American College of Osteopathic Internists • Stay True to Why You Pursued Medicine

September 9, 2024

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 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

Dear Administrator Brooks-LaSure,

The American College of Osteopathic Internists (ACOI), representing the nation's osteopathic internists, medical subspecialists, fellows, residents, and students, welcomes the opportunity to provide comment on the CY 2025 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1807-P) as published in the *Federal Register* on July 30, 2024.

The challenges that confront the Medicare physician payment system threaten beneficiary access to care. In their May 2024 report[1], Medicare's Trustees noted that current-law negative payment updates for physician services will be below the rate of inflation in all future years and, consequently, patient access to Medicare-participating physicians is expected to become a "significant" issue. A primary concern among ACOI members is the continuation of the statutorily set update of zero through 2025, and, starting in 2026, updates of just 0.75 for qualified physicians in advanced alternative payment models (A-APMs), and 0.25 for all other physicians. These updates are inadequate, and, as noted by Medicare's Trustees in 2023, "do not vary based on underlying economic conditions, nor are they expected to keep pace with the average rate of physician cost increases."[2]

[1] 2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds https://www.cms.gov/oact/tr/2024
[2] 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds https://www.cms.gov/oact/tr/2023

Payment inadequacy is driving physicians to become employees of hospitals or corporate entities.[3] According to the data from Avalere gathered in a study sponsored by the Physicians Advocacy Institute, 6 out of 10 (58.5%) physician practices are now owned by hospitals, health systems, and other corporate entities. This dramatic shift from independent physician practice to employment is punctuated by the staggering statistic that more than three quarters (77.6%) of U.S. physicians now work for hospitals, health systems, or corporate entities.[4]

With Medicare reimbursement that has not kept pace with inflation, payment cuts on the horizon and regulatory and administrative burdens, the trends in practice consolidation and acquisition ar e not shocking and come at a cost to the Medicare system and to patients.

A fundamental restructuring of the Medicare physician payment system is needed. ACOI is urging Congress to pass legislation this year providing physicians with an annual inflation-based update tied to the full Medicare Economic Index (MEI).

Additionally, we ask CMS to refrain from policy changes in the future that could trigger budget neutrality while Congress considers reforms, including increasing the budget neutrality threshold from $20 million to $53 million, capping the year-to-year variance in the conversion factor at 2.5 percent, and instituting a two-year look-back period for CMS to correct utilization misestimates prospectively.

The ACOI offers comment on the following topic areas contained within this rule:

- Enhanced Care Management
- Request for Information: Advanced Primary Care Hybrid Payment
- Payment for Medicare Telehealth Services
- Payment for Caregiver Training Services
- Office/Outpatient (O/O) Evaluation and Management (E/M) Visit Complexity Add-on Implementation
- Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment and Management Services
- Revised Payment Policies for Hepatitis B Vaccine Administration
- Merit-based Incentive Payment System (MIPS)

Enhanced Care Management

Advanced Primary Care Management (APCM) Services

[3] Physician Employment Trends, Physicians Advocacy Institute; April 2024 https://www.physiciansadvocacyinstitute.org/PAI-Research/PAI-Avalere-Study-on-Physician-Employment-Practice-Ownership-Trends-2019-2023
[4] Ibid.

CMS proposes to incorporate some payment and service delivery elements from CMS Innovation Center models, including Comprehensive Primary Care Plus and Primary Care First (PCF), into three new APCM services, which could be furnished per calendar month, following the initial qualifying visit for new patients and obtaining patient consent.

APCM services would include elements of existing care management codes, including chronic care management (CCM), transitional care management (TCM), and principal care management (PCM), as well as communication technology-based services (CTSB), including virtual check-in services.

Unlike existing care management codes, CMS is proposing that the code descriptors for APCM services would not be time-based. In addition, unlike the current coding to describe certain CTSB services, CMS is proposing that APCM services would not include time frame restrictions, which CMS has heard are administratively burdensome. For example, virtual check-in services cannot be billed when there is a related evaluation and management (E/M) service within the previous seven days.

