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Submitted via email to catherine.hayes@mail.house.gov and amy.zhou@mail.house.gov

January 16, 2026

United States House of Representatives
Washington, DC 20515

Dear Members of the GOP Doctors Caucus and Congressional Doctors Caucus:

The American College of Gastroenterology (ACG) appreciates the opportunity to comment on the request for input from the GOP Doctors Caucus and Congressional Doctors Caucus on the modernization of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA). We applaud you for taking steps to address the financial and regulatory burdens independent medical providers experience in an effort to improve access to patient care and improve the viability of the independent practice of medicine.

ACG is a physician organization representing gastroenterologists and other gastrointestinal (GI) specialists. Founded in 1932 and representing over 20,000 GI clinicians, ACG's mission is to enhance the ability of our members to provide world-class care to patients with digestive disorders and advance the profession through excellence and innovation based upon the pillars of patient care, education, scientific investigation, advocacy, and practice management.

We urge Congress to consider reforms to the Quality Payment Program (QPP) for Medicare services, prior authorization, and the federal Anti-Kickback Statute (AKS) safe harbor on ambulatory surgical centers (ASCs), described in more detail below. In addition, we urge Congress to leverage artificial intelligence (AI) to develop a reimbursement pathway that would ensure continued innovation. Such revisions would reduce unnecessary regulatory burden and increase access to care for patients.

If MIPs were to be reformed or replaced entirely, what would a new physician-led quality program look like? How can we ensure a new program reduces administrative burdens and is applicable to all types of clinicians in all settings, while focusing meaningfully on real outcomes?

ACG welcomes the opportunity to support Congressional efforts to replace or reform MIPS.

In general, the existing MIPS program significantly underestimates the administrative burden required to participate, while insufficiently supporting small and rural practices. As a result, ACG believes that MIPS, as currently constructed, is exacerbating healthcare consolidation trends and accelerating the decline of physician-led practices. In addition to quality program changes, ACG urges Congress to consider legislative

reforms to the Medicare physician fee schedule, the anti-kickback statute safe harbor, and the Stark law – which, taken together, would benefit physicians in all settings.

QPP

The Regulatory Burden Estimates Associated with the QPP are Significantly Underestimated

As part of the annual Medicare Physician Fee Schedule (PFS) rules, the Centers for Medicare & Medicaid Services (CMS) provides cost and burden estimates for participating in the QPP. These annual administrative and financial burdens associated with participation in the QPP's Merit-based Incentive Payment System (MIPS) are grossly underestimated. Since these estimates are inaccurate, the Administration may be implementing policies without a clear picture of the true impact borne by GI practices across the country, especially among small and rural healthcare providers. Small, rural, and independent physician practices need relief from burdensome regulations that may originate from inaccurate estimates. We therefore urge Congress to direct the Administration to review these estimates and make revisions to consider accurately administrative and financial burdens that physicians experience as a result of participating in MIPS.

For example, in the *Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments* final rule (CY 2025 Medicare PFS final rule), CMS estimated roughly 38 hours of work per clinician was required for MIPS participation, at a cost of nearly $7,800.[1],[2] However, the available research suggests those figures are woefully low. One qualitative study revealed that physician practices across the U.S. spent more than 200 hours per physician on MIPS-related activities, at an average cost of $12,811 to participate in MIPS in 2019.[3] The wide variance in estimates may underscore why larger practices with ample resources and staff are more likely to receive bonuses versus small and rural providers.

To participate in MIPS, eligible providers must meet the health IT thresholds in the "Promoting Interoperability" category. CMS' latest estimate is that the cost per clinician for this category is $287.[4] However, the start-up costs of investing in health IT are significant, and even the maintenance fees are much greater than CMS' estimates. Moreover, the cost of electronic health record (EHR) software can vary widely depending on the factors discussed above, but for small practices with one to five providers, EHR software typically costs between $100 and $600 *per provider per month* for cloud-based systems. In

