., clinical labor pricing, supply/package corrections).

If CMS' proposal is finalized, independent practices will have less than two months to adjust their practice models to mitigate the negative payment impact and for hospital-based practices to try to renegotiate contracts that hold them responsible for paying administrative and overhead costs. While models for office-based endoscopy exist, they are typically limited to states that have specific regulations and accreditation standards for office-based surgery, including endoscopy, like New York. Changing a practice model cannot happen in a matter of months. A delay and gradual phase-in are required to allow time for practices to adopt the kind of practice models CMS is trying to incentivize.

We urge CMS to delay implementation of this proposal to work with the AMA, the medical specialties and other stakeholders to consider how the AMA 2024 Physician Practice Information (PPI) PE/HR could be utilized instead of the 2007 data. However, if CMS chooses to move forward with its current proposal, we urge the agency to phase in the PPI PE/Hour Data and modify the indirect practice expense methodology over a four-year period.

Proposed Valuation of Specific Codes for 2026 (4XX04, 91XX1 and 91XX2)

Endoscopic Sleeve Gastroplasty (ESG) (4XX04)

ESG, a minimally invasive treatment option for obesity – a condition at epidemic levels in the U.S. and within the Medicare population – is a technically demanding, advanced endoscopic procedure requiring specialized training, mastery of full-thickness endoscopic suturing, and proficiency with device platforms not included in standard gastroenterology fellowship curricula. The procedure involves multiple device passes, tissue manipulation, and precise suture placement to create a durable gastric sleeve, each step carrying heightened risks of bleeding, perforation, and the need for advanced intra-procedural judgment. ESG patients typically require an overnight stay and three follow-up visits within the 90-day global period, reflecting substantial physician intensity, responsibility, and longitudinal involvement.

Our societies object to CMS' proposal to reduce the RUC-recommended work RVU (wRVU) of 13.50 for AMA current procedural terminology (CPT) code 4XX04 to 12.56 wRVUs based on a formulaic reduction to the recommendation attributed to the CMS 23-Hour Stay Outpatient Surgical Services with Subsequent Hospital Visits Policy.

The RUC used a crosswalk to CPT code 36823 to establish the recommended value of 13.40 wRVUs for 4XX04. We note that CPT code 36823 contains no inpatient hospital visits. Therefore, the RUC correctly applied the CMS 23-hour stay policy which resulted in 43 minutes of immediate post-service time. The intra-service time was reallocated from the same-day E/M code 99232 (*Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter*) to the immediate post-service time of the outpatient service, which added 20 minutes of intra-service time from 99232. ***By reducing the wRVUs from the RUC recommended 13.50 to 12.56, CMS is erroneously applying the CMS 23-Hour Stay Outpatient Surgical Services with Subsequent Hospital Visits Policy twice.*** Further, the equation outlined in CMS' rationale is based on "reverse building block methodology" which is not allowed under current RUC rules. CMS is also lowering the intensity of intra-service work per unit of time (IWPUT) inappropriately.

The RUC already substantially reduced the wRVU our societies recommended to less than the 25th percentile wRVU of the survey results, which was based on survey data from 107 gastroenterologists, bariatric surgeons, and gastrointestinal and endoscopic surgeons. ***We urge CMS to accept the RUC recommendation and the physician times based upon the survey:*** 40 minutes pre-service evaluation, 3 minutes pre-service positioning, 10 minutes pre-service scrub/dress/wait time, 90 minutes intra-service time, 43 minutes immediate post-service time, which includes application of the CMS 23-hour stay policy as it relates to the immediate post-service time component, and 0.5-99238 discharge visit and 3-99213 office visits.

CMS' statement in the proposed rule that "The RUC also revised the global period of CPT code 4XX04 to reduce the work and time value of CPT code 99238 to half of the original value" is inaccurate. We note that CMS determines the global periods at the specialty's recommendation. The CPT Coding Change Application (CCA) for 4XX04 that was submitted by industry and approved by the AMA CPT Editorial Panel for new code 4XX04 recommended a 090-day global, which was supported by the advanced endoscopist members of our expert panel. CMS is part of both the CPT and RUC processes and could have alerted us if they disagreed with the 090-day global period listed on the CCA. Hearing no objection, the surveying societies used the 90-day global survey instrument to administer the survey. We hope ***we have clearly demonstrated that the RUC did not revise the global period for this code, and the reduction of 99238 to 0.5 day discharge was due to the 23-hour stay policy discussed above.***

Although we addressed this issue in the "Efficiency adjustment" section of our letter, we would like to take the opportunity to highlight the irrationality of applying the proposed efficiency adjustment to a brand-new code scheduled for implementation in CY2026 with no historical utilization or claims experience. Applying efficiency adjustments at this stage is premature and inappropriate. Doing so disregards the steep learning curve, higher risk profile, and intensive physician work inherent to ESG, and artificially suppresses the wRVU before the service has even been established. This distorts relativity, undermines adoption, and sets a precedent that penalizes innovation.

We urge CMS not to apply the proposed efficiency adjustment to 4X004.

For these reasons, ***we urge CMS to accept the RUC recommended wRVU of 13.50 and physician times for 4XX04.***

Colon Motility Services (CPT codes 91XX1 and 91XX2)

We thank CMS for proposing to accept the RUC recommended wRVUs for CPT codes 91XX1 and 91XX2 without refinement. We ask CMS to reconsider its proposed refinements to the practice expense inputs for the codes, including reducing the amount of clinical labor time to clean the equipment and reducing the amount of cleaner. We would like to provide additional information to clarify the need for the RUC-recommended staff time and supplies.

CMS recommends reducing staff equipment cleaning time (CA024) from 30 minutes to 10 minutes for consistency with cleaning standards for rigid scopes and proposes cross walking their 10-minute cleaning time recommendation to the cleaning time for the proctosigmoidoscopy base code 45300. However, the proctosigmoidoscopy codes use rigid scopes while the motility codes (91XX1 and 91XX2) require flexible catheters which are similar to the flexible endoscope used for colonoscopy. ***We recommend maintaining 30 minutes of equipment cleaning time (CA024) for consistency with cleaning standards for flexible scopes which can be cross-walked to CPT code 45378 (Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)***. Manometry catheters are single-use and require significant additional time for patient safety, to ensure that all potential infectious contaminants have been removed. Please note that 30 minutes was requested for CA024 (*Clean room/equipment)* by clinical staff rather than CA025 (*Clean scope)* because a catheter is utilized as the "equipment," not a scope, although the work is similar.

