



September 6, 2022

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 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

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 2023 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1770-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

- Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers
- Physician Conversion Factor
- Valuation of Specific Codes for CY 2023: Endoscopic Bariatric Device Procedures (CPT codes 43X21 and 43X22)

- Services to be Removed from the Medicare Telehealth Services List After 151 Days Following the End of the PHE
- Split (shared E/M) Visits
- Indirect Practice Expense (PE)
- Request for Information: Medicare Potentially Underutilized Services
- Rebasing and Revising the Medicare Economic Index (MEI)

Quality Payment Program

- Quality Performance Category: Gastroenterology
 - Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma
 - Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV)
 - Age Appropriate Screening Colonoscopy
- Quality Performance Category: Expanding the definition of high priority measures to include health equity-related quality measures
- Quality Performance Category: Data Completeness Criteria
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- Quality Performance Category Health Equity Request for Information
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- MIPS Performance Threshold
- MVPs and APM Participant Reporting Request for Information
- MVP Development and Maintenance Processes

Medicare Physician Fee Schedule

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

Our societies thank CMS for proposing to expand the regulatory definition of “colorectal cancer screening tests” and waive cost sharing for a necessary follow-on screening colonoscopy after a Medicare covered noninvasive stool-based colorectal cancer (CRC) screening test returns a positive result and for permitting coverage of certain CRC screening tests beginning at age 45. We believe CMS’ proposal to align Medicare policy with requirements for commercial plans will reduce confusion among patients, close the remaining coverage loopholes that often result in surprise bills, and increase CRC screening rates. **We applaud CMS for recommending this expansion of CRC screening benefits.**

We ask CMS to consider changing the language in Section 410.37 to allow for the coverage of future non-invasive screening tests. Some non-stool-based CRC tests are commercially available now, and we anticipate additional noninvasive tests will be available in the future. These tests include, but are not limited to, blood-based tests and urine-based tests. The same principles of management of noninvasive stool-based CRC screening tests apply to any noninvasive screening program.¹ Making the change to strike “stool-based” as a requirement will mean that noninvasive tests recommended by United States

¹ Evaluating key characteristics of ideal colorectal cancer screening modalities: the microsimulation approach: [https://www.giejournal.org/article/S0016-5107\(21\)00134-6/pdf](https://www.giejournal.org/article/S0016-5107(21)00134-6/pdf)

Preventative Services Task Force (USPSTF) in the future and covered by Medicare would not require CMS to make additional changes to the regulation. ***Therefore, we recommend striking “stool-based” from the regulation as indicated:***

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.
* * * * *

(k) A complete colorectal cancer screening. Effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive ~~stool-based~~ colorectal cancer screening test returns a positive result. The frequency limitations described for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

We urge CMS to provide guidance to physicians for coding follow-on screening colonoscopy after a positive non-invasive screening test result. We do not believe it is necessary to create new codes or modifiers to report this procedure. We believe the follow-on screening colonoscopy should be coded and reported the same way as a screening colonoscopy. ***We urge CMS to issue guidance confirming that follow-on colonoscopy should be coded as a screening colonoscopy using the appropriate HCPCS G code (G0121 or G0105) and confirming that the PT modifier (colorectal cancer screening test; converted to diagnostic test or other procedure) is still needed for the appropriate CPT code (e.g., 45384, 45385, 45388) if the follow-on screening colonoscopy becomes diagnostic/therapeutic.***

We noted that in exercising its authority under section 1861(pp)(1)(D) of the Act to expand coverage of certain CRC screening tests to begin for individuals at age 45, CMS included barium enema tests (coverage described in § 410.37(h)) and blood-based biomarker tests (coverage described in NCD 210.3). We would like to call to CMS’ attention that barium enema is not a recommended CRC screening modality in guidance from the U.S. Preventative Services Task Force² or the U.S. Multi-Society Task Force on Colorectal Cancer.³ While it once was considered a CRC screening modality and has been included in guidelines in the past, barium enema is no longer included in any recent CRC guidelines and is rarely performed today as it is considered inadequate for the exclusion of CRC. ***For these reasons, we urge CMS to remove barium enema as a covered CRC screening test for all individuals.***

Physician Conversion Factor (CF)

Our societies are alarmed by the proposed reduction to the CY 2023 Medicare physician conversion factor (CF). CMS is proposing \$33.0775, representing a \$1.53 (4.42%) reduction from the CY 2022 PFS CF of \$34.6062. This payment cut, which impacts all services across the fee schedule, results from a statutory 0% update scheduled for the PFS in CY 2023, the statutorily required budget neutrality adjustment to account for changes in work relative value units (RVUs) and the expiration of the 3.0% funding patch which partially mitigated the scheduled 3.75% decrease in the 2022 CF resulting in a

² U.S. Preventive Services Task Force Recommendations on Colorectal Cancer Screening: <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/colorectal-cancer-screening>

³ U.S. Multi-Society Task Force on Colorectal Cancer Colorectal Cancer Screening Recommendations: https://journals.lww.com/ajg/Fulltext/2017/07000/Colorectal_Cancer_Screening_Recommendations_for_13.aspx

0.82% decrease compared to 2021. The change in work RVUs, which represents the remaining ~1.5% is driven largely, but not entirely, by updates to E/M services.

Since 2021 the physician CF has experienced negative updates and prior to that since 2017 and the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) the increases were largely flat or minimal. The physician CF has not kept up with inflation or other drivers increasing practice costs these past few years. These rising costs are in addition to the financial pressures gastroenterology practices are facing due to the COVID-19 pandemic. There is an underlying unfairness that the real increase in clinical labor costs for physician practices is not recognized through an update to the CF. We urge CMS and Congress provide a positive update to the Medicare conversion factor in 2023 and all future years.

