American Society for Gastrointestinal Endoscopy

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October 31, 2022

The Honorable Ami Bera, M.D.
U.S. House of Representatives

The Honorable Larry Bucshon, M.D.
U.S. House of Representatives

The Honorable Kim Schrier, M.D.
U.S. House of Representatives

The Honorable Michael C. Burgess, M.D.
U.S. House of Representatives

The Honorable Earl Blumenauer
U.S. House of Representatives

The Honorable Brad R. Wenstrup, D.P.M.
U.S. House of Representatives

The Honorable Bradley Scott Schneider
U.S. House of Representatives

The Honorable Mariannette Miller-Meeks, M.D.
U.S. House of Representatives

Delivered by email to macra.rfi@mail.house.gov

Dear Members of Congress:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to respond to your request for feedback on actions Congress could take to stabilize the Medicare physician payment system, including reforming the current payment structure so it supports a system that provides greater value to patients and to physicians.

The increasing cost to physician practices to provide care without adequate inflationary updates and the new threat of annual cuts to the Medicare physician payment conversion factor due to the restraints of budget neutrality point to the need to re-evaluate the physician payment system, and, specifically, the Medicare Access and CHIP Reauthorization Act (MACRA). The COVID-19 pandemic also uncovered weaknesses in our nation's health care infrastructure and payment systems that have led to significant health care consolidation.

On behalf of its members and the patients they serve, ASGE is grateful for your outreach to health care providers, advocacy organizations and others for feedback on the current state of MACRA and associated payment mechanisms and ideas for reform. ASGE is pleased to provide its perspective on the following topics:

- Medicare Physician Payment
- Barriers to Timely Care for Medicare Beneficiaries
- Medicare's Appropriate Use Criteria Program
- Medicare's Quality Payment Program

MEDICARE PHYSICIAN PAYMENT

Inflationary Updates and Payment Adequacy

When MACRA was passed, it replaced the sustainable growth rate (SGR) formula and ended roughly 12 years of repeated congressional intervention to prevent Medicare physician payment cuts that were triggered by the SGR when overall physician costs exceeded target expenditures that were pegged to growth in the national economy.

In its place, MACRA was intended to create payment stability and provide incentives to physicians for performing efficiently while delivering high-quality care. MACRA statutorily set modest Medicare physician payment updates, starting at 0.5 in 2015 through 2019, and 0 percent for 2020 through 2025. For 2026 and beyond, it is 0.75 percent for eligible alternative payment model (APM) participants and 0.25 percent for all others.

Over a 12-year period, during which the SGR was in effect, annual payment increases to physicians averaged about 0.3 percent, while the cost of running a medical practice increased about 3 percent annually.[1] The fact is that physicians are still paying for nearly two decades of insufficient payment updates. Taking inflation in practice costs into account, Medicare physician payment plunged 20 percent from 2001 to 2021. Minimum wages have, appropriately, gone up nationally; however, practice reimbursement has not changed in a similar fashion.

As recognized by the Medicare's trustees in their June 2022 report, the physician payment system put in place by MACRA "avoided the significant short-range physician payment issues" resulting from the SGR, yet raises long-range concerns that will "almost certainly" need to be addressed by future legislation.[2] As noted by Medicare's trustees, the updates set by MACRA "do not vary based on underlying economic conditions, nor are they expected to keep pace with the average rate of physician cost increases."

A fundamental and critical step Congress can take to create payment stability is to provide, beginning in 2023, a positive annual physician payment update that reflects inflation in practice costs.

After the COVID-19 pandemic began, more physicians left independent medical practices for employment with hospitals/health systems and corporate entities, or they left the workforce entirely exacerbating concerns about a mounting physician shortage. A just-released study estimates that 333,942 health care providers dropped out of the workforce in 2021, of which 117,000 were physicians.[3] The COVID-19 pandemic didn't cause this shift; rather, it was a tipping point for physicians looking to escape declining reimbursements, the inability to compete with hospitals in tight labor markets and increasing regulatory burden.