CMS proposes that APCM services could not be billed by the same practitioner or another practitioner within the same practice for the same patient concurrent with these other services: CCM, PCM, TCM, inter-professional consultation, remote evaluation of patient videos/images, virtual check-ins, and e-visits.

To bill for APCM services, CMS is requiring the following service elements and practice-level capabilities: 24/7 access to care and care continuity; comprehensive care management; patient-centered comprehensive care plan; management of care transitions; practitioner- home- and community-based-organization coordination; enhanced communication opportunities; patient population-level management; and performance measurement. CMS does not propose that all elements included in the code descriptors for APCM services must be furnished during any given calendar month for which the service is billed, but billing physicians must have the ability to furnish every service element.

ACOI acknowledges the new APCM codes and payment are intended to reflect the "effectiveness" and "growing adoption" of the advanced primary care approach to care, and APCM codes could be a way to simplify billing and documentation requirements for those using an advanced primary care model. However, given substantial infrastructure requirements to bill the proposed APCM codes, coding complexity, and low-to-modest payment rates, we anticipate uptake of new APCM activities would be limited to practices already participating in alternative payment models.

Uptake will also be constrained by a fee-for-service system within which most primary care physicians are in employed practice arrangements.

An issue brief published by The Commonwealth Fund in July 2024 examined why more primary care practitioners are not participating in value-based models.[5] Among the reasons were financial but out of the hands of the primary care practitioners. According to the issue brief:

> "Many VBP model participants are part of large health systems that include hospitals and specialty care. Without changing incentives for specialty and hospital-based services, health systems have little reason to meaningfully invest in disease prevention and maintenance by changing primary care delivery. That's because primary care cognitive services are poorly compensated compared to more procedurally oriented specialty services. In fact, PCPs and experts noted that many health systems see VBP models as an avenue to increase referrals to their more lucrative specialty and hospital facility services rather than improve primary care delivery."

The paper concluded that creating future value-based payment models could demand commitments from health systems to ensure that model resources go toward their intended purposes. **ACOI concurs with the American Medical Association that CMS should review the RUC's recommendations for a patient-centered medical home and consider its framework for tiering payment based on capabilities of the practice, ranging from entry-level to comprehensive, which may enable more primary care physician practices, including independent physician practices, to qualify to report APCM services.**

On the topic of APCM levels, CMS proposes that Level 1 would have an approximate national payment rate of $10.00. CMS is basing the APCM levels on the number of chronic conditions a Medicare beneficiary has, as well as whether the patient is a Qualified Medicare Beneficiary. We want to point out that a patient with one chronic condition, depending on the chronic condition, could require as many, if not more, APCM services that a beneficiary with two chronic conditions; yet, the payment for Level 1 is proposed at $40 less than the approximate payment rate for Level 2, which is proposed at $50.

In summary, ACOI supports the concept of payment for complexity of care and proper management of the patient and health care team. However, providers, health systems, and patients are unlikely to embrace added complexity to the Medicare physician payment system. Efforts to reduce health care barriers must start by increasing the supply of primary care physicians as leaders of the health care team. The proposed APCM codes create complexity and add another layer of reasons why more physicians do not pursue careers in primary care.

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[5] Why Primary Care Practitioners Aren't Joining Value-Based Payment Models: Reasons and Potential Solutions; Issue Brief July 17, 2024, The Commonwealth Fund. https://www.commonwealthfund.org/publications/issue-briefs/2024/jul/why-primary-care-practitioners-arent-joining-value-based-payment

Request for Information: Advanced Primary Care Hybrid Payment

CMS is seeking feedback regarding potential changes to coding and payment policies for advanced primary care services to be incorporated in traditional Medicare, including mechanisms that create pathways to recognize movement away from encounter-based to population-based care. For example, CMS states coding for APCM services could be revised to include additional service elements, including traditional E/M services.