CMS recommends reducing the enzymatic detergent (SM015) for cleaning the catheters from 120 oz. to 8 oz. We would like to clarify that the manufacturer instructions require a gallon (120 oz.) of enzymatic

cleaner, which is represents eight unique cleansers recommended by the vendor, to "ensure that the entire catheter is submerged in detergent, up to about 3 inches below the yellowtag" *(Attachment A)* for the catheter used for both 91XX1 and 91XX2. ***Based on this additional explanation of the vendor's cleaning instructions and supporting documentation, we ask CMS to restore SM015 to 120 oz.***

CMS recommends reducing the time to prepare the room, equipment and supplies (CA013) from 17 minutes for code 91XX2 to the 2-minute standard for that activity. However, CMS did not indicate the same for 91XX1 which also has 17 minutes for CA013. CMS "recognizes it is not typical to have different values for the same clinical labor activity across a code family, and we welcome comments as to the appropriateness of these refinements." We believe CMS may have missed the supporting materials in the PE Summary of Recommendation (SOR) form prepared by our societies and approved by the RUC which explained in granular detail what is happening during the 17 minutes for 91XX1 and 91XX2. Most of the clinical labor time is for the calibration of the equipment and testing the catheter to ensure there is no leakage which are both shared features of 91XX1 and 91XX2. In addition to including the PE SOR form (Attachment B), we also offer the following detailed description of the activities below:

91XX1 Intra-Service Clinical Labor Activities = RN/LPN/MTA,

CA013 (Prepare room, equipment, and supplies) standard = 2 minutes

We recommend 15 more minutes to prepare the room, equipment, and supplies for a total of 17 minutes. Clinical staff must set up the equipment, including the following activities:

1. Calibrate rectal barostat equipment

2. Tie balloon to the catheter and reinforce with paraffin wrap.

3. Test catheter to assure that the balloon deploys properly and that there is no leakage.

4. Fan fold barostat balloon for easier insertion.

91XX2 Intra-Service Clinical Labor Activities = RN/LPN/MTA

CA013 (Prepare room, equipment, and supplies) standard = 2 minutes

We recommend 15 more minutes to prepare the room, equipment, and supplies for a total of 17 minutes. Clinical staff must set up the equipment, including the following activities:

1. Turn on the ManoScan High Resolution machine. Turn on computer tower.

2. Connect the manometry catheter to the ManoScan HRM Module with red connector to red input and blue connector to blue input. Push connector straight in. Do not turn or twist for this will damage connector pins.

3. Click the ManoScan 3.0 icon to open the application.

4. Select the catheter by its serial number. Enter patient information before calibration.

5. Click the 'Start' button to enter patient's information, which includes first and last name, medical record number, date of birth, sex, height in feet and inches, attending physician, referring physician, nurse performing the procedure, procedure name, and indication for procedure (s).

7. Click 'Next' to calibrate the catheter with patient information. Follow software instructions to complete catheter calibration.

8. Remove catheter from calibration chamber and apply the ManoShield AR sheath.

9. Tie the balloon to the catheter with two strings at non-sensor locations along the catheter. Test catheter with air syringe to assure that the balloon deploys properly and that there is no leakage.

Based on the supporting information above and in the PE SOR form (Attachment B) we urge CMS to accept the RUC-recommended direct practice expense inputs for CPT codes 91XX1 and 91XX2.

In line with our prior comments regarding the proposed efficiency adjustment, we further urge CMS not to apply the proposed efficiency adjustment to 91XX1 and 91XX2.

Digital Mental Health Treatment (DHTM) and Gastrointestinal Care

CMS requests comments on whether the agency should establish coding and payment for devices classified under 21 CFR 876.5960: *Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions*.

Our societies recognize the role of various therapeutic approaches for irritable bowel syndrome (IBS) management, including brain-gut behavior therapies (BGBTs) such as DHTM. We believe digital therapeutics (e.g., Parallel™ by Mahana Therapeutics, Nerva™ by Mindset Health) have a place and benefit in the treatment of IBS. The AGA Clinical Practice Update on Management of Chronic Gastrointestinal Pain in Disorders of Gut–Brain Interaction recommends, "Nonpharmacological therapies should be considered routinely as part of comprehensive pain management and ideally brought up early on in care."[3] The ACG Clinical Guideline: Management of Irritable Bowel Syndrome suggests "that gut-directed psychotherapy be used to treat global IBS symptoms."[4]

We recognize that digital therapeutics which are FDA cleared and classified under §876.5960 provide cognitive behavioral therapy or gut-directed hypnotherapy are safe and offer benefits to patients as adjunctive therapies in the management of IBS.

While our societies recommend gastroenterologists treating patients with IBS considering BGBTs as part of comprehensive patience care, we also understand that the cost of BGBTs can be prohibitive because patients are often forced to pay out-of-pocket.

[3] Keefer L, Ko CW, Ford AC. AGA Clinical Practice Update on Management of Chronic Gastrointestinal Pain in Disorders of Gut–Brain Interaction: Expert Review. Clin Gastroenterol Hepatol. 2021;19(12):2481-2488. doi:10.1016/j.cgh.2021.07.006.https://www.cghjournal.org/article/S1542-3565(21)00717-5/fulltext

[4] Lacy, B. E., Pimentel, M., Brenner, D. M., Chey, W. D., Keefer, L. A., Long, M. D., & Moshiree, B. (2021). *ACG clinical guideline: Management of irritable bowel syndrome* [PDF]. American Journal of Gastroenterology.https://webfiles.gi.org/links/PCC/ACG_Clinical_Guideline__Management_of_Irritable.11.pdf

We encourage CMS to explore ways to increase patient access to BGBTs for gastrointestinal conditions. like IBS, by removing coverage and financial barriers. We support the establishment of payment for devices classified under 21 CFR 876.5960 as part of the existing Digital Mental Health Treatment (DMHT) code set (G0552, G0553, G0554) or by creating an additional device supply code as part of this code set for CY 2026 to ensure increased access to recommended behavior therapies for gastrointestinal conditions like IBS.

Average Sales Price: Units Sold at Maximum Fair Price

Under the Medicare Drug Price Negotiation Program, selected drugs payable under Medicare Part B will be set at 106% of the Maximum Fair Price (MFP) rather than 106% of average sales prices (ASP). Further, as CMS clarified in this proposed rule that because statutory language does not expressly or implicitly exempt units of Medicare Part B or Part D MFP sales from the calculation of the manufacturer's ASP, units of selected drugs sold at MFP will be included in the calculation of the manufacturer's ASP described effective January 1, 2026.

Our societies strongly urge CMS to exclude the MFP from calculation of the ASP. By excluding MFP from the calculation of ASP, it would help address challenges associated with the Medicare Drug Price Negotiation Program in which provider reimbursement will be based on the MFP rather than the ASP plus an add-on fee that covers the acquisition, storage and administration of a medicine.

Prior to the passage of the Inflation Reduction Act of 2022 (Public Law 117–169), our societies warned that cuts to add-on payments for Part B drugs included in the bill would place extreme pressure on physician practices. Nevertheless, lawmakers moved forward with the provision.