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[1] Parke DW 2nd. The SGR Fix: Was It? Mo Med. 2015 Nov-Dec;112(6):408-9. PMID: 26821437; PMCID: PMC6168105.

[2] 2022 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds; June 2, 2022. https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf

[3] Physicians left their jobs by the hundreds of thousands in 2021: report. Modern Healthcare. Oct. 20, 2022. https://www.modernhealthcare.com/physicians/physicians-left-their-jobs-droves-2021-report?utm_source=modern-healthcare-daily-dose-thursday&utm_medium=email&utm_campaign=20221020&utm_content=article1-readmore

According to data from Avalere gathered in a study sponsored by the Physicians Advocacy Institute, almost three quarters of U.S. physicians now work for hospitals, health systems or corporate entities, up from 69 percent a year ago. Avalere found that 108,700 physicians became employees of larger health organizations or other corporate entities over a three-year period between Jan. 1, 2019, and Jan. 1, 2022, and, of that total, 83,000, or 76 percent, made the switch after the COVID-19 pandemic began.[4]

It is indisputable that consolidation — vertical, horizontal, and cross-market — results in increased costs to the health care system which outweigh any suggestion that consolidation can lead to better care coordination and efficiency. Vertical consolidation, which can lead to care shifting from a lower to a higher acuity setting, has been met with calls for site-neutral Medicare payment policies that are often focused on driving rates to levels that are unsustainable and that contributed to physician practices selling out to hospitals/health systems in the first place. It is time Congress dig to the roots of consolidation and the increasing number of physicians who are choosing to forego independent practice for employment — payment inadequacy and instability and regulatory burden.

ASGE has endorsed the American Medical Association (AMA) principles for reform[5] as a starting point for discussion about fundamental restructuring of the physician payment system. In addition to providing a payment update that reflects inflation in practice costs, Congress must also replace or revise budget neutrality requirements to allow for appropriate changes in spending growth. The zero-sum structure of the Medicare physician fee schedule means the Centers for Medicare and Medicaid Services (CMS) can't improve payment in any area of the fee schedule without cutting it somewhere else.

Because it will take time to secure a massive, badly needed overhaul of the Medicare physician payment system, immediate action is needed to stop harmful cuts that will take effect on Jan. 1, 2023 and to ensure future payment stability. ASGE urges Congress to take action before the end of this year to:

- stop the scheduled 4.42 percent budget neutrality cut to 2023 Medicare physician fee schedule payments;
- end the statutory annual freeze and provide a Medicare Economic Index update for 2023; and
- waive the 4 percent PAYGO sequester triggered by passage of the *American Rescue Plan Act*.

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[4] COVID-19's Impact On Acquisitions of Physician Practices and Physician Employment 2019-2021; Physicians Advocacy Institute, April 2022. http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/PAI-Research/PAI%20Avalere%20Physician%20Employment%20Trends%20Study%202019-21%20Final.pdf?ver=ksWkgjKXB_yZfImFdXlvGg%3d%3d

[5] Characteristics of a Rational Medicare Payment System. American Medical Association. https://www.ama-assn.org/system/files/characteristics-rational-medicare-payment-principles-signatories.pdf

Medicare Part B Drugs

Securing payment predictability and adequacy also extends to payment for office-administered Part B drugs. Gastroenterologists treat disorders of the bowel for which biologics, oftentimes administered in the physician's office and reimbursed under Part B, are the primary treatment. Therefore, any changes to the way in which Part B drugs are acquired and reimbursed could have a significant effect on gastroenterologists and their patients.

The *Inflation Reduction Act of 2022* empowers Medicare to negotiate directly for the price of prescription drugs, but it also puts physician practices in a financially vulnerable position because they may not be able to purchase medications at the government negotiated rate, or "maximum fair price" (MFP). If the MFP is the basis for reimbursement for Part B drugs, but physician practices cannot acquire the drug at MFP or their "supply" was negotiated at a higher price point, the physician will refer the patient out of the office-based infusion suite to the hospital where it costs the Medicare program and the patient more. To ensure that physician practices can continue to afford to administer Part B drugs, Congress should exempt Part B drugs for the current 2 percent sequestration that was triggered by the *Budget Control Act*.