We are dismayed about the proposed reduction of the proposed physician CF. In order for physicians to be able to provide high quality care and equitable patient access, we urge CMS to work with Congress to offset or avert these cuts.

In addition to the reduction in the CF, physicians are facing other payment cuts that can only be averted with Congressional action. These payment reductions include the reinstatement of Medicare sequestration on July 1, 2022, and statutory sequestration cuts required by Pay-As-You-Go (PAYGO) legislation, which were triggered by the significant additional spending in the American Rescue Plan enacted in March 2021 and are scheduled to be implemented on January 1, 2023, absent Congressional action. For gastroenterologists to maintain healthy practices and to provide patient access to high-quality and equitable care, it is imperative that CMS work with Congress to address these cuts to reimbursement in 2023.

Valuation of Specific Codes for CY 2023: Endoscopic Bariatric Device Procedures (CPT codes 43X21 and 43X22)

CMS proposed to reduce three practice expense (PE) inputs for codes 43X21 and 43X22 from the RUC recommendations. We believe CMS may have missed the detailed explanations our societies submitted to the RUC as part of the PE Summary of Recommendation (SOR) form. We have attached the form to our comment letter.

43X21

CMS proposed to reduce L037D (Complete pre-service diagnostic and referral forms) for code 43X21 from the RUC recommendation of 5 minutes to 3 minutes with the rationale, "Refined clinical labor time to conform with identical labor activity in other codes in the family."

In 2012, the RUC approved two standard pre-service packages for 000 and 010-day global codes for pre-service clinical activities for "Use of Clinical Staff" and "Extensive Use of Clinical Staff." The RUC agreed with our societies' recommendation that the "Extensive Use of Clinical Staff" package should be used for insertion of the balloon (43X21). Note that the 5 minutes for completing pre-service diagnostic and referral forms is the standard for codes requiring the "Extensive Use of Clinical Staff" pre-service package in the non-facility setting. Note that we did not apply the 7-minute standard in the "Extensive

Use of Clinical Staff” package for CA004 (provide pre-service education/obtain consent) because that activity is captured in CA011; otherwise, the recommendations match the “Extensive Use of Clinical Staff” pre-service clinical activities package.

Below is a table showing the current pre-service standards and the RUC recommendations for reference.

		Approved by PE Subcmte in Oct. 2012		GI/SAGES Recommendations		
		Non Facility	Non Facility	43235	43X21	43X22
Activity Code	Description of Pre-service Clinical Activities - 000 and 010	Use of clinical staff	Extensive use of clinical staff	EGD base code	Balloon insertion	Balloon removal
CA001	Complete pre-service diagnostic and referral forms	0	5	3	5	3
CA002	Coordinate pre-surgery services (including test results)	0	3	3	3	3
CA003	Schedule space and equipment in facility	0	0	0	0	0
CA004	Provide pre-service education/obtain consent	0	7	0	0	0
CA005	Complete pre-procedure phone calls and prescription	0	3	3	3	3
	Other clinical activity	0	0	0	0	0
	TOTAL	0	18	9	11	9

We urge CMS to accept the RUC recommendation and allow use of the “Extensive use of Clinical Staff” package for pre-service clinical activities for a total time of 5 minutes for CA001 (Complete pre-service diagnostic and referral forms) as supported by the rationale above.

CMS proposed to reduce L037D (Provide education/obtain consent) for code 43X21 from the RUC recommendation of 15 minutes to 10 minutes with the rational, “See preamble text.”

The RUC recommended additional minutes above the standard for CA011 (Provide education/obtain consent) due to the extent of patient instruction required. The following detailed account of the activities involved was included in the PE SOR submission to the RUC (attached). In addition to obtaining consent, staff instructs the patient about the six medications they will take after the procedure to address nausea, vomiting, and pain (i.e., narcotic pain medication, antispasmodic, Scopolamine Patch, Zofran, Phenergan, Ativan) and the schedule for taking the medications to prevent interactions as well as NARCAN and answers the patient’s questions about the medications. Staff reviews instructions for NARCAN with the patient and provides counseling for interaction of benzodiazepines and narcotics, which is required by most states. Staff also reviews with patient what to do and avoid doing during the first 24-hours, first 3 days and first week following the procedure (e.g., drink at least 8 cups of liquid per day. Take small sips. Wait a minute or two between sips. Slowly take more with each sip. Drink only 1/3 cup at a time. Sit upright for 3 to 4 hours after drinking). See p. 13-14 of “Orbera Patient Booklet” (https://www.orbera.com/resource/us_orbera_pdfs/pdfs/GRF-00345-00R08.pdf). Staff counsels the

patient on expectations for side effects (e.g., side effects to expect, timing of side effects, how long they should last, how to manage them, when to call the office and when to go to the emergency department). Staff also provides counseling on dietary recommendations. Please note that we have not included any minutes for education/consent activities in CA004 so there is no overlap or duplication. ***We urge CMS to accept the RUC recommendation of 15 minutes for CA011 as supported by the rationale above.***

43X22

CMS proposed to reduce L037D (Prepare, set-up and start IV, initial positioning and monitoring of patient) for code 43X22 from the RUC recommendation of 10 minutes to 2 minutes with the rationale, “Refined time to standard for this clinical labor task.”

