September 6, 2024

Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

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:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services (CMS) notice of proposed rulemaking regarding changes to the Medicare Physician Fee Schedule (PFS), Quality Payment Program (QPP), Medicare Shared Savings Program (MSSP), Medicare Prescription Drug Inflation Rebate Program, and other federal programs for Calendar Year (CY) 2025 and beyond. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Our comments include detailed recommendations and rationale. ACP is confident that implementing these changes would strengthen CMS proposals, improve access to affordable care for Medicare patients, advance health equity efforts, and support physicians in delivering quality, innovative care while protecting the integrity of the Medicare trust funds. ACP appreciates the opportunity to provide feedback and looks forward to working with CMS to implement policies that support and improve the practice of internal medicine.

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Regulatory Impact Analysis

Conversion Factor

ACP appreciates many of CMS's proposals that could help strengthen primary care and drive equity and innovation. However, we remain greatly concerned about the proposed 2.8% payment cut for 2025 due to a decrease in the conversion factor to remain budget neutral. This payment cut is proposed on top of a payment cut for 2024 that was only partially fixed through congressional action, a fix that will expire at the end of this calendar year.

Congress must step in to stop the payment cut from going into effect. ACP has been calling on Congress for several years to take long-term action to fix this issue. In previous rulemaking cycles and this proposed rule, CMS has taken the necessary steps to support a well-functioning primary care system and strong primary care workforce, recognizing this is the foundation of a high-functioning health care system. It is critical, though, that CMS and Congress make more significant, uniform steps toward a permanent solution to fix these payment cuts that repeat year after year. If this rule is finalized, it will mark the fifth consecutive year that CMS has cut physician payments. Meanwhile, predictions about the MEI project an increase by 3.6%, further widening the gap between the cost of delivering care versus Medicare payments for that care. Physician payments under Medicare have not kept pace with inflation, contributing to payment cuts over the last two decades that harm the physician workforce and patients' access to care.

While ACP understands that CMS has little discretion in the proposed conversion factor for 2025 as this is statutorily set, it is not sustainable for the clinician community to continue to face these cuts. There are complexities involved in moving forward with Medicare payment reform. The College also recognizes the congressional concern to step in and fully mitigate the cut due to the cost associated with a complete payment adjustment. Still, at the very least, Congress must address the conversion factor cuts and the potential PAYGO cut before the end of this calendar year. Decades worth of flawed policies have left physicians without consistent, positive, and stable payment updates and are leading to workforce shortages and service limitations that result in longer wait times or other disruptions in patient care. CMS and Congress must work uniformly to reform physician payment and align policies. ACP continues to advocate for congressional action to strengthen the PFS and reform budget neutrality requirements, including supporting the following House bills.

> *H.R. 2474, the Strengthening Medicare for Patients and Providers Act,* would preserve access to care for Medicare beneficiaries by providing an annual inflation update equal to the MEI for Medicare physician payment. This legislation is essential to physicians' ability to maintain their practices and make needed investments to continue delivering high-quality patient care.
>
> *H.R. 6545, the Physician Fee Schedule Update and Improvements Act,* would allocate 3% to the 2024 Medicare conversion factor and update the threshold for implementing budget-neutral payment cuts in the PFS. This bill would raise the budget neutrality threshold to $53 million and use cumulative MEI increases to update the threshold every five years afterward. ACP believes that this is an approach that would help account for inflation. We also support the provisions in the bill that would require CMS to update the direct costs associated with practice expenses

(clinical labor, equipment prices, and medical supplies) simultaneously at least once every five years.

Clinical Labor Pricing Update

The College is pleased that CMS underwent a four-year transition period to update clinical labor pricing, ending with CY 2025. This update is long overdue as wage rates are inadequate and do not reflect current labor rate information, which creates distortions in the allocation of direct PE. In the future, the College encourages CMS not to have decades-long gaps between clinical labor pricing updates and to partner with physician organizations to update cost data more frequently to improve compensation. Please reference ACP's comments on the Development of Strategies for Updates to Practice Expense Data Collection and Methodology for additional feedback.

Development of Strategies for Updates to Practice Expense Data Collection and Methodology

Preparation for Incorporating Refreshed Data and Request for Information (RFI) on Timing to Effectuate Routine Updates

ACP appreciates CMS's efforts to encourage interested parties to provide feedback and suggestions that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. CMS has consistently updated direct PE inputs, but ACP is concerned that the indirect PE data inputs remain tied to legacy information from the Physician Practice Information Survey (PPIS). This survey was fielded by the AMA over 15 years ago and relies on data from 2006. The AMA has recently fielded a survey to update these inputs, and we are hopeful that the results will be available and published ahead of next year's rulemaking. We support CMS's decision to defer implementing Medicare Economic Index (MEI) changes to the distribution of relative value unit components until the survey is complete. Still, the data becomes outdated as time passes and distorts true costs. These data inputs are necessary for determining reimbursement rates, and inaccuracies can disproportionately impact specialties that spend considerable time providing direct patient care and maintaining clinical staff to support the practice and provision of care.

While relying on outdated data is not a viable option going forward, fielding frequent surveys will also not help with optimal PE data collection. These surveys can be burdensome, especially for smaller, independent practices that care for vulnerable and underserved populations. This approach could lead to biased and unreliable survey results. Larger health systems and practices are typically more equipped to respond to these surveys than smaller, less resourced systems and practices. These surveys often rely on financial experts in systems and practices to provide the information, which is a less burdensome ask to better-resourced ones and limits instances where time must be taken away from direct patient care to provide requested information. CMS must work with these smaller, less resourced systems and practices to establish robust collection efforts.

As the AMA completes the PPIS data collection, CMS must consider contingencies or alternatives that might be necessary and available to address the lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers paid under the PFS. ACP believes it is essential to reflect on the current methodology's challenges and consider alternatives that improve the stability and

accuracy of the overall PE methodology. We appreciate CMS contracting with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs to implement updates under the PFS. It is essential that CMS and the RAND Corporation work with medical societies and organizations to ensure all aspects of these efforts are well-informed from the perspective of physicians, patients, and those charged with facilitating the provision of high-quality care.

ACP supports CMS's suggestion to establish a cycle of timing to update inputs every four years but questions why these updates would be limited to supply and equipment costs. Advancing shared goals of stability and predictability must include consideration of clinical labor alongside supply and equipment costs. If recurring updates to all PE costs do not occur uniformly, there is the unintended consequence of distortions in allocations, and true costs will continue to differ drastically from payment under the PFS. CMS should focus not only on supply and equipment costs but also on methodological refinements that update all PE costs. We also urge CMS to consider how failures to update PE costs routinely impact independent physician practices that are typically less resourced than large health systems, resulting in an increasing share of physicians being employed and shifting the dynamics in medicine.

We also strongly recommend CMS consider PE costs not currently captured under the PFS, such as AI-related medical services. The AMA's Digital Medicine Payment Advisory Group (DMPAG) is actively considering how AI medical services fit into the CPT code set, creating a terminology and taxonomy that charts a path to payment for AI-related medical services and procedures. Just as the DMPAG and medical societies are overcoming the limitations in the existing landscape, CMS must work to ensure resource costs are appropriately and adequately captured. ACP strongly urges CMS to consider these future developments in the context of its work with the RAND Corporation. It is essential that CMS, commercial payers, and others do not stifle innovation or these efficiencies but also appropriately contextualize and value the physician's work and intensity.

