

james.madara@ama-assn.org

September 5, 2024

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services Hubert H. Humphrey Building, Room 445–G 200 Independence Avenue, SW Washington, DC 20201

Re: File Code CMS-1807-P. 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 Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2025 Notice of Proposed Rulemaking (Proposed Rule) on the revisions to Medicare payment policies under the Medicare Physician Payment Schedule (MPFS) and Quality Payment Program (QPP), published in the *Federal Register* on July 31, 2024.

As CMS continues to navigate the complexities of health care policy, it is important to first address our growing concerns about the sustainability of Medicare payment and the costly, flawed structure of incentive programs like the Merit-based Incentive Payment System (MIPS).

CMS Needs to Reckon with the Impact of Declining Medicare Physician Payment

CMS proposes a 2.8 percent cut to Medicare physician payments starting January 1, 2025, while estimating that the costs of practicing medicine, as measured by the Medicare Economic Index (MEI), will increase by 3.6 percent. In other words, while the costs of paying clinical and administrative staff, rent, and purchasing equipment and supplies are projected to rise by 3.6 percent, physicians' payments will decrease by nearly three percent. Yet, this proposed rule is silent on the impact of the growing gap between what Medicare pays for care and what it costs to provide that care. A chorus of authorities on the Medicare program has expressed concern about the ability of patients to continue receiving high-quality care as physician payments erode.

CMS must be fully transparent with the public about the impact of these payment cuts by including the expiration of temporary statutory increases to the conversion factor in the specialty impact table. If those cuts affect the conversion factor, they will also affect specialists' payment rates. We urge the Biden-Harris Administration to work with Congress enact a permanent, annual inflation-based update to Medicare physician payments.

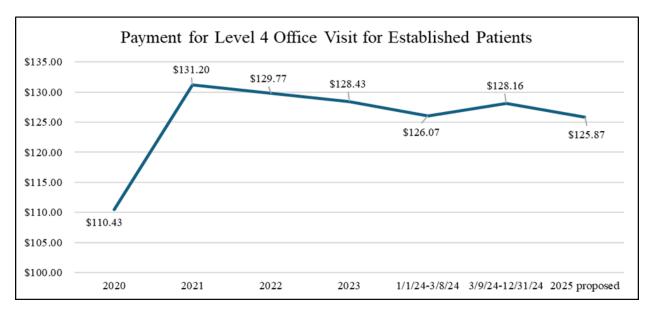
The Medicare Trustees and the Medicare Payment Advisory Commission (MedPAC) have issued warnings about beneficiaries losing access to high-quality care due to insufficient Medicare physician payment. In their 2024 report, the Medicare Trustees again reiterated their concern that, without Congressional action to change the delivery system or level of payment update, "the trustees expect access to Medicare participating physicians to become a significant issue in the long-term." In the June 2024 Report to Congress, MedPAC specifically addresses the gap between the costs of providing care and Medicare payment and states, "[t]his larger gap could create incentives for clinicians to reduce the number of Medicare beneficiaries they treat or stop participating in Medicare entirely." MedPAC also expressed concern about how the lack of an inflation-based update for physician payment is exacerbating the site of service differential, which distorts competition and could increase vertical consolidation, increasing spending by the Medicare program, patients, and taxpayers. As a result, organized medicine is strongly supporting the swift passage of H.R. 2474, the "Strengthening Medicare for Patients and Providers Act," bipartisan legislation that would provide an annual physician payment update in Medicare tied to the MEI.

The impact of payment cuts on physician practices is being felt across the country as discussed in the quotes below from practicing physicians:

- "Emergency rooms are seeing this crisis in a very specific and targeted way," said an emergency medicine physician from Ohio. "What we're seeing is more patients coming to the emergency department because they can't access care [for (sic)] their primary doctor or their specialist physicians, who either can [no] longer cover Medicare patients because of decreasing reimbursement or have reduced hours or services because of Medicare reimbursement... we're not necessarily the best place to provide ongoing primary care or to make medication adjustments or things that really patients should be seeing their primary or specialist physician for."
- "Since many of the insurance products that we take in our office are indexed off of Medicare, every time Medicare cuts payment, since they're indexed off of Medicare, their payment is cut as well," said a family medicine physician in Virginia. "So it's not like Medicare will cut their payment and everybody else will stay the same and we'll be able to balance it. When Medicare goes down, everything goes down."
- A general surgeon from Oregon told the AMA that "[a]s a private practice surgeon, I'm a small business owner, so ongoing Medicare cuts have forced me to spend less time with the patients ... whom I want to take care."

Moreover, cuts to Medicare physician payment impede the Biden-Harris Administration's policy priorities. The Biden-Harris Administration has prioritized ending cancer as we know it through the Cancer Moonshot. Yet in 2024, payment for a bilateral screening mammography, which is a diagnostic test that screens for breast cancer and is recommended every other year for women between the ages of 40 and 74, dropped 2.5 percent compared to 2023. Multiple agencies across the U.S. Department of Health and Human Services (HHS) have committed to strengthening primary care. Yet in 2024, payment for an office visit with an established patient needing a moderate level of medical decision-making fell 0.7 percent and would fall 4.1 percent below the 2021 payment rate in 2025 after several consecutive years of cuts (see table below). The Biden-Harris Administration has stood up a whole-of-government initiative to improve maternal health. Yet in 2024, the bundled payment for obstetrical care throughout the prenatal, childbirth, and postpartum period was cut 0.6 percent compared to 2023. While Medicaid, not Medicare, is the single largest payer of maternity care in the U.S., Medicaid payments are typically a percentage of Medicare and according to the American College of Obstetricians and Gynecologists, the rates are on

average only 82 percent of Medicare payment. In other words, a cut to Medicare payment for maternity care is a cut to the already low Medicaid maternity care payment.



Looking ahead to 2025, payment for all services provided by physicians and qualified health care professionals to America's seniors and persons with disabilities will be cut 2.8 percent. Services aimed at increasing access for behavioral health care and improving suicide prevention will be cut by 2.8 percent. Services for connecting patients with health-related social needs to community-based resources and care coordination services for Medicare patients who are transitioning out of the hospital or who have multiple chronic conditions will be cut 2.8 percent. Services to improve and preserve patients' eyesight, including surgery for patients losing their vision, will be cut 2.8 percent. The 2025 cuts compound across-the-board cuts in 2021, 2022, 2023, and 2024, AND are not sustainable for physicians and their patients, and risk jeopardizing the Administration's priorities and access to critical services.

President Biden has said, "[d]on't tell me what you value, show me your budget, and I'll tell you what you value." CMS' statements in this rule about prioritizing behavioral health, advanced primary care, health equity, and cancer prevention are at odds with the proposed Medicare payment rates that would cut physician payment nearly three percent next year. We strongly urge CMS to acknowledge the negative effects of the proposed payment cut on Medicare beneficiaries in the final rule and the Biden-Harris Administration to support any congressional action to replace the cut with a positive update.

Importance of Collaboration Between CMS and the CPT Editorial Panel to Achieve Shared Goals

The AMA is concerned with the growing number of requested revisions and clarifications to newly created Current Procedural Terminology (CPT®) codes. These concerns are most notably seen in two sections: Skin Cell Suspension Autograft and Transcranial Doppler Studies. Additionally, the significant increase in the number of proposed HCPCS Level II (or "G") codes creates a considerable administrative burden for physicians and other qualified health care professionals who report medical services to both Medicare and commercial payers.

For decades, the CPT Editorial Panel process has prided itself on bringing all interested parties to the table to discuss complex coding issues openly and transparently. The Panel process relies on the expertise

and input of practicing physicians and other health professionals. For each of those years, CMS has sat at the table. The collaboration we have received from the Agency has been greatly valued by the AMA and the House of Medicine, as it has allowed us to make important decisions in a timely manner to affect significant shifts in the way medical services are provided.

Furthermore, it was this model of transparency that allowed the CPT Editorial Panel to appoint two new seats for representatives from the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). The CPT Editorial Panel process is structured so that every health care interested party group (including the national medical specialty societies, federal agencies, commercial payers, and industry representatives) has an opportunity to provide iterative review and comment on code change applications.

This was most notably demonstrated in the successful collaboration efforts the CPT Editorial Panel received during the evaluation and management (E/M) revisions implemented in 2021 and 2023. The impetus for these landmark changes was a proposal put forward by CMS in the 2019 MPFS Proposed Rule. Recognizing the significance of these changes, the AMA requested that CMS work with the CPT Editorial Panel to enact a complete restructuring of the CPT E/M code section. With CMS agreeing to participate in the initiative, the AMA led a consensus-driven, open, and transparent workgroup process to ensure that the reimagined approach to office visits reflected input from the broad array of medical specialties that perform these visits. The workgroup was comprised of members with experience on both the CPT Editorial Panel and the AMA/Specialty Society RVS Update Committee (RUC). Additionally, the process engaged participants from diverse medical specialties, including primary care, several surgical specialties, private payers, and qualified health care professionals. The workgroup held numerous open conference calls, where on average, more than 300 individuals participated to provide direct input.

This model of success is what precipitates the AMA's concern with several issues outlined in the proposed rule. At each CPT Editorial Panel meeting, AMA staff allow ample opportunity for CMS officials to comment directly on the active proposals under review by the Panel. This iterative, collaborative model was designed to allow the Agency flexibility to submit comments, which we understand can be complex given CMS' size and scope. It is during this transparent process that comments should be received, and issues addressed.

The AMA also notes, with concern, the increase in proposed G-codes in this proposed rule. In some instances, these proposed codes duplicate existing CPT codes, potentially leading to confusion and increased administrative burden. Specifically, we believe existing CPT codes may be reported for tympanostomy services and caregiver training.

CMS is considering an add-on payment for tympanostomy using CPT code 69433 (Tympanostomy [requiring insertion of ventilating tube], local or topical anesthesia) as a crosswalk, along with industry-provided invoices to determine the device costs. However, this proposal overlooks the existing CPT Category III code 0583T (Insertion of tympanic ventilation device into the tympanic membrane under local or topical anesthesia with iontophoresis and automated insertion) which already covers automated tube delivery systems with iontophoresis anesthesia.

Additionally, CMS is proposing to establish new coding and payment for caregiver behavior management and modification training that could be provided to the caregiver(s) of an individual patient. CPT codes already exist for several different caregiver training services: training for patient self-management (98960-98962), training in strategies and techniques to facilitate the patient's functional performance (97550-97552) and multiple-family group behavior management/modification training (96202, 96203).

In both instances, CMS should avoid creating duplicate G-codes and instead first utilize the existing CPT codes to describe these services. If CMS has specific programmatic needs for separate codes, the most productive approach to address these concerns is to work directly with the AMA and the CPT Editorial Panel to consider revisions to the existing codes or new CPT codes altogether.

For all of these reasons, we strongly encourage CMS to continue collaborating with the CPT Editorial Panel through their transparent review process. We believe this approach benefits all interested parties by allowing them to engage during the CPT Editorial Panel's adoption phase, rather than at the CMS rulemaking stage. Our shared history of successful collaborations has significantly improved the quality of our work and the impact of our decisions.

MIPS Problems Require Wholesale Solutions

Physicians participating in the MIPS program face penalties that can cut their Medicare payment by as much as negative nine percent. Yet, research shows that the program is about as good as random chance at identifying high quality care; disproportionately penalizes small, rural, and independent practices; and exacerbates health inequities. The cost measures hurt specialists whose patients incur higher spending when they receive evidence-based care, like oncologists, and the inadequate number of specialty-specific quality measures artificially limits the scoring potential of specialists whose services are vital to diagnostic accuracy, such as radiologists and pathologists, among others. While Congress recognized the importance of timely feedback to physicians participating in MIPS, CMS does not provide initial performance feedback for six to 18 months after the performance is measured, when the physicians are already well into the subsequent measurement year and have no opportunity to modify their performance on the measures. Without timely feedback, MIPS cannot work as intended because physicians need data to monitor their ongoing performance and identify gaps or variations in care that can be addressed to improve quality of care and reduce avoidable costs.