It has become increasingly difficult for gastroenterology practices to acquire biologics used to treat inflammatory bowel disease (IBD) at ASP-reimbursed rates. This is because rebates between pharmaceutical companies and pharmacy benefit managers (PBMs) are reflected in manufacturers' quarterly ASP reporting to CMS. Consequently, ASP has been lowered for some biologics to the point that many providers' acquisition costs substantially exceed Medicare and other private health plan payments. Physicians commonly refer to this situation as being "underwater." If CMS finalizes its proposal to include units of selected drugs sold at MFP in the calculation of a manufacturer's ASP, the outcome will likely be the same. That is, physician practices may not be able to purchase medications at the government negotiated rate. Rather than risk being reimbursed less than the acquisition cost for a medication, a physician will refer the patient out of the office-based infusion suite to the hospital where it costs the Medicare program, the health care system, and the patient more. Because Part B drug reimbursement by commercial insurers has traditionally been based on the ASP, CMS' proposed policy to require MFP in the calculation of a manufacturer's ASP will have a significant ripple effect throughout the health care system.

We note that the language in the proposed rule is unclear as to whether CMS intends to continue to publish ASP. This data is used by our members and by payers that use it as the basis for their payments.

We urge CMS to confirm in the final rule that ASP data will continue to be reported by CMS as it has in the past.

Telehealth Services List

CMS is proposing to revise the 5-step process for reviewing requests to the Medicare Telehealth Services List. Our societies support the proposal to simplify the process by focusing on whether the service can be provided via telehealth technology. Our societies also agree with CMS, that with their knowledge of a patient's clinical needs and professional judgement, physicians and other practitioners are best positioned to determine if a service can be of benefit and provided safely via interactive telehealth technology. Our societies also support the removal of the designations of "provisional" and "permanent" and the placement of all codes currently on the telehealth list on the Medicare Telehealth Services List.

Direct Supervision Via the Use of Two-Way Audio/Video Communications Technology

Our societies support the proposal to permanently adopt a definition of "direct supervision" that allows for "immediate availability" of the supervising provider via audiovisual real-time communication for certain services provided under Medicare's "incident to" policy. Prior to the COVID-19 public health emergency (PHE) declaration, direct supervision required the presence of the supervising provider in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. During the PHE for COVID-19, this definition was amended to allow for direct supervision to be provided via audio-visual communications for certain services. As recognized in the proposed rule, this flexible approach to the direct supervision provision has been widely utilized by physicians and other providers. Our societies believe this flexibility has facilitated access to care particularly for patients with physical and/or geographic limitations without compromising patient safety and quality of care.

Our societies agree that this flexibility should be extended to all services under current regulation (§ 410.26 (incident-to services)) with the exception for services with a global surgery indicator of 010 and 090. Our societies believe this approach safeguards patient safety while enhancing access to care for the allowed services. We agree that the physician or other provider be entrusted to determine the appropriate supervision modality on a case-by-case basis when considering applying this flexibility.

Teaching Physician Supervision of Residents with Virtual Presence

CMS has allowed teaching physicians to supervise residents through real-time audio-video technology when the resident and patient are together in person and for telehealth services in all residency training locations during the COVID PHE. This flexibility was extended beyond the PHE by CMS until the end of 2025.

The proposal to not allow virtual presence in Metropolitan Statistical Areas (MSA) creates a disparity in supervision requirements based solely on area. In non-MSA settings, teaching physicians would still be allowed to continue utilizing audio/video real-time communications technology to fulfill the presence requirement. Experiences using audio-visual supervision have shown that patient safety and clinical needs have been maintained in all teaching locations. Removing this flexibility in MSAs impacts patient access to academic care and limits opportunities to train residents to provide patient care using telehealth modalities.

We support the continued documentation requirements to clearly demonstrate the teaching physician's physical or virtual presence during key portions of the service. We note that the Accreditation Council for Graduate Medical Education (ACGME) has guidelines and strict limits concerning supervision via interactive telecommunications technology that ensure maintaining levels of patient care and teaching physician direction. We support these efforts to ensure patient safety and appropriate resident education when utilizing audio/video real-time supervision.

We urge CMS to permanently allow teaching physicians to provide virtual supervision of residents when they are delivering a service using telecommunications technology for both remote and in-person services in all locations.

RFI: Artificial Intelligence and Software as a Service (SaaS)

CMS is seeking comments on integrating the costs of SaaS (e.g., Artificial Intelligence (AI)) into the rate-setting process for the Medicare Physician Fee Schedule. Our societies appreciate CMS acknowledging that current PE valuation does not reflect the cost of software-as-a-service (SaaS) and AI-driven technologies, and the opportunity to provide feedback on the factors CMS should consider when paying for SaaS.

Our societies also appreciate the importance of a reimbursement pathway to ensure continued innovation of AI-enabled medical technology. Medicare reimbursement should provide a fair valuation of physician work and practice expenses. Over time, the introduction and adoption of AI technology for medical services will continue to grow and expand, providing valuable data that was previously not available to physicians and their patients. Funding for this must come from outside the current physician payment system. In the rate-setting process, CMS should separately identify and pay for the cost of this new technology. To set the rates, data should be gathered from a wide range of sources, including manufacturers, clinicians who purchase and use the technology, as well as other stakeholders.

Quality Payment Program

Our societies offer the following comments in response to the Quality Payment Program (QPP) and proposed changes. We share the agency's commitment to consistently improving the quality of care for Medicare beneficiaries, while reducing the administrative burdens borne by GI practices.

Maintain the MVP Group Reporting Option for Small Practices

Our societies support continuing to allow small practices to report as a group; however, we believe that CMS should explore additional parameters to reduce reporting burden. For example, we are concerned that there is significant potential for larger multi-specialty practices to have to report many MIPS Value Pathways (MVPs), which further increases the number of measures and activities on which a group would have to focus, reducing the potential for true quality improvement gains.

We encourage CMS to explore additional avenues to minimize work at the point of care such as capping the number of MVPs for multi-specialty groups.

High-Priority Measure Definition

CMS proposes to remove health equity from the definition of a high-priority measure, saying that its definition of health equity was "confusing and that health disparities are best addressed through efforts to improve overall healthcare quality for all beneficiaries." Our societies are collectively committed to reducing disparities in digestive disease outcomes, particularly in screening and early detection rates of colorectal cancer among racial and ethnic minorities who are less likely to have regular colorectal cancer screenings than White individuals.[5]

Reducing disparities in health cannot be achieved simply through efforts to improve overall health care quality for all beneficiaries. Rather, it requires targeted investments and efforts. Therefore, the development of quality measures in this regard should be encouraged and prioritized. While CMS is interested in measures around well-being and nutrition and possibly including them as high-priority quality measures, we want to make it very clear that our societies do not regard measures that assess overall health, happiness, and satisfaction in life as a substitute for measures that are targeted at reducing health disparities and achieving health equity.