Valuation of Specific Codes

Telemedicine Evaluation and Management (E/M) Services (CPT codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091)

ACP appreciates CMS's consideration of the CPT Editorial Panel's addition of 17 new codes for reporting telemedicine E/M services. As participants, we also understand the time and effort dedicated to describing and valuing these new codes. The College supports CMS's proposal to assign CPT codes 9X075-9X090 a Procedure Status indicator of "I" and use the existing O/O E/M codes currently on the Medicare telehealth services list billed with the appropriate POS code and modifier to identify the service as being furnished via audio-only communication technology. The College also supports CMS's proposal to accept the RUC-recommended values for CPT code 9X091 and to delete HCPCS code G2012. We agree that the coding and payment recommendations for this code accurately reflect the resources associated with this service and believe that maintaining separate coding for purposes of Medicare payment could create confusion given the similarity between CPT code 9X091 and HCPCS code G2012.

However, the College is greatly concerned that the statutory restrictions on geography, site of service, and clinician type in place before the COVID-19 public health emergency (PHE) will go back into effect on

January 1, 2025, unless Congress acts. There are significant concerns about maintaining access to care using Medicare telehealth services with the expiration of the statutory flexibilities that were successively extended by legislation following the PHE for COVID-19. Millions of patients have utilized interactive communications technology for visits with clinicians for a broad range of health care needs for almost five years. Patients have grown accustomed over several years to broad access to telehealth services. It is critical that Congress mitigate the negative impact of the expiring telehealth flexibilities, preserve access, and assess the magnitude of potential reductions in access and utilization.

ACP supports the expanded role of telehealth as a method of health care delivery that can enhance the patient-physician relationship, improve health outcomes, increase access to care from physicians and members of a patient's care team, and reduce medical costs. Telehealth can be an option for patients who lack access to in-person primary or specialty care due to various social drivers of health such as a lack of transportation or paid sick leave, or insufficient work schedule flexibility to seek in-person care during the day. Current telehealth flexibilities have been instrumental in improving access to care for patients across the U.S. ACP was pleased that the Consolidated Appropriations Act of 2023 extended many of these flexibilities through the end of CY 2024, helping ensure access to care. With these flexibilities set to expire, ACP has strongly urged Congress to pass the following bills.

> S. 2016/H.R. 4189, *the Connect for Health Act of 2023*, would permanently expand access to essential telehealth services, including expanding originating sites, lifting geographic requirements for telehealth services, and allowing FQHCs and RHCs to continue providing telehealth services.
>
> S. 1636/H.R. 3440, the *Protecting Rural Telehealth Act*, and H.R. 7623, the *Telehealth Modernization Act*, would ensure that seniors may continue to access audio-only telehealth consults with their physician after this option expires at the end of CY 2024. ACP strongly supports using audio-only telehealth as an effective modality to address gaps in health equity. These services are instrumental for patients who do not have the requisite broadband/cellular phone networks, have privacy concerns, do not feel comfortable using video technology, or do not possess the digital literacy to use video technology.

<u>COVID Immunization Administration (CPT code 90480)</u>

The College supports CMS's proposal to adopt the RUC-recommended work RVU of 0.25 for CPT code 90480 and the RUC-recommended direct PE inputs for CPT code 90840.

<u>Annual Alcohol Screening (HCPCS codes G0442 and G0443)</u>

The College supports CMS's proposal to adopt the RUC-recommended work RVU of 0.18 for HCPCS code G0442 *(Annual alcohol misuse screening, 5 to 15 minutes)* and the RUC-recommended work RVU of 0.60 for HCPCS code G0443 *(Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes)*. ACP agrees that an increase in the work RVU for HCPCS code G0443 is warranted based on the time and intensity of the service in preventing alcohol misuse. We also agree with CMS's belief that the codes in the adjacent Behavioral Counseling & Therapy family, which includes HCPCS codes G0445 *(High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes:*

education, skills training, and guidance on how to change sexual behavior; performed semi-annually, 30 minutes), G0446 *(Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes)*, and G0447 *(Face-to-face behavioral counseling for obesity, 15 minutes)*, may be undervalued as their respective intensities may be lower than what is warranted for these services. ACP will work to ensure these codes undergo additional review to recognize the intensity of these services.

ACP also agrees with CMS's proposal to maintain the current 15 minutes of clinical labor time for HCPCS code G0442. It would not be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. For G0443, we support CMS's proposal to accept the RUC-recommended direct PE inputs without refinement.

As CMS considers how best to implement and maintain payment for preventive services and develop new payment policies in future rulemaking to address this issue more comprehensively, we urge CMS to work alongside medical societies and the RUC to ensure consistent access and adequate payment for these services.

Annual Depression Screening (HCPCS code G0444)

ACP supports CMS's proposal to adopt the RUC-recommended work RVU of 0.18 for HCPCS code G0444 *(Annual depression screening, 5 to 15 minutes)*. Like CMS's proposal for HCPCS code G0442, we agree with CMS's decision to maintain the current 15 minutes of clinical labor time, as it is not typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. We believe that the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure.

Behavioral Counseling & Therapy (HCPCS codes G0445, G0446, and G0447)

The College appreciates CMS's proposal not to adopt the RUC-recommended direct PE inputs for G0445 *(High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes education, skills training, and guidance on how to change sexual behavior; performed semi-annually, 30 minutes)*, G0446 (*Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes)*, and G0447 *(Face-to-face behavioral counseling for obesity, 15 minutes)*. Given the insufficient survey responses, ACP agrees that these changes are not substantiated. Low survey response rates are not unusual for RUC surveys, particularly among the primary care community, and we strongly urge CMS to consider this reality alongside future developments to the valuation process, given the potential for these under-representations to distort the RBRVS, with significant downstream consequences. ACP has regularly raised concerns about this and refers CMS to the College's comments on the CY 2024 PFS proposed rule and CMS's *Request for Comment About Evaluating E/M Services More Regularly and Comprehensively*.

Payment for Caregiver Training Services (CTS)

The College supports policy changes designed to improve the workforce of caregivers through comprehensive training and reimbursement. Adequately trained caregivers are essential to promoting

the health and safety of patients. Overall, the College believes that these proposed codes could be beneficial to both caregivers and patients. Still, we want to guarantee that the agency has a robust plan to educate caregivers about these new codes. This would ensure the adequacy and accuracy of payment for CTS. If these codes are finalized as proposed, CMS should closely monitor the uptake and utilization to guarantee that caregivers are supported and trained as intended.

We urge CMS to further partner with subspecialty and local physician organizations to focus on alignment and care coordination. The College has been highly supportive of the Guiding an Improved Dementia Experience (GUIDE) Model and the Patient-Centered Medical Home (PCMH) model of care, which focus on comprehensive care coordination and care management, as well as caregiver education and support. These models also work closely with subspecialists to improve patient experience and better manage complex, chronic conditions.

If these codes were finalized, ACP would also be concerned about their impact on private practices and implementation challenges. CTS could pose a cost concern in these practices, thus negatively impacting uptake and utilization.

RFI for Services Addressing Health-Related Social Needs (Community Health Integration (CHI) (G0019, G0022), Principal Illness Navigation (PIN) (G0023, G0024), Principal Illness Navigation-Peer Support (G0140, G0146), and Social Determinants of Health (SDOH) Risk Assessment (G0136))

ACP appreciates CMS's initiative to introduce new G codes for CHI and SDOH risk assessment. CHI services are crucial in addressing unmet SDOH needs that significantly impact a patient's diagnosis and treatment. ACP recommends thoroughly documenting these services in the medical record and encourages using ICD-10 codes from categories Z55-Z65 for data standardization. Additionally, ACP recommends that CMS permit patient consent for CHI services via telephone, recognizing that some aspects of these services can be effectively performed over the phone.

ACP also supports introducing HCPCS codes for PIN services and PIN-Peer Support. These services are vital in guiding patients through complex health care systems, particularly those in underserved communities. ACP recommends that CMS consider the unique challenges practitioners face in these settings and provide clear guidelines to facilitate the effective delivery of PIN services. Additionally, ACP appreciates CMS's focus on clinicians in geographically isolated or underserved communities and recommends seeking feedback to better understand barriers and opportunities related to coding Z codes on claims for CHI, PIN, and SDOH risk assessment.