We appreciate that CMS proposes a couple of policies that have the potential to improve MIPS, such as changing the cost measure scoring methodology to increase physicians' final scores. However, this proposed rule does not resolve many of the root causes of the problems in the MIPS program as they require statutory remedies. To fix these problems, the AMA, all 50 state medical associations, the District of Columbia, and 76 national medical specialty societies are <u>calling on</u> Congress to replace key elements of MIPS with a new Data-Driven Performance Payment System (DPPS) that:

- Freezes performance thresholds for three years to allow recovery from the COVID-19 Public Health Emergency (PHE) and Change Healthcare cyberattack.
- Eliminates the current tournament model and replaces corresponding payment penalties of up to nine percent with payment adjustments assessed as a percentage of statutorily mandated payment updates (i.e., 0.25 percent or MEI).
- Ensures CMS provides quarterly feedback reports by holding physicians harmless from penalties should the Agency fail to provide this data.
- Aligns program requirements with other CMS hospital value-based programs, simplifies reporting by allowing cross category credit, and enhances measurement accuracy.

The following table compares the status quo under MIPS with organized medicine's proposed reforms in the DPPS discussion draft.

	MIPS	Data-Driven Performance Payment System (DPPS)	
Performance threshold	The performance threshold is set at the mean or median. Physicians who score between zero points and the performance threshold are penalized, while physicians who score between the performance threshold and 100 points receive a bonus. In 2024, the performance threshold is 75 points.	Congress would freeze the performance threshold at 60 points for the 2025, 2026, and 2027 performance periods while physicians recover from the COVID-19 PHE, Change Healthcare cyberattack, and CMS implements legislative improvements to the program. This is consistent with the 2021 performance threshold, which was set based on the transitional policies of MIPS and should continue to apply as the program remains in flux following a five-year interruption due to COVID-19 and subsequent disruption by the cyberattack. There is an option for the Secretary to extend the performance threshold freeze at 60 points beyond the 2027 performance period. For the 2028, 2029, and 2030 performance periods (or, if the Secretary extends the period of the freeze at 60 points, for the three years following the last year of such extension), the Secretary shall gradually and incrementally increase the threshold before transitioning to the mean or median.	
Threshold reform	Not applicable	Government Accounting Office (GAO) must submit a report to Congress and the HHS Secretary in consultation with physician organizations by the end of 2029 which includes detailed recommendations for establishing a replacement performance threshold. If legislation is not enacted to establish a replacement performance threshold within three years from the date of the enactment of the DPPS Act, the Secretary is required to promulgate final	
Payment adjustments	MIPS adjusts physicians' Medicare payments upward or downward by extremely wide margins, ranging from -9% to a hypothetical +27%. Under MACRA, MIPS payment adjustments apply to the physicians' paid amount. For example, in 2024, we understand the maximum increase is 8.25% and the maximum decrease is -9%,	regulations establishing a replacement performance threshold based on the GAO recommendations. While budget neutrality would be preserved, DPPS would repeal the tournament model. Instead, payment adjustments would be applied as a percentage to the annual payment update (e.g., 0.25% beginning in 2026 under current law or the increase in MEI under HR 2474). The payment adjustments would apply as follows: • Physicians who score above the performance threshold would receive an increase of one-quarter of the update. • Physicians who score at the performance threshold would receive the annual update.	

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	which apply on top of the conversion factor cuts that stem largely from budget neutrality requirements.	 Physicians who participate but receive a score below the threshold receive a penalty equivalent to one-quarter of the update. Physicians who do not participate would receive a penalty equivalent to one-half of the update. A floor of zero would prevent DPPS payment adjustments from imposing negative updates. The adjustment would not be applied in a year for which the update to the conversion factor is negative.
		These updates are for one year only.
		To illustrate, if physicians will receive an update tied to inflation in 2027 and the update is 2%. Physicians who score above the performance threshold would receive 2.5%. Physicians who score at the performance threshold would receive a 2% update. Physicians who participate in MIPS but score below the threshold would receive a 1.5% update. Physicians who do not submit any MIPS data would receive a 1% update. All physicians would receive a positive update unlike under current law.
		As another example, under current law, the update in 2027 is 0.25%. Physicians who score above the performance threshold would receive a 0.3125% update. Physicians who score at the performance threshold would receive a 0.25% update. Physicians who participate in MIPS but score below the update would receive a 0.1875% update. Physicians who do not submit any MIPS data would receive a 0.125% update. All physicians would receive a positive update unlike under current law.
		Finally, in this example, under current law the update in 2025 is 0%. In this scenario, all physicians would receive a 0% update regardless of their performance in MIPS.
Improvement Fund	Bonuses are paid based exclusively on MIPS performance. The Small, Underserved, and Rural Support technical assistance program ended in 2022 due to	DPPS penalties would fund bonuses to MIPS participants that perform well in DPPS, as well as a new fund for improvement and investments in value-based care, such as data analytic capabilities. CMS would make grants to small, rural, underserved practices and practices with low

	lack of funding. It had previously provided support for small practices (fewer than 15 clinicians) and practices in rural locations, health professional shortage areas, or medically underserved areas.	composite scores for these value-based care funds. Importantly, these investments would also help practices transition to APMs.
Timely and Actionable Feedback and Data	Despite statutory requirements that CMS provide timely MIPS and claims data, physicians received their most recent MIPS Feedback Report, based on 2022 performance, in August 2023. No physician in MIPS has ever received Medicare claims data similar to what Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) receive, which includes Medicare Parts A, B, and D claims data for their assigned beneficiaries.	Physicians who do not receive quarterly feedback reports on administrative claims-based quality and cost measures would be exempt from any DPPS penalty (i.e., any amount below the annual update).
	Physicians do not know in real time or even on a quarterly basis which cost measures are being attributed to them, which patients are being assigned to them, and what costs outside of their practice they are being held accountable for until well after the performance year is already over, making it impossible for them to leverage this data to implement changes that would improve patient care, outcomes, and use resources more efficiently, saving costs.	
Multi- category credit	MIPS performance is measured across four categories – quality, improvement activities, promoting interoperability (health IT use), and cost. Each category has disparate measures, scoring rules, and attribution methods. CMS has	CMS would be required to give automatic credit in each applicable performance category for a measure or activity that satisfies multiple performance category requirements as determined via rulemaking. If a MIPS eligible professional does not report on such a measure or activity for a performance category and automatic application of the measure for that performance category would

	informed the AMA that their Office of General Counsel interprets the statute as requiring data submissions in each category, thus preventing automatic or seamless multi- category credit.	result in a lower performance score for the professional, then the Secretary would not automatically apply such measure or activity for that performance category.
Expansion of Facility-based Scoring	Certain MIPS eligible clinicians receive their facility's Hospital Value-Based Purchasing (VBP) Program score for the quality and cost categories without submitting any additional quality measures. To qualify, physicians must furnish 75% or more of their services in a hospital setting (POS codes 21, 22, or 23), bill at least one service in an inpatient hospital or emergency department, and their facility participates in the VBP Program. For groups, 75% of the clinicians billing under the tax identification number (TIN) must meet the definition of facility-based.	This bill would allow the Secretary to expand the existing facility-based scoring option by applying scores from hospital outpatient department and other care setting value-based payment programs to all four DPPS categories. Further, CMS would expand the facility-based scoring option to physicians who furnish 50% of their services in facility settings other than the hospital, including ASCs, inpatient psychiatric facilities, and SNFs. Similarly, for groups, 50% of clinicians in the group must meet the definition of facility-based.
Clinical data registries and innovative health IT	Despite clinical data registries' proven ability to meaningfully improve patient care and numerous statutory obligations to promote and incentivize the use of clinical data registries, CMS has created numerous obstacles for clinical data registries to succeed within the program and has limited the ability of physicians to leverage their participation in these quality improvement efforts for MIPS. Further, highly prescriptive measures in the PI (health IT) category restrict the program's ability to grow with new technological innovations that drive the industry forward.	CMS would be required to treat physicians who attest to reporting quality measures via clinical data registries as automatically satisfying the requirements of the Promoting Interoperability and Improvement Activities categories. Further, the requirements for the Promoting Interoperability category would be met via "yes/no" attestation of using certified electronic health record technology (CEHRT) or interacting technology products, participation in a clinical data registry, or other less burdensome means.

Cost	CMS continues to use Total	By aliminating the requirement that CMC must			
Cost CMS continues to use Total Per Capita Cost (TPCC)		By eliminating the requirement that CMS must account for at least one-half of all Parts A and B			
lileasures	- '	expenditures with its cost measures and affording			
	measure that holds physicians accountable for costs outside of	_			
		CMS the ability to test new cost measures, CMS			
	their control. Additionally,	could significantly improve the cost category by			
	CMS develops new episode-	developing and validating measures that have a			
	based cost measures around	potential high impact for change at the physician			
	costly Medicare conditions	level. In addition, the requirement to measure total			
	despite concerns about access	Parts A and B costs would be eliminated.			
	to care (e.g., psychoses) in				
	order to meet statutorily	Finally, new and substantively revised cost			
	imposed requirements that cost	measures would be informational only for a			
	measures must account for at	minimum of two years. Physicians would receive			
	least one-half of Medicare Part	quarterly feedback reports as required above. CMS			
	A and B expenditures. This	would be required to provide for a public comment			
	forces CMS to develop	period on the measures that allows for MIPS eligible			
	measures based on volume,	professionals who are commenters, as applicable, to			
	rather than based on	take into consideration the information they received			
	opportunities to reduce	during the informational period. Then for the			
	variations in care and produce	measures to be included for assessment and scoring			
	savings in Medicare. Finally,	purposes, CMS would propose the measures for			
	CMS does not have the	inclusion through rulemaking.			
	authority to test new cost				
	measures before they are used				
	to impact physician payment.				
Cost and	MIPS cost and quality	GAO would be required to submit a report to			
quality	measures are not aligned and	Congress and the HHS Secretary within 12 months			
measure	typically do not reflect the	of passage of the bill about whether this program			
alignment	same care provided to the same	incentivizes lower quality to achieve lower costs.			
	patients. Physicians may be	Specifically, the study calls for identification of the			
	penalized for providing	misalignments, gaps, and other potential causes for			
	preventative services, which	such incentives, including that the cost measures are			
	are important for high quality	not aligned with the quality measures (e.g., not			
	care, under the TPCC measure,	corresponding to the same conditions or episodes,			
	which is a blunt summation of	not applying to the same timeframes, not applying to			
	all Medicare Parts A and B	the same physicians, or not applying to the same			
	spending by a beneficiary	panel of patients). GAO would provide			
	during a year. While CMS	recommendations for modifications to eliminate			
	believes MVPs will solve this	these gaps or misalignments and would identify			
	issue, they are merely a	whether the changes require legislation or			
	repackaging of existing	regulation.			
	measures and do not get at the				
	root cause.				
Quality	Investing in new quality	CMS would be required to incentivize reporting of			
measures	measures is extremely costly	new and substantively revised quality measures, as			
	and time-consuming. Worse,	well as quality measures without a benchmark and			
	there are disincentives for	MIPS quality measure collection types that are			
	physicians to use new quality	being used by a physician for the first time, by			

measures in MIPS as they are likely to be scored worse than existing measures with a benchmark. Physicians are inherently taking a risk when reporting any new measure, which hinders the program's ability to continue to grow and adapt into the future.

treating them as pay-for-reporting for three years. In other words, physicians who meet the reporting criteria would automatically receive full credit (e.g., 10 points) for that measure for three years.

CMS Should Not Create a Mandatory New Specialist Alternative Payment Model Based on MIPS Value Pathways

The AMA strongly opposes creating a new pay-for-performance program for specialists based on MIPS Value Pathways (MVPs) and mandating that they participate in that program, as CMS has outlined in its *Building Upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care* Request for Information (RFI). CMS' existing mandatory pay-for-performance program (MIPS), as described above, has created large administrative burdens for physician practices without improving clinical outcomes for patients or reducing Medicare spending. There is no evidence that the approach CMS is considering would have better results. In fact, the AMA believes it is likely to exacerbate health disparities. Instead, the AMA urges CMS to work with specialists to develop and implement condition-specific payment models that provide the resources physicians need to deliver the most effective services to their patients, including underserved patients and those with complex needs. Many alternative payment models already developed by specialty physicians would improve the quality of patient care and reduce Medicare spending if adopted by CMS. The AMA recommends that CMS implement one or more of these models instead of creating yet another mandatory pay-for-performance program.