[1] 89 Fed. Reg. 97710 (Dec. 2024); 90 Fed. Reg. 4926 (Nov. 2025).
[2] In the CY 2026 Medicare PFS final rule, CMS did not outline any updates to its burden estimates due to the burden estimates not being affected by the policy provisions in the final rule. The applicable burden changes were submitted to OMB for approval under control number 0938-1314 (CMS-10621) and can be found here: https://omb.report/icr/202509-0938-009/doc/162402700.
[3] 89 Fed. Reg. 97710 (Dec. 2024); JAMA Health Forum, *Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System* (May 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2779947.
[4] 89 Fed. Reg. 97710 (Dec. 2024).

addition, on-premises solutions may require upfront costs ranging from $15,000 to $70,000, plus ongoing maintenance fees.[5]

ACG urges Congress to task CMS with reevaluating these burden estimates. They appear woefully inaccurate, risk unintended adverse consequences for our members, and are a contributing factor in the retreat of the independent practice of medicine.

Assistance for Small Practices and Rural Practices Clearly Are Not Working

Medicare providers are exempted from MIPS if they fall below the low-volume threshold, which includes:

- Billing more than $90,000 for Medicare Part B covered professional services;
- Treating more than 200 Medicare Part B patients; and
- Providing more than 200 professional services to Medicare Part B patients.

CMS also provides "special status" designations for rural and small practice providers. While this is well-intended, data and experience reports show that participating in the MIPS program continues to strain small and rural practices.[6] In the *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* final rule (CY 2026 Medicare PFS final rule), CMS estimates that in 2026, nearly 50 percent of solo practices and over 20 percent of practices with 2-15 providers will receive a payment cut for failing to successfully participate in the QPP.[7] The estimates are roughly the same for rural practices as well.[8] The typical participating clinician cannot rely on MIPS to help offset PFS cuts because the average adjustment for 2025 was just 0.59 percent and the median was a meager 0.90 percent. This is lower than previous years, given the removal of the "exceptional" performance adjustment in 2024. Meanwhile, the Medicare Economic Index (MEI) was 3.5 percent in 2025 (there is a 2-year lag with the reporting year and payment year).[9]

In the meantime, the number of independent physicians in U.S. rural areas fell 43 percent from 21,956 in January 2019 to 12,467 in January 2024.[10] Similarly, the number of medical practices in rural areas declined 11 percent from 30,000 in January 2019 to 26,700 in January 2024.[11]

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[5] DocVilla, *How Much Does EHR Software Cost? Discover Affordable EHR Pricing with DocVilla*, https://www.docvilla.com/2024/08/16/how-much-does-ehr-software-cost/#:~:text=EHR%20Pricing:%20What%20to%20Expect,exceed%20$500%2C000%20in%20upfront%20costs.

[6] *See* Quality Payment Program, *Participation and Performance Data*, https://qpp.cms.gov/resources/performance-data.

[7] 90 Fed. Reg. 4926 (Nov. 2025).

[8] *Id.*

[9] *See* https://qpp.cms.gov/resources/performance-data.

[10] Becker's Clinical Leadership, *Rural US loses 43% of independent physicians: 5 things to know*, https://www.beckershospitalreview.com/quality/hospital-physician-relationships/rural-us-loses-43-of-independent-physicians-5-things-to-know/.

[11] Becker's Clinical Leadership, *The state of the physician workforce in 2025*, https://www.beckershospitalreview.com/quality/hospital-physician-relationships/the-state-of-the-physician-workforce-in-2025/.

We urge Congress to consider legislative solutions such as requiring CMS to stratify and calculate QPP bonuses by practice size and geographic area. The QPP experience reports clearly show that small, rural providers are at a competitive disadvantage to larger practices when trying to earn QPP bonuses. In addition, we urge Congress to consider additional legislative solutions such as expanding the low-volume thresholds and "special status" designations for small and rural providers to ease the burdens and challenges of participating in the QPP, especially in high-cost performance categories such as "Promoting Interoperability."

We urge Congress to also consider additional exemptions for smaller practices, allowing them to become more efficient and competitive. The federal government exempts small businesses with fewer than 50 employees from various employment and labor laws. ACG encourages Congress to follow the same precedent and exempt small and independent practices from certain QPP reporting requirement.