Evaluation and Management (E/M) Visits

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

ACP strongly supports CMS's proposal to refine its current policy for payment for the O/O E/M visits complexity add-on code, HCPCS code *G2211 (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient*

evaluation and management visit, new or established). Specifically, the College supports CMS's proposal to allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported by the same practitioner on the same day as an annual wellness visit (AWV), vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting. Allowing payment for the O/O E/M visit complexity add-on code in this scenario would support CMS's goals of paying for previously unaccounted resources inherent in the complexity of all longitudinal primary care office visits since, in part, this add-on code recognizes the inherent costs of building trust in the physician-patient relationship. This trust-building is significantly important in making decisions about administering immunizations and other Medicare Part B preventive services. The College appreciates CMS's efforts to align its current policy with policy objectives for establishing the add-on payment.

As CMS continues to refine its policy for payment of the O/O E/M visits complexity add-on code, ACP urges CMS to allow this code to be reported across all sites of service, including Home or Residence E/M services that meet the requirements of the add-on code. The principles that resulted in the appropriate recognition of the additional work and other resources related to a longitudinal care relationship in primary care or the care of a patient with a serious or complex condition are identical whether the care is in the office or the patient's home. Patients receiving care in the home are typically underserved and more dependent on continuity relationships. In principle and policy, these vulnerable beneficiaries should be supported by accurate payment to those who serve them.

The College is also very concerned about the lack of coverage for the O/O E/M visits complexity add-on code across private payers, such as Medicaid, Medicare Advantage (MA), and commercial insurance companies. Since these payers are not required to pay for services associated with G2211, coverage and policies vary considerably. Per UnitedHealthcare's (UHC) June 2024 policy update, the payer will no longer pay claims with G2211 for services rendered to commercial plan members beginning September 1st. Under the policy update, UHC will pay Medicare plans separately, while claims for commercial plan holders will be denied with an indication from UHC that the payment is bundled into the primary E/M services. ACP is concerned that this change could cause payment frustration for physicians who provide comprehensive care to patients with complex conditions, upending CMS's intentions in establishing separate payments. Aetna, too, is not paying the full allowable amount and is erroneously paying only one cent to physicians for G2211 claims. ACP strongly urges CMS to work directly with Congress to ensure physicians receive appropriate payment for the care they provide and that this is carried through to all payers.

Enhanced Care Management

ACP greatly appreciates and supports CMS's efforts to continue strengthening primary care, including the proposals to build on its experience with discrete primary care models under CMMI. The College generally supports the APCM-related proposals as there is the potential for a guaranteed income stream, upfront payments to help practices providing this care, increased support for primary care under the PFS, and simple attribution policies. However, we have concerns about the proposed valuation for the three codes, the constraints of budget neutrality and its impact on utilization, proposed EMR capabilities, utilization in MA, and patient copays.

The College supports CMS's efforts to align APCM services with other Medicare programs and initiatives, such as the MSSP and the QPP, including MIPS and Advanced APMs. This alignment reflects ACP's longstanding advocacy for integrated and streamlined health care delivery that reduces administrative burdens and enhances patient care continuity and access. The proposal to create a low-burden way for practitioners to furnish APCM services by appropriately recognizing how they may meet APCM billing requirements as part of these programs and initiatives is commendable. ACP appreciates CMS's initiative to seek feedback on duplication within the APCM service elements and practice capabilities they should consider addressing.

ACP also supports CMS's proposal to pay for APCM services under codes GPCM1, GPCM2, and GPCM3, as this will help primary care practices expand their services to meet patients' needs better. ACP suggests that bundling reimbursement for care management services into a monthly billable code that is not based on time is a positive step, addressing that E/M codes do not capture much of the care provided between patient visits. However, ACP recommends allowing consent for APCM services to be covered under the global consent used for E/M codes, as obtaining individual consent for nearly all patients would be logistically and ethically challenging. We also recommend CMS explore the option of offering yearly consent provided by the patient. Additionally, ACP suggests increasing the reimbursement of GPCM 2 from $50 to $65 and GPCM 3 from $110 to $125. GPCM 1 reimbursement must be increased to $56. Many practices have robust and effective transitional care management (TCM) programs and utilize the existing TCM codes to reimburse for the services. Under the proposed rule, for a patient with chronic conditions, the practice would be billing the APCM code whether that patient received TCM services that month or not. However, significantly more resources would be used for the patient receiving TCM services. The practice could not bill APCM that month for that patient and only bill TCM; then, the practice would not be receiving reimbursement for any other care management or interprofessional consultation services the patient receives. Alternatively, ACP suggests not including TCM services in the APCM bundle due to the significant resources required for TCM services and the potential loss of reimbursement for other care management services. Instead, ACP recommends gaining experience and feedback on the proposed APCM codes before considering additional codes that include TCM services.

As proposed, CMS should not include integrated mental health services into APCM. It is difficult to price out and reimburse these services accurately, and one of our primary concerns is that physicians would be providing behavioral services without adequate compensation. While APCM may not be the best avenue to promote mental health services in primary care, ACP strongly believes in behavioral health integration and its benefits for patients and clinicians. We look forward to continuing to partner with CMS to determine how to best serve patients with comprehensive, whole-person care, which includes mental health services. ACP encourages the continued use of the psychiatric Collaborative Care Model (CoCM), the most evidence-based and efficient way to deliver integrated mental health.

We are also concerned about the challenges in staffing for 24/7 access, which is easier for larger organizations but difficult for smaller practices, especially in rural areas. Ensuring continuity of care with

a designated physician is challenging, and real-time access to medical records can be burdensome for physicians and their support staff. We are worried about the administrative burden due to detailed notes and questions about what qualifies as a care plan. While this might be easier in larger health systems and seen as a stimulus for more AWVs, it is hard to achieve in smaller practices without being part of an ACO.

ACP additionally urges CMS to consider timely EHR information exchange issues, especially across different systems, and the 7-day follow-up requirement. Introducing new payment codes for BHI raises concerns about bundling payments and the need for PCPs to be reimbursed for services they already provide. We are greatly concerned about the impact of adding work without proper compensation for already provided care, which can lead to physician burnout and negatively impact strained physician resources.

We look forward to working with CMS to address these concerns and improve APCM services. As CMS considers this feedback, we recommend CMS finalize the APCM services but delay implementation until CY 2026, allowing interested parties to work with CMS to effectively refine and enhance the APCM services to provide the care patients need and deserve.

RFI on Advanced Primary Care Hybrid Payment

ACP supports CMS's RFI in expanding and accelerating the adoption of value-based models of care, including hybrid payment models for primary care. As expressed in our letter to Sen. Whitehouse and Sen. Cassidy, we recommend that a hybrid payment model be voluntary and tested before any consideration for widespread implementation into the PFS. We support a model that builds on the learnings of these past and current models and is introduced for nationwide voluntary implementation. Clear mechanisms must also be included to evolve and improve this hybrid model over time to account for unintended or adverse consequences.

Strategies for Improving Global Surgery Accuracy

Over the last several years, ACP has expressed support for CMS's ongoing review of opportunities to clarify or revise longstanding policy and billing instructions for global practices, consistent with CMS's objectives to pay more accurately for services and to right-size valuation of PFS services based on how practitioners currently furnish these services. ACP greatly appreciates CMS's proposals to (1) revise the transfer of care policy for global packages to address instances where one physician furnishes the surgical procedure and another physician furnishes related post-operative E/M visits during the global period and (2) to develop a new add-on code that would account for resources involved in post-operative care provided by a physician who did not furnish the surgical procedure. ACP believes that finalizing these policies is an essential step in aligning payment with how surgical procedures are currently furnished, as evidenced in years of data, and would make meaningful progress toward more accurate payment for these services and improve relative valuation for PFS services overall.