Furthermore, as discussed in our detailed response to the MVP RFI below, it is essential that CMS first improve MVPs for physicians in MIPS. The AMA has developed an alternative MVP framework, which we call the Condition-Stratified MVP Framework, to address many of the pitfalls of the current CMS approach to MVPs and based on direct conversations with specialty societies and CMS in the winter and spring of 2024, including an MVP Roundtable on February 26, 2024. This alternative framework categorizes quality and cost measures into condition-specific subdivisions within a broader MVP. Physicians who specialize in treating a particular condition would be able to clearly identify the available measures for that condition and register to be held accountable for those condition-specific quality and cost measures within the MVP. By creating MVPs through the proposed framework, CMS and physicians could also more easily identify and remedy gaps in measurement and scoring challenges, such as no or limited condition specific measures or measures without a benchmark. We strongly urge CMS to adopt this alternative framework for MVPs in the final rule.

We thank you for the opportunity to provide input on this Proposed Rule. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,

James L. Madara, MD

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Calendar Year 2025 Physician Payment Schedule and Quality Payment Program Proposed Rule Detailed Comments of the American Medical Association

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I. UPDATES TO PAYMENT PROVISIONS

A. Determination of Practice Expense Relative Value Units (Section II.B.)

Medicare Economic Index and the Physician Practice Information Survey

Recommendation:

• The AMA supports the CMS decision to defer implementation of Medicare Economic Index (MEI) changes and recommends that CMS review the Physician Practice Information (PPI) Survey data before proceeding with any re-weighting.

The AMA appreciates and supports the CMS decision to defer implementation of MEI changes to the distribution of relative value unit components (work, practice expense, and professional liability insurance) within the RBRVS. The AMA agrees that CMS should allow for the review of data from the PPI Survey before implementing re-weighting that would result in significant redistribution within physician payment.

The PPI Survey, which closed on August 31, 2024, collected information on physician and other health care professional compensation, practice costs, and direct patient care hours worked. The AMA will collaborate with Mathematica to analyze the data and plans to share information with CMS in early 2025. The survey is intended to collect information to utilize in a payment system based on relative costs between physician specialties and other health care professionals. Therefore, we must note that the statement in the Proposed Rule that the PPI Survey letter signed by more than 170 national medical specialty societies, health care professional organizations, and all state medical societies might somehow create bias in the survey is inaccurate. It is critical to ensure that individual practices understand that these organizations support the PPI Survey. This letter was consistent with similar endorsement letters distributed with the former PPI Survey and in every AMA Socioeconomic Monitoring Survey that came before the PPI surveys going back to 1981.

High-Cost Disposable Supplies

Recommendation:

• The AMA strongly supports the long-standing RUC recommendation that CMS separately identify and pay for high-cost disposable supplies priced more than \$500 using appropriate Healthcare Common Procedure Coding System (HCPCS) codes. The pricing of these supplies should be based on a transparent process, where items are annually reviewed and updated.

For CY 2025, the RUC considered several high-cost disposable supplies (i.e., priced more than \$500) as part of its recommendations for direct PE inputs for physician services. These new supply inputs included an *iTIND device* with a cost estimate of \$2,695 for Bladder Neck and Prostate Procedures, *RF Electrodes 18 Gauge 70 mm Length* with a cost estimate of \$1,995 for Percutaneous Radiofrequency Ablation of the Thyroid, and the *TULSA-PRO Disposable Kit* with a cost estimate of \$8,967 for MRI-Monitored Transurethral Ultrasound Ablation of Prostate. The AMA continues to call on CMS to separately identify and pay for high-cost disposable supplies. The AMA makes this recommendation to address the outsized impact that high-cost disposable supplies have within the current practice expense RVU methodology.

The 2025 Medicare Physician Payment Schedule includes 86 supply items with a purchase price of more than \$500. These high-cost supplies represent \$1.245 billion dollars in direct costs for 2025 and 19 percent of all practice expense supply costs in the non-facility setting. The current system not only accounts for a large amount of direct practice expense for these supplies but also allocates a large amount of indirect practice expense into the PE RVU for the procedure codes that include these supplies. The practice expense methodology derives code-level indirect practice expense in part from code-level direct practice expense inputs, including high-cost disposable supplies. When CPT codes include a high-cost disposable supply, a larger portion of indirect practice expense is allocated to the subset of practices performing the service, which is subsidized by the broader specialty and all other physicians and qualified health care professionals. If high-cost supplies were paid separately with appropriate HCPCS codes, the disproportionate indirect expense would no longer be associated with that service. The result would be that indirect PE RVUs would be redistributed throughout the entire specialty practice expense pool.

The AMA strongly supports the long-standing RUC recommendation that CMS separately identify and pay for high-cost disposable supplies priced more than \$500 using appropriate Healthcare Common Procedure Coding System (HCPCS) codes. The pricing of these supplies should be based on a transparent process, where items are annually reviewed and updated.

There are several CMS proposals in this proposed rule that support the RUC recommendation to separately code and pay for high-cost disposable supplies. We urge CMS to consider the RUC's broader proposal as you consider these issues. Q codes, as already established for casting supplies and skin substitutes, would be more appropriate than G codes describing physician services.

GMEM1 / CardioMEMSTM Patient Electronics System (smart pillow)

Recommendation:

• The AMA urges CMS to treat the 86 high-cost medical supply items in an equivalent manner. All high-cost supplies should be reported with a Q code, reviewed and priced annually, and not impact the practice expense relative values.

CMS proposes a new HCPCS code GMEM1 Provision of replacement patient electronics system (for example, system pillow) for home pulmonary artery pressure monitoring including provision of materials for use in the home and reporting of test results to physician or qualified health care professional to report the provision of a replacement pillow or additional pillow from the one already provided in the system, which is captured in the Outpatient Prospective Payment System (OPPS) payment for CPT code 33289 Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed. The AMA urges CMS to treat the 86 high-cost medical supply items in an equivalent manner. All high-cost supplies should be reported with a Q code, reviewed and priced annually, and not impact the practice expense relative values.

Tympanostomy

Recommendation:

• The AMA urges CMS to treat the other 86 high-cost supply items in an equivalent manner. All high-cost supplies should be reported with a Q code, reviewed, and priced annually and not impact the RBRVS practice expense relative values.

CMS is seeking comment on whether to establish an add-on payment for the service using inputs from CPT code 69433 *Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia* as a crosswalk reference, plus direct costs from invoices for the surgical devices at the request of an industry proposal to establish payment for their specific technology. CMS does not mention that a CPT Category III code already exists that may be related to this industry request. CMS should not create duplicate ways to report the same procedure and should first look to CPT code 0583T *Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia.* If CMS is specifically attempting to pay separately for the surgical devices mentioned, the AMA urges CMS to treat the other 86 high-cost supply items in an equivalent manner. All high-cost supplies should be reported with a Q code, reviewed, and priced annually and not impact the RBRVS practice expense relative values.

Human Amniotic Membrane Allograft

Recommendation:

• The AMA urges CMS to assign a distinct Q code to the SD248 human amniotic membrane allograft, allowing for its pricing to be separately managed and updated annually based on a transparent review of current market invoices.

CMS is soliciting comments regarding the price of supply item SD248 human amniotic membrane allograft mounted on a non-absorbable self-retaining ring, which was considered in January 2023 as part of the Ocular Surface Amniotic Membrane tab. The Agency is proposing a new price of \$1,149 for the supply item although it was recently priced for CY 2024. At that time, the RUC submitted an average of two invoices (for Prokera Slim and Prokera Classic devices) totaling \$872. CMS states they previously updated the price of this supply in using the average of 3 device prices (Prokera Slim, Prokera Classic, and Prokera Plus) for a total of \$931.33. The Agency implemented a price of \$931.33 (rather than \$872.50) and now proposes a further increase to the pricing of SD248 to \$1,149 due to newer invoices submitted by an unnamed, interested party. CMS seeks "any information as far as whether one of these three devices (the Prokera Slim, Prokera Classic, and Prokera Plus) would be more typical than the other two for use as a supply in CPT code 65778." The AMA believes this illustrates how unreasonable it is for these costs to be bundled into physician services rather than paid separately via a specific supply code. CMS does not know which is the most typical of the three types of devices, all with disparate prices. The Agency is proposing to increase the price of the supply input only one year after receiving invoices from the clinicians that provide the service. This supply item clearly should have its own supply Q code(s) separately paid from the Physician Payment Schedule so those prices can be monitored and, when appropriate, updated annually.

Invoice Submission

Recommendation:

• The AMA agrees it would be practical to update clinical staff, medical supply and medical equipment pricing consistently, for example, every five years. Updates to clinical staff prices and medical supply and equipment prices should occur simultaneously to reduce the redistribution effects of these updates across medicine.

CMS discusses the invoice submission process for use in updating supply and equipment pricing, stating "We welcome public comments on this general topic of more comprehensive updates to supply and equipment pricing, and we may consider comments we receive to inform future rulemaking." The AMA supports a deliberate, systematic approach to supply, equipment, and clinical labor updates. CMS also specifically requests feedback "regarding scheduled, recurring updates to PE inputs for supply and equipment costs." The AMA agrees that it would be practical to update clinical staff, medical supply and medical equipment pricing consistently, for example, every five years. Updates to clinical staff prices and medical supply and equipment prices should occur simultaneously to reduce the redistribution effects of these updates across medicine.

B. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section II.D.)

The COVID-19 PHE clearly demonstrated the value of telehealth services and more broadly of digitally enabled medical care combining in-person, virtual, remote monitoring, and other service modalities to deliver care that meets patient needs. It is critically important that patients with Medicare all over the United States be able to continue receiving telehealth services and that they can continue receiving them in their homes. The AMA strongly urges the Biden-Harris Administration to join us in supporting legislation to permanently extend these Medicare telehealth policies, including the Acute Hospital Care at Home program.

New CPT Codes for Synchronous Audio-Video and Audio-Only Evaluation and Management (E/M) Services

Recommendation:

• The AMA believes that CMS does have the statutory authority to recognize and pay for the new CPT codes for synchronous audio-video and audio-only E/M services and strongly urges it to do so starting in 2025.

For 2025, the CPT Editorial Panel created the following four sets of codes describing E/M furnished via a synchronous audio/video or an audio-only telecommunications system:

- 9X075-9X078 E/M services for *new patients* delivered via an interactive *audio/video* telecommunications system.
- 9X079-9X082 E/M services for *established patients* delivered via an interactive *audio/video* telecommunications system.
- 9X083-9X086 E/M services for *new patients* delivered via an interactive *audio-only* telecommunications system.

• 9X087-9X090 – E/M services for *established patients* delivered via an interactive *audio-only* telecommunications system.

The new telemedicine E/M codes streamline reporting, creating code descriptors so that modifiers become unnecessary to report these services. This fundamental change to the code descriptors leads to administrative simplification, providing a consistent mechanism for all payers to recognize the newer modalities of synchronous audio-video and audio-only E/M services. Much like the distinct E/M codes for office/outpatient, inpatient hospital, home visits, and nursing facility visits, the new codes provide the ability to distinguish the distinct resource costs required to provide the services. In addition to providing the benefit of consistency, reducing administrative burden, and describing accurate resource costs, the new coding structure for synchronous audio-only visits provides additional differentiation on the time ranges, consistent with how audio-only visits are being addressed today. These audio-only codes differentiate new and established patients, unlike the previous telephone E/M codes (99441-99443).

The direct practice costs of synchronous audio-video and audio-only E/M visits differ from the direct costs of in-person office or outpatient E/M visits, as displayed below.