The RUC recommended 8 minutes above the standard for CA016 (Prepare, set-up and start IV, initial positioning and monitoring of patient). Positioning the patient for balloon removal is identical to positioning for endoscopic retrograde cholangiopancreatography (ERCP) (43260 family) which has 10 minutes for positioning the patient. The patient is placed face up with their head resting on a pad positioner or pillow and their neck in a neutral position. The patient’s arms are positioned to maintain a neutral thumb-up or supinated position and may be tucked at their sides or abducted to less than 90 degrees on arm boards. Patient is intubated while supine and staff must then move the patient into left lateral position. No other procedure in the 43235 family is performed in this position, which is why extra time is required. The RUC recommended 10 minutes for CA016 because it is the standard for ERCP procedures which require the same patient positioning. ***We urge CMS to accept the RUC recommendation of 10 minutes for CA016 as supported by the rationale above.***

Services to be Removed from the Medicare Telehealth Services List After 151 Days Following the End of the PHE

We are disappointed CMS has proposed to remove telephone E/M codes 99441-99443 from the telehealth list 151 days following the expiration of the public health emergency (PHE). There is a growing body of evidence supporting the addition of telephone E/M (99441-99443) to the Medicare telehealth services list on a permanent basis, especially among the elderly Medicare beneficiaries and those living in rural areas. This policy creates inequities in care for these patient populations. In our comment letter on the 2022 MPFS proposed rule we provided several studies supporting the addition of telephone E/M codes 99441-99443 to the Category 1 list. Since then, many more studies have demonstrated that seniors, non-English speakers and Black patients are more reliant on telephone than video for care. Elimination of coverage for telephone E/M will only exacerbate disparities and structural biases.

The only difference between telehealth office visits and telephone E/M is the absence of real-time video. The physician time, intensity and level of medical decision making for telephone E/M and telehealth office visits are identical. Practice resource costs are identical, including staff time for the pre- and post-service tasks and equipment/software costs, since the EHR and encrypted methodologies are utilized. 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 equally well 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. *Therefore, we urge CMS to reconsider its proposal to remove 99441-99443 from the Medicare Telehealth Services List after 151 days following the end of the public health emergency (PHE).*

We recognize that expansions of telehealth will present challenges, including potential increases in utilization and spending and increased program integrity risks. However, CMS should continue its current coverage and payment policies for telephone visits and audio-visual telehealth services until the joint CPT/RUC Telemedicine Office Visits Workgroup determines accurate coding and valuation, as needed, for office visits performed via audio-visual and audio-only modalities. We and many other organizations are committed to assisting CMS as it works toward establishing policies that balance the value of ongoing access to medically necessary virtual care with CMS' financial stewardship and program integrity responsibilities.

Split (shared E/M) Visits

In the CY 2022 PFS final rule, CMS finalized its proposal regarding who should bill for split or shared visits when elements of the visit are performed by both a physician and a qualified healthcare professional in the same group practice in the facility setting where "incident to" billing is not available. In the CY 2022 PFS final rule, it was determined that whoever performs more than 50% of the total visit time should bill the split or shared visit. CMS agreed to revise the rule after providing another opportunity for public comment on this policy.

CMS is proposing to delay the split (or shared) visits policy finalized in the CY 2022 PFS for the definition of substantive portion, as more than half of the total time, for one year with a few exceptions. For CY 2023, as in CY 2022, the substantive portion of a visit may be met by any of the following elements:

- History
- Performing a physical exam
- Making a medical decision.
- Spending time (more than half of the total time spent by the practitioner who bills the visit)

We thank CMS for proposing this delay and urge CMS to allow physicians or QHPs to bill split or shared visits based on time or medical decision making. We support the inclusion of all four elements; History, performing a physical exam, making a medical decision, and spending time, when determining who should bill for the visit in order to best capture accurate contributions. We urge CMS to revise the split or shared visit policy 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. Billing solely based on time could disincentivize the collaboration between physicians and QHPs. For example, medical decision making, which impacts the management of patients care and outcome of the visit, typically requires less time than other less rigorous elements of the visit such as paperwork and visit 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.

Indirect Practice Expense (PE)

CMS is seeking comments from the public on how to better refine their practice expense methodology, including the collection of better data, the cadence of future updates and how to appropriately value direct practice expenses. 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 practice expense allocation and seeks a way to move towards a standardized and routine approach to valuation of indirect PE. CMS seeks comments on a survey methodology as well as alternatives.

The GI societies support more frequent updates to indirect practice expense 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 health care markets all suggest significant transformation in practice expenses. The survey currently used to determine indirect practice costs is extremely dated and significant administrative changes have occurred leading to additional costs.

We support the concept of an AMA led survey to refine practice expense methodology. Since 2006, there has been a significant amount of change that would not have been captured such as AI technology and cybersecurity. Improving methodology and capturing up to date data is essential for projecting meaningful and accurate PE relative values.

The collection of indirect practice expense 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. The GI 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. CMS should collaborate with the AMA on this new data collection effort to ensure consistency and reliability in physician payment.

Request for Information: Medicare Potentially Underutilized Services

We are pleased CMS is seeking comments on:

1. Ways to identify specific services and to recognize possible barriers to improved access to these kinds of high value, potentially underutilized services by Medicare beneficiaries,
2. How CMS might best mitigate some of these obstacles, including for example, through examining conditions of payment or payment rates for these services or by prioritizing beneficiary and provider education investments,
3. How to best define and identify high value, potentially underutilized health services, and
4. How to understand what existing services within current Medicare benefits may represent high value, potentially underutilized services, including cancer screenings.