ACOI recommends that CMS work through the CPT Editorial Panel and RUC process to create an appropriate bundled payment for primary care services that reduces physician administrative burden. This approach would safeguard against inappropriate bundling of CPT codes by Medicare and other health plans that follow Medicare's lead, which could result in insurers not recognizing separate billing for certain services, such as increased time in screening, counseling, and treatment for health-related social needs or co-morbid conditions that increase risk of morbidity or mortality.

Further, any new approach to increase payment for primary care services, including through a primary care hybrid payment model, should be done outside Medicare's budget neutrality parameters.

Payment for Medicare Telehealth Services

Section 4113 of the Consolidated Appropriations Act (CAA), 2023, extended the availability of telehealth services that can be furnished using audio-only technology and provided for the extension of other public health emergency (PHE)-related flexibilities, including removal of the geographic and location limitations under section 1834(m) of the Act through December 31, 2024.

Utilization of telehealth has fallen since its peak during the COVID-19 pandemic,[6] but still remains elevated, easing access to care for Medicare beneficiaries. Congress needs to extend the PHE-related telehealth flexibilities because telehealth benefits not just those who live in rural areas and those who require behavioral health services; it also benefits those who lack easy access to transportation, have limited mobility or other barriers that make it challenging to access health care in the office setting. Extending the PHE-related telehealth flexibilities also provides an opportunity to gather knowledge, learn best practices, and advance health equity.

[6] Telehealth use declined across groups in 2022: survey; June 20, 2024 https://www.healthcaredive.com/news/telehealth-use-declines-national-center-health-statistics/719422/

ACOI encourages CMS to explore policies to better integrate telehealth with in-person care, and to support the use of patient navigators to help connect patients to telehealth appointments and follow-up support.

ACOI also supports proposed additions to the Medicare Telehealth Services List to include pre-exposure prophylaxis (PrEP) for HIV, home International Normalized Ratio monitoring, and caregiver training services.

Audio-only Coverage

According to data released by the Department of Health and Human Services (HHS) in February 2022,[7] the majority of adults 65 or older with a recent telehealth visit used audio-only. According to the report, these findings were consistent with a study that found that 26 percent of Medicare beneficiaries lack access to a desktop, laptop, or smartphone at home. The report noted that some seniors may also encounter barriers related to technological literacy, cognitive decline, and physical disability. The report analyzed data regarding telehealth use from the Census Bureau's Household Pulse Survey from April to October 2021. The HHS data analysis of telehealth use also found that Black, Latino, and Asian adults are more likely than their white counterparts to use audio telehealth services rather than video.

ACOI strongly supports CMS' proposal for a new permanent policy allowing audio-only telehealth for services delivered to patients in their home (when the patient's home is a permissible originating site) if the physician is capable of using audio-video, but the patient does not have or does not consent to video use.

Distant Site Practitioner

CMS previously finalized through CY 2024 that it would continue to permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. **We support CMS' proposal to extend the flexibility for telehealth practitioners to bill from their currently enrolled location instead of their home address on the basis the Agency continues to hear from stakeholders who have stressed the importance of continuing this flexibility for the safety and privacy of health care professionals. This policy should be made permanent.**

Direct Supervision Through Communications Technology

[7] Karimi M, Lee F, Couture S. National Survey Trends in Telehealth Use in 2021: Disparities in Utilization and Audio vs. Video Services. Feb. 1, 2022. https://aspe.hhs.gov/sites/default/files/documents/4e1853c0b4885112b2994680a58af9ed/telehealth-hps-ib.pdf

ACOI thanks CMS for defining, since the COVID PHE, the physician's "immediate availability" for services that require direct supervision to include real-time audio and visual interactive telecommunications technology. **ACOI supports CMS' proposal to permit virtual direct supervision as permanent policy for a subset of services requiring direct supervision which CMS views as being typically performed in their entirety by auxiliary personnel, including services described by CPT code 99211 which, by definition, "may not require the presence of a physician or other qualified health professional."**