Synchronous Audio-Video Evaluation and Management Services

Current CPT Codes	Current CPT Short Descriptors In-person Visits	2025 Total Direct PE Costs	CPI	2025 Short Descriptors Audio-Video Visits	2025 Total Direct PE Costs
99202-95	OFFICE O/P NEW SF 15 MIN	\$24.26	9X075	SYNCH AUDIO-VIDEO NEW SF 15	\$7.02
99203-95	OFFICE O/P NEW LOW 30 MIN	\$29.18	9 X II / 6	SYNCH AUDIO-VIDEO NEW LOW 30	\$7.56
99204-95	OFFICE O/P NEW MOD 45 MIN	\$35.20	9 X () / /	SYNCH AUDIO-VIDEO NEW MOD 45	\$9.72
99205-95	OFFICE O/P NEW HI 60 MIN	\$42.29	9X078	SYNCH AUDIO-VIDEO NEW HI 60	\$10.80
99212-95	OFFICE O/P EST SF 10 MIN	\$20.96	9X079	SYNCH AUDIO-VIDEO EST SF 10	\$6.48
99213-95	OFFICE O/P EST LOW 20 MIN	\$25.31	9 X (1X()	SYNCH AUDIO-VIDEO EST LOW 20	\$7.02
99214-95	OFFICE O/P EST MOD 30 MIN	\$33.57	U X HX I	SYNCH AUDIO-VIDEO EST MOD 30	\$9.72
99215-95	OFFICE O/P EST HI 40 MIN	\$39.57	9X082	SYNCH AUDIO-VIDEO EST HI 40	\$10.26

Synchronous Audio-Only Evaluation and Management Services

CPT Codes	CPT Short Descriptors Crosswalked to Office Visits	Total Direct PE Costs
99441(99212)	PHONE E/M PHYS/QHP 5-10 MIN	\$20.96
99442 (99213)	PHONE E/M PHYS/QHP 11-20 MIN	\$25.31
99443 (99214)	PHONE E/M PHYS/QHP 21-30 MIN	\$33.57

2025 CPT Codes	2025 Short Descriptors Audio-Only Visits	2025 Total Direct PE Costs
9X083	SYNCH AUDIO-ONLY NEW SF 15	\$5.94
9X084	SYNCH AUDIO-ONLY NEW LOW 30	\$6.48
9X085	SYNCH AUDIO-ONLY NEW MOD 45	\$8.64
9X086	SYNCH AUDIO-ONLY NEW HIGH 60	\$9.72
9X087	SYNCH AUDIO-ONLY EST SF 10	\$5.40
9X088	SYNCH AUDIO-ONLY EST LOW 20	\$5.94
9X089	SYNCH AUDIO-ONLY EST MOD 30	\$8.10
9X090	SYNCH AUDIO-ONLY EST HIGH 40	\$9.18

Telemedicine E/M Services are not Duplicative of Office/Outpatient E/M Services

In the 2025 MPFS proposed rule, CMS proposes to assign CPT codes 9X075-9X090 a procedure status indicator of "I", meaning that there is a more specific code that should be used for purposes of Medicare. CMS' logic for this decision is that there are services already describing audio-video and audio-only telemedicine E/M codes on the Medicare telehealth services list—the office/outpatient E/M code set—that these new codes duplicate.

The AMA respectfully disagrees. The new E/M codes are fundamentally different than the office/outpatient E/M codes in that they are performed remotely rather than in person and as shown above, require fewer direct cost inputs. By definition, the new E/M codes do not include a face-to-face visit and the telecommunications technology does not substitute for the face-to-face visit. The codes are not duplicative of the office/outpatient E/M code set.

As CMS notes in the proposed rule, section 1834(m) of the Act specifies the circumstances under which Medicare makes payment for services that would otherwise be furnished in person but are instead furnished via telecommunications technology. That is, services that are paid under section 1834(m) of the Act are those services that are, by definition, furnished in-person where an interactive telecommunications system substitutes for the in-person presence. That is not the case with any of the codes 9X075-9X090. The interactive telecommunications system does not substitute for the in-person

nature of the service. By definition, the services described by the 9X075-9X090 codes are furnished via an interactive telecommunications system and not in person.

In the 2025 MPFS proposed rule, CMS indicates similarities between the office E/M services and the above codes. CMS states "that except for the element of 'modality' (that is, audio-video or audio-only), the service elements of the new telemedicine E/M code family are no different than the [office/outpatient] E/M codes." (89 FR 61652) This statement ignores that at least some of the work values for new remote codes are less than for the in-person visits indicating that, in at least some cases, the physician work associated with the remote service is less than when the physician has a face-to-face visit with the patient. Further, as previously demonstrated, the new codes require fewer direct cost inputs than the in-person codes. In addition, as noted above, the use of an interactive telecommunications system makes the 9X075-9X090 codes listed above fundamentally different services that are ineligible to be added to the list of telehealth services because, by definition, they are never furnished in-person.

There are other differences between the office/outpatient visit (99202-99215) and the 9X075-9X090 codes. The office/outpatient visit codes (99202-99215) are specifically for E/M services furnished in an office setting or the outpatient department of a hospital. The remote E/M codes can originate from a patient's home or any other site including a health care site. This distinction has implications for the telehealth facility fee as explained below.

There are parallels between the 9X075-9X090 codes to other services that are paid outside of section 1834(m) of the Act as noted by CMS in the proposed rule. CMS states:

In the CY 2019 PFS final rule, we stated that "[w]e have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional." (83 FR 59483). Under this interpretation, services that are coded and valued based on the understanding that they are not ordinarily furnished in person, such as remote monitoring services and communication technology-based services, are not considered Medicare telehealth services under section 1834(m) of the Act and thus not subject to the geographic, site of service, and practitioner restrictions included therein. (89 FR 61652)

The above statement would equally apply to the 9X075-9X090 codes because the patient interacts with the medical professional via remote communications technology. The services are coded and valued based on the understanding that they are not considered Medicare telehealth services.

CMS raises a concern that:

Section 1834(m)(2)(A) of the Act expressly requires payment to the distant site physician or practitioner of an amount equal to the amount that such physician or practitioner would have been paid had such service been furnished without the use of a telecommunications system. (89 FR 61652)

Section 1834(m) is a *payment rule* for services that are identified as telehealth services and furnished to telehealth eligible individuals. The payment rule specifies that if a service is a telehealth service that is furnished by a physician or practitioner through a telecommunications system to a telehealth eligible individual then the payment amount to the physician or practitioner for that service must be an amount

equal to the amount that the physician or practitioner would have been paid if the services were furnished in person. If a service is not identified as a telehealth service, the rules and limitations under section 1834(m) do not apply to that service.

The restriction that payment be equal between remote E/M services and the existing office E/M services does not apply as the remote E/M services are distinct and separate services from the existing office E/M services. The payment restriction under section 1834(m)(2)(A) only applies to in-person services that are furnished remotely via interactive telecommunications systems. If CMS were to allow payment for CPT codes 9X075-9X090, it would not be under section 1834(m) of the Act as the services cannot be furnished without the use of a telecommunications system. The payment restriction, therefore, under section 1834(m)(2)(A) of the Act would not apply.

After the current waivers to the Medicare telehealth regulations that have been in place since the COVID-19 PHE expire on December 31, 2024, most Medicare telehealth services will once again, in general, be available only to beneficiaries in rural areas and only when the patient is located in certain types of medical settings as CMS states in the proposed rule. (89 FR 61653)

Except for treatment of a mental health condition or an ESRD-related clinical assessment, E/M services that originate from the patient's home may not be covered under section 1834(m) of the Act. In addition, when services originate from medical settings under the telehealth benefit, section 1834(m) of the Act authorizes a telehealth facility fee to pay for the originating site that would not be applicable when a 9X075-9X090 code outside of the telehealth benefit is furnished that originates from a patient's home or a health care site.

For a remote office/outpatient E/M service originating from a patient's home in a non-rural area, the services would be ineligible to be furnished under section 1834(m) of the Act because the interactive telecommunications system is not substituting for a face-to-face visit. Therefore, they could be billed when originating from a patient's home in a non-rural area. Further, no telehealth facility fee would be payable even if the remote E/M service originates from a patient care site. For all these reasons, the remote E/M codes are distinct and different from the office/outpatient visit codes and should be recognized and paid separately by Medicare.

In the proposed rule, CMS indicates that:

We understand that millions of Medicare beneficiaries have utilized interactive communications technology for visits with practitioners for a broad range of health care needs for almost 5 years. We are seeking comment from interested parties on our understanding of the applicability of section 1834(m) of the Act to the new telemedicine E/M codes, and how we might potentially mitigate negative impact from the expiring telehealth flexibilities, preserve some access, and assess the magnitude of potential reductions in access and utilization.

As noted above, the AMA believes that it is within CMS' statutory authority to pay for E/M services delivered remotely via interactive remote audio/video or audio-only telecommunications systems outside of section 1834(m) of the Act. If CMS were to recognize and pay for CPT codes 9X075-9X090, it would substantially mitigate the concerns about the expiring waivers to section 1834(m) of the Act as the office/outpatient E/M services are likely the largest single category of services paid under the Medicare telehealth benefit. For these services, the 9X075-9X090 codes would be available for use as an alternative to the office/outpatient E/M services leaving a much smaller universe of services on the telehealth

services list that would no longer be payable when waivers under section 1834(m) of the Act expire on December 31, 2024.

Budget Neutrality Issues

Recommendation:

• CMS' presumption that it should not apply a budget neutrality adjustment related to telehealth services utilization is correct and no budget neutrality adjustment should be made.

CMS Request for Comment on Budget Neutrality for Telehealth Utilization

Section 1848(c)(2)(B)(ii)(I) of the Act requires CMS to make updates for changes in "medical practice, coding changes, new data on relative value components or the addition of new procedures." Section 1848(c)(2)(B)(ii)(II) limits the change in expenditures from changes to RVUs to \$20 million.

In the CY 2025 PFS proposed rule, CMS indicates that it has

...developed proposed PFS payment rates for CY 2025, including the statutory budget neutrality adjustment, based on the presumption that changes in telehealth utilization will not affect overall service utilization. We also note that historically we have not considered changes in the Medicare telehealth policies to result in significant impact on utilization such that a budget neutrality adjustment would be warranted.

CMS' historical policies only take into account service utilization when determining budget neutrality if there is a price change associated with a given service. That is, budget neutrality only applies if the product of the price change for a service and its service utilization across all services where there is a price change exceeds \$20 million. CMS' longstanding historical practice has been to only apply budget neutrality when it makes changes to RVUs for existing services, not when paying for new services not previously paid.

For instance, effective January 1, 2024, Congress added a new Medicare benefit category for "Marriage and Family Therapist Services and Mental Health Counselor Services." The addition of the new benefit category will increase PFS spending but budget neutrality does not apply because the new benefit is not a change in payment for services already being paid. Similarly, CMS clarified its policies on Medicare payment for dental services in the CY 2023, CY 2024 PFS rules, and again in the 2025 PFS proposed rule. These clarifications are a change in policy that is resulting in more services being paid, not a change in payment for individual services that would be subject to budget neutrality.

When CMS began paying for additional services via the telehealth benefit during the COVID-19 PHE using its waiver authority under section 1135 of the Act, there was a policy change that allowed additional services to be paid. There was not a change in prices for any existing services already paid for under the PFS. Budget neutrality did not apply then and would not apply now with potential expiration of section 1834(m) of the Act telehealth waivers that may result in less spending under the telehealth benefit.

Budget Neutrality Does Not Apply to the Audio/Visual E/M Codes if Paid by CMS

As noted above, budget neutrality only applies when CMS makes changes to RVUs for existing services. When CMS pays for new CPT codes, it may or may not apply budget neutrality depending on the scenario.

For instance, under the misvalued code initiative, the CPT Editorial Panel and the AMA/Specialty Society Relative Value Scale Update Committee (RUC) created new codes in place of predecessor codes for services commonly performed together. In this instance, the RUC provides utilization crosswalks to CMS between the old and new codes in order for CMS to apply budget neutrality. This is a clear case where budget neutrality applies, and the AMA RUC's utilization crosswalks assist CMS by furnishing data to determine the adjustment.

In other cases, the CPT Editorial Panel creates new codes that CMS does not subject to budget neutrality. In these cases, the CPT Editorial Panel is creating CPT codes for new services not previously paid that may be resulting from technological change, expansion of medical knowledge or other factors. For modeling purposes, CMS will assign these codes a utilization of one service such that its payment models will function and no budget neutrality adjustment is applied for the new service codes. Budget neutrality does not apply because CMS is paying for additional services, not changing the payment rate for services that are already being paid.