We urge CMS to include CRC screening as an area of focus as it is a high-value, underutilized services. CRC is the second most diagnosed cancer and a leading cause of cancer death among cancers that affect both men and women in the United States. Only 69.4% of adults aged 50 to 75 years reported being up to date with CRC screening in 2020.⁴ There are significant disparities in CRC incidence and outcomes that exist for African Americans and people of color. Compared to whites, African Americans

⁴ U.S. Centers for Disease Control and Prevention: https://www.cdc.gov/pcd/issues/2022/22_0001.htm#:~:text=B%2C%20Percentage%20of%20US%20adults,2000%20US%20standard%20million%20population

have a 20% higher incidence of CRC, are more likely to develop CRC at younger ages, be diagnosed further along in their illness, and are more likely to die of their disease.⁵ We cannot hope to close the screening gap without addressing disparities in CRC screening.

The U.S. Centers for Disease Control and Prevention (CDC) estimates the average Medicare health care spending for patients with newly diagnosed CRC ranges from \$40,000 to \$80,000, depending on the stage and the total annual medical cost of CRC is \$14.1 billion.⁶ Significant programmatic cost savings can be achieved from increasing screening rates for CRC. Studies have identified the following barriers that must be addressed to improve uptake of, and adherence to, CRC screening^{7 8}

- Lack of awareness; their provider had not recommended it
- Financial challenges, such as lack of insurance or cost of testing
- Logistic challenges, such as transportation and time
- Low perceived susceptibility

Awareness of CRC screening guidelines are low, especially among non-Hispanic Black males, socioeconomically disadvantaged individuals, and those diagnosed at public healthcare facilities. Only 20% and 13% of patients knew colonoscopy and fecal test guidelines, respectively. Low awareness of CRC screening tests is a risk factor for symptomatic detection of colon cancer. Awareness and knowledge are predictors of colon cancer screening and initiation. Non-Hispanic Black males and socioeconomically disadvantaged patients and those diagnosed at public facilities may need extra attention and engagement with healthcare professionals to increase awareness. Health education can help identify target populations for enhanced education to increase knowledge and awareness of colon cancer screening. Medicare should investigate how to increase patient education and outreach, especially to vulnerable populations. The provider community is willing to partner with CMS to increase patient engagement and encourage shared decision-making strategies about colon cancer screening, a strategy with demonstrated potential to increase screening rates.⁹ However, it is important that CMS compensate providers appropriately for additional outreach not currently included in patient care. We urge CMS to work with our societies to address this barrier.

Financial challenges, including co-payments and deductibles, are barriers to screening and contribute to socioeconomic disparities. Cost sharing for CRC screening occurred in 77.9% of patients with Medicare coverage. These are significant barriers to screening, which contribute to racial and ethnic and

⁵ Racial disparities and early-onset colorectal cancer: A call to action: <https://www.health.harvard.edu/blog/racial-disparities-and-early-onset-colorectal-cancer-a-call-to-action-202103172411>

⁶ Cost-Effectiveness of Colorectal Cancer Interventions: <https://www.cdc.gov/chronicdisease/programs-impact/pop/colorectal-cancer.htm>

⁷ Patients' self-reported barriers to colon cancer screening in federally qualified health center settings: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6531912/>

⁸ Barriers to utilization of three colorectal cancer screening options – Data from a national survey: <https://www.sciencedirect.com/science/article/pii/S2211335521001984>

⁹ Race and gender differences in awareness of colorectal cancer screening tests and guidelines among recently diagnosed colon cancer patients in an urban setting: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7293559/>

socioeconomic inequities in CRC outcomes, requiring the need for policy changes.^{10 11 12}We are pleased coinsurance requirements are being eliminated for Medicare beneficiaries, but as the full removal of coinsurance requirement will not occur until 2030 it will continue to be a barrier for beneficiaries until then.

Logistical challenges are reported by 19% of patients and include not being able to find the time to do the preparation and completion of a colonoscopy as well as transportation issues to and from the colonoscopy, from not having transportation at all, to not being able to drive the distance to the procedure, and/or not having someone to go with them.¹³ CMS should investigate a non-emergency medical transportation program as a way to address inadequate logistical barriers to CRC screening. We also CMS to review pharmacy benefit managers' restricted coverage of bowel preparation kits, requiring less tolerable high-volume preparations. The ability to tolerate these preparations can be significant for Medicare beneficiaries.

Modeling and recent studies demonstrate that organized, equitable delivery of screening can not only improve adherence to screening and reduce CRC incidence and mortality, but also eliminate health disparities.^{14 15} CMS should investigate how patient navigators (PNs) could improve CRC screening in the Medicare program. Results suggest that PN activities may be instrumental in recruiting people into cancer screening and ensuring completed screening and follow-up.¹⁶ We thank CMS for investigating barriers to improved access to high value, potentially underutilized services, including colorectal cancer care, by Medicare beneficiaries. We look forward to working with CMS to improve access and remove barriers to care.

Rebasing and Revising the Medicare Economic Index (MEI)

We recognize that data currently used for the MEI is out-of-date and should be updated. The Proposed Rule lays out the case for needing to do so: the current MEI is based on 2006-based costs and the cost weights should reflect current market conditions. The 2017 weights for the proposed rebased and revised MEI are significantly different than the 2006-based current weights reflecting changes in the cost of providing physician services. The practice expense share of overall physician costs, for example, increased by 6.5 percentage points from 44.8% to 51.3%, while the share of physician work and malpractice declined. Gastroenterology faces a projected cut of 3% from the MEI changes as noted in Table 148.