ACP supports CMS's proposal to create a new add-on code for use when follow-up care is provided by a physician of a different specialty than the physician who performed the procedure. The College appreciates the agency's acknowledgment of the extra work required by a physician providing follow-up care if the physician is not of the same specialty. This work includes reading the available surgical notes, researching the procedure and potential complications, evaluating, and physically examining the patient, and communicating with the clinician who performed the procedure. This work typically occurs in addition to an O/O E/M visit and requires additional resource costs not accounted for in the base code.

Although a wide range of codes likely warrant reexamination using new data and analyses, the 10- and 90-day global surgical codes need revaluation. Of the approximately 8,000 billing codes in the PFS, half are global codes. Since MACRA stopped CMS from implementing its finalized policy in 2014 that would have converted all these codes to 0-day global codes and allowed clinicians to bill separately for each postoperative visit, CMS has collected the required data and CMS's grounds for converting 10- and 90-day global surgical codes to 0-day global codes have only grown stronger. RAND researchers working for CMS found that most of the postoperative visits Medicare intended to pay for as part of these global codes are not actually being provided. For procedures with 10-day global periods, only 4% of the expected postoperative visits are provided; for procedures with 90-day global periods, only 38% of expected postoperative visits are provided. RAND has estimated that if payment rates for 10- and 90-day global surgical codes were reduced to reflect the actual number of postoperative visits being provided, total Medicare payments to certain surgical specialties would decline by as much as 17 to 18%.

ACP has continued to support CMS's proposal to convert all 10- and 90-day global surgical codes to 0-day global codes and allow clinicians to separately bill for postoperative visits on a fee-for-service basis. We have also supported and provided feedback on CMS's requests to evaluate E/M services more regulatory and comprehensively, including proposals to address the substantial overvaluation of 10- and 90-day surgical global codes. While ACP acknowledges the deficiencies and fundamental biases in the RUC process, particularly the systemic undervaluing of cognitive, including primary care, services, we believe it is important that CMS work with the RUC and its participant specialty societies to ensure that the revaluation of the global surgical codes is well-informed, comprehensive, and completed imminently.

The College appreciates CMS's efforts toward more accurate payment for these services. When subsets of services are overvalued, it creates widespread distortions in the RBRVS, hurts the integrity of the Medicare system, and adversely affects the primary care workforce. As the National Academy of Science, Engineering, and Medicine (NASEM) report points out, the nation's health is directly linked to the strength of its primary care delivery system and workforce. As the current payment system and inaccuracies in the allocation of resources drive down the value of primary care, there has been a shortage of primary care physicians. This shortage has profoundly impacted the quality of care and patient health outcomes, particularly for our most vulnerable populations. As CMS considers finalizing its CY 2025 proposals alongside long-term solutions to this issue, ACP looks forward to continuing working with the agency to ensure it has accurate information on the resources involved in furnishing components of global surgical packages and can appropriately value the time and resources involved.

Medicare Telehealth Services

Changes to the Medicare Telehealth Services List/Requests to Add Services to the Medicare Telehealth Services List

The College supports the streamlined, more straightforward process for the additions, deletions, and changes to the Medicare Telehealth Services List. We are pleased that CMS has removed the Category 1-3 taxonomy. We believe categorizing services as permanent or provisional will eliminate confusion from interested parties and recognize that evidence showing clinical benefit does not always occur on a linear, annual timeline.

Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

For CY 2025, CMS proposes to continue removing the frequency limitation of codes for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations, first established in CY 2024. The codes affected are 99231, 99232, 99233, 99307, 99308, 99309, 99310, G0508 and G0509.

ACP is pleased that CMS has proposed to continue removing the frequency limitation of codes for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations via Medicare. The College is glad to see that decision-making remains with physicians through CY 2025 and is pleased that CMS is gathering more data for future decision-making.

Audio-Only Communication Technology to Meet the Definition of "Telecommunications System"

The College is pleased that CMS is revising the definition of telecommunications to include audio-only communications. We appreciate the flexibility and waivers that CMS has granted over the past few years due to the COVID-19 PHE and how important telehealth is to reaching patients who cannot have traditional, in-office visits. Expanding the definition to include audio-only phone calls will be especially beneficial to these patients, especially those who are elderly, lack access to advanced technology, or do not have adequate access to broadband services. ACP is especially encouraged by how audio-only technology can positively impact behavioral and mental health among rural and underserved populations, as these populations are more likely to have access to audio-only technology than audio-video technology. We believe that physicians should continue to be empowered to determine when services can be furnished via audio-only formats.

Distant Site Requirements

In the past, commenters shared concerns for safety and privacy with CMS about listing their home address rather than their practice location when furnishing services via telehealth. To address this, CMS allowed physicians to bill from their practice address through CY 2024, and in the current rulemaking cycle, proposes to extend the flexibility through CY 2025.

The College is pleased to see that CMS proposes to continue to permit practitioners to use their practice locations instead of home addresses when providing telehealth services from the home through CY 2025. The College supports patients' and doctors' safety and privacy. We are pleased that CMS has considered this in the proposed rule and urge CMS to make this flexibility permanent.

Proposal to Extend Definition of "Direct Supervision" to Include Audio-Video Communications Technology through 2025

CMS proposes to temporarily continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2025. The College is pleased that CMS will continue to allow direct supervision through audio-video communications technology through December 31, 2025, an extension from the previous policy. ACP continues to urge CMS to make the direct supervision flexibility permanent.

In previous comments to CMS, ACP advocated for making the direct supervision flexibility permanent, stating that it would expand telehealth services and protect health care workers by enabling appropriate social distancing. While social distancing may not be a primary concern at this time, the College believes clinicians should be able to supervise staff virtually, whether a PHE is in effect. ACP remains concerned that ending this flexibility will mandate synchronous supervision, which the College opposes, as it unnecessarily burdens supervisors by requiring them to be physically present.

Proposal to Permanently Define "Direct Supervision" to include Audio-Video Communications Technology for a Subset of Services

CMS proposes adopting a permanent definition of direct supervision that allows "immediate availability" of the supervising clinician using audio/video real-time communications technology (excluding audio-only) for specific incident-to-services. For all other services, the definition expansion would be temporary through CY 2025.

ACP is pleased that some services will be changed permanently to allow online supervision. However, as mentioned above, ACP continues to urge CMS to make direct supervision flexibility permanent for all services so that physicians can decide for themselves what is appropriate.

Teaching Physician Billing for Services Involving Residents with Virtual Presence

The College is pleased with the proposal to continue the current policy to allow teaching physicians to bill for virtually furnished services involving residents through December 31, 2025. The College is invested in medical education and is pleased with the efforts to compensate teaching physicians for their work with the future generation of medicine.

Advancing Access to Behavioral Health Services

Digital Mental Health Treatment (DMHT)

CMS is proposing Medicare payment to billing practitioners for DMHT devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. In previous comments to Congress, ACP highlighted that the number of individuals in need of mental or behavioral health services significantly increased during the COVID-19 pandemic and thereafter and that there have been significant, worsening shortages in available mental health clinicians across the country. CMS acknowledges that there has been limited access to behavioral health care due to clinician shortages ("[g]iven nationwide behavioral health workforce shortages combined with increasing demand for behavioral health care services, some Medicare beneficiaries may have limited access to these services"). Indeed, the latest available data from HRSA substantiates this problem and suggests it will only continue to worsen. Specifically, HRSA Workforce Projection data for behavioral health care workers indicate the total supply of this workforce is projected to decrease by 10% between 2024 and 2036, while the demand is projected to increase by 45%, resulting in only 53% adequacy by 2036.