The 9X075-9X082 codes describe E/M services for new and established patients delivered via an interactive audio/video telecommunications system. As stated above, these are new services not previously paid (e.g., they are not services that are bundled into the office/outpatient E/M services). In the case of remote E/M audio/video telecommunications, the COVID-19 pandemic led to technological improvements that allowed these types of services to be more commonly furnished. As the CPT Editorial Panel does when there is sufficient utilization of a newly provided service, it creates codes to identify the services so the new codes can be used to identify services being provided that are included in the patient's medical record and for payment by 3rd parties such as Medicare, Medicaid, and private insurers.

For the audio/video E/M codes (9X075-9X082), budget neutrality would not apply for any new Medicare spending associated with these codes any more than it would apply to a new diagnostic or therapeutic service not previously paid by Medicare. In this case, budget neutrality would not apply because CMS is not changing the payment rate for an existing service but is instead paying for a new service previously not paid.

Budget Neutrality for the Audio-Only E/M Codes

With respect to CPT codes 9X083-9X090, the budget neutrality issue may be viewed differently. Historically, CMS did not pay for audio-only E/M services between a physician and patient and considered these services to be bundled into payment for the applicable E/M code that was furnished face-to-face. However, as part of the waiver of the telehealth requirements under section 1834(m) of the Act beginning in 2020, CMS began allowing for payment of audio-only E/M services originating from any location or site without applying a budget neutrality adjustment.

If CMS were to begin paying for audio-only E/M services in 2025 for the first time without having previously paid for them, it would have been consistent with CMS' historical policy to apply a budget neutrality adjustment for unbundling audio-only E/M service from other E/M services. However, CMS has been paying separately for audio-only E/M services under current policy for several years and any

additional spending has been incorporated into the base level of payment CMS uses for its budget neutrality calculations.

If CMS were to adopt the AMA's recommendation to recognize audio-only E/M codes 9X083-9X090 as a substitute for allowing the office/outpatient E/M codes with a modifier when furnished audio-only, budget neutrality would only apply for the difference in payment rates between the two sets of codes. The budget neutrality adjustment would be based on the office E/M code payment less the 9X083-9X090 payment rate and the product of the utilization of the office/outpatient E/M codes with the requisite modifier identifying the service as being furnished via a telehealth waiver as an audio-only service.

Expanded Coverage for Audio-Only Communication Technology

Recommendation:

• The AMA applauds CMS' proposal to permanently change the regulation defining an interactive telecommunications system to include two-way, real-time audio-only communication technology for telehealth services furnished to patients in their homes.

Current Medicare telehealth regulations define an "interactive telecommunications system" as multimedia communications equipment that includes audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site physician. In response to the COVID-19 PHE, CMS allowed the use of audio-only technology for audio-only telephone visits, behavioral counseling, and educational services. Pursuant to Section 4113 of the Consolidated Appropriations Act, 2023, CMS extended the availability of audio-only services, in addition to lifting geographic and originating site restrictions, through the end of 2024. Beginning in 2022, CMS modified its regulations to permanently permit use of audio-only equipment for telehealth furnished to established patients in their homes to diagnose, evaluate, or treat a mental health disorder, including substance use disorders. Audio-only technology may only be used if the distant site physician can use audio-video communications technology but the patient either cannot use or does not consent to the use of video technology. CMS stated that mental health services differ from most other Medicare telehealth services as they primarily involve verbal conversation where visualization between the patient and physician may be less critical.

CMS now proposes to extend its policy allowing use of audio-only technology when any telehealth service is furnished to a patient in their home, not just for those related to mental health or substance use. The same conditions would apply; that is, the distant site physician can use audio-video technology, but the patient cannot or does not consent to its use. For audio-only services, CPT modifier 93 must be appended to the claim to verify that the service meets these conditions.

The AMA applauds the proposal for Medicare to cover audio-only services and urges CMS to finalize it. The AMA has longstanding policy supporting "coverage and payment of audio-only services in appropriate circumstances to ensure equitable coverage for patients who need access to telecommunication services" but do not have access to two-way audiovisual technology. Broadband and audiovisual telehealth services are not accessible by all Medicare patients. Access to broadband internet is a social determinant of health, and discontinuing audio-only coverage would exacerbate health inequities, including for historically marginalized, minoritized and underserved populations. Physicians have also made it clear that audio-only services can enhance quality and improve patient health outcomes. Some patients are more comfortable speaking with their physicians without video. Audio-only services can also be used to manage treatment for patients with chronic conditions like diabetes and hypertension.

Although few patients would want to obtain all their health care services over the phone, in the nearly five years since CMS has been allowing payment for audio-only services, it has become clear that they play an important role in digitally enabled hybrid models of in-person and virtual care.

Direct Supervision via Communications Technology

Recommendation:

• The AMA supports the CMS proposal to permanently allow physicians to be immediately available for direct supervision via audio-video real-time communications technology for a subset of services that require direct supervision and appreciates the proposal to continue to allow virtual provision of direct supervision for other services through 2025.

Since the COVID-19 PHE, CMS has defined the physician's "immediate availability" for services that require direct supervision to include real-time audio and visual interactive telecommunications technology. CMS extended this policy after the end of the PHE and requested comments on whether virtual direct supervision should be permitted on a permanent basis. The AMA has recommended in previous comment letters that the current policy be made permanent. The fact that remote supervision may be inappropriate in some cases does not justify refusing to pay for it under any circumstance. In many rural and underserved areas, patients may be unable to access important services if the only physician available must supervise or deliver services at multiple locations and may not be available to supervise services in-person when all patients need them. Under these circumstances, failure to allow use of audio-video communications technology for direct supervision could mean that a patient would be unable to receive the service at all, rather than forcing in-person supervision to occur. Both patients and CMS rely on physicians' professional judgment to determine the most appropriate services to deliver, and the same principle should apply to how supervision is provided.

CMS has identified a subset of services requiring direct supervision for which it proposes to allow virtual direct supervision on a permanent basis. These are services that 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." The AMA agrees with the proposal to permanently allow virtual direct supervision for a subset of services.

For other services subject to direct supervision, CMS states that it is exercising an abundance of caution and extending the ability for physicians to be immediately available through real-time audio-visual telecommunications technology on a temporary basis, through 2025. The AMA urges that the policy also be made permanent for these services. Several factors, including inadequate payments and burdensome administrative requirements in Medicare and other health insurance programs, have resulted in increasingly severe shortages of physicians in many specialties and geographic areas. These shortages are forcing physician practices, hospitals, and other providers in many communities to organize and staff services in different ways than in the past, including through remote physician supervision. In addition, some innovative approaches to care, such as hospital-at-home, are only feasible if they can be delivered using remote supervision. It will be more difficult to recruit and retain non-physician staff with the necessary training and experience to safely deliver services under remote physician supervision, and it will be more difficult for innovative programs to recruit and retain physicians who can effectively provide remote supervision, if those staff and physicians are concerned that the policy enabling remote supervision could be revoked within a year. This uncertainty could force the services to be delivered using less capable staff or prevent the services from being delivered at all. As a result, rather than protecting patients, the temporary status of the supervision policy could worsen patients' care. The AMA

believes that the current policy has been in place long enough that any serious problems should already have been identified, so it is time to end the uncertainty and make the policy permanent.

Supervision of Residents by Teaching Physicians via Communications Technology

Recommendation:

• The AMA supports the one-year extension, through 2025, of CMS' current policy allowing teaching physicians to provide virtual supervision of residents when they are delivering a service using telecommunications technology. The AMA also recommends that CMS establish a permanent policy allowing virtual supervision of residents for both remote and in-person services provided by residents in non-Metropolitan Statistical Areas (MSA) and MSA areas.

CMS proposes to continue the policy that it established in last year's rule on virtual supervision of residents by teaching physicians for an additional year, through 2025. Under this policy, teaching physicians may supervise services provided by residents using audio-video communication technology, but only when the service is furnished virtually (e.g., when the patient, resident, and teaching physician are all in separate locations).

The AMA appreciates that CMS expanded the availability of remote resident physician supervision to services furnished in residency training sites that are located within a MSA when the service is furnished virtually through 2024 and supports CMS' proposal to extend this policy through December 31, 2025. The AMA urges CMS to establish a permanent policy allowing teaching physicians to supervise residents permanently, and to extend flexibility to allow for virtual supervision of residents providing in-person services. Virtual supervision of residents has become an important means of maintaining patient access to academic medical care in MSA and non-MSA areas during and after the COVID-19 PHE and it is vital to permanently continue this additional supervision option regardless of location. Significant workforce shortages are affecting access to care in many regions of the country, with millions of people residing in Mental Health and/or Primary Care Shortage Areas.

Accreditation Council for Graduate Medical Education (ACGME) <u>rules</u> allow for audio-visual supervision of residents and its guidelines state that direct supervision 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." ACGME also provides more specific guidance for each <u>specialty</u>. In accordance with ACGME guidance, the AMA acknowledges and supports individually tailoring the virtual supervision of each resident according to their level of competency, training, and specialty since this would enable residents to provide additional services while still garnering the support needed from their teaching physicians. The AMA also recommends guardrails be included to ensure virtual supervision is efficacious and to mitigate risk:

- Decisions regarding how residents will be supervised via audio-visual real-time communication technology should be implemented, reviewed, and overseen at the program level, in accordance with ACGME policy.
- Training programs should outline audio-visual supervision requirements in advance to promote consistent understanding between the resident and the teaching physician. Each program must define when the physical presence of a supervising physician is required, and each resident must know the limits of their scope of authority.

- Residency programs should encourage Residency Review Committees and ACGME to increase
 monitoring of clinical and educational work hour standards in the context of the larger issue of
 patient safety and acknowledge the impact of the changes of the supervision requirements on the
 residents and their optimal learning environment to ensure that appropriate education and
 supervision are maintained.
- Advice should be provided on when and how physicians must inform the patient that direct supervision by interactive telecommunication technology is being used.

Teaching physicians will still be required to review the resident physician's interpretations and services and ACGME has strict limits concerning supervision via interactive telecommunications technology, so appropriate levels of patient care and teaching physician direction will be maintained. Moreover, the permanent addition of audio-visual supervision would not change the responsibility of the institutions' GME Committees. They would still be required to monitor programs' supervision of residents and ensure that it is consistent with provision of safe and effective patient care, residents' educational needs, the progressive responsibility appropriate to residents' level of education, competence, and experience, and any other applicable program requirements. In alignment with the <u>Association of American Medical Colleges</u> and the ACGME, therefore, the AMA recommends a permanent expansion of supervision of residents via audio-video real-time communications technology, beyond non-MSAs, especially since these methods of supervision have already been successfully employed for more than four years since the start of the COVID-19 PHE.

Frequency Limitations on Certain Medicare Telehealth Services

Recommendation:

• The AMA supports the CMS proposal to continue lifting the telehealth frequency limits on subsequent inpatient and nursing facility visits and critical care consultations through 2025 but urges CMS to permanently lift these restrictions.

Long before the COVID-19 PHE and the dramatic rise in the adoption and provision of telehealth services that accompanied it, CMS had imposed frequency limits on the number of subsequent inpatient hospital visits, subsequent nursing facility visits, and critical care consultations that could be provided through telecommunications technology. The frequency limits were lifted during the PHE and, although they technically resumed when the PHE expired, CMS has suspended any enforcement of them through 2024. It now proposes to continue this suspension for an additional year.

The environment for telehealth services has transformed in the many years since CMS first imposed the frequency limits for these services. Digitally enabled services provided by the more than 300 hospitals participating in CMS' Acute Hospital Care at Home program allow patients to receive hospital-level care in their own homes, including through virtual visits with their physicians. These programs free up inpatient hospital beds for the patients who really need them and cannot be cared for at home. Limitations on the number of nursing facility visits that can be provided via telehealth are unnecessary as the visits that are required by regulation must already be provided in-person. Amid workforce shortages of physicians and other health professionals who treat nursing facility patients, it has become difficult in some communities to find nursing facilities where hospital patients can be discharged. Continuing to allow telehealth visits to nursing facility patients can allow their physicians to practice more efficiently and allow them to be available for in-person visits with those patients who cannot be effectively treated in a telehealth visit.