BARRIERS TO TIMELY CARE FOR MEDICARE BENEFICIARIES

There are a number of contributors to physician burnout, but prior authorization is one of the biggest causes. Medicare Advantage (MA) and other private insurance plans routinely subject complex drugs, biologics, treatments, diagnostic tests and procedures to cumbersome authorization processes that lead to substantial treatment and diagnosis delays. Gastroenterologists are not given rules or indications of how these authorizations will be adjudicated. When it comes to therapeutics, physicians must frequently prove a patient failed other therapies, including sometimes one or more drugs in the same category, before the requested therapy will be approved. Prior authorization and step therapy protocols unnecessarily delay patient care and shift costs onto providers who are uncompensated for the administrative time and staff required for authorization and appeals.

Denials of prior authorization requests are raising concerns about beneficiary access to medically necessary care. A report from the Office of the Inspector General found, upon examination of a random sample of prior authorization denials by MA plans, 13 percent met Medicare coverage rules and likely would have been approved for these beneficiaries under original Medicare.[6] Prior authorization and step-therapy requirements are one-sided with no disincentive for plans to deny or delay care. It is time that MA plans be held to some level accountability when medically necessary appropriate treatment is withheld or delayed.

With nearly half the Medicare eligible population enrolled in a MA plan, legislation is urgently needed to reduce the burden of prior authorization on physician practices, as well as to improve patient outcomes by preventing delays in care and minimizing the number of patients who forego treatment altogether when it is denied or subjected to a lengthy appeal.

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[6] Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. U.S. Department of Health and Human Services, Office of Inspector General. April 2022. https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

ASGE endorses the *Improving Seniors' Timely Access to Care Act* (S. 3018 / H.R. 3173) as a way to increase transparency and streamline prior authorization in the MA program and protect timely access to care for Medicare patients and calls upon Congress to pass the legislation this year. ASGE also endorses the *Getting Over Lengthy Delays in Care as Required by Doctors* (GOLD CARD) Act of 2022 as a complement to S. 3018/H.R. 3173. The *GOLD CARD Act* creates a more rationale approach to prior authorization used by MA plans by exempting physicians from prior authorization when at least 90 percent of prior authorization requests for a particular item or service are approved.

MEDICARE'S APPROPRIATE USE CRITERIA PROGRAM

The *Protecting Access to Medicare Act* (PAMA) of 2014 established a program promoting the use of appropriate use criteria (AUC) for advanced imaging services. If ever implemented, CMS has estimated 579,687 ordering professionals will be subject to this program, crossing almost every medical specialty, including gastroenterology, and primary care. This past July, CMS announced on its website that the payment penalty phase of the program is indefinitely delayed.[7] CMS has repeatedly recognized the complexity of the program and its lack of authority to modify or mitigate the statutory requirements.

In the CY2022 Medicare physician fee schedule final rule, CMS noted the "challenging nature" of the program because the furnishing professional is subject to an immediate penalty based on the ordering professional's actions (or lack thereof), whose behavior the furnishing professional is unable to control.[8]

The opportunity exists for Congress to utilize Medicare's Quality Payment Program (QPP) as a platform for encouraging the consultation of AUC. In the eight years since enactment of PAMA, opportunities have been lost to advance clinically appropriate ordering of AUC through physician education and by leveraging other Medicare quality improvement programs and innovative payment models.

The FY2022 House-passed Labor-Health and Human Services-Education spending bill requests a report from CMS to Congress on implementation of the AUC program, including "challenges and successes." ASGE looks forward to CMS' report and asks Congress to repeal the complex and administratively burdensome stand-alone AUC program and instead consider existing quality improvement programs and innovative payment models to facilitate appropriate use of advanced diagnostic imaging.