ACP also previously highlighted that as the number of patients in need of treatment for mental health care has risen, the use of telehealth to access mental and behavioral health services has also increased and has proven to be an effective method of treatment. According to the Commonwealth Fund, "telemental health has a robust evidence base," and "numerous studies have demonstrated its effectiveness across a range of modalities (e.g., telephone, videoconference) and mental health concerns (depression, substance use disorders)." Digital behavioral health treatments improve the ability of the primary care and behavioral health workforce to deliver this much-needed care to more people regardless of their physical proximity to clinicians or treatment centers. Furthermore, major entities such as the Substance Abuse and Mental Health Services Administration, American Psychological Association, and the Kaiser Permanente Institute for Health Policy cite digital mental health technologies or therapeutics to increase behavioral health care access and equity.

Therefore, ACP strongly supports integrating behavioral health care services into primary care, as empirical evidence supports the effective use of telehealth and other technologies to improve access to this much-needed care. However, we caution that certain rural, underserved, or economically disadvantaged communities often lack access to the requisite technologies (e.g., broadband, smartphones, computers, etc.) to benefit from expanding digital mental health treatment. Disparities in access to these technologies must be addressed as their use grows throughout behavioral health and primary care settings.

Payment for Digital Mental Health Treatment (DMHT) Devices

ACP agrees that digital therapeutics can offer an innovative way to access certain behavioral health services and supports CMS's proposal to create three new HCPCS codes for DMHT devices. The College

supports research and innovation to further integrate behavioral health into the primary care setting, and these devices can be helpful tools for comprehensive, whole-person care. If finalized, practitioners must be educated on these codes and the specific situations in which they can be used. Additionally, we want to ensure that DMHT devices are safe and beneficial for clinicians and patients. These devices do not always provide better health outcomes, and only high-quality, safe, and effective devices should be used.

We look forward to how DMHT devices are used to enhance care and are encouraged by CMS's development of these codes.

Interprofessional Consultation Billed by Practitioners Authorized by Statute to Treat Behavioral Health Conditions

The College is extremely encouraged by CMS's proposal of six new G codes for all practitioners to bill for interprofessional consultations, and we are hopeful that this further promotes BHI. Access to behavioral health care remains limited for patients nationwide, and we urge CMS to continue expanding and supporting the behavioral health workforce and paying more accurately for these services. Treating behavioral health conditions requires care coordination and a team of clinicians with special expertise, and facilitating interprofessional consultations will help to minimize gaps in care.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Telecommunication Services

ACP was pleased that under the CAA, 2023, telehealth flexibilities for the in-person requirement were relaxed through January 2025. However, as mentioned in previous comments, the College is disappointed that CMS is not proposing permanently eliminating the in-person requirements for mental health visits and certain other health care services, including E/M services.

Direct Supervision via Use of Two-way Audio/Visual Communications Technology

Earlier in the rule, under the PFS, CMS proposed that for all other services that require direct supervision, "immediate availability" should include telecommunications only through December 31, 2025. CMS proposes maintaining RHC and FQHC virtual presence flexibility, in line with those under the PFS, through December 31, 2025.

ACP supports including virtual communications in the definition of "immediate availability" for actions requiring direct supervision in RHCs and FQHCs, aligning with the PFS. As mentioned, we are pleased that this definition has been expanded but are disappointed that these changes are not permanent. As mentioned here and in previous comments to CMS, ACP advocated for the permanency of direct supervision flexibility. The College believes clinicians should feel empowered to supervise clinical staff virtually, at their discretion, regardless of whether there is a PHE. Furthermore, the College believes this provisioning should extend to all health care professionals, including those in RHCs and FQHCs.

Payment Proposal for Non-Behavioral Health Telecommunication Technology Services

ACP is appreciative of all the telecommunication technology flexibility awarded from CMS over the past four years, especially in RHCs and FQHCs, which are more likely to reach underserved, vulnerable populations. This flexibility has been important in the continuation of non-behavioral health services and the ability of physicians to consistently care for patients. The College is encouraged that CMS will continue the temporary payment for these visits furnished via telecommunication technology and continues to urge the agency to permanently allow payment for non-behavioral health visits. ACP agrees with CMS's reasoning that significant changes to the payment methodology would increase administrative burden and supports the proposal to continue using the weighted average under the PFS.

Payment for Preventive Vaccine Costs in RHCs and FQHCs

CMS is proposing to allow RHCs and FQHCs to bill for administering Part B preventive vaccines (pneumococcal, influenza, hepatitis B, and COVID-19) at the time of service. The College strongly supports this proposal because it streamlines the payment of all Part B vaccine claims, where all vaccine products are paid at 95% of the Average Wholesale Price, and vaccine administration is paid based on the PFS. We favor proposals that streamline and simplify payment across health care settings to minimize administrative burden and paperwork and increase the time physicians can spend with patients.

Conditions for Certification and Conditions for Coverage (CfCs)

CMS is proposing changes to the provision of CfCs to ensure that RHCs and FQHCs continue to provide primary care services but would no longer enforce the standard for RHCs to primarily engage in furnishing primary care services. This would allow for more outpatient specialty services at these clinics and enable practitioners to better meet the needs of the patient population. The College agrees with the importance of improving access to care for rural patients and emphasizes that primary care physicians are an essential part of RHCs and FQHCs. As always, we want to ensure that primary care physicians are adequately compensated for their services, including behavioral health.

Medicare Diabetes Prevention Program (MDPP)

Changes to MDPP, including a revision of the “online” definition and introducing a “combination with an online component,” are particularly relevant to the ACP’s stance on telemedicine and patient outcomes. ACP is encouraged by CMS’s proposed revisions to the MDPP, particularly the alignment with CDC DPRP terminology and the introduction of the “in-person with a distance learning component” modality, offering greater program delivery flexibility. However, ACP is concerned about excluding purely online modes under the extended COVID-19 flexibilities, as online modalities could expand access, especially for rural populations. We support the hybrid payment structure rewarding attendance and diabetes risk reduction outcomes and welcome the new G code for virtual services, which will promote better engagement and aid in collecting essential data on the effectiveness of these approaches. ACP is pleased with the continued evolution of the MDPP and supports the proposed changes with the recommendation that purely online care be reconsidered for future inclusion.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OPTs)

ACP policy supports lifting barriers that impede access to medications to treat opioid use disorder, including buprenorphine, naltrexone, and methadone. The ACP supports the proposed changes in section III.F.2 to permanently extend telecommunication flexibilities for periodic assessments, including the use of audio-only communications when two-way audio-video technology is not available to the beneficiary. We also support allowing OTPs to use audio-visual telecommunications under certain circumstances to initiate methadone treatment for any new patient for whom the OTP determines that an adequate patient evaluation can be accomplished via an audio-visual telehealth platform. These policies may help broaden access to OUD for beneficiaries facing transportation, scheduling, and other access barriers, as well as help achieve health equity for communities experiencing racial and ethnic disparities in OUD treatment access.

The ACP supports CMS's efforts to adjust payment rates to encourage higher uptake of SDOH risk assessments to better identify unmet health-related social needs and provide harm reduction and/or recovery support services. Generally, ACP supports policy and reimbursement interventions to enable physicians and other clinical care team professionals to address SDOH and identify unaddressed health-related social needs, like food insecurity, homelessness, and housing instability. CMS should provide financial, technical, and policy support to health care teams, including those providing care in OTPs, to assess SDOH-related risks during the patient visit.