RFI: Core Elements Request for Information

CMS expresses concerns in the proposed rule that MVP reporting "may not produce sufficient comparative performance data on standardized measures to support patient choice of care." As such, CMS states it is considering requiring the reporting of a subset of measures within an MVP that are "meaningful" for clinicians and patients. If CMS is going to mandate MVP measure reporting, it should not *also* mandate which MVP measures clinicians must report. The entire rationale for the MVP concept was to compile measures that were applicable to a specific specialty. ***We oppose the concept generally of requiring physicians to report on "Core Element" measures.***

Should CMS move forward with this concept, selection of core measures should be carefully considered with specialty society input. Information should be available to patients to evaluate physicians based on quality measures that are directly relevant to the specific services they provide. This is what allows for more meaningful comparisons and assists patients in finding the right provider for their health care needs.

CMS includes cross-cutting quality measures in MVPs. In the GI Care MVP, for example, these measures currently include:

- Colorectal Cancer Screening (QID 113)
- Documentation of Current Medications in the Medical Record (QID 130)
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (QID 226)
- Closing the Referral Loop: Receipt of Specialist Report (QID 374)
- Gains in Patient Activation Measure (PAM®) Scores at 12 Months (QID 503)

[5] American Cancer Society, Colorectal Cancer Facts & Figures 2023-2025; https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2023.pdf

Our societies along with the GI Quality Improvement Consortium (GIQuIC), which supports the only GI specialty-specific clinical benchmarking registry and qualified clinical data registry (QCDR), provided extensive feedback on the GI Care MVP, including the Colorectal Cancer Screening (QID 113) and Closing the Referral Loop (QID 374). These measures are generally geared toward primary care providers and not gastroenterologists. Yet, CMS forced the inclusion of these measures in the GI Care MVP. If CMS is going to mandate MVP reporting and further Core Elements, it should not *also* mandate the reporting of measures that are not particularly applicable or specific to GI care. This highlights the troubling requirement of specialty registries to support reporting of quality measures that are not currently supported or directly relevant and meaningful to their participants such as QID 113 for the GI Care MVP. This colorectal cancer (CRC) prevention measure is not intended for gastroenterologists to report but is intended to assess primary care physicians ordering CRC screening. We fully support the availability of this important measure for primary care physicians. Although there are rare instances where a gastroenterologist may have cases qualifying for this measure, it is an exception to the rule. Using this measure to assess gastroenterologists constitutes measuring a 'standard of care' for these specialists. Supporting non-specialty-specific quality measures is not a meaningful effort for specialty registries or their participants and comes at significant costs to the registries in terms of direct and indirect costs, which may be passed on to the practices.

CMS states in the rule that one of its concerns is "Core Elements" that are specified for only a few collection types. CMS states that one solution would be to include "Core Elements" with several different collection types. CMS' goal should be to reduce, not increase, the administrative burden on physician practices associated with participation in the QPP. If a physician reports data to CMS for an MVP through a qualified registry and that registry cannot support the addition of a "Core Element" measure either because of technical or financial reasons, that physician would be forced to either abandon participation in the registry or use multiple mechanisms for reporting required MVP measures. This could become particularly onerous for multi-specialty physician groups that have to report multiple MVPs.

Physicians are already frustrated with the onerous requirements of the QPP; our societies urge CMS to reduce, not increase, its reporting burden. The addition of a "Core Element" reporting requirement would be an additional administrative burden.

Medicare Procedural Codes RFI

Gastroenterology covers a wide range of complex conditions and grouping gastroenterologists solely based on procedural billing codes fails to account for all aspects of patient care provided by many gastroenterologists. Conditions such as IBD, liver disease, and pancreatic disorders require long-term management and several aspects of this care such as diagnosis, treatment planning and long-term patient care are not adequately captured in current procedural coding systems.

Assigning gastroenterologists to MVPs based on procedural billing codes will create inaccurate and inequitable comparisons between clinicians who treat vastly different patient populations. A gastroenterologist who specializes in more complex conditions may be assessed using quality measures primarily focused on routine colon cancer screenings, rather than the management of those intricate conditions. This could result in unfair penalties for clinicians, as their comprehensive, long-term care is not adequately represented by short-term procedural billing codes.

The proposal to assign gastroenterologists to MVPs based on procedural billing codes does not adequately reflect the full scope of their care and may result in misleading performance evaluations that unfairly penalize clinicians. We strongly urge CMS to reconsider this approach and develop a system that more accurately mirrors the diverse and multifaceted nature of gastroenterology.

RFI: Well-being and Nutrition Measures

We support the development and implementation of measures on health and well-being that are patient-centered, evidence-based, and demonstrated to be reliable and valid. However, these measures must also be clinically appropriate and directly attributed to the quality of care provided by the intended medical specialty. For example, the two preventive care and screening measures that are proposed for inclusion in the Low Back Pain episodes for the ambulatory specialty model (ASM) model were originally developed to be applicable to primary care physicians and do not necessarily function as key drivers of quality improvement when applied to a different specialty such as neurosurgery or orthopedic surgery. CMS must ensure that any measure on health and well-being will result in incentivizing quality improvement and be clinically appropriate.

Gastroenterology Care MVP

According to an analysis of the 2023 MIPS Program, only 186 entities — 98 groups, 5 subgroups, and 83 individuals — received a MIPS score through an MVP. Of the 12 MVPs available, more than half of the entities participated in just two MVPs — the Cancer Care MVP and the Anesthesia MVP. CMS states that its "internal data" shows there were more than 2,000 MVP "registrations" for the CY 2024 MIPS performance period, but without more information, it is difficult for stakeholders to make a full assessment on what impact MVPs are truly making on MIPS participation.

CMS promotes MVPs as a "more connected assessment of quality of care," with meaningful groups of measures and activities.[6] Yet, CMS added measures to the GI Care MVP that are most applicable to primary care providers despite objections from our societies. This is not meaningful to the gastroenterologists who are expected to participate in the GI Care MVP.

CMS also touts MVPs as "streamlined" compared to the administrative burden associated with Traditional MIPS. CMS states, "With a reduced list of measures and activities to choose from in each MVP, there are fewer options which create deeper measure and activity links and less administrative burden."[7]

Our societies would expect more physicians to participate in MVPs if they are more meaningful and streamlined than Traditional MIPS. We suspect physicians with an available MVP are not voluntarily migrating to them because they mirror many of the flaws of MIPS, including scoring methodologies, low statistical reliability of quality measures, lack of confidence in measure benchmarks, lack of timely and actionable feedback, program burden, and the marginalization of clinical data registries. These flaws drive

[6] Learn about the MVP Reporting Option. https://qpp.cms.gov/mips/mvps/learn-about-mvp-reporting-option
[7] Ibid.

physicians toward measures that have greater performance certainty and away from measures that could be more meaningful to their specialty and their patients.