¹⁰ ACG Clinical Guidelines: Colorectal Cancer Screening 2021:

https://journals.lww.com/ajg/Fulltext/2021/03000/ACG_Clinical_Guidelines_Colorectal_Cancer.14.aspx

¹¹ Reducing the Burden of Colorectal Cancer: AGA Position Statements:

[https://www.gastrojournal.org/article/S0016-5085\(22\)00500-5/fulltext](https://www.gastrojournal.org/article/S0016-5085(22)00500-5/fulltext)

¹² ASGE Policy Recommendations for the Biden-Harris Administration and the 117th Congress:

https://www.asge.org/docs/default-source/default-document-library/asge-policy-recommendations_v5_jan26.pdf

¹³ Patients' self-reported barriers to colon cancer screening in federally qualified health center settings:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6531912/>

¹⁴ U.S. Multi-Society Task Force on Colorectal Cancer Colorectal Cancer Screening Recommendations:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>

¹⁵ Association between Improved Colorectal Screening and Racial Disparities:

<https://www.nejm.org/doi/full/10.1056/NEJMc2112409>

¹⁶ Patient Navigation in a Colorectal Cancer Screening Program:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4618371/>

There have been many changes within the MPFS recently including 2020 E/M updates resulting in a budget neutrality adjustment of -10.2 % to the PFS conversion factor when implemented in 2021, even though the impact has been partially offset and delayed by legislation on a year-to-year basis. In 2021, the update of clinical wages also resulted in significant decreases to practice expense values, particularly for those codes with high supply or equipment costs; over 325 codes had declines of practice expense relative value units of 18% or more. Even with a four-year phase-in, many office-based procedures will see further reductions over the remaining three years of the four-year phase-in. These policy changes have occurred over a span where the PFS conversion factor has not kept pace with overall changes in price inflation. We also point out the annual physician fee schedule MEI update has consistently been less than inflation for every year going back to 2012. It is for these several reasons that the MEI be updated after CMS takes into consideration comments provided by stakeholders to its current proposal.

We support CMS' approach to delay implementation of these adjustments to the PE calculation until the public has commented on the data sources and methodology of the rebased and revised MEI. We believe a multi-year transition is appropriate given the large specialty specific impacts of implementing the proposed rebased and revised MEI fully in one-year. Such a transition would also be consistent with other significant payment changes in the PFS including how CMS updated prices of supply and equipment inputs and its current transition of clinical labor updates for use in its PE methodology.

Quality Payment Program

Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma

The ACG, AGA and ASGE support the addition of the measure submitted by the College of American Pathology (CAP) for Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma to the MIPS program. Testing for loss of mismatch repair (MMR) proteins and microsatellite instability (MSI) have crucial diagnostic, prognostic, and predictive implications. These are key steps to identifying patients at risk for Lynch Syndrome, the most common hereditary colorectal cancer (CRC) syndrome. While gastroenterologists and other clinicians order testing for loss of MMR proteins/MSI for individuals with CRC to screen for Lynch Syndrome, they depend on pathologists' interpretations of the results of these tests and recommendations for further testing to provide high-quality patient care. If the status of these test results is not indicated in each pathology report, important findings may be missed with implications for patients and their families, or unnecessary testing may be performed leading to inappropriate treatment and/or increased cost. This measure is applicable to numerous specialties (for example, gastroenterology, pathology, oncology, surgery) and fits the larger paradigm of cross-cutting measures, which are particularly relevant. It also represents a crucial step in the care process by promoting effective communication of critical information for the purpose of care coordination and efficient use of resources.

Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV)

The ACG, AGA and ASGE do not support the removal of QID 275 - Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status from the 2023 Merit-based Incentive Payment System (MIPS) program.

CMS' rationale for removing this measure is that "the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement."

QID 275 has been a quality measure in both the PQRS and MIPS programs for approximately 10 years and is the only measure specific to patients with Inflammatory Bowel Disease (IBD) remaining in

national reporting programs. Furthermore, despite a decade of use, CMS had not informed the measure steward about any benchmarking issues prior to recommending the removal of the measure from the 2023 MIPS program. As a result, the measure steward has not had an opportunity to address any concerns.

Before initiating biologic or small molecule therapy such as anti-TNF drugs for a patient with IBD, it is essential to screen the patient for HBV, as reactivation of HBV after such therapy can occur with significant risks for patient decompensation. Severe reactivation of the hepatitis B virus can occur during immunosuppression—especially if biological agents such as monoclonal antibodies, or a combination of immunomodulators (e.g. 6 mercaptopurine) and biological agents, are used. Early antiviral treatment is important because delaying treatment may reduce survival if the patient has acute fulminant hepatitis or reactivating hepatitis.¹⁷ Assessment of hepatitis B virus in immunosuppressed patients including those who are initiating IBD biologic therapies is critical to the safety of the patient, thus underscoring the need to retain QID 275 in MIPS .

Age Appropriate Screening Colonoscopy

The ACG, AGA and ASGE do not support the removal of QID 439 – Age Appropriate Screening Colonoscopy from the 2023 MIPS program.

In this proposed rule, CMS proposes to remove this measure from MIPS because the agency believes this measure has a very low adoption rate which does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement.

The goal of QID 439 is to eliminate inappropriate screening. This measure assesses eligible clinicians routinely performing screening colonoscopy, including those doing lower volumes, to determine if unnecessary screening of the elderly is being performed.