Congressional Relief is Needed Now

Practice management burdens are increasing as Medicare reimbursement fails to keep up with the cost of providing care to beneficiaries. As required by statute, beginning in 2026, there will be two separate conversion factors (CFs): one for items and services furnished by a qualifying alternative payment model (APM) participant ("qualifying APM CF") and another for other items and services ("nonqualifying APM CF"), equal to the respective CF for the previous year (or, for calendar year (CY) 2026, equal to the single CF for CY 2025) multiplied by the update established in statute for such respective CF for such year. The qualifying APM CF is $33.57 and the nonqualifying APM CF is $33.40. While this is a slight increase, it does not account for the increasing costs of providing care to Medicare beneficiaries.[12]

CMS also finalized changes to how physician practice expenses (PE) are calculated, despite warnings from ACG and other specialty societies about the impact of this proposal on high-quality GI care. The change results in significant payment increases for office-based services and significant cuts for services performed in the ASC and hospital-outpatient setting. This reallocation of PE resources does not accurately reflect the cost of providing services in the facility environment. These new policies fail to distinguish between physicians who are hospital employed versus those who are private/independent practice but *typically perform procedures in a facility setting (ASC or HOPD), as is the standard of care in many states across the U.S*. New "efficiency adjustment" also cuts relative value units (RVUs) for GI procedures, cutting 2.5 percent to work RVUs for endoscopy and other non-time-based codes. These "efficiency" cuts would be recalculated and applied every three years with no floor for how much a service could be devalued. Collectively, these policies eclipsed the increased 2026 CF that Congress passed in July 2025.[13]

Adjusted for inflation, Medicare physician payment has declined 33 percent since 2001, while hospitals and other facilities receive annual positive updates.[14] This comes at a time of rising practice costs and challenges for GI practices, exacerbated by healthcare workforce shortages, as well as increasing medical

[12] 90 Fed. Reg. 49266 (Nov. 2025).
[13] *Id.*
[14] *See* https://www.ama-assn.org/system/files/2025-medicare-updates-inflation-chart.pdf.

device and equipment prices. The Medicare PFS is the only Medicare payment system not tied to an inflationary update. Moreover, GI practices, like all Medicare providers, are subject to a congressionally mandated two percent sequestration cut. We therefore urge Congress to take steps to pass temporary or long-term reimbursement reforms to support physicians caring for Medicare patients.

Moreover, healthcare workforce shortages are increasing, impacting access to care and slowing patient care.[15] The Association of American Medical Colleges projects a shortage of more than 85,000 physicians by 2036.[16] A study by the National Rural Health Association found there are about 30 physician specialists for every 100,000 residents in rural areas, compared to 263 specialists per 100,000 people in urban communities.[17]

We therefore urge Congress to consider legislative solutions that would exempt from the QPP altogether those providers in areas deemed a "health professional shortage area." This will help retain and recruit more healthcare providers in areas of the country reeling from workforce shortages.

Anti-Kickback Statute Safe Harbor Reform

The federal AKS prohibits intentionally rewarding or incentivizing referrals of health care business reimbursed under federal health care programs, although there are a number of statutory and regulatory safe harbors that Congress has enacted and the Office of Inspector General (OIG) has promulgated to protect certain arrangements that it views as constituting a low risk of fraud and abuse. Among these statutory and regulatory safe harbors, the safe harbor for ASCs protects referral source investors in ASCs and contains four sub-safe harbors for ASCs with various ownership structures.[18] Each of these sub-safe harbors contains mostly identical elements. The hospital/physician ASC sub-safe harbor specifically embeds the other sub-safe harbors, requiring physician investors to meet the elements of another safe harbor (which are substantially identical) to comply with the hospital/physician ASC safe harbor.[19]

This confusing and unnecessary regulatory structure could and should be consolidated into a single safe harbor for payments of returns on investment interests from ASCs to investors that are also referral sources. There is no need for multiple ASC safe harbors, and a single safe harbor with many of the same elements would significantly streamline the regulatory regime, simplify and drive compliance with this often misunderstood safe harbor, and still appropriately protect the federal government from fraud and abuse. We therefore urge Congress to direct the OIG to make these necessary changes.