While conversations continue among congressional lawmakers about reforming MIPS, we ask CMS to halt progression toward mandatory MVP reporting, including mandatory subgroup reporting for multi-specialty groups reporting an MVP beginning in CY 2026.

Meaningful Measurement of Gastroenterologists

CMS has stated that the agency considers the relationship between cost and quality as an essential component of defining value. Our organizations agree that a value-based payment system must balance cost and quality. Towards that end, our physician members and staff have devoted significant time and expertise to support the development of episode-based cost measures and quality measures. Despite these efforts, there is a notable imbalance between cost and quality measures in the GI Care MVP as highlighted by the updated format of the MVP tables, which stratify quality measures into groupings by clinical conditions and/or episodes of care for each MVP.

We would also note that the GI Care MVP groupings imply a correlation between cost and quality. However, for a few exceptions, there is no true correlation. For example, why are cost measures "COST_SSC_1: Screening/Surveillance Colonoscopy" and "COST_LGH_1: Lower Gastrointestinal Hemorrhage" in the *General Gastroenterology* and *Advancing Health and Wellness* groupings? Further, why is the "TPCC_1: Total Per Capita Cost" measure in the *Interventional / Endoscopy* grouping when there are two relevant GI cost measures already in that grouping? Aside from the long-standing issues the physician community has with the TPCC measure, it is unclear why CMS continues to rely on the TPCC when there are two GI cost measures (COST_SSC_1 and COST_LGH_1) that align with the *Interventional / Endoscopy* grouping.

Among the most striking issues about the GI Care MVP in the updated format is the limited number of quality measures in MIPS - either as MIPS clinical quality measures (MIPS CQM) or QCDR measures - specific and important to gastroenterologists that would inform practice improvement and patients about the care delivered by these specialists. As CMS looks to sunset Traditional MIPS, the agency must address the administrative burden associated with the lack of relevant measures available to specialty care clinicians and consider the challenges of getting quality measures into the program given the timelines associated with measure development alongside the timelines for rulemaking.

The process of submitting quality measures into the QPP for acceptance as a MIPS CQM is highly complex, involving multiple stages of rigorous evaluation, revision, and testing to ensure that the measure is evidence-based, clinically meaningful, reliable, valid, and ultimately capable of improving patient outcomes. An example of this complexity is the development of the Sustained Virological Response (SVR) measure for patients with hepatitis C. In the summer of 2022, the AGA was approached by CMS and Mathematica following a request from the White House Office of Science and Technology Policy (OSTP) to help advance the national priority of testing, treating, and eradicating hepatitis C from the U.S. population. The AGA, with support from various levels of government, contractors, content experts, and financial assistance, worked diligently to develop, test, and submit the SVR measure for the Pre-Rulemaking Measure Review (PRMR) process. Despite receiving broad support, access to top-tier data

science teams, and significant financial resources, the development process still took nearly 4 years to complete and is finally included in the CY 2026 proposed rule. The first benchmarking data for this measure is expected in CY 2028, marking approximately six years from initial development to real-world implementation and the first available data to see if there has been any impact from this measure on patients with the hepatitis C virus. This example underscores the complexity and length of the process required to ensure that any measure introduced into the QPP meets the highest standards for patient care and outcomes. It also highlights the immense effort and time commitment, expertise, and resources needed to successfully submit a measure into the program.

The pathway for submitting a quality measure as a QCDR measure - while maintaining equal rigor to ensure that the measure is evidence-based, clinically meaningful, reliable, valid, and ultimately capable of improving patient outcomes - can be just as challenging The GIQuIC QCDR measure set has changed nearly every year since CY 2014, with currently only three GIQuIC QCDR measures available for reporting for CY 2025. While registry participants appreciate that quality measures foundational to their quality improvement programs available in their clinical benchmarking registry can also serve the purpose of accountability in public reporting, the instability of the GIQuIC QCDR measure set has been a point of frustration and can be added burden if a clinician or group needs to do supplemental reporting of cross-cutting measures through an alternate mechanism to ensure program requirements are met.

While our societies appreciate the intention that the updated format makes the MVPs more user-friendly for eligible clinicians, these examples highlight the glaring gaps in meaningful quality measures available for reporting. Without a clear priority from CMS to fill these gaps in a timely manner, it remains unclear to our societies what the goals are with MVPs versus Traditional MIPS.

Our societies urge CMS to change its position of maintaining a parsimonious quality measure inventory as limited measure choice is more administratively burdensome to clinicians who are being driven to reporting for the sake of reporting.

Third Party Intermediaries Support for MVPs

We appreciate CMS' recognition that QCDRs and qualified registries may need additional time to implement and fully support new MVPs and agree with the additional flexibility that is proposed. We urge CMS to consider building in additional lead times for measure implementation across MIPS since it continues to be challenging, costly, and burdensome for practices, qualified registries, QCDRs, electronic health record system (EHR) vendors, and others to implement new or adapt existing measures within the current timeframe (approximately two months from the time that the final rule is released and the program year reporting begins). This need has been recognized for eCQMs as those specifications are released several months prior to the start of a program year. Additional time to implement measures (both new and modified) will become increasingly more complex as we move to greater numbers of electronic clinical quality measures (eCQMs) and in the future digital quality measures (dQMs).

RFI: Toward Digital Quality Measurement in CMS Quality Programs

Our societies support the intended move to a standard based on Fast Healthcare Interoperability Resources (FHIR), which will allow physicians, hospitals, and APM entities to incorporate alternative sources of data into quality reporting and should ease reporting burden. Specifically, it will allow specialties such as radiology and gastroenterology to use their digital data sources, as well as other physician specialties, providers, and APM entities, to seamlessly incorporate novel sources of information and data. Therefore, to best use government, provider, and physician practice resources, we recommend that CMS focus its efforts on FHIR-based dQMs rather than the interim step of FHIR specifying eCQMs.

The direct transition to dQMs will meaningfully reduce data collection, reporting burdens, and deliver far greater efficiency than a phased approach. Developing FHIR-based eCQMs requires multiple complex, costly steps that disproportionately impact smaller hospitals and medical practices, many of which lack the needed infrastructure and resources. Unlike eCQMs, adopting FHIR dQMs will enable all entities to primarily use EHR data while allowing organizations with broader capabilities or specialties that leverage digital technologies that are not eligible for certification to incorporate additional sources.

Broadening adoption of FHIR dQMs not only positions the health care system to achieve a modern, efficient standard for data exchange and interoperability but also directly supports the Administration's goals of advancing health innovation, reducing unnecessary burden, and addressing the chronic disease epidemic.