Medicare Shared Savings Program

Eligibility Requirements and Application Procedures

ACP supports CMS's proposal to update the antitrust language in the ACO application procedure and streamline the process of sharing ACO applications with the Federal Trade Commission (FTC) and the Department of Justice (DOJ) to hamper anti-competitive practices.

Proposed Revisions to the Definition of Primary Care Services

ACP supports CMS's proposed revisions to the definition of primary care as this will capture more of the services rendered by primary care physicians to Medicare beneficiaries. Further, this will improve capturing primary care utilization by Medicare beneficiaries and facilitate a more appropriate allocation of resources to support physicians delivering primary care.

Medicare Part B Payment for Preventive Services

Revised Payment Policies for Hepatitis B Vaccine Administration

CMS proposes expanding hepatitis B vaccinations to include those who have not completed a full vaccination series and those with an unknown vaccination history. The College supports coverage for expanded hepatitis B vaccinations when it is medically appropriate. These preventive vaccines are essential for overall patient safety and health. ACP also supports the change to align payment for

hepatitis B vaccinations in RHCs and FQHCs with the other Part B vaccines at 100% of reasonable cost. This streamlines the payment process for these vaccines, which should lead to a lower administrative burden and more time providing care for clinicians who administer vaccines. Allowing mass immunizers to use the roster billing process to submit hepatitis B claims should also minimize paperwork for practitioners. The College is encouraged by CMS's steps to reduce the administrative burden and expand access to preventive services.

RFI on Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

Participant Definition

ACP recommends that CMS leverage administrative data, claims data, and EHRs to maintain up-to-date information on clinician affiliations and specialties. Utilizing the National Provider Identifier (NPI) and the Provider, Enrollment, Chain, and Ownership System (PECOS) can help accurately track clinician movements and specialty designations. Additionally, CMS should consider implementing a dynamic classification system that adjusts for clinician turnover and integrates real-time data from Qualified Clinical Data Registries (QCDRs) to ensure accurate identification of specialists and sub-specialists. This approach will enable CMS to effectively identify and support specialists participating in an ambulatory specialty model while minimizing administrative burdens.

MVP Performance Assessment

ACP recommends that CMS prioritize measures and activities that address performance gaps, have meaningful benchmarks, and are reliable, given the expected sample size. ACP is pleased with the emphasis on evidence-based measures strongly linked to outcomes and those that capture an adequate number and representativeness of clinicians intended by the model. Additionally, ACP supports measures that drive specialty integration with primary care and meaningful involvement with accountable entities. ACP recommends prioritizing measures focusing on equity, population health, and patient-reported outcomes and experiences. By adopting these principles, CMS can ensure that the selected measures are relevant and impactful, enhancing the quality of care.

ACP requests clarity on whether CMS will create a new MVP or allow the specialty/sub-specialty physicians to report on MVPs relevant to them. ACP recommends adding another principle related to relevant and meaningful specialty and subspecialty practice measures. To build on the cardiology MVP example, the current MVP for cardiologists includes only two measures specific to the subspecialty of electrophysiology. This is not aligned with the intent of MVPs, which is to make MIPS reporting more relevant and meaningful for specific specialties or medical conditions.

Payment Methodology

ACP recommends that CMS develop a model for applicable specialists that incorporates standardized performance metrics to improve the comparison of similar specialists for future Medicare Part B payment adjustments. ACP is pleased with the consideration of a balanced range of upside and downside risks to incentivize meaningful participation of specialists in APMs, care transformation, and

integration between primary and specialty care. Additionally, ACP recommends that CMS design ambulatory specialty care models with features that gradually increase risk over time, ensuring these models can potentially qualify for Advanced APM status under the QPP.

Care Delivery and Incentives for Partnerships with Accountable Care Entities and Integration with Primary Care

ACP recommends that CMS consider additional model design features that incentivize primary and specialty care clinicians to enhance care coordination, such as shared savings programs and integrated care teams. ACP is pleased with the idea of encouraging specialist clinicians and accountable care entities to collaborate by establishing clear care pathways and protocols to optimize patient outcomes and ensure efficient resource utilization. ACP recommends identifying specialists engaged in care management and coordination through performance metrics and participation in care improvement activities. ACP also suggests defining clear expectations and performance metrics for specialists beyond current MVP measure sets to foster collaboration with ACOs and primary care clinicians, using levers like MIPS Improvement Activities to support closing the care loop. Additionally, ACP recommends that CMS account for variations between ACOs, such as ownership structure and regional healthcare landscapes, in the model design.

ACP is deeply concerned about increased consolidation and recommends measures to ensure integration efforts do not reduce competition or negatively impact healthcare quality and costs. Finally, ACP suggests that risk categorization of ACOs should influence incentive structures, with adjustments to accommodate different risk levels.

ACP has previously supported the medical neighborhood model (MNM) by recommending the MNM to the HHS Secretary, aiming to strengthen relationships between primary care specialists and other specialist physicians. Additionally, ACP has been a strong advocate for the PCMH model, emphasizing its potential to improve patient care and the viability of the health care delivery system. These past efforts align with ACP's current recommendations to CMS, which focus on enhancing care coordination, establishing clear care pathways, and fostering collaboration between primary and specialty care clinicians to optimize patient outcomes and resource utilization.

Health Information Technology and Data Sharing

ACP supports HHS's continued commitment to developing the policies, procedures, and technical framework to facilitate secure, seamless, and sustainable health information exchange to improve care across the entire care continuum. Effective, practical, and secure interoperability is crucial to improving the patient experience and the patient-physician relationship, reducing the burden on physicians and, in turn, improving the quality of care. The College believes that current efforts to improve interoperability, including the Trusted Exchange Framework and Common Agreement (TEFCA), still do not focus on the types of health information exchange needed for useful clinical management of patients as they transition through the health care system. Patients and clinicians need a seamless exchange of valuable, meaningful data at the point of care, the ability to incorporate clinical perspective, and the ability to query health IT systems for up-to-date information related to specific, relevant clinical questions. We

caution that if this model should require or mandate any increased data sharing, practices – especially those that are small or independent – must ensure sufficient capital to make any required health IT changes.

ACP has long advocated for promoting and adopting FHIR standards and using standard API functionality to promote interoperability and believes the proposed model should incorporate these technologies to enhance interoperability. Additionally, collaboration and agreement across the health care industry on the standards to use and how they should be implemented are essential elements to drive improvements in interoperability and allow disparate health IT systems to communicate effectively. As the interoperable infrastructure expands, ACP recommends implementing these interoperability efforts (including standards, implementation guides, and certification criteria) in stages so the effects on patient care, privacy, security, clinical workflow, and data visualization and interpretation are assessed and mitigated.

To reduce clinician burden and improve usability, health IT developers, particularly those who develop EHRs, must comply with requirements for user-centered design and the science of usability. In addition to improved physician-EHR user interfaces and more uniform information presentations, another critically important element of health IT usability is whether the system is clinically useful. Clinicians need new tools within their EHR, including workflow support, data visualization tools, and shared decision-making tools that leverage existing data within the EHR and remove the need to click through numerous pages and templates to find truly useful and actionable data. Vendors should be strongly encouraged to partner with cognitive and memory scientists to improve this functionality, as other industries have done. Screen views and data management are all enhanced by implementing knowledge available on human-computer visualization and memory methodology. The College insists that any health IT and data sharing required for this model adhere to these burden reduction and usability recommendations.

Expand Colorectal Cancer Screening

CMS proposes to remove coverage of barium enema for colorectal cancer screening. The justification for this comes from scientific evidence and professional guidelines that recommend other, more modern techniques for screening patients for colorectal cancer. ACP guidelines align with this rationale, and we support CMS's coverage proposal to remove barium enema for colorectal cancer screening.