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[15] *See* Mercer, F*uture of the U.S. Healthcare Industry: Labor Market Projections by 2028*, https://www.mercer.com/assets/us/en_us/shared-assets/local/attachments/pdf-us-2024-future-of-us-healthcare-industry-labor-market-projections-by-2028.pdf; *see also* Becker Hospital Review, *10 headwinds for health systems in 2025*, https://www.beckershospitalreview.com/hospital-management-administration/10-headwinds-for-health-systems-in-2025/.

[16] AAMC, New AAMC Report Shows Continuing Projected Physician Shortage, https://www.aamc.org/news/press-releases/new-aamc-report-shows-continuing-projected-physician-shortage.

[17] *See* NRHA, *About Rural Health Care*, https://www.ruralhealth.us/about-us/about-rural-health-care.

[18] 42 C.F.R. § 1001.952(r).

[19] 42 C.F.R. § 1001.952(r)(4).

Congress should also direct the OIG to take steps to eliminate the requirement prohibiting non-physician investors from "providing items or services to the [ASC] entity or any of its investors."[20] We believe that this is inconsistent with the ownership structure of many ASCs that participate in Medicare, many of which are owned or partially owned by a manager of the ASC or a person or entity that otherwise provides goods or services to the entity. We are not aware of any active or meaningful enforcement of this provision (in the ASC safe harbor or the small investment safe harbor at § 1001.952(a)(2)), and the focus is typically on investors that bring or send referrals to the ASC, rather than sources of goods or services. This provision should be eliminated.

Additionally, Congress should direct the OIG to codify certain protections and positions that the OIG has taken in advisory opinions and other guidance related to ASC ownership. Specifically, OIG Advisory Opinion No. 21-02 reviewed a scenario where not all physician investors in an ASC met the safe harbor requirement that at least one-third of their medical practice income was derived from the performance of ASC-qualified procedures (the "Practice Income Test").[21] However, the OIG issued a favorable advisory opinion because the physician investors used the ASC on a regular basis as part of their medical practices (i.e., as an extension of their practice), and the cross-referrals to other physicians to perform ASC procedures were minimal (less than one percent). Congress should direct the OIG to replace the Practice Income Test with a requirement that any physician investor regularly use the investment ASC as an extension of their practice and rarely cross refer patients to other physicians for procedures in the investment ASC (e.g., less than five percent of the ASC's procedures are not personally performed by the referring physician). This will guarantee that (1) physician investors do not profit from and are not incentivized to make cross-referrals, and (2) safeguards are in place against the fraud and abuse risks of which the OIG is concerned.

The multi-specialty ASC sub-safe harbor also has another one-third requirement and only protects payments to investor physicians who conduct at least one-third of their surgical procedures in the investment ASC.[22] This element is difficult to track and does not further mitigate fraud and abuse concerns that cannot be mitigated through the requirement described in the previous paragraph. As such, this requirement should also be eliminated.

Further, in OIG Advisory Opinion No. 23-07, the OIG approved paying physician employees of a physician practice that owned and operated an ASC directly based on the facility fees that the ASC received for referrals made by those physician employees.[23] The OIG found that this arrangement was protected by the employee safe harbor at § 1001.952(i), and did not mention the ASC safe harbor. However, the ASC safe harbor could be revised to clarify that employees of the ASC, or an entity under common control and ownership of an ASC, may be protected by the employee safe harbor. This should also be extended to ASCs and practices that are managed by the same management services organization, if they operate as the same economic enterprise with consolidated tax reporting.[24] These advisory opinions (and other federal guidance) demonstrate that the IRS and the federal government describe that there may be separation of legal ownership to meet state law restrictions on ownership of certain entities, while also

[20] *Id.*
[21] *See* https://oig.hhs.gov/documents/advisory-opinions/781/AO-21-02.pdf.
[22] 42 C.F.R. § 1001.952(r)(3).
[23] *See* https://oig.hhs.gov/documents/advisory-opinions/1132/AO-23-07.pdf.
[24] *See* IRS Private Letter Ruling 202049002 (Dec. 4, 2020), *available at* https://www.irs.gov/pub/irs-wd/202049002.pdf; IRS Private Letter Ruling 201451009 (Dec. 19, 2014), *available at* https://www.irs.gov/pub/irs-wd/201451009.pdf.

acknowledging that these separate legal entities can often constitute a single economic enterprise and should be treated as such.