To ensure this transition is successful, objective criteria and deliverables must be established to determine whether the field (i.e., providers and technology developers) is ready to progress to the next stage of implementing FHIR dQMs:

- *Demonstrated technical capability, such as successful end-to-end testing of FHIR dQM reporting.*
- *Sufficient adoption rates of FHIR-enabled systems across provider types.*
- *Training and technical support readiness for provider organizations.*
- *Evidence of data quality and completeness in reported dQMs.*
- *Stakeholder consensus on burden, feasibility, and patient safety considerations.*

By confirming readiness, we can help the health care community adopt new standards with confidence, we can accelerate the availability of more timely and accurate information, ultimately improving patient experiences of care and outcomes. We urge CMS to release a transparent timeline and actively engage with the health care community for feedback (physicians, hospitals, APMs, health plans, patients, and EHR developers). Specifically, the process and timeline must outline when the technical requirements for FHIR-based reporting will be available with adequate time for developers to integrate them into their products, and when these requirements will be incorporated into federal certification requirements.

At the same time, CMS should build the internal capabilities needed to receive dQM data through FHIR-based application programming interfaces and release guidance and education to assist the health care ecosystem in this transition. Subsequently, once CMS determines that developers are ready and certified to support this reporting and CMS can receive the data, a reasonable timeframe during which practices, hospitals, ACOs, and others must begin reporting these measures should be proposed.

The glidepath must also include appropriate positive incentives to support providers and physician practices, particularly those that are small and rural, through each step of the transition in a thoughtful way. By using a stepwise approach with initial activities focused on building the required infrastructure, followed by data collection and reporting by practices, CMS can achieve its goals. It will be essential for each step to include adequate time and resources. A critical component is a transparent process to assess readiness before progressing from one stage to the next. Evaluation also must incorporate input from the provider and developer community to confirm there is broad consensus that the majority of participants are equipped to successfully report FHIR dQMs.

Proposed Removal of Quality Measure 185, Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

We strongly oppose CMS' proposal to remove Measure 185 - Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use from the QPP and request CMS utilize its discretion to maintain this measure in the QPP due to the importance as described below. This measure is integral to ensure that care for patients with a history of adenomatous polyps adheres to evidence-based guidelines, promotes preventive care, reduces unnecessary healthcare costs, and aligns with CMS' broader goals outlined in the CY 2026 Medicare PFS.

Adheres to Evidence-Based Guidelines for Colonoscopy Surveillance

This proposed rule emphasizes the importance of preventive services and appropriate care in reducing overall healthcare costs and improving patient outcomes. Measure 185 directly supports these objectives by ensuring that patients who have undergone polypectomy follow appropriate surveillance intervals, typically every three to five years depending on the individual's risk profile, and do not receive unnecessary colonoscopies.

Regular colonoscopy surveillance is essential for patients with a history of adenomatous polyps to detect potential recurrence or new polyps before they become cancerous. However, overuse of colonoscopy surveillance may result in unnecessary complications, increased patient anxiety[8] as well as an increased cost burden to the patient and the healthcare system. Surveillance intervals are recommended to be based on the findings of the initial colonoscopy and individual patient risk-factors, with more frequent intervals being reserved for those at higher risk.[9] [10] Measure 185 ensures that clinicians avoid over-screening, thereby preventing unnecessary procedures and ensuring that patients receive care that is appropriate for their specific clinical needs.

Reduces Unnecessary Healthcare Costs and Improves Cost-Effectiveness

CMS committed in this proposed rule to reduce unnecessary healthcare costs while improving care quality. Overuse of colonoscopies, particularly in patients who do not meet the criteria for more frequent

[8] American Gastroenterological Association: Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer, Gupta, Samir et al., Gastroenterology, Volume 158, Issue 4, 1131 - 1153.e5.
[9] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening
[10] https://www.asge.org/home/resources/publications/practical-solutions/practical-solutions-june-uspstf-2021-colorectal-cancer-screening-guidelines

surveillance, leads to substantial avoidable costs and Measure 185 helps to avoid this overuse by ensuring that colonoscopies are only conducted when clinically indicated.

Unnecessary colonoscopies increase both direct healthcare costs and indirect costs related to complications and lost productivity. Unnecessary procedures may also contribute to wasteful spending in the healthcare system. Reducing unnecessary procedures like colonoscopies without an appropriate indication results in significant cost savings without sacrificing patient outcomes.[11] Measure 185 directly contributes to the goal of improving value-based care in the QPP, improving the cost-effectiveness of healthcare while preserving patient safety.

Promotes Upstream Drivers of Health and Population Adjustment

CMS has affirmed the focus on upstream drivers of health and population adjustment for all patient populations in this proposed rule. Measure 185 plays an important role in promoting these drivers, particularly for vulnerable populations who may otherwise face increased risks from unnecessary screenings. Racial and ethnic minorities often have lower colonoscopy adherence rates due to barriers such as access to care and lower health literacy.[12] Patients from underserved communities may be subjected to unnecessary follow-up procedures at a higher rate than other communities due to inconsistent care standards or lack of awareness of appropriate guidelines and Measure 185 helps clinicians offer more equitable care and reduces the risk of harming communities that are already burdened by healthcare access challenges.[13]

Aligns with CMS' Long-Term Goals for Quality Measurement

Measure 185 is aligned with CMS' long-term goals for quality measurement and value-based care. In this proposed rule, CMS acknowledges the need for a balanced set of quality measures that reflect high-value care, preventive services, and patient-centered outcomes. Measure 185 is an excellent example of such a measure, focusing on improving patient outcomes by promoting appropriate care while reducing unnecessary procedures and their associated risks. Removing Measure 185 would undermine these long-term goals, particularly by diminishing efforts to prioritize preventive care, reduce waste, and improve patient outcomes. This measure remains a crucial tool in ensuring that clinicians provide appropriate, evidence-based care for patients at risk of colon cancer while reducing unnecessary healthcare costs while improving the overall efficiency of the healthcare system.

We strongly urge CMS to use its discretion and retain Measure 185 in the QPP.

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[11] Fraiman J, Brownlee S, Stoto MA, Lin KW, Huffstetler AN. An Estimate of the US Rate of Overuse of Screening Colonoscopy: a Systematic Review. J Gen Intern Med. 2022 May;37(7):1754-1762. doi: 10.1007/s11606-021-07263-w. Epub 2022 Feb 25. PMID: 35212879; PMCID: PMC8877747.

[12] Nagelhout E, Comarell K, Samadder NJ, Wu YP. Barriers to Colorectal Cancer Screening in a Racially Diverse Population Served by a Safety-Net Clinic. J Community Health. 2017 Aug;42(4):791-796. doi: 10.1007/s10900-017-0319-6. PMID: 28168395; PMCID: PMC5517041.