QID 439 was first introduced in public quality reporting for the 2016 performance year. Recognizing that there was opportunity for misinterpretation of the measure specifications as evidenced by benchmarking results of this high-priority, inverse measure, the measure owners and CMS agreed to modify the measure specifications redefining the target population to clarify the measure’s intent and ultimately to strengthen analysis and benchmarking of the measure. The modified measure specifications were introduced beginning with the 2021 performance year, the year for which CMS automatically applied its Extreme and Uncontrollable Circumstances exception to individually eligible clinicians. The GI Quality Improvement Consortium (GIQuIC), the largest clinical benchmarking registry for the specialty of gastroenterology with over 4,500 participants of which approximately 1,000 report annually to MIPS via the GIQuIC qualified clinical data registry (QCDR) reporting benefit, experienced nearly a 50% drop in QCDR reporters for the 2021 performance year compared to the 2020 performance year. Of those individual clinicians and groups reporting via the GIQuIC 2021 QCDR, 71% reported QID 439 despite the measure having an initial estimate of only 3 points due to its updated measure specifications, demonstrating the value of this clinical concept. CMS should allow QID 439 with its updated measure specifications to have at least two full performance years in MIPS, without extreme limitations to public quality reporting, to assess the adoption rate of the measure and its continuation in the program, especially given that the measure focuses on a vulnerable population.

¹⁷ Life threatening liver disease during treatment with monoclonal antibodies:
<https://pubmed.ncbi.nlm.nih.gov/19224957/>

QID 275 and 439 were recommended for inclusion in the 2022 Core Quality Measures Collaborative (CQMC) Gastroenterology Measures Set for 2023 implementation which involves CMS leadership and participation.

The CQMC was created in 2015 as a “broad-based coalition of healthcare leaders working to facilitate cross-payer measure alignment through the development of core sets of measures to assess the quality of healthcare in the United States” with the aims of:

Identifying high-value, high-impact, evidence-based measures that promote better patient outcomes, and provide useful information for improvement, decision-making and payment.

Aligning measures across public and private payers to achieve congruence in the measures being used for quality improvement, transparency, and payment purposes.

Reducing the burden of measurement by eliminating low-value metrics, redundancies, and inconsistencies in measure specifications and quality measure reporting requirements across payers. (www.qualityforum.org/cqmc/).

Since the initial development of the gastroenterology measures set, both measures 275 and 439 were determined by multiple stakeholders, including CMS, to be of high value such that they were recommended to be included in the 2022 gastroenterology measure set for 2023 implementation. The identification and selection process for the measure set includes multiple stakeholders, including CMS, who all voted in favor of retaining these measures in the gastroenterology measure set. The current CMS recommendation for removal of these measures from the MIPS program, despite having had ample opportunities to address concerns during the workgroup meetings and public comment periods, conflicts with previously agreed upon processes.

The ACG, AGA and ASGE do not support the removal of QID 425 - Photodocumentation of Cecal Intubation from the 2023 MIPS program.

CMS proposes to remove this measure from his measure MIPS because, according to CMS, “we believe this process measure represents performance outcomes that are clinically a standard of care and does not drive quality outcomes for patients.”

The goal of QID 425 is to establish a complete screening or surveillance examination based on photodocumentation of at least two landmarks of cecal intubation. This measure assesses eligible clinicians performing screening and surveillance colonoscopy to determine if examinations are truly complete so that appropriate follow-up intervals can be recommended. After high-quality screening and surveillance colonoscopy, patients with polyps are stratified based on their potential risk for advanced neoplasia and colorectal cancer. Understanding a colonoscopist’s rate of complete examination in turn helps to understand if the provider is recalling patients for surveillance colonoscopy too soon or later than recommended by the U.S. Multi-Society Task Force on Colorectal Cancer.

The GIQuIC registry has included this priority indicator of colonoscopy quality since its launch in 2010, as it is a core measure for any colonoscopy quality improvement program, and in its QCDR measure set since 2014, the first year of QCDR reporting. The measure became more widely available for reporting as QID 425 with the 2016 performance year. The measure specifications were updated beginning with the 2019 performance year to align with the now recognized best practice of photo documenting two cecal landmarks, rather than one, to establish a complete colonoscopy.

The impact of the public health emergency on providers’ ability to report for the 2020 and 2021 performance years cannot be understated. The GIQuIC QCDR experienced a 44% drop in QCDR

reporters for the 2020 performance year compared to the 2019 performance year and then a drop of 48% in QCDR reporters for the 2021 performance year compared to the 2020 performance year. CMS should allow QID 425 with its updated measure specifications to have at least two full performance years in MIPS, without disruption in public quality reporting as was experienced for the 2020 and 2021 performance years, to assess the performance of the measure and its continuation in the program. This is especially critical given that the measure provides insight into potential over- or under-utilization of screening and surveillance colonoscopy when considered in the context of a GI measure set.

Further, on review of data from the GIQuIC clinical benchmarking registry and QCDR, our societies believe that this measure continues to demonstrate that disparities in care remain; specifically, when we analyze the data by race, ethnicity, and age:

Patient Race/Ethnicity	Patient Age
<ul style="list-style-type: none"> • American Indian: 90.6% • Asian: 90.7% • Black: 87.8% • Hispanic: 89.8% • Pacific Islander: 81.1% • White: 89.4% • Other race: 89.4% 	<ul style="list-style-type: none"> • < 45: 90.7% • 45-49: 91.3% • 50-54: 91.0% • 55-59: 90.3% • 60-64: 90.0% • 65-69: 89.6% • 70-74: 89.0% • 75-79: 88.2% • 80-84: 86.8% • 85+: 82.3%

CMS should continue inclusion of this measure in public reporting until performance variability on QID 425 relative to race, ethnicity, and the senior population is reduced, and performance is consistently closer to 100%.

Quality Performance Category: Expanding the definition of high priority measures to include health equity-related quality measures

Our societies support broadening the definition of high priority measures to also include health equity-related quality measures but were unable to identify any guidance or further detail explaining how CMS will determine which measures would be considered to be health equity-related. We encourage CMS to provide additional information on what characteristics or other features of a quality measure would enable it to be classified with this label. In addition, we recommend that CMS consider classifying a measure as health equity-related if a measure developer is able to demonstrate that there are variations in performance across patient populations or other characteristics. For example, our societies submitted data from the GIQuIC registry demonstrating that there are disparities in care when results for QPP 425, Photodocumentation of Cecal Intubation, are analyzed by race, ethnicity, and age. If a measure developer is able to demonstrate that performance varies across race, ethnicity, insurance, or another factor, we believe that measures with this variability should not be removed from the program, rather they should be defined as high priority to promote physician activities to address inequities in care.