MEDICARE'S QUALITY PAYMENT PROGRAM

A goal of MACRA was to improve care for Medicare patients by shifting the payment system from volume to value. MACRA set up the Merit-based Incentive Payment System (MIPS) as a pathway to alternative payment models (APMs). The law lowered payment updates over time for MIPS participants to incentivize their move to APMs. For most specialties, including gastroenterology, MIPS is a path to nowhere because of a lack of specialty APMs. As a result,

[7] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program

[8] Medicare Program: CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc. Nov. 18, 2021. https://www.regulations.gov/document/CMS_FRDOC_0001-3212

physician practices are investing in MIPS participation to avoid payment penalties, but participation requires significant practice resources with little return on those investments amidst questions about whether MIPS even accurately captures quality or is incentivizing improvements in care delivery. Truthfully, these changes have not resulted in better care for patients.

A recent published study on the costs for physician practices to participate in MIPS found physicians, clinical staff, and administrative staff together spent 201.7 hours annually on MIPS-related activities at a per-physician, per-year cost of $12,811.[9] According to a survey conducted by the Medical Group Management Association, 90 percent of physician practice respondents said positive payment adjustments did not cover the costs of time and resources spent preparing for and reporting under MIPS.[10] And, a disproportionate burden of MIPS participation falls on small practices. In its CY2023 Medicare physician fee schedule proposed rule regulatory impact analysis, CMS estimated that among the clinicians who would not engage with MIPS, nearly 80 percent are in small practices (16,614 out of 20,810 clinicians), and those from solo small practices who do engage are more likely to receive a negative payment adjustment.[11]

MIPS Value Pathways

Recently, CMS has begun a programmatic shift from MIPS to MIPS Value Pathways (MVPs). The MVP concept is a CMS iteration of the "Accountable Clinician Episodes" (ACE) concept developed and put forth to CMS by the AMA and other medical societies, including the ASGE. The intent behind the ACE option was to award MIPS credit to clinicians who engage in performance activities that satisfy the requirements of multiple MIPS performance categories ("multi-category credit"). For example, if a clinician reported quality measures electronically via a Qualified Clinical Data Registry (QCDR) that interfaces with their EHR, the clinician would receive full credit for the Promoting Interoperability category. The ACE concept was also envisioned as a long-run, performance-based model or as a stepping-stone for clinicians between participation in separate, unrelated MIPS measures and participation in an APM or Advanced APM.

MVPs, as currently designed, mirror many of the flaws in MIPS. If CMS moves ahead with MVPs as currently structured, it will be impossible to convince physicians that MVPs are anything more than a rebranding of MIPS with little-to-no benefit to physician practices or their patients.

The CMS-designed MVPs framework groups measures in a specific clinical area into bundles, and while ASGE supports this general concept, CMS still requires physicians to report in each performance category and maintains the status quo with Promoting Interoperability and Improvement Activities categories. Giving CMS the authority to award credit for activities that cut across performance categories would make MVPs a more desirable MIPS pathway.

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

[10] MGMA Annual Regulatory Burden Report - 2022. https://www.mgma.com/practice-resources/government-programs/mgma-annual-regulatory-burden-report-2022

[11] Centers for Medicare & Medicaid Services CMS–1770–P

MACRA should be revised at Sec. 101 (c)(2)(A) to eliminate the statutory requirement of four separate MIPS categories and a composite performance score.

Participation Incentives

In addition to making MIPS participation more cohesive and, ideally, more meaningful, ASGE asks Congress to re-examine the incentive structure for participation.

MACRA's $500 million exceptional performance bonus expires with payment year 2024 (performance year 2022). Because of the budget neutral redistributive nature of MIPS, there is very little return on investment, and therefore incentive, for MIPS participation. Budget neutrality is the fundamental flaw of the entire MIPS program – it needs winners and losers. A physician or physician practice can fully engage and still lose. Ideally, financial incentives for participation in MIPS would help practices build the infrastructure to move to APMs when they become available. ASGE asks Congress to allocate additional funds to extend the exceptional performance bonus beyond the 2024 payment year.