[13] Hollis RH, Chu DI. Healthcare Disparities and Colorectal Cancer. Surg Oncol Clin N Am. 2022 Apr;31(2):157-169. doi: 10.1016/j.soc.2021.11.002. Epub 2022 Mar 8. PMID: 35351271; PMCID: PMC8968072.

This measure plays a critical role in ensuring appropriate surveillance intervals for patients with a history of adenomatous polyps, aligns with CMS' commitment to preventive care, value-based care, health equity, and national cancer prevention goals. Measure 185 reduces unnecessary colonoscopies, promotes cost-effective care, and improves patient outcomes, all of which are vital to achieving the objectives set forth in this proposed rule. Removing this measure would be detrimental to patient care, increase healthcare costs, and deviate from the broader goals outlined in the QPP.

Proposed Substantive Changes to the Total Per Capita Cost (TPCC) Measure

Our societies appreciate the opportunity to comment on the CY 2026 PFS proposed updates to the TPCC measure. We support CMS' goal of advancing cost measurement that is methodologically sound, clinically relevant, transparent, and equitable. However, several aspects of the proposed TPCC modifications, operational updates, and the two-year informational feedback period require further refinement to ensure fairness, accuracy, and meaningful clinician engagement.

Substantive TPCC Modifications

We recognize CMS' ongoing measure maintenance process and support the intent to ensure that TPCC specifications reflect current coding, clinical practice, and policy changes. However, TPCC's broad attribution logic risks assigning costs for beneficiaries to clinicians without a meaningful or primary clinical relationship, particularly for specialists who provide episodic care or a consultative role. When multiple cost measures are implemented, the TPCC may double count costs already captured in episode-based measures (e.g., Screening/Surveillance Colonoscopy). That could lead to distorted cost scores and inequitable penalties that inaccurately reflect a clinician's performance.

We recommend that CMS develop a system to track and map procedures, events or episodes, such as colonoscopies, that have already been counted in the episode-based measure to prevent them from inclusion and biasing the TPCC measure. We also request that the TPCC measure not be used if a gastroenterology cost measure can be applied.

We believe this will promote fairness and improve the success of the cost performance measures. We also encourage TPCC's risk adjustment methodology to continue to incorporate socioeconomic and demographic factors to account for differences in patient populations, particularly in high-risk or underserved areas.

Operational List Updates

We support CMS' proposal to update the operational list of care episodes and patient condition groups on an annual basis to reflect coding changes identified through measure maintenance. Accurate coding is essential to maintaining measure accuracy and for ensuring that TPCC attribution reflects actual clinical care. However, we would like CMS to consider several variables that could lead to unintended consequences when updating the operational list from these coding changes.

Updates to ICD-10, CPT, or HCPCS codes can substantially change which beneficiaries trigger TPCC attribution, how patients are grouped into condition categories, and which clinicians are held accountable for those costs and potentially shifting a patients' risk profile. For example, changes to diagnostic or

procedural codes could reclassify patients from low risk to high-risk categories, thereby altering how their care is managed. Similarly, a change in diagnostic codes can alter which patients are attributed to a particular physician or care team and shift attribution. If a code update redefines a patient's condition as more complex or high-cost, the physician temporarily manages that patient may now be accountable for a significantly higher portion of the patient's care costs. Without prior modeling and transparency, coding updates can cause unexpected changes in clinician performance that may deviate from actual care delivery patterns.

We recommend that CMS involve relevant specialty societies, measure developers, and technical expert panels (TEPs) prior to implementation to ensure that code modifications do not unintentionally expand or narrow the scope of attribution in ways that misrepresent care patterns or penalize clinicians for costs they did not influence or who may have served primarily in a consultative role. We also recommend where modeling indicates a significant statistical shift in attribution or performance results, CMS should consider delaying implementation to allow for clinician education and operational readiness.

Two-Year Informational-Only Feedback Period

We commend CMS for proposing a 2-year feedback period for newly implemented cost measures, as this approach offers a critical opportunity for clinicians and healthcare systems to adjust to the new requirements and is consistent with prior protocols implemented for new quality measures. While we support this new feedback period, we urge CMS to continue to identify ways in which periodic feedback (e.g., at least once during the performance period) can be provided to program participants to further inform their efforts to manage costs for their patients in relation to existing cost measures. Qualified registries and QCDRs must provide feedback at least 4 times a year to participants on quality measures so that clinicians and groups can identify areas where they can improve their performance. This same intent must be applied to cost measures given the aim of the QPP is to balance quality and cost in healthcare.

Although TPCC is not a new measure, the substantive specification changes proposed under the CY 2026 updates can have unintended consequences and should be benchmarked after 2years of program experience, like those of newly introduced quality measures. Changes to attribution methods, risk adjustment algorithms, or adjustments to the specific codes tied to TPCC can significantly impact which clinicians are held responsible for a patient's care and how the cost of that care is calculated. Changes in how comorbidities or complex conditions are coded, like those conditions often managed by gastroenterologists, could mean that more or fewer patients are linked to their primary physician, leading to a potentially significant shift in the financial and clinical responsibility attribution. Specialists often treat complex conditions that are higher cost than lower risk conditions that could result in unfair attribution to providers who temporarily manage a patient's condition.

Reliability and Validity of the Revised Measure

As our societies submitted in previous comment periods a >0.7 threshold is needed to ensure stability and accuracy and the measure must be correlated to at least one relevant quality measure to demonstrate its validity. In addition, the revised attribution model could be evaluated to ensure that these changes work as expected. In light of the changes to the measure, we would expect to see updated results to allow us to

assess whether reliability and attribution improved and that correlations to cost exist as hypothesized. We encourage CMS to provide these results as soon as possible. We support CMS' commitment to keeping TPCC clinically relevant and operationally accurate. To protect fairness, validity, and clinician trust, CMS should refine attribution logic, raise reliability thresholds, and apply the 2-year informational feedback period to substantive TPCC changes.

Proposals to Update the Improvement Activities Inventory

CMS included the Improvement Activities (IA) performance category in the QPP to assess clinician and group participation in activities that improve clinical practice and support patient engagement. As implemented and as it is evolving, the IA performance category has not supported this aim or the spirit of quality improvement, which should empower healthcare teams to identify opportunities to enhance the effectiveness, efficiency, and safety of their healthcare services and implement evidence-based solutions. Society members and GIQuIC QCDR reporters frequently contact our society and registry staff seeking clarification on the CMS improvement activities - specifically their descriptions and supporting documentation requirements. One example of a meaningful activity well understood by GI healthcare teams that enhances patient outcomes was "IA_CC_1 Implementation of use of specialist reports back to referring clinician or group to close referral loop." Our societies opposed its finalized removal from MIPS reporting as it was an impactful activity for specialists that also earned achievement points.