Quality Performance Category: Data Completeness Criteria

We appreciate the proposal to continue the data completeness criteria at 70% for the 2023 performance period and oppose the increase to 75% for the 2024 and 2025 MIPS performance period. 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.

Percentage requirements of 75% or higher do not account for physicians who provide care beyond a single site and wrongly assume that data is easily shared across sites. Some specialties, including gastroenterology, provide services across multiple locations using the same NPI/TIN; however, not all sites (including across sites of service) may: (1) participate in MIPS; or (2) use the same registry or EHR that the physician uses for MIPS reporting. 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.

Quality Performance Category: Screening for Social Drivers of Health (SDOH) Proposed Measure

Our societies support activities and measures that begin to address the social drivers that can also impact an individual's health outcomes; however, we do not believe that this measure is adequately specified and tested for implementation in MIPS at this time. There is significant risk that implementation of this measure will lead to increased screening in the absence of actions and a coordinated effort across the health care ecosystem including how to best address patients' needs and provide interventions is required first.

This measure as currently defined does not provide sufficient detail to enable physicians and others to understand whether this measure would be applicable to them. For example, is the denominator intended to capture only those patients with an established relationship with primary care or would other encounters or procedures also be counted? Are individuals who currently reside in a skilled nursing facility included or excluded? These questions must be answered and tested for reliability and validity prior to implementation in MIPS.

In addition, we do not believe that all of the social drivers included in this screening are aligned with data standards (e.g., only food insecurity has been finalized by the HL7 Gravity Project) nor is it clear that the use of any screening tool will generate results that are reliable and valid. The lack of standardization of the tool or factors assessed or testing for reliability and validity goes against fundamental measure development principles outlined by NQF and the CMS Blueprint. CMS would be better served to focus on the typical measure development process for this measure rather than the trial-and-error data submission and reporting approach currently proposed. **As a result, we do not support the inclusion of this measure in MIPS at this time.** In addition, this measure should not be considered for use in MVPs until best practices and education are widely available, the measure is adequately specified and tested, and there has been multiple years of reporting experience in MIPS.

Quality Performance Category Health Equity Request for Information

Our societies support the current list of self-reported patient characteristics on which CMS should focus data collection efforts. Each will provide useful information that is important for measuring disparate care and further enable physicians and others to improve the quality of life and outcomes of patients. While all of these items are important, we encourage CMS to be selective and used a staged approach on which factors should first be prioritized for data collection and reporting and within which settings of care. The current lack of data availability and standardization on the social determinants of health and other

disparities, limited implementation of the surveys needed to collect this information, and piecemeal implementation of sources and tools to address these needs must first be addressed.

Moving forward with any characteristic for which the data are not yet standardized and education on best practices for data collection are not available would just add burden at the point of care and creates the potential to exacerbate any inequities or harm the individual patient's and community's trust with individual physicians, hospitals, and other providers. How the collection and use of data could further disparities must always be considered. Prior to initiating a data collection effort or expanding the type of data collected, CMS must evaluate whether all of these characteristics should be widely collected across primary and specialty care and settings or if these efforts should be more narrowly focused for specific patient interactions.

We encourage CMS to ensure that there are the resources and tools to assess and address a patient's social needs and these other characteristics with accompanying financial and other incentives widely available at the point of care to accompany the collection of these data. While programs, toolkits, and other efforts to address these social needs are increasingly prevalent, their availability remains fragmented across markets, regions, and states. The burden of identifying, selecting, and implementing the most effective programs for a specific social determinant of health and within a community or region should not be left to the individual physician or practice and there must be financial or other incentives to assist in covering the initial and ongoing implementation costs. We also encourage pilot testing of innovative strategies to improve health equity and reduce disparities to demonstrate their effectiveness as well as to continue to expand the library of available resources and tools.

MIPS Final Score Methodology

Scoring administrative claims measures in the quality performance category using performance period benchmarks

While we support this change to timeframes that will likely better represent current clinical care, it does not address our ongoing concerns of using a representative sample of historic data. Many of the baseline periods will include data from 2019, 2020, and 2021 data—all of which are impacted by the COVID-19 pandemic. We urge CMS to avoid the use of these data for benchmarking purposes.

MIPS Performance Threshold

Our societies appreciate CMS' recognition of the challenges related to the ongoing public health emergency and recommend that CMS apply the automatic Extreme and Uncontrollable Circumstances Hardship Exception in the 2022 MIPS performance period. Physicians continue to prioritize providing care to their patients first and many report difficulty hiring and retaining administrative and clinical staff, particularly as they are competing against local hospitals for the same talent. We are very concerned that these challenges will jeopardize MIPS participation.

We also urge CMS to work with Congress to extend the \$500 million exceptional performance bonus, which expires in payment year 2024 under current law and reduce the performance threshold to avert more penalties. **We join the AMA in their opposition of the application of budget neutrality in Medicare physician payment, including MIPS payment adjustments and request to extend the bonus payment as there must be incentives to participate in a program that continues to be overly complex and burdensome. In addition, we also support the AMA's recommendation to lower the MIPS performance threshold to a degree that avoids penalizing one-third of MIPS eligible clinicians.** The COVID-19 pandemic continues to disrupt the healthcare system and while the program has only been existing since 2017, it was dramatically scaled back as a result of COVID-19 in three of its

first five years of implementation. Continuing to require physicians and practices to achieve a target higher than 75 points in 2023 is unreasonable and CMS must reconsider this requirement.