Requirements for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan

CMS proposes that prescriptions written for a beneficiary in a long-term care (LTC) facility would not be included in determining compliance with the EPCS Program requirements until January 1, 2028, and that compliance actions against prescribers would commence on or after January 1, 2028. ACP supports these proposals and thanks CMS for making this change to ease concerns about implementing the new NCPDP SCRIPT standard in LTC facilities. As CMS acknowledges, delaying the inclusion of prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities in the CMS EPCS Program

compliance threshold calculation from January 1, 2025, to January 1, 2028, would align EPCS Program compliance calculations to the date by which the NCPDP SCRIPT standard version 2017071 is retired and the new NCPDP SCRIPT standard version 2023011 is required for prescribers when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, thereby reducing potential compliance challenges due to misaligned timelines.

CY 2025 Updates to the Quality Payment Program (QPP)

ACP supports CMS's cohesive approach toward transforming the QPP. ACP is encouraged to see CMS continue to move forward with the Universal Foundation initiative in this proposed rule. While ACP has previously outlined flaws in some of the Universal Foundation measures, ACP agrees that smaller core measure sets are needed across the most common clinical conditions with the greatest impact on health outcomes. ACP believes this approach will go a long way toward streamlining reporting across public and private payer programs and, more importantly, easing the burden of measurement leading to burnout across the physician community.

MIPS Value Pathways Development and Maintenance

ACP is pleased to see the development of new MVPs and important modifications to the maintenance process. CMS notes that if these six additional MVPs are finalized, 80% of specialties participating in the program would have applicable MVPs to report. ACP cautions that although broad MVPs are covering a specialty, e.g., gastroenterology, there are physicians who further subspecialize and to whom some or many of the measures may still not apply. CMS must work directly with the specialty groups and invested interested parties to ensure that MVPs are relevant to the practicing physicians and their patients.

As noted in ACP's comments from last year, ACP was disappointed to learn that CMS proposed consolidating the measures in Promoting Wellness and Optimizing Chronic Disease Management MVPs into a Value in Primary Care MVP through the 2024 proposed rule. As indicated, this modification was not included in the public-facing webinar. ACP appreciates the additional outreach opportunities being considered and believes that one webinar is insufficient for sharing proposed updates with the MVPs.

MVP Scoring

<u>Prepaid Shared Savings and Health Equity Benchmark</u>

ACP acknowledges CMS's efforts in proposing the new "prepaid shared savings" option and the Health Equity Benchmark Adjustment (HEBA) to incentivize ACOs to serve more beneficiaries from underserved communities. However, ACP recommends that CMS consider revising the allocation of prepaid shared savings. Instead of the proposed 50% to be spent on direct beneficiary services, ACP encourages CMS to allocate some of these funds directly to support primary care. Primary care is the cornerstone of health care and is crucial in improving beneficiaries' health outcomes, including those in underserved communities. By investing in primary care, ACOs can enhance preventive care, manage chronic conditions more effectively, and reduce health disparities.

ACP supports the idea of ACOs partnering with community partners to address the health-related social needs of their population. However, ACP also emphasizes the importance of strengthening primary care

infrastructure to achieve sustainable improvements in health equity. Therefore, we recommend that CMS revise the prepaid shared savings allocation to ensure a more significant investment in primary care. This approach would address immediate beneficiary needs and contribute to the long-term sustainability and effectiveness of the ACO model.

MIPS Performance Category Measures and Activities

Quality Performance Category

ACP supports the 75% data completeness threshold but encourages consideration for smaller practices. We also commend the RFIs on CAHPS survey expansion and PROMs/PRO-PMs development, emphasizing the need for patient-centered measures.

Cost Performance Category

ACP supports adding new episode-based measures and the 20-episode case minimum while encouraging CMS to monitor administrative burdens. We also support the criteria for removing outdated cost measures.

Improvement Activities Performance Category

ACP appreciates the updates to improvement activities but urges CMS to provide clear rationale for activity removals and consider their impact on clinical practice. We support changes to reporting and scoring but recommend careful evaluation of their effects.

Table Group A: New MIPS Quality Measures Proposed for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

Adult COVID-19 Vaccination Status

Developing preventive measures that support current evidence-based vaccinations is critically important, particularly for primary care physicians. A strong recommendation from a trusted clinician is one of the most effective strategies to increase vaccine uptake. It is important for everyone eligible, especially those at higher risk, to receive the up-to-date COVID-19 vaccination as recommended by the CDC.

However, developing and subsequently implementing a performance measure addressing COVID-19 vaccination rates is premature. Holding a clinician accountable for COVID-19 vaccination rates is troubling, given the well-documented vaccine hesitancy throughout the U.S., particularly among communities of color and in rural areas. Some patients already lack trust in the health care system, and forcing physicians to press for vaccine acceptance puts undue strain on the patient-physician relationship. There are also valid patient concerns, e.g., the long-term impact of an mRNA vaccine on children. Additionally, the battle against misinformation is arduous, given the widespread popularity of social media. Patients receive information from these sites, which can be more convincing than science-based advice from their primary care physician. While it is the primary care physician's responsibility to combat misinformation, a physician cannot force a patient to get the vaccine.

Measurement programs, particularly the MIPS program, include static measures, making it impossible to modify a measure as soon as new evidence becomes available. Although the numerator defines up-to-date as determined by the CDC recommendations, this definition cannot account for changing recommendations nor the patient's willingness to get a booster, which was the CDC's recommendation for the fall of 2023/winter of 2024.

A vaccine measure with such variability across patient populations needs to be risk-adjusted to account for the geographic and racial/ethnic disparities, or it will lead to misclassifications of a clinician's performance. 2022 CDC COVID-19 vaccination statistics show that only eight states with 25% or higher of residents have proper vaccination. If a state with extremely low COVID-19 vaccination rates improves, its score would still reflect poorly compared to the national mean score.

Furthermore, ACP is concerned that the measure has yet to be tested. ACP cannot support a measure that has yet to demonstrate its reliability and validity at all levels for which it is implemented. These concerns are highlighted in this proposed rule regarding MIPS measure #492, Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure. CMS states, "In order for this measure to be available at the individual clinician level, the measure would need to be tested at the individual clinician level to establish validity, reliability, and risk adjustments at the individual clinician level. It is not appropriate for the measure to be available at the individual clinician level without further testing. Consequently, any assessment of data for this measure at the individual clinician level would produce invalid and unreliable results."

ACP does not support this measure and urges you to reconsider including this performance measure in a federal program.

Table Group D: Proposed Substantive Changes to Previously Finalized MIPS Quality Measures for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

Quality #492: Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure

ACP fully supports the substantive change to this administrative claims measure. ACP is pleased to see CMS acknowledge that this measure's application at the individual clinician level could result in invalid and unreliable results, given that it has not been tested. As noted above regarding the Adult COVID-19 Vaccination Status measure, ACP cannot support a measure that has yet to demonstrate its reliability and validity at all levels for which it is implemented.

RFI Questions

Compared with medical health IT systems, public health IT systems often lack the functionalities needed for interoperability and real-time data sharing. To improve public health, ACP strongly supports the development of a modern national public health data infrastructure capable of real-time bidirectional data sharing among public health departments, physicians, hospitals, laboratories, and others. The federal government should develop common data collection and reporting standards to achieve interoperability and advance health equity. Efforts to allow information sharing among health care and public health entities should include strong patient privacy and confidentiality protections and establish clear, understandable, adaptable, and enforceable rules for data use. ACP has also recommended that

lawmakers provide relevant federal agencies the authority to require mandatory laboratory and health care data reporting.