For other services, CMS proposes that virtual direct supervision would continue to be allowed through December 31, 2025. **ACOI believes a policy of direct supervision through communications technology should be made permanent in an effort to address health care professional and physician workforce shortages, which are severe in certain parts of the United States. A permanent policy of virtual driest supervision will also facilitate innovative care delivery models, including "hospital at home."**

Supervision of Residents in Teaching Settings

ACOI supports CMS' proposal to extend through December 31, 2025, its current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, when the service is furnished virtually (for example, a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations). We concur with CMS that the extension of this policy allows CMS to continue to consider clinical scenarios in which it would be appropriate to permit the virtual presence of the teaching physician.

ACOI appreciates CMS previously established a policy that, after the end of the PHE for COVID-19, teaching physicians may meet the requirements to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites located outside of an Office of Management and Budget (OMB)-defined metropolitan statistical area (MSA). In such cases, all parties (patient, teaching physician and resident) must be in separate locations.

Based on ACOI member experiences, there are times when telemedicine is used for patients at home when the resident is covering an outreach clinic area, and the attending physician must be in the inpatient setting. These scenarios take place in MSA and non-MSA areas. **ACOI encourages CMS to create a permanent policy allowing virtual supervision of residents for both non-MSA *and* MSA areas. We also believe this policy should include virtual supervision of residents who are providing in-person services.**

The Accreditation Council for Graduate Medical Education (ACGME) guidelines[8] state direct supervision of residents can occur when "the supervising physician and/or patient is not physically present with the resident and the supervising physician is concurrently monitoring the patient care through appropriate telecommunication technology." Alongside ACGME guidance, teaching physicians should have the discretion to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident.

Payment for Caregiver Training Services

ACOI supports payment for caregiver training for direct care services. CMS proposes to implement three new codes (GCTM1-3) for these services, which would be in addition to existing CPT codes for caregiver training services (97550-52, 96202-03). Based on conversations with ACOI members, oftentimes providers, especially those in smaller practices, are unaware of add-on codes or are afraid to use them out of fear of repercussions from making a coding mistake. As such, **ACOI asks CMS to consider whether duplicate G-codes are necessary, or whether revisions to the existing CPT codes or new codes would be a better approach, especially to avoid confusion, and potentially under-utilization of the G codes, by providers.**

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

CMS previously finalized a policy that the E/M visit complexity add-on code (G2211) is not payable when the E/M visit is reported with CPT Modifier -25, which denotes a significant, separately identifiable E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other service. ACOI appreciates CMS is listening to concerns regarding nonpayment of G2211when it is reported on the same day as a preventive immunization or other Medicare preventive service. ACOI has heard from members that claims for G2211 are getting kicked back when billed with an Annual Wellness Visit, and we agree that a change in policy is needed. Therefore, **ACOI supports CMS' proposal to amend its previously finalized policy to allow payment of the add-on code when reported with Modifier -25 and to pay for the add-on code when the E/M visit is reported by the same practitioner on the same day as an annual wellness visit, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting.**

Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment and Management Services

[8] Common Program Requirements (Residency); 2023 Accreditation Council for Graduate Medical Education https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023v3.pdf

ACOI supports building upon the CMS Innovation Center's Million Hearts® model test through the creation of new codes (GCDRA and GCDRM) and payment for Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment and risk management services.

We know that for those with a known risk for cardiovascular disease, receiving optimal care through preventive services like tobacco use cessation and blood pressure monitoring, as well as medication management and adherence, can reduce the likelihood of a heart attack or stroke. CMS proposes to pay for the risk management code for beneficiaries with a medium-to-high risk score (greater than 15 percent in 10 years). The American Heart Association classifies intermediate 10-year risk for CAD at 7.5-19.9 percent.[9] **While we understand the Million Hearts® model test focused on individuals with a risk score of greater than 15 percent in 10 years, we recommend payment for risk management services should capture all individuals in the intermediate- (7.5-19.9 percent) and high- (20+ percent) risk groups.**