CMS indicates that Medicare data show that less than five percent of these services have been provided via telehealth during the period that the frequency limits have been lifted, but this does not mean the service or policy is unimportant or unnecessary. Instead, it indicates that the flexibility is not being abused and that the more frequent telehealth visits are most likely being provided to the subset of patients who really need them. It is likely that greater use of the flexibility may be needed in the future, particularly given the increasing frequency of severe weather events across the country and the growing shortages of physicians in many communities. Moreover, continuing the uncertainty about whether the policy will be made permanent or terminated could result in the loss of programs and services that are only viable in an area that has a shortage of physicians because the available physicians know they will have the flexibility to use virtual visits for a greater portion of patient care. As a result, rather than protecting patients, continuing the temporary status of the policy could harm them.

Reporting of Physician Home Addresses

Recommendation:

• The AMA remains concerned about any potential requirement for physicians to report their home address and supports CMS' proposal to not require such reporting at least through 2025.

As the COVID-19 PHE was ending in 2023, CMS initially outlined a new policy that would have required physicians who provide telehealth services from their homes to report their home addresses to Medicare. This policy did not take effect, but in comments on the 2024 proposed rule, the AMA expressed concerns related to the public display of a physician's home address on Medicare websites that include a physician lookup feature. Specifically, the AMA advised CMS to permanently allow physicians to render telehealth services from their homes without reporting their home address on their Medicare enrollment form while continuing to bill from their currently enrolled location. Physician privacy and safety is an utmost concern, and we fear the unintended consequences of this personal information becoming available to the public. For example, physicians who provide behavioral health services may conduct telemedicine visits from their home and the nature of the medical conditions treated by these physicians may introduce a heightened level of safety concerns that outweigh any potential benefit to CMS from having data on physician home addresses. Concerns for privacy and safety are not new, and escalating trends in violence towards physicians and other health professionals demonstrate that they have never been at a greater risk of injury due to work-related violence. Any effort towards preserving the privacy and safety of health professionals must be a top priority for CMS.

CMS now proposes to continue its current policy of not requiring physicians to report their home address through the end of 2025 and to use their currently enrolled practice location when providing telehealth services from their home. The AMA appreciates this extension but continues to recommend that CMS establish this as permanent policy. In addition, should CMS decide to allow the flexibility to lapse in the future, the Agency should allow sufficient time for physicians to provide an alternate address or have their home address suppressed if they desire.

Additions to the Medicare Telehealth List

Recommendation:

• The AMA supports the proposal to add the CPT codes for caregiving training services to the Medicare telehealth list on a provisional basis and to add codes describing individual counseling

for pre-exposure prophylaxis (PrEP) to prevent human immunodeficiency virus (HIV) on a permanent basis.

CMS received a request to add two CPT codes for caregiver training in strategies and techniques to facilitate patient functional performance, 97550 and 97551, to the Medicare telehealth list on a permanent basis. As caregiver training services are not currently on the Medicare telehealth list and the codes were just added to the physician payment schedule in 2024, CMS is proposing to add them to the telehealth list on a provisional instead of a permanent basis. It also proposes to provisionally add three other CPT codes for caregiver training to the telehealth list: 97552, 96202, and 96203. CMS is also proposing to establish national payment rates for two codes for individual counseling for PrEP to prevent HIV, consistent with an anticipated final National Coverage Determination for PrEP for HIV. As CMS views these PrEP counseling services to be similar to certain services that are already on the Medicare telehealth list on a permanent basis, it proposes to add the codes for PrEP for HIV as permanent telehealth codes. The AMA supports these proposals.

C. Enhanced Care Management (Section II.G.)

Advanced Primary Care Management (APCM) Services

Recommendation:

• CMS should review the RUC's recommendations for a patient-centered medical home and consider its framework for tiering payment based on infrastructure capabilities.

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 (CTBS), 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 CTBS services, CMS is proposing that APCM services would not include timeframe restrictions, which CMS has heard are administratively burdensome. For example, virtual check-in services cannot be billed when there is a related 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, interprofessional 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. Participation in certain alternative payment models (APMs), including accountable care organizations, PCF, and Making Care Primary, satisfies some of the practice-level capabilities, such as population-level management and

performance measurement. MIPS-eligible physicians must register for and report the Value in Primary Care MIPS Value Pathway (MVP) to satisfy the performance measurement service element to bill APCM services.

The AMA has long supported efforts to develop a voluntary, nationwide patient-centered medical home model and other APMs that give primary care physicians more flexibility to provide services not otherwise covered, sufficiently support primary care services that patients need, and base incentives or penalties on quality and spending outcomes within the control of the primary care physician. In 2008, the RUC submitted comprehensive recommendations to CMS regarding the resources required to provide medical home services. CMS, the American Academy of Family Physicians, and the American College of Physicians expressed appreciation for the RUC's unanimous decision to submit robust recommendations for the physician work and practice costs required to serve as a medical home. Given the substantial infrastructure requirements to bill the proposed APCM codes, the AMA urges CMS to 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. A tiering approach would enable more primary care physician practices, including independent physician practices, to qualify to report APCM.

Cardiovascular Risk Assessment and Risk Management

Recommendation:

• The AMA supports the proposal to pay for new services to assess patients' risk for atherosclerotic cardiovascular disease (ASCVD) and provide risk management, with several modifications outlined below. The AMA strongly supports improving access to self-measured blood pressure (SMBP) devices to improve hypertension control for ASCVD risk management.

CMS proposes to build upon the CMS Innovation Center's Million Hearts® model test, which coupled payments for cardiovascular risk assessment with cardiovascular care management, and reduced mortality rates by lowering heart attacks and strokes. ASCVD risk assessment and risk management services are proposed starting in 2025 (new codes GCDRA and GCDRM). As proposed, ASCVD risk assessment would be performed with a visit and the output must include a 10-year estimate of the patient's ASCVD risk. For patients at medium or high risk for CVD, ASCVD risk management services are proposed to include blood pressure management, cholesterol management, smoking cessation, and other elements.

The AMA supports establishing an ASCVD risk assessment service and agrees with CMS that the Million Hearts model provides excellent evidence on which to base this policy. The AMA also agrees with the flexibility that is proposed for selecting the specific assessment tool, as these will likely change over time and different tools may be more appropriate for different patients. CMS should modify the proposal so that the ASCVD risk assessment is not required to be done on the same date as an E/M visit. As CMS notes in the discussion on page 61728, "This determination requires both data collection at a visit and laboratory data, which may not be available at an initial visit." Because physicians will often need to wait for the results of a laboratory test until after the E/M visit, restricting the risk assessment to the E/M visit date may prevent optimal utilization of this service. Patients also should not be required to schedule an additional visit to complete the ASCVD risk assessment just so that it can be done on the same date as an E/M service. In addition, CMS should consider allowing ASCVD risk assessment with other preventive services, such as the Welcome to Medicare and Annual Wellness visits. The AMA agrees that once per year is an appropriate interval for ASCVD risk assessment.

The AMA also supports the new proposed service for ASCVD risk management, for which the Million Hearts experience also provides an excellent foundation. We agree that the service should be available to patients at medium or intermediate risk, not just those at high risk as in Million Hearts. CMS should modify its eligibility requirements for this service, however, as 30 percent, 10-year risk is quite high and would be late to start initiating ASCVD risk management. The proposed cut-off of 15 percent to be considered medium risk also does not align with current clinical guidelines and risk assessment interpretation. Instead, most current ASCVD risk assessments interpret 7.5 to 19.9 percent as "intermediate risk" and greater than or equal to 20 percent as "high risk," with recommended clinical interventions defined for those groupings. The AMA encourages CMS to adopt these definitions of intermediate and high risk for ASCVD risk assessment and management services.

The AMA recommends that there be a greater focus on hypertension.control in the ASCVD risk management service because it is such an important component of managing ASCVD risk and improving patient health outcomes. For example, the proposed ASCVD specific risk management service defines medication management as "including aspirin or statins" – it should also mention blood pressure medications. In addition, patients with hypertension who are eligible for ASCVD risk management should be able to obtain an SMBP device to measure their blood pressure at home to assist with their self-management of this condition as part of the service. It would also be helpful for CMS to confirm that physicians will still be able to report CPT code 99474 for SMBP data collection and interpretation and/or the appropriate CCM services for patients who need them in the same month as ASCVD risk management. For example, a patient who has chronic obstructive pulmonary disease and/or diabetes would be eligible for CCM due to these conditions, but if the patient also has elevated ASCVD risk with hypertension or high cholesterol, they may need all three services.

Strategies for Improving Global Surgery Payment Accuracy

Transfer of Care Modifiers

Recommendations:

- CMS should implement the AMA's prior recommendation that the full increase of work and physician time for the inpatient hospital and observation care visits (99231-99233, 99238, and 99239), and office visits (99202-99215) be incorporated into the surgical global periods for each CPT code with a global period of 10-day and 90-day. The AMA also recommends that the practice expense inputs should be modified for the inpatient hospital and observation care visits and office visits within the global periods.
- If CMS finalizes its proposal to expand the usage of the transfer of care modifier, the modifiers should not apply to any services that have the multiple procedure reduction modifier -51, the Agency should require informed consent for transfers of care, and CMS should provide extensive education and outreach to ensure appropriate use and documentation of the modifiers.

CMS has proposed to require the use of the appropriate transfer of care modifier (modifier -54, -55, or -56) for all 90-day global surgical packages in any case when a practitioner plans to furnish only a portion of a global package, both when there is a formal, documented transfer of care (current policy) and when there is an informal, non-documented but expected, transfer of care. If CMS opts to implement the proposal to expand the usage of the transfer of care modifier, the accompanying payment reduction should not apply to any services that have the multiple procedure reduction modifier -51. This would necessitate a change in current policy, particularly as it has been applied to ophthalmologists. The -

51 modifier already reduces the payment for second and subsequent services to remove payment for postoperative care. Applying a 50 percent reduction and a -54 surgical care only modifier reduction on top of that would duplicate the reduction and be inappropriate.

As noted in the proposed rule, -54/-55 modifiers are used appropriately in ophthalmic services, particularly cataract surgery. The American Society of Cataract and Refractive Surgery (ASCRS) comanagement guidelines outline when a transfer of care is appropriate between an operating physician and a non-operating physician or QHP, as well as explicit instructions on documentation of the patient consent and formal transfer of care. Ophthalmologists, specifically cataract surgeons, have been successful in the formal transfer of care from post-operative care to non-operating QHPs for many years. However, there are extensive educational efforts required for the operating and non-operating physicians and QHPs to ensure the appropriate use of the -54 and -55 modifiers. Furthermore, the co-management guidelines stress the importance of patient choice. In instances where patients request to return to their nonoperating practitioner and co-management is determined to be appropriate by the operating ophthalmologist, the patient makes an informed decision in writing to be seen by the non-operating practitioner for postoperative care. If CMS finalizes its proposal to expand use of these modifiers, it should ensure patient choice is preserved by requiring informed consent for transfers of care and provide detailed guidance to ensure operating and non-operating physicians and QHPs fully understand the appropriate use and documentation of the modifiers.

Over the past decade, CMS has articulated several concerns with the global packages related to the accuracy of valuation and payment under the MFS. These new proposals are aimed at addressing that concern, at least in part. As the Agency works to address its concerns with global period valuation, the RUC would again like to remind CMS of the RUC's bundled-postoperative visit recommendation to address the misvaluation of bundled post-operative visits relative to analogous stand-alone E/M visits.

The AMA urges CMS to implement our prior recommendation that the full increase of work and physician time for the inpatient hospital and observation care visits (99231-99233, 99238, and 99239), and office visits (99202-99215) be incorporated into the surgical global periods for each CPT code with a global period of 10-days and 90-days. The AMA also recommends that the practice expense inputs should be modified for the inpatient hospital and observation care visits and office visits within the global periods.