Congress should also consider policies to bridge the gap between MIPS and APMs, including by permitting alternative payment methodologies that support creative MVP design. For example, an MVP could permit payment policy changes, such as being able to bill for chronic care management for patients with the condition even if they do not have two or more chronic conditions, or paying for collaborative care to help support team-based approaches to managing patient care.

Future MVPs should have a better participation incentive structure. Physicians who participate in MVPs should also be held harmless from downside risk for at least the first two years of participation while they gain familiarity with a model that is more consistent with an APM and while CMS collects and shares data about whether MVPs are meeting their goal to improve quality and reduce unnecessary costs for the Medicare program and beneficiaries.

MIPS Performance Threshold

CMS should lower the MIPS performance threshold to a degree that avoids penalizing one-third of MIPS eligible clinicians.[12] Sec. 101(c)(6)(D) of the statute requires CMS to set the performance threshold at the mean or median of the composite performance scores for all MIPS eligible professionals, and CMS proposes to maintain it at 75 points for the 2023 performance period.

As opposed to a pre-set formula, CMS is in a better position to determine each year whether physicians are ready to move to an increased performance threshold given the agency has access to all the previous year's performance data. CMS may also decide to establish different thresholds for small and large practices.

[12] Centers for Medicare & Medicaid Services CMS–1770–P

MVPs and Quality Measure Development

To undertake a fundamental reassessment of MIPs/MVPs, clear expectations must be set on how CMS engages with medical societies and their data repositories and QCDRs. Nonprofit societies are committed to supporting their members in delivering effective, efficient, safe, timely, equitable, and patient-centered care. ASGE and other medical societies are partners in transforming the health care system to benefit patients, serving as not-for-profit vendors providing quality data reporting services via a qualified clinical data registry. The ASGE, in partnership with the American College of Gastroenterology (ACG), operate a registry (GIQuIC). Participants in that registry may report MIPS quality measures via its QCDR as a free benefit, but at significant expense to the registry.

The increasing burdens on QCDRs as reporting vendors divert limited resources nonprofits have to meaningfully expand their work. As an example, the GIQuIC QCDR measure set has changed every year since 2014 with its clinical experts and staff scrambling to justify to CMS the measures well-established as fundamental to quality in the delivery of colonoscopy and upper endoscopy services. A chief example is the sunsetting of QPP343 Screening Colonoscopy Adenoma Detection Rate (ADR) beginning with the 2020 performance year and its conversion to a more narrowly available measure for reporting via QCDRs. ADR has been recognized nationally and internationally as the most important outcome measure in gastroenterology since 2006. The three major GI societies (ASGE, ACG and the American Gastroenterological Association) collaborated on the development and ongoing maintenance of the QPP343 measure. The societies, along with volumes of evidence, should be trusted when they speak to this or any measure's importance; yet, CMS continues to direct measure specifications changes to ADR as reportable through a QCDR. It was a single measure with multi strata measurement identified as GIQIC22 for the 2020 and 2021 performance years. For the 2022 and 2023 performance years CMS agreed with the societies to recognize the strata as individual measures (GIQIC 24 and 25) but has also indicated the measure should be modified for the 2024 performance year, returning to a single measure with multi strata measurement. Constant revision to the only outcome measure in gastroenterology available for public reporting is unnecessarily burdensome on clinicians and their teams, as well as to QCDRs. Year-over-year performance assessment is only confused by constant revisions to the measure specifications. Further, it presents challenges in meeting the strict CMS measure testing requirements.