We support that CMS is not proposing any specific tool that would have to be used for the ASCVD risk assessment, although the assessment tool must be standardized and evidence-based. **We ask CMS to clarify in a final rule whether a patient with a finding of coronary artery calcium would be considered as having a cardiovascular disease diagnosis for purposes of a clinician being able to separately bill for code GCDRM.**

We acknowledge CMS is proposing ASCVD risk management services could be billed no more often than once per calendar month, and that payment is limited to one practitioner per beneficiary per month. **ACOI supports that CMS would not require a minimum service time for ASCVD risk management services in a month.** CMS states that each of the proposed elements must be addressed to bill for the service, unless a particular element is not medically indicated or necessary at that time for that specific patient. **We ask CMS to clarify in the final rule whether the same practitioner could bill for GCDRM and separately for other risk management services (e.g., tobacco cessation counseling services) in any one month.**

Revised Payment Policies for Hepatitis B Vaccine Administration

According to the Centers for Disease Control and Prevention, Hepatitis B is a global public health threat and the world's most common serious liver infection. Up to 2.4 million people in the United States are chronically infected, and rates of acute Hepatitis B infection have risen 50-450 percent in states impacted by the opioid crisis.[10] **ACOI supports CMS' proposal to**

[9] PREVENTTM Online Calculator, American Heart Association, https://professional.heart.org/en/guidelines-and-statements/prevent-calculator

[10] Hepatitis B Foundation, https://www.hepb.org/what-is-hepatitis-b/what-is-hepb/facts-and-figures/#:~:text=Two billion people have been,of infected individuals are diagnosed

expand, effective CY2025, coverage of Hepatitis B vaccinations to all individuals who have not previously received a completed Hepatitis B vaccination series or whose vaccination history is unknown. Further, we cautiously support CMS' proposal to remove its policy that requires the administration of a Part B Hepatitis B vaccine be preceded by a doctor's order. Removing this requirement would allow mass immunizers to use the roster billing process to submit Medicare Part B claims for Hepatitis B vaccines and their administration. Our concern with this policy is that by removing the requirement for a physician order before administration of the Hepatitis B vaccine, a patient's primary or regular physician may not be aware of the administration of the Hepatitis B vaccine. **ACOI also supports CMS' proposal to pay for a drug in the "additional preventive services" benefit category without patient cost-sharing like other Medicare preventive services.**

Merit-based Incentive Payment System (MIPS)

Physicians value meaningful quality improvement activities; however, a zero-payment update and another cut to the conversion factor make it increasingly difficult for practices, especially solo and small practices, to dedicate resources to successful participation in MIPS.
On this basis, the ACOI recommends the following to CMS:

- **Maintain the MIPS performance threshold at 75 points in 2025.**
- **Maintain current policy to score the highest of the scores received when there are multiple data submissions for the quality and improvement activity (IA) categories.** ACOI does not support CMS' proposal to score the most recent data submission when it receives multiple submissions from submitters within the same organization for the quality or IA categories.
- **Finalize proposed changes to the cost measure scoring methodology beginning with the 2023 performance period rather than 2024**. If CMS cannot apply this policy retroactively, then it should zero out the cost performance category for the 2023 performance period. ACOI believes retroactive application of this proposed policy is necessary because of the fundamental unfairness of comparing physicians who are scored on cost measures against physicians who are not scored on cost measures.
- **Finalize the proposal to eliminate the "high" and "medium" weighting distinctions of IAs and to reduce the number of IAs that physicians must report.**
- **Continue to encourage *voluntary* participation in MIPS Value Pathways, including subgroup participation.**

Conclusion

ACOI appreciates the opportunity to comment on the CY 2025 PFS proposed rule and issues of importance to osteopathic internists. Any questions or requests for additional information should

be directed to Tim McNichol, ACOI Deputy Executive Director, at tmcnichol@acoi.org or (301) 231-8877.

Sincerely,

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