MVPs and APM Participant Reporting Request for Information

Traditional MIPS remains overly complex and confusing with minimal upside reward for the significant investment that physician practices make for successful participation. Our societies urge CMS to offer incentives to physicians to opt into a novel value-based track that holds them accountable based on aligned quality and cost measures within their control. While we support the idea of a MVP pathway, we continue to believe that the MVP pathway is a re-arrangement of the current MIPS requirements that lacks significant incentive for participation and adds another layer of complexity to the overall understanding of the program.

Recent studies underscore our concerns with the amount of time and investments that physicians currently make to participate in MIPS. It costs \$12,800 per physician per year to comply with the MIPS requirements, and on average, physicians spent more than 53 hours per year on MIPS-related tasks. These 53 hours are equivalent to a full week of patient visits. Regrettably, there is no evidence that this reverse Robin Hood effect improves outcomes for patients and common sense dictates otherwise. In fact, these findings position MIPS directly counter to the Administration’s goals to improve health equity.

CMS should immediately remedy these problems by redesigning MIPS through MVPs that are geared toward improving patient outcomes around an episode, condition, or other public health priority and we support the seven recommendations put forward by the AMA. Our societies also remain ready to assist CMS in the creation of a well-constructed and well-defined colorectal cancer prevention MVP.

MVP Development and Maintenance Processes

While the proposed addition of a 30-day comment period for new MVPs would allow for broader stakeholder input, it would not solve the current issue that any changes made to an MVP prior to its inclusion in a proposed rule remain a “black box” to specialty societies and implementers (e.g., registries) and we are extremely troubled by CMS stating that interested parties would not be notified in advance of rulemaking. CMS also does not define what criteria would be used to determine when an MVP is “ready” for feedback. The addition of a public facing webinar to review potential changes to existing MVPs and receive feedback is also inadequate as it does not provide sufficient opportunities for relevant specialty societies to have a meaningful and productive dialogue on the impact that MVP modifications may have.

While CMS’s proposals attempt to increase transparency, CMS must also consider the potential impact that new or modified MVPs will have on those groups responsible for their implementation. The MVP development and maintenance processes must provide sufficient time for registries, electronic health record system vendors, and others to integrate the new MVPs or changes to existing MVPs well before the start of the performance year. We support the AMA’s recommendation for CMS to model these processes off of the electronic clinical quality measure (eCQM) annual timeline (<https://ecqi.healthit.gov/ecqm-annual-timeline>) with new MVPs or potential changes to existing ones posted for public comment in the first quarter of the calendar year followed by collaboration and input by relevant specialty societies in the second quarter, and posting of the new/updated MVP prior to rulemaking to ensure that broad input is received. This process would also provide a balance by giving registries, vendors, and others the advance notice needed.

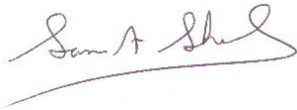
Conclusion

Thank you for the opportunity to comment on the CY 2023 PFS proposed rule and issues concerning gastroenterology. Our societies:

- Applaud CMS for recommending an expansion of CRC screening benefits and urge CMS to issue guidance confirming that follow-on colonoscopy should be coded as a screening colonoscopy.
- Urge CMS to work with Congress to offset or avert forthcoming Medicare reimbursement cuts.
- Revise practice PE inputs for endoscopic bariatric device procedure codes 43X21 and 43X22.
- Urge CMS to reconsider its proposal to remove 99441-99443 from the Medicare Telehealth Services List after 151 days following the end of the PHE.
- Thank CMS for proposing this delay and urge CMS to allow physicians or QHPs to bill split or shared visits based on time or medical decision making.
- Support more frequent updates to indirect practice expense data to reflect current costs associated with running a practice and the concept of an AMA led survey to refine practice expense methodology.
- Urge CMS to include CRC screening as an area of focus as it is a high-value, underutilized services.
- Support CMS' approach to delay implementation of these adjustments to the PE calculation until the public has commented on the data sources and methodology of the rebased and revised MEI
- Support the addition of the measure submitted by the College of American Pathology (CAP) for Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status in Colorectal Carcinoma, Endometrial, Gastroesophageal, or Small Bowel Carcinoma to the MIPS program.
- Maintain the following MIPS quality measures: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV), Age Appropriate Screening Colonoscopy, and Photodocumentation of Cecal Intubation.
- Provide additional information on broadening the definition of high-priority measures to also include health equity-related quality.
- Avoid the use of 2019, 2020, and 2021 data for benchmarking purposes
- Avoid the application of budget neutrality in Medicare physician payment
- Lower the MIPS performance threshold to a degree that avoids penalizing one-third of MIPS eligible clinicians.
- Revise the MVP construct and lower reporting burdens among providers.

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; or Lakitia Mayo, ASGE, at 630-570-5641 or lmayo@asge.org.

Sincerely

A handwritten signature in black ink that reads "Samir A. Shah". The signature is fluid and cursive, with a long horizontal stroke underneath.

Samir A. Shah, MD, FACP
President, American College of Gastroenterology

A handwritten signature in blue ink that reads "John M. Carethers". The signature is cursive and somewhat stylized.

John M. Carethers, MD, AGAF
President, American Gastroenterological Association

A handwritten signature in black ink that reads "Bret T. Petersen". The signature is cursive and clearly legible.

Bret T. Petersen, MD, MASGE
President, American Society for Gastrointestinal Endoscopy