With further reductions to the overall improvement activities inventory and further narrowing of improvement activities available for reporting via the GI Care MVP, fulfilling the requirements of the IA performance category is becoming more administratively burdensome than meaningful to improving the delivery of healthcare. ***Our societies encourage CMS to sunset the Improvement Activities performance category, when reforming the QPP.***

Scoring for Topped Out Measures with Limited Measure Choice

CMS is proposing that 19 quality measures receive the previously defined topped out measure benchmarks for the CY 2026 performance period to address the challenge of specialty sets and MVPs with limited measure choice and a high proportion of topped out measures, precluding meaningful participation in MIPS. Included among the 19 quality measures is "QID 320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients" (Medicare Part B Claims). While our societies appreciate application of the previously defined topped out measure benchmarks to this measure, we remain concerned about the limited number of meaningful quality measures for gastroenterologists to report and the benchmarks associated with those few available. This is even more alarming given the proposed removal of QID185 (addressed earlier in this letter).

The American College of Radiology published a study using 2019 data analyzing the impact of the topped out and extremely topped out status of measures by specialty societies and found "*A preponderance of topped out measures within a specialty's available measure set will greatly impair that specialty's ability to do well in MIPS given the potentially capped scoring for those reporting such measures, as well as the eventual inability to report such measures at all as they become phased out. In this regard, variation between specialties in the preponderance of topped out measures may*

predispose certain specialties to be more likely in succeeding or failing under MIPS"[14] and gastroenterology continues to be one of those specialties impaired by this policy given the limited number of measures specific and important to gastroenterologists.

Our societies urge CMS to look beyond the alternative benchmarking methodology being applied to a subset of topped out measures to meaningfully address the flaws in the topped-out measure policy. This should be concurrent to the analysis CMS proposes to conduct of each MVP to identify if the prevalence of topped out measures within an MVP hinders a clinician's ability to successfully participate in the MIPS Quality performance category, a proposal our societies support.

Benchmark Methodology for Scoring Administrative Claims-based Quality Measures in the Quality Performance Category

Our tri-societies appreciate the proposed change to update the benchmarking methodology used for calculating administrative claims-based quality measures, but we urge CMS to consider applying this approach to all quality measures. Expanding this methodology to all quality measures will encourage physicians to report more condition-specific measures and it will reduce the administrative burden physicians currently face when attempting to determine why they received a high or low MIPS quality score. Physicians would be scored by a singular methodology in MIPS, not multiple approaches depending on the measure type and data source. We do not believe that it is necessary to use a different approach to benchmark non-administrative claims-based measures. We support the AMA's recommendations to explore the use of prior year levels of data when benchmarking administrative claims measures; to assign the points to the median performance level from the benchmark period using 10 percent of the MIPS performance threshold, not 6.0 as it is today; use standard deviations from the median to determine points for all quality measures rather than the current decile-based approach; and establish the specific thresholds in regulation and only change them after soliciting formal comments.

Performance Threshold

We support maintaining the MIPS performance threshold at 75 points in CY 2026 and advocate for statutory changes that would freeze it at 60 points for at least three years.

[14] Parks Golen, L, Nicola, G, Duzak Jr., R, Rosenkrantz, A. *The Quality Measure Crunch:* How CMS Topped Out Scoring and Removal Policies Disproportionately Disadvantage Radiologists. JACR.2020 Jan.17(1). 110-117. https://doi.org/10.1016/j.jacr.2019.08.014

Conclusion

Thank you for the opportunity to comment on the CY 2026 MPFS proposed rule and issues concerning gastroenterology. **On behalf of the nation's gastroenterologists, our societies respectfully urge CMS to:**

- ***Collaborate with Congress to develop a long-term solution to the persistent challenges within the MPFS, most significantly, the continued absence of a meaningful payment update that reflects actual practice costs.***
- ***Reconsider the proposal to apply an efficiency adjustment to certain services and instead collaborate with the physician community on evidence-based approaches that preserve relativity while ensuring continued access to high-quality patient care.***
- ***Delay implementation of the efficiency adjustment proposal to work with the AMA, the medical specialties and other stakeholders to consider how the AMA 2024 Physician Practice Information PE/HR could be utilized instead of the 2007 data.***
- ***Not apply the proposed efficiency adjustment to new procedures 4X004, 91XX1, 91XX2.***
- ***Accept the RUC recommended wRVU of 13.50 and physician times for 4XX04.***
- ***Accept the RUC recommended wRVUs for CPT codes 91XX1 and 91XX2 without refinement.***
- ***Accept the RUC-recommended direct practice expense inputs for CPT codes 91XX1 and 91XX2 based upon the supporting information provided in this letter.***
- ***Explore ways to increase patient access to BGBTs for gastrointestinal conditions. like IBS, by removing coverage and financial barriers.***
- ***Establish payment for devices classified under 21 CFR 876.5960 as part of the existing Digital Mental Health Treatment (DMHT) code set (G0552, G0553, G0554) or by creating an additional device supply code as part of this code set for CY 2026***
- ***CMS to exclude the MFP from calculation of the ASP.***
- ***Confirm in the final rule that ASP data will continue to be reported by CMS as it has in the past.***
- ***Permanently adopt a definition of "direct supervision" that allows for "immediate availability" of the supervising provider via audiovisual real-time communication for certain services provided under Medicare's "incident to" policy.***
- ***Permanently allow teaching physicians to provide virtual supervision of residents when they are delivering a service using telecommunications technology for both remote and in-person services in all locations.***

Quality Payment Program

- ***Explore additional avenues to minimize work at the point of care such as capping the number of MVPs for multi-specialty groups.***
- ***Not implement the proposed "Core Element" reporting requirement.***
- ***Reconsider the approach to assign gastroenterologists to MVPs based on procedural billing codes and develop a system that more accurately mirrors the diverse and multifaceted nature of gastroenterology.***
- ***Halt progression toward mandatory MVP reporting, including mandatory subgroup reporting for multi-specialty groups reporting an MVP beginning in CY 2026.***
- ***Use its discretion and retain Measure 185 in the QPP.***

- ***Develop a system to track and map procedures, events or episodes, such as colonoscopies, that have already been counted in the episode-based measure to prevent them from inclusion and biasing the TPCC measure. We also request that the TPCC measure not be used if a gastroenterology cost measure can be applied.***
- ***CMS involve relevant specialty societies, measure developers, and technical expert panels (TEPs) prior to implementation of operational list updates and consider delaying implementation when modeling indicates a significant statistical shift in attribution or performance results.***
- ***Sunset the Improvement Activities performance category, when reforming the QPP.***
- ***Look beyond the alternative benchmarking methodology being applied to a subset of topped out measures to meaningfully address the flaws in the topped-out measure policy.***
- ***Maintain the MIPS performance threshold at 75 points in CY 2026 and advocate for statutory changes that would freeze it at 60 points for at least three years.***

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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