Post-Operative Care Add-on Code (GPOC1)

Recommendation:

• Prior to implementation, CMS should address ambiguities raised by the proposed G-code. CMS is also proposing to create a new HCPCS G code, GPOC1, to capture the additional time and resources spent in providing follow-up post-operative care by a practitioner who did not perform the surgical procedure and who has not been involved in a formal transfer of care agreement. This proposed add-on code would only be reported with an office or other outpatient E/M visit for a new or established patient for the first visit the other practitioner performs.

This proposed add-on code raises several questions not contemplated or answered by the Agency in this proposed rule. In concept, CMS is assuming that, unlike formal transfers of care with documented comanagement agreements and patient consent, informal transfers of care happen when a physician or QHP other than the operating surgeon or another physician in the same specialty sees a patient during the post-operative period for care related to the surgery. Yet, this scenario creates significant ambiguity.

- Does GPOC1 require patient consent?
- Does GPOC1 require coordination between the surgeon and non-operating physician or QHP performing post-operative care?
- If the surgeon did not use a -54 modifier because the surgeon intends to provide all post-operative care for the patient and not to transfer care, would GPOC1 be denied? Would the surgeon or non-operating physician or QHP be audited?
- Would multiple non-operating physicians or QHPs be able to report GPOC1 during the same 90-day global surgical period?

CMS should address these questions and provide detailed billing guidance prior to implementation of this proposed G-code.

D. <u>Supervision Policy for Physical Therapists (PTs) and Occupational Therapists (OTs) in</u> Private Practice (Section II.H.)

Recommendations:

- CMS should prioritize patient safety and ensure that PTAs and OTAs only work within the confines of their state-based licensure and education.
- Changes to the certification process for therapy plans of treatment should ensure that the physician is still the head of the care team, while not hindering access to needed therapy.

CMS proposes a regulatory change to allow for general supervision of physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) by PTs in private practice (PTPPs) and OTs in private practice (OTPPs) for all applicable physical and occupational therapy services. Currently OTPPs and PTPPs must remain on-site and immediately available when Medicare patients are treated in order to bill for therapy services furnished by their supervised OTAs and PTAs. However, CMS would like to change this requirement and argues that this will help to increase patient access and align supervision requirements with those required of PTAs and OTAs that work in institutional settings.

The AMA supports physician led team-based care where each provider works within their scope of practice. If these changes are implemented, we would urge CMS to ensure that patient safety is prioritized and that PTAs and OTAs only work within the confines of their state-based licensure and education.

Certification of Therapy Plans of Treatment with a Physician or NPP Order

CMS proposes amendments to the certification and recertification regulations and would provide an exception to the physician/nonphysician practitioner (NPP) signature requirement for occupational therapy, physical therapy, and speech-language pathology (SLP) established treatment plans for purposes of the initial certification in cases where a written order or referral from the patient's physician/NPP is on file and the therapist has documented evidence that the treatment plan was transmitted to the physician/NPP within 30 days of the initial evaluation. However, CMS is not proposing to establish an exception to the signature requirement for purposes of recertification of the therapy plan of treatment to ensure ongoing oversight and to prevent the potential overutilization of therapy services without appropriate clinical review.

Currently the regulations require that a physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) who has knowledge of the case sign the initial certification for the patient's

plan of treatment. This is meant to demonstrate that the patient is under the care of a physician, and that the plan of treatment/care for the physical therapy, occupational therapy, or speech-language pathology services has been established by a physician or by a qualified PT, OT, or SLP and is periodically reviewed by a physician.

The AMA believes that the order of medical services for patients constitutes the practice of medicine and believes that non-physicians should not be authorized to prescribe physical therapy and other medical care services. Moreover, the AMA acknowledges that physicians who prescribe physical therapy should closely monitor their prescriptions to ensure that treatment is appropriate. However, the AMA does understand the effort by CMS to streamline the certification process and to clarify regulatory requirements. We realize that these proposals are intended to address the challenges faced in managing the administrative aspects of therapy plans of care and appreciate the importance of all providers, including physicians, NPs, PTs, OTs, and SLPs, in the development and execution of these therapy plans. Collaborative involvement is important for the highest quality of patient care. We believe that any changes to the certification process should carefully consider the roles and contributions of each provider involved in the patient's care plan and ensure that the physician is still the head of the care team, while not hindering access to needed therapy.

E. Advancing Access to Behavioral Health Services (Section II.I.)

Recommendation:

• The AMA absolutely shares CMS' goal of advancing access to behavioral health services but disagrees that proposing a confusing set of G-codes will accomplish this aim, especially when expanded use of existing or revised CPT codes could serve the same purpose.

CMS proposes new coding and payment for safety planning interventions (SPI) for patients in crisis in a variety of settings, including those with suicidal ideation or at risk of suicide or overdose. Add-on code GSPI1 could be reported along with a visit or psychotherapy service when SPI are performed by the billing practitioner in a variety of settings. SPI can include assisting the patient in following a personalized safety plan, utilizing family members and friends to help resolve the crisis, contacting mental health professionals, and others. An additional monthly code, GFCI1, would support specific protocols for follow-up telephone calls after discharge from the emergency department (ED) for a crisis encounter, such as suicide risk or drug overdose, as a bundled service covering four calls in a month. Six G-codes are also proposed to allow certain nonphysician mental health professionals to provide interprofessional consultations to help better integrate behavioral health treatment into primary care and other settings. In addition, CMS proposes three new G-codes for digital mental health treatment devices furnished under a behavioral health treatment plan of care.

In 2018, the American College of Emergency Physicians submitted a <u>proposal</u> to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for the Acute Unscheduled Care Model. The model was specifically designed to allow emergency physicians to ensure safe discharges for patients to their home and community after an ED visit, facilitate care coordination during the post-discharge period, and help avoid hospital admissions and repeat ED visits for patients seen in the ED. A key reason that the model was needed is because emergency physicians cannot report and be paid for transitional care or discharge day management services. As a result, there is a scarcity of resources available to help patients safely return to their home environment, connect them to primary care or other follow-up care services, ensure that they can obtain prescribed medications, healthy food, or caregiver services, and understand

and follow discharge instructions. The PTAC <u>recommended</u> the proposal to the Secretary for implementation and said that it met all 10 of the PTAC's criteria, yet CMS has not tested or implemented the model. Instead of establishing G-codes, CMS could propose extending the use of or revising the existing CPT codes for <u>transitional care</u> and/or discharge day management services to help patients safely return to their home or community from the ED or other settings and coordinate needed support services following an ED visit.

CMS is also proposing a duplicative set of G-codes for interprofessional consultations for use by health professionals whom CMS states cannot report the current CPT codes (99446, 99447, 99448, 99449, 99451) for these services under current policies. While it is generally understood that E/M services are only reported by physicians or other qualified health care professionals (QHPs), which CMS defines, the interprofessional consultation CPT codes are unique in that they are "assessment" and management codes. CPT generally uses "assessment" to expand services outside of the types of services only used by physicians or other QHPs in the E/M section. While the codes do fall into the E/M section, there is nothing in the CPT guidelines that precludes other health care professionals who are trained, certified, and can independently report services from reporting these codes. Instead of establishing a parallel set of G-codes, CMS could propose an exception to these policies or education to clarify the use of the existing CPT codes.

Digital Mental Health Treatment (DMHT) Devices

The AMA appreciates the opportunity to comment on the three new proposed HCPCS codes (GMBT1, GMBT2, GMBT3) for digital mental health treatment (DMHT). CMS states that it is refining terminology that has been used in the past to reference "digital cognitive behavioral therapy" (see: 88 FR 52262, 52370 through 52371, 88 FR 78818, 79012, and 79013) and is starting to use the term "digital mental health treatment (DMHT) device" to include the term "digital cognitive behavioral therapy (CBT)." Importantly, Food and Drug Administration (FDA) guidance refers to computerized behavioral therapy by the same acronym "CBT" which represents a large segment of the medical devices used within the digital therapeutics landscape. For CPT 2023, the CPT Editorial Panel developed a Category I CPT code 98978 based on FDA market-authorized medical devices that support the monitoring of cognitive behavioral therapy.

CMS proposes a change in terminology to create a distinction between GMBT1 and the existing CPT codes 98975 and 98978. We are not sure that this distinction is necessary as the existing CPT terminology conforms with, and relates to, medical devices that are supported by ample evidence, have achieved medical device regulation designation, and were presented before the CPT Editorial Panel. Starting January 1, 2025, the CPT code set does update guidelines for codes 98975, 98976, 98977, and 98978 to reflect changes to the devices in the marketplace. The guidelines allow for the reporting of RTM codes when the device also has a therapeutic intervention functionality. While we understand that the new G-codes are poised to include a broader range of services, the Agency should use caution in creating codes for a small number of devices that may not be covered through CPT coding, as it may cause confusion. As technology advances, it is important to synchronize terminology to ensure we all speak the same language. We also remind the Agency that coding and valuation benefit from the clinical input of physicians and other qualified health care professionals that comes from the CPT and RUC processes. Lastly, creating a bifurcated code set does increase the administrative burden for practices. Since G-codes tend to be covered only by Medicare, it puts practices, especially pediatric practices, at a disadvantage. These practices primarily bill private payers and Medicaid, so having multiple codes for the same or similar services provides a challenge and often a delay in payment for services rendered.

F. <u>Payment for Dental Services Inextricably Linked to Specific Medicare Covered Services</u> (Section II.J.)

KX and GY Modifiers

Recommendation:

 Overall, the AMA supports CMS' proposal to require a modifier for all dental service claims inextricably linked to covered medical services on the dental and professional claim forms.
 However, we underscore the importance of physician education, detailed guidance, and a longer grace period until the end of 2025 to allow time to resolve potential claims processing issues.

CMS proposes that, effective January 1, 2025, a KX modifier would be required for all dental service claims inextricably linked to covered medical services on both the dental claim forms 837D and the professional claim forms 837P to demonstrate coordination between the dental and clinical professional. The Agency also seeks comments on whether to recommend use of the GY modifier in instances where a dental service does not meet Medicare coverage criteria.

The AMA believes strongly that a physician-led care team is the most effective way to work collaboratively with multiple providers and the patient and family to accomplish shared goals within and across settings to achieve coordinated, high-quality, patient-centered care. We appreciate CMS clarifying that an exchange of information between the physician or other medical professional and dental professional is considered necessary to establish an inextricable link between the dental and covered medical service for purposes of Medicare payment for dental services. In comments in response to last year's proposed rule, we sought further clarification as to what constitutes an exchange of information between a dental and clinical provider. We believe these proposed modifiers would generally help to establish a more clear, transparent standard to help ensure coordination between the dental and clinical professional and agree that it will help to demonstrate when dental services are inextricably linked to Medicare covered services.

This said, we have concerns about the logistics of implementing this change by January 1, 2025. First, there is currently no place on dental claim forms to accommodate modifiers, which presents a major hurdle. Furthermore, physicians are not steeped in the details of this relatively nascent and evolving Medicare policy and may not know in each instance whether individual dental services do or do not meet Medicare payment requirements.

While we appreciate CMS' proposal that medical and dental professionals can begin billing these modifiers in 2024 to familiarize themselves ahead of the proposed January 1, 2025 implementation date, given these policies will not be finalized until early November 2024, and that the Medicare claims processing systems will not be able to submit the dental claim form until January 1, 2025, we strongly recommend a longer grace period through the end of 2025 to allow physicians to familiarize themselves with these new requirements and for any claims processing issues to be identified and resolved through future guidance or resources. If a modifier is not included in the claim, the remittance should include clear instructions for how to meet this requirement (i.e., affix a modifier) moving forward, along with a short description as to what meets the requirements for affixing the modifier (i.e., examples of coordination between the dental and medical professional).

During this time, we urge CMS to educate physicians about these new requirements through clear, detailed guidance including a centralized chart or list of all the individual dental services that are considered inextricably linked to particular Medicare-covered services, as well as guidance answering several key questions related to how these new modifiers would impact claims processing. For example, what constitutes an "exchange of information" between a dental and medical professional to demonstrate coordination? What evidence is needed to support using the KX modifier in the case of an audit? In the event a KX (or GY) modifier is not attached to a physician claim, will the dental claim be denied? If so, can claims be resubmitted? If a claim for a Medicare-covered service has already been successfully submitted, will CMS allow a modifier to easily be retroactively affixed, rather than requiring the entire claim to be resubmitted? The AMA welcomes future opportunities to collaborate with the Agency on physician education regarding Medicare coverage of dental services, including coding changes proposed in this rulemaking.