Measure development and maintenance is a costly endeavor, as CMS is well aware through its multi-year funding of the Physicians Consortium on Performance Improvement and, more recently, the episode-based cost measures. When ASGE must divert resources to unproductive activities, such as fighting for well-established, specialty-specific quality measures and recalibrating plans and activities to fulfill the ever-changing requirements of QCDR vendors, it slows its ability to expand to new clinical topics, such as inflammatory bowel disease and obesity/bariatric endoscopy. At some point, the benefit of self-nominating to be a QCDR may cease, with the larger goals for why clinical registries were established to pursue far outweighing the pursuit of QCDR status.

CMS should be required to work with medical societies on the development of quality measures, as well as MVPs, in the same manner it did for the development of the episode-based cost

measures, which our members found to be a worthwhile collaboration. Further benefits of requiring this collaboration would be assurance of alignment between quality and cost measures and an agreed roadmap for future measure development for the specialty as opposed to CMS unilaterally modifying the time-consuming, thoughtful, and evidence-driven work that has been conducted by the societies independently.

Congress should also set expectations for CMS partnership with medical societies for determining how measures are scored and benchmarked. The Agency provides little flexibility in its view of what a quality measure is for the purpose of MIPS and its scoring methodology. The program should be built based on the proper implementation of the measures and quality measure sets. The ADR quality measure is a useful example to illuminate this point as well. ADR is a measure that has been widely adopted in gastroenterology quality improvement programs as valid, reliable, feasible and universally understood within the specialty. Performance targets of ≥ 30 percent in a male population of screening colonoscopies and ≥ 20 percent in a female population of screening colonoscopies are appropriate for ADR for quality improvement programs and rates in the range of 75-100 percent would be inconsistent with the evidence on which these measures were established. ADR was sunset because the Agency lacked an appreciation for its utility, as it did not fit its expectations of a standard measure. This despite Corley, et al. having demonstrated that each 1 percent increase in ADR was associated with a 3 percent decrease in the risk of interval colorectal cancer and a 5 percent decrease in the risk of fatal interval cancers.[13] ADR would not be the only example of a measure challenged to fit in public quality reporting programs. CMS needs to support innovation and a program built on meaningful measures, some of which may require, for example, two years of data collection to render meaningful performance feedback.

Physician Access to Timely, Actionable Data

Physicians should be held accountable for the costs that are within their control and should have access to their claims data analysis to identify and reduce avoidable costs. Though Congress has taken action to give physicians access to their claims data, to this day physicians do not receive timely, actionable feedback on their resource use and attributed costs in Medicare. What is a lower-cost physician doing differently from a high-cost physician? For example, is it that they are better at care coordination? If we do not know the answer, we cannot achieve the goal of reducing avoidable costs and overuse. Physicians and specialty societies need access to their claims data analysis to identify variations in spending that are not accounted for by differences in patient needs and to eliminate unnecessary costs.

Furthermore, CMS needs to provide more detailed, specialty-specific and site-of-service specific breakdowns of MIPS performance data in the Experience Report or accompanying Appendix. The Public Use File (PUF) is not usable for national medical specialty societies that are evaluating opportunities for improvements in quality, cost, Promoting Interoperability, and Improvement Activities, nor in developing MVPs. The 2020 QPP PUF provides some site-of-

[13] Adenoma Detection Rate and Risk of Colorectal Cancer and Death. Corley DA, et al. N Engl J Med 2014; 370:1298-1306 DOI: 10.1056/NEJMoa1309086

service information, such as whether the physician bills in an Ambulatory Surgery Center or is considered hospital-based, but it is limited.

CONCLUSION

It took nearly a dozen years for Congress to take action to repeal the flawed SGR in an attempt to replace it with a more rationale payment system. Over time, underlying problems with the physician payment system and challenges with the QPP, and MIPS in particular, have revealed themselves much to the frustration of physicians. Many of the problems and challenges outlined above cannot be addressed administratively and, therefore, require congressional action. We appreciate that reaching consensus on solutions to these problems will not be an easy task. However, there is consensus on actions that Congress can take immediately that will better allow MACRA to fulfill its purpose of increasing value in the U.S. health care system.

Should you have questions or require additional information, please contact Camille Bonta, ASGE policy consultant, at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

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