In previous comments to the CDC, the College emphasized that unless public authorities are compelled to coordinate and simplify reporting requirements, physicians and other clinicians are guaranteed undue complexity and expense. ACP urged that the definition of "active engagement" must be expanded to require that all public health data exchanges be bidirectional. Otherwise, these reporting measures demonstrate clerical data entry rather than improvements in health. Patients and their physicians will benefit from requirements that public health agencies report back promptly and with meaningful data, such as intelligence about what is happening in the community. We reiterate these positions in the context of this RFI.

In past comments to CMS and ASTP/ONC, ACP noted that a typical medical practice might be required to report in multiple states using entirely different technologies, standards, and processes, leading to unacceptably high costs and burdens. The College recommended that the burden must be placed upon the public health community to develop a single reporting hub where all reports for all purposes are submitted using the same technologies, standards, and processes. Significant costs and effort could be saved by requiring that reporting entities work together to simplify the reporting burden, which could be accomplished by developing a standard Application Programming Interface (API) for all public health, quality, and registry reporting.

ACP has also advocated that EHRs be configurable to share data seamlessly with public entities. For physicians, this would mean a more effective, less burdensome way to report and no duplicative reporting where different interfaces must be created and managed for each use. The burden should be on public health authorities to present health care delivery organizations with a single target for all data reporting. This could be delivered as a single national portal/registry or local/regional entities such as health information exchanges supporting common data and process standards for all reporting by clinicians and data query/collection by public health authorities.

Additionally, the College reiterates that public health agencies would benefit from reevaluating their data needs. When public health agencies require data from practices and hospitals, they usually require that the data elements be defined, structured, and formatted differently from how the data are collected while delivering clinical care. This means that reporting clinicians must manipulate the data in ways that decrease the accuracy and value of the data elements. Public health agencies believe they receive data that matches their intentions, but this is often not the case. The data that public health agencies typically receive may be so distorted by the conversion or double-entry processes that they will not serve public health purposes. Rather than forcing data collectors to enter duplicative data to match public health specifications manually, public health should redesign its processes to accept and use the clinical data in the form and structure that they are routinely collected by clinicians during the care delivery processes.

MIPS Final Scoring Methodology

Scoring the Quality Performance Category

ACP supports the removal of the 7-point score cap for topped-out measures in specialty sets, which should provide fairer scoring for clinicians with limited measure options. We also support the Complex Organization Adjustment for virtual groups and APM Entities, recognizing it as a necessary step to accommodate these organizations' unique challenges.

Scoring the Cost Performance Category

ACP approves the proposed cost performance scoring methodology changes, including the new cost measure exclusion policy, which will help prevent unfair penalization. Using a 75-point performance threshold based on historical scores is a balanced approach, but we emphasize the need for CMS to offer robust support for physicians adapting to these updates.

MIPS Payment Adjustments

ACP appreciates CMS's decision to maintain the performance threshold at 75% for CY 2025. Maintaining this threshold provides stability and predictability for clinicians participating in the MIPS program, allowing them to adequately prepare and align their practices with the program's expectations. ACP is pleased that the data completeness threshold will remain at 75% until 2028.

Advanced APM Proposals

Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs Request for Information

ACP offers the following comments in response to the "Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs" RFI.

Several previous reports were developed by the National Quality Forum (NQF) with financial support from CMS. These reports described guiding principles when selecting PROMs as well as attributes of high-quality PROMs for inclusion in performance measurement, noted below for easy reference. ACP believes the 2013 report was foundational to understanding PROMs and PRO-PMs and that the guiding principles remain relevant today. The 2021 report describes attributes that are methodologically sound and critical to developing PRO-PMs.

Guiding Principles: Psychometric Soundness, Person-Centered, Meaningful, Amenable to Change, Implementable

Attributes

1. *Covers desired PROs from patient and/or caregiver perspective*
2. *Outcome measured in PROM is result of care for which relevant clinical quality is being measured*
3. *Interpretable scores, defined and actionable cut points or targets, and anchors and/or defined meaningful change*
4. *Clear conceptual and measurement models*
5. *Psychometric Soundness: Reliability*

6. *Psychometric Soundness: Validity*
7. *Psychometric Soundness: Responsiveness*
8. *Usability/Feasibility of Use: Low burden (e.g., length, time/effort to complete) and feasibility*
9. *Usability/Feasibility of Use: Fits with standard of care and related workflows (e.g., actionable, incorporated, and discussed at point of care)*
10. *Usability/Feasibility of Use: Cultural appropriateness, Language, Translated with culturally appropriate items*
11. *Usability/Feasibility of Use: Availability of standardized clinical terminology and codes*
12. *Usability/Feasibility of Use: Guidance on standardized data collection (including modes and methods)*

As noted in those reports and alluded to in this RFI, a PROM is distinct from a PRO-PM. A PROM is an instrument or tool to evaluate a PRO (e.g., PHQ-9 evaluates depressive symptoms and severity). However, a PRO-PM assesses the degree to which a patient's PROM score indicates better quality of care for the accountable entity.

We believe leveraging the NQF work completed in 2013 and 2021 is important, as described above. These reports detail what characteristics are necessary for a PROM to be included in a PRO-PM. While PROM selection for PRO-PMs has been studied and described, ACP has identified a significant lack of guidance regarding principles for PRO-PMs. As a result, it would be most useful to refer to the essential considerations for PROMs from previous reports. ACP urges CMS to focus its efforts on addressing the gap regarding the principles for developing PRO-PMs and considerations for including PRO-PMs in CMS programs.

As the consensus-based entity, the Partnership for Quality Measurement has emphasized that clinical quality measures derived from instruments or surveys must be **specified and tested** at the accountable entity level (e.g. clinician or facility). We strongly support that requirement. However, ACP believes additional factors unique to PRO-PMs must be considered before implementation.

- Data are needed to demonstrate that the PRO-PM can improve the quality of care and is an effective tool to accurately compare performance across the accountable entity level.
- Empirical evidence is needed to demonstrate a relationship between a patient-reported outcome (PRO) and at least one health care structure, process, intervention, or service that is actionable by the accountable entity.
- Risk adjustment is necessary to account for patient and population characteristics proven to affect outcomes independent of treatment. Patient factors selected for inclusion in risk-adjustment models should be evidence-based and specific to the PRO concept.
- The data collection process needs to be feasible, low burden, and have minimal impact on existing workflow.

Regarding the other questions in the RFI, ACP strongly believes PRO-PM development needs to be as rigorous as any other type of measure development, if not more. As a result, we do not see a way to accelerate PRO-PM development for them to be more readily included in CMS programs.

A substantial number of PROMs are available, both general and disease-specific. Assuming the PROM meets the attributes referenced in NQF's 2021 report, we would encourage using existing PROMs instead of creating new ones. As for the developing PRO-PMs that include either 1) general or 2)

disease-specific PROMs, we acknowledge there are different schools of thought. Nevertheless, ACP supports the use of disease-specific tools. Furthermore, we prefer performance measures that allow for a variety of tools rather than performance measures that require the use of one tool. PROMs can vary by age, focus of interest (e.g., functioning, health-related quality of life) and other factors with advantages and disadvantages to each instrument. As a result, clinicians should be able to use a validated PROM that is applicable to their patient population and based on their clinical judgment.

Conclusion

Thank you for this opportunity to comment on CMS's notice of proposed rulemaking regarding changes to the Medicare Physician Fee Schedule, Quality Payment Program, and other federal programs for CY25 and beyond. ACP is confident these recommended changes would improve the strength of these proposals and help promote access to affordable and equitable care for Medicare patients, while supporting physicians in their ability to deliver innovative care and protecting the integrity of the Medicare trust funds. The College appreciates the opportunity to offer our feedback and looks forward to continuing to work with the agency to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Ph.D., Director, Regulatory Affairs for the American College of Physicians, at boutland@acponline.org or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,

Leslie Algase, MD, FACP
Chair, Medical Practice and Quality Committee
American College of Physicians