Finally, Congress should act to direct the OIG to remove the requirement that non-physician investors cannot be in a position to make or influence referrals directly or indirectly to the ASC.[25] This element is directly at odds with the requirement that physicians/providers actively use the ASC as an extension of their practice to meet the one-third tests.

Stark Law and other AKS Reforms

ACG also encourages Congress to direct CMS to reassess its final rule entitled, *Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations*.[26] The final rule was designed to reduce the burdens and challenges that smaller practices face when navigating through the Stark and AKS requirements. However, these laws are complex and highly technical, with severe penalties for violations—even unintentional ones. Small practices often lack in-house legal or compliance teams.

We urge Congress to consider additional Stark and AKS reforms or exemptions for smaller practices, allowing them to become more efficient and competitive. For example, we urge Congress to consider freeing up the ability for referral arrangements, partnerships with laboratories, infusion centers, and other services. In addition, the federal government exempts small businesses with under 50 employees from various employment and labor laws. ACG encourages Congress to consider utilizing the same precedent to exempt small and independent practices from Stark and AKS requirements.

Finally, we believe that a reevaluation of the Stark Law is warranted, especially because it was enacted in 1989 and no significant modifications have been made since then, despite significant changes over the years to the practice of medicine and to our health care system as a whole. This reevaluation should explore whether such a law is still needed and examine its adverse impacts on independent and private practice.

Other

Finally, similar to how physicians are liable for medical malpractice, insurers should be accountable for the negative implications resulting from delays in care caused by prior authorization and denials of services. UM tools without the backing of clinical data result in insurers usurping the physician/patient relationship. Physicians and patients must be the key decision-makers when it comes to determining the appropriate treatment plan.

[25] 42 C.F.R. § 1001.952(r).
[26] 85 Fed. Reg. 77492 (Dec. 2, 2020).

What legislative reforms are most needed to ensure future CMMI models deliver real improvements in cost and quality, while also ensuring successful scaling of innovations?

CMMI and Prior Authorization

Prior authorization can be extremely burdensome for providers and lead to care delays and serious negative outcomes for patients that would otherwise be avoidable. ACG believes any utilization management (UM) tool without the backing of clinical data—including prior authorization—allows insurance companies to practice medicine without a license. This interferes with the patient-physician relationship. The impact that prior authorization requests have on delays in care and serious adverse events for GI patients is well documented.

Specifically, more than 70 percent of Inflammatory Bowel Disease (IBD) patients face insurance barriers to accessing their necessary first-line medications (most commonly prior authorization), and prior authorization was directly associated with poor clinical outcomes.[27] In addition, according to another ACG study, 97 percent of the 373 gastroenterologists surveyed said prior authorization worsened patient care in some fashion, and 83 percent reported a prior authorization-related delay contributed to hospitalization.[28] More than 90 percent of ACG members reported a high burden to comply with the requests, and nearly 70 percent said they urge their patients to help get medications and procedures approved by their insurance company. In an average week, ACG members reported zero peer-to-peer reviews with another gastroenterologist. Ninety-three percent of physicians in a February 2025 American Medical Association (AMA) survey reported care delays due directly to the prior authorization process. Also, 23 percent said prior authorization led directly to a hospitalization.[29] We must eliminate or meaningfully restrict prior authorization to preserve patient care and prevent avoidable adverse events.