Coverage of Dental Services

Recommendation:

• In the short-term, CMS should consider its judicious approach of approving certain dental services for Medicare coverage provided there is clear evidence that they are inextricably linked to the clinical success of Medicare-covered medical services. The Agency should produce detailed information about the utilization and spending for Medicare-covered dental services and outcomes on the inextricably related Medicare-covered clinical services.

CMS proposes to allow Medicare payment for dental or oral examinations and diagnostic and treatment services to eliminate an oral or dental infection for dialysis patients and seeks information regarding dental services that may be inextricably linked to Medicare-covered services in the treatment of diabetes, autoimmune diseases requiring immunosuppressive therapies, sickle cell disease, hemophilia, and obstructive sleep apnea.

The AMA recognizes the link between dental and physical health. We also recognize the potential future implications on physician payment of continuing to add more Medicare-covered dental services. We appreciate CMS' point in the 2023 MPFS final rule that because adding dental services codify and update existing policy, they do not impact budget neutrality under the PFS, or require adjustments to the PFS conversion factor in the immediate term. However, should any of those codes be revalued in future years, they would impact budget neutrality estimates and the conversion factor. We also appreciate CMS' point that at this stage, dental services do not appear to have a significant impact in the context of overall spending and utilization under the MPFS. However, if CMS continues to add more dental services year after year, this could change, particularly as CMS explores Medicare-covered services that apply to a greater number of Medicare beneficiaries. As such, in the short-term, we implore the Agency to continue its judicious approach of adding new Medicare-covered dental services that appropriately balances the need for access with coverage of dental services that are integral to Medicare-covered services. We appreciate that the Agency continues to emphasize in this rule the difference between dental services that are inextricably linked to the clinical success of Medicare-covered services versus those that are associated with improved outcomes more generally.

We likewise appreciate the Agency <u>previously stating</u> that it would closely study the trends in utilization and payment for these services. We reiterate our <u>previous calls</u> for CMS to make this information available to the public, and to publish data regarding the impact that reimbursing these dental services has

on clinical outcomes for Medicare-covered services, which we believe is necessary to demonstrate that these dental services meet the definition of being inexplicably linked to these Medicare-covered services.

G. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (Section III.B.)

Productivity Standards

Recommendation:

• CMS should finalize its proposals to remove productivity standards for RHCs and FQHCs and codify requiring RHCs and FQHCs to provide primary care services, while no longer enforcing the standard that RHCs be "primarily engaged in furnishing primary care services" by counting the number of total hours spent on primary care.

CMS proposes to remove the productivity standards that had served as a way of limiting RHC payment rates. The productivity standards have been a major problem for RHCs. For example, the productivity standards for physicians are twice as high as for nurse practitioners and physician assistants. The standards make it difficult for physicians practicing at RHCs to provide the services their patients need because if they spend too much time treating more complex patients and do not reach the productivity standard as a result, then payment rates could be significantly reduced. The AMA believes removing the productivity standard would empower physician-led care teams in RHCs to deliver more flexible, patient-centered care that can better meet their patients' needs.

The AMA also believes that CMS' proposal to remove the requirement that the majority (i.e., greater than 50 percent) of hours must be spent on primary care would allow RHCs greater flexibility in tailoring services to meet the needs of their unique patient populations, as well as address shortages in access to specialty services in rural areas, including for behavioral health and substance use disorder services. Finalizing this policy could facilitate additional rural specialized medical residency rotations as RHCs often serve as rotation sites, which would be well-timed with Congress' recent historic approval of 1,200 additional medical residency spots and the Biden Administration's commitment to expanding medical residencies in rural communities. Removing this standard would enable RHC physicians to provide the types of services that cannot be sustained in independent practices in the community and thereby help residents of rural communities receive as broad of a range of primary care and specialty services as possible. It could also promote more coordinated, patient-centered care across specialties and ease concerns among physicians practicing within their scope. For example, when a person's primary care physician diagnoses a patient with anxiety, it is unclear whether this visit should be counted as a primary care or behavioral health visit. The AMA supports continuing to require RHCs and FQHCs to offer a full spectrum of primary care services.

Telehealth

Recommendation:

 CMS should finalize its proposal to delay in-person visit requirements for telehealth services for mental health conditions until January 1, 2026, extend virtual direct supervision in RHCs through the end of CY 2025, and continue to allow RHCs to furnish non-behavioral health visits via telecommunications technology.

CMS proposes to extend existing telehealth flexibilities for RHCs through 2025, including delaying the requirement for patients with mental health conditions to have an in-person visit within six months of a telehealth visit, extending virtual direct supervision, and extending the ability for RHCs to serve as a distant site for non-behavioral health care visits to be furnished via telecommunications technology. As discussed in our comments on the telehealth proposals for the MPFS, CMS should consider providing permanent extensions of these policies, not just for one additional year.

H. Medicare Diabetes Prevention Program (MDPP) (Section III.E.)

Alignment with CDC

Recommendation:

• The AMA supports CMS' proposed definitional changes to align MDPP and CDC Diabetes Prevention Recognition Program (DPRP) standards and clarification that MDPP suppliers can maintain either CDC's longstanding "in-person" or the new "in-person with a distance learning component" requirement. We reiterate our previous calls for CMS to expand on these by removing the once per lifetime limit cap on MDPP, and allowing fully online suppliers, as well as fully online, asynchronous services in the MDPP, all of which are already permitted by CDC in the DPRP standards and would promote greater consistency between the two programs, as well as broader participation in the MDPP.

The AMA strongly supports the MDPP overall and is actively working with CMS to promote physician and supplier participation in the program, which has been low but underwent significant modifications in the 2024 MPFS final rule which we strongly supported and believe will result in positive impacts on program participation. To this end, the AMA also continues to support further alignment with the CDC's DPRP and flexible modalities of care to expand the program's reach to additional MDPP suppliers and Medicare beneficiaries. We believe both these goals and the MDPP would greatly benefit by accepting fully online suppliers into the program and allowing online, asynchronous services, both of which are already permitted by the CDC's DPRP, which notably has significantly higher levels of participation. Importantly, this would expand the MDPP's reach particularly to rural and underserved communities, as well as those that experience mobility issues, lack of access to transportation, or other barriers to care, thereby advancing the administration's health equity goals. We similarly urge CMS to remove the once per lifetime cap on MDPP benefits, which does not exist in the CDC's DPRP and unnecessarily restricts participation in and effectiveness of the MDPP. Losing weight, the core metric of success in the program, often takes several attempts and Medicare beneficiaries should be supported in those efforts.

MDPP Flexibilities

Recommendations:

 The AMA strongly supports CMS' proposed changes to allow make-up sessions to be held on the same day as a regularly scheduled MDPP session and to allow more flexible standards for selfreporting weight, including live video technology with an MDPP coach or two date-stamped photos or video recordings.

• We request that photo/video metadata be permitted to qualify as "date-stamped" and ask for CMS to consider additional approaches to reporting weight, such as using digital scales that electronically report the data to MDPP suppliers.

The AMA appreciates CMS' proposals, which align with longstanding priorities of the Diabetes Advocacy Alliance, in which the AMA participates. We believe these flexibilities will both broaden participation in the program and allow more participants to successfully complete program requirements. We request further guidance on what constitutes a "time stamped" photo or video. For example, there is often metadata associated with pictures and videos, and we strongly believe this should satisfy this requirement. If beneficiaries must use some sort of photo or video editing software to display the date on the physical photo or video, we worry this will be an unnecessary deterrent. We ask CMS to clarify this definitional understanding in future guidance. We also urge the Agency to consider additional methods, such as use of a digital scale or applications that automatically send data to MDPP suppliers.

I. <u>Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (Section III.F.)</u>

Recommendation:

The AMA supports the proposals to expand telecommunications flexibilities for OTPs and
establish payments for social determinants of health (SDOH) risk assessment and new FDAapproved opioid agonist and antagonist medications.

CMS has previously finalized several flexibilities for OTPs regarding the use of telecommunications, both during and after the COVID-19 PHE. For example, OTPs can already provide substance use counseling and initiate buprenorphine treatment with audio-video or audio-only telecommunications. In the current rule, CMS proposes to expand these flexibilities by permanently allowing OTPs to furnish periodic assessments via audio-only and to initiate methadone treatment via audio-video telecommunications. CMS is also proposing to pay for OTPs to provide SDOH risk assessments and to provide new medications to patients, including a new nalmefene hydrochloride product, Opvee®, and a new injectable buprenorphine product, Brixadi®.

Through the AMA Substance Use and Pain Care Task Force, the AMA and its member medical societies have been working for many years to help bring an end to the <u>drug-related overdose epidemic</u>, especially by improving access to treatment for substance use disorders and harm reduction services. OTPs are an important component of efforts to end this epidemic and we support the proposed policies to increase their effectiveness.

J. Medicare Shared Savings Program (Section III.G.)

Medicare Shared Savings Program (MSSP) EHR Requirements

Recommendations:

• The AMA continues to vehemently oppose CMS' 2024 finalized policies requiring that all eligible clinicians in MSSP ACOs must report MIPS Promoting Interoperability (PI) data, regardless of Qualifying APM Participant (QP) status, and raising the CEHRT use criteria for all Advanced APMs from 75 percent to "all" eligible clinicians. CMS should rescind these changes.

- At a minimum, CMS should leverage the flexibilities it recently approved for MSSP and ACO REACH and apply the 90-day CEHRT use requirement and MIPS exclusions, including the small practice exception, to all models. It should also produce detailed guidance about what types of compliance actions it will take should a single TIN or minority of participating TINs fail to report all PI measures or use CEHRT, specifically whether shared savings or elimination from the program are on the table, and what would warrant this.
- The AMA also urges CMS to work in earnest with the AMA, medical specialties, and other interested parties to develop additional exceptions, as well as model-specific CEHRT criteria to further mitigate burden on physician practices.

Despite <u>widespread opposition</u> from the AMA and others, CMS previously finalized a requirement that all MSSP participants, regardless of track or QP status, must begin reporting MIPS PI category measures and earn a MIPS PI category score unless they would generally be excluded from reporting this data under MIPS beginning in 2025. In addition, beginning January 1, 2025, CMS also finalized a policy that raised the Advanced APM CEHRT use criterion from 75 percent to "all" eligible clinicians in an Advanced APM Entity (which includes MSSP ACOs and all Advanced APMs). As discussed in the AMA's 2024 proposed rule <u>comments</u>, both policies will hinder APM participation and move medicine backwards. **Moreover**, **both policies defy the statutory language of MACRA**, **which expressly exempts QPs from MIPS**. Congress established relief from burdensome MIPS requirements as a core incentive to join APMs.

The AMA continues to support policies that drive data exchange forward. Unfortunately, as specified, both policies result in substantial burden for physician practices with no clear positive impact on information exchange. In fact, we believe both policies will force ACOs and other APM entities to omit practices that they are not convinced can meet both requirements, which will hinder, not help, CEHRT adoption and APM participation. CMS also ignores forthcoming data sharing regulations including the HL7 Fast Healthcare Interoperability Resources (FHIR) standard and Insights Condition and Maintenance of Certification data finalized in the Health Data, Technology, and Interoperability (HTI-1) Final Rule, which will render the MSSP EHR policies duplicative and obsolete.

Since the policies were proposed last year, we have been actively engaging with the Administration to refine the requirements and mitigate the potentially harmful effects of both policies, including increases in burden and drops in APM participation, particularly amongst practices with disproportionate resources such as small, rural, and safety net practices. We were very pleased to see CMS recently issued through sub-regulatory guidance a clarification in response to AMA advocacy to use the MIPS small practice exception for the MSSP PI reporting requirement. We commend CMS for this change, which we believe will keep small practices in the MSSP and allow them to use shared savings to reinvest in CEHRT and other technology advancements over time in the program. We similarly commend CMS for recently posting guidance that clarified that ACO REACH participants must use CEHRT for one quarter of 2025 and that an ACO's PI score will not affect shared savings calculations, which will provide