We urge Congress to address the duplicative quality reporting requirements that are especially burdensome for providers. We therefore request that Congress consider requiring CMS to implement a Center for Medicare and Medicaid Innovation (CMMI) model that would allow all Medicare providers to participate in the Medicare Advantage Quality Reporting Program instead of the QPP. There is no reason why physician practices need to devote resources to participating in *two separate Medicare quality programs* for fee-for-service (FFS) and Medicare Advantage (MA). Congress should align and combine these two programs to ease practice management challenges and unnecessary burdens.

Ensuring Successful Scaling of Innovation and Artificial Intelligence (AI)

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[27] *The American Journal of Gastroenterology. Insurer-Mandated Medication Utilization Barriers are Associated With Decreased Insurance Satisfaction and Adverse Clinical Outcomes: An Inflammatory Bowel Disease Partners Survey* (Oct. 2024), https://journals.lww.com/ajg/abstract/2024/10000/insurer_mandated_medication_utilization_barriers.26.aspx

[28] *Prior Authorizations Delay Therapy, Impact Decision-making, and Lead to Adverse Events in Inflammatory Bowel Disease: 2022 Provider Survey*, https://www.cghjournal.org/action/showPdf?pii=S1542-3565%2823%2900506-2.

[29] *2024 AMA prior authorization physician survey*, https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

Further, given the large role that AI continues to play in clinical care, we urge Congress to consider the role that AI can play in new physician-led quality programs. Specifically, ACG believes that the adoption of AI across the healthcare continuum should include the development of a reimbursement pathway to ensure continued innovation.

Reimbursement Pathway

AI is used to develop technology to help diagnose and treat patients. While not an exhaustive list of AI-enabled medical technology, the U.S. Food and Drug Administration maintains an AI/Machine Learning (ML)-Enabled Medical Device List of all AI/ML-enabled medical devices authorized for marketing in the United States. The list contains 1,016 entries for medical devices used across many specialties. For gastroenterology, AI-enabled technology is used for image recognition analysis, clinical data analysis, and practice management.

Physician services are described by CPT codes that are reported on claims for reimbursement. The annual CPT book, published by the CPT Editorial Panel of the American Medical Association (AMA), has developed a helpful framework to categorize AI technology in a medical context. As described in the figure below, CPT categorizes AI technology as assistive, augmentative, and autonomous. A reimbursement pathway must be developed for all three types of AI-enabled technology.

Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
Primary objective	Detects clinically relevant data	Analyzes and/or quantifies data to yield clinically meaningful output	Interprets data and independently generates clinically meaningful conclusions
Provides independent diagnosis and/or management decision	No	No	Yes
Analyzes data	No	Yes	Yes
Requires physician or other QHP interpretation and report	Yes	Yes	No
Examples in CPT code set	Algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (0764T, 0765T)	Noninvasive estimate of coronary fractional flow reserve (FFR) (75580)	Retinal imaging (92229)

Source: CPT 2025 Professional Edition, Appendix S, American Medical Association.

The healthcare community's current challenge is that there is no methodology to capture the costs of AI-enabled technology that may enhance or improve medical treatment. There is a lag between the development of AI-enabled technology and the establishment of reimbursement pathways to capture its costs. A lack of a clear reimbursement pathway will discourage innovation and reduce developers' interest, resulting in patients who will not be able to benefit from these advances. While there will not be a one-size-fits-all reimbursement solution for AI technology, reimbursement is key to ensuring the continued innovation of AI-enabled technology and improving patient access.

Current AI-enabled technology has demonstrated how it can transform the clinician's and patient's experience. It also has the potential to save the system money. Without a pathway for reimbursement,

we fear innovation will be stifled, patients will lose the benefits that AI can provide, and any future expectations of cost savings to the system will not be achieved. ACG recommends that the current reimbursement landscape be considered in developing a new physician-led quality program, and prioritization is given to establishing reimbursement pathways for AI-enabled technology.

Conclusion

Thank you for your consideration of these comments. We look forward to working with you to reduce regulatory burden to ensure increased access to care for patients and ensure a more healthy and viable business regulatory environment for private practice medicine. Please contact Brad Conway, VP Public Policy, Coverage & Reimbursement, at 301.263.9000 or bconway@gi.org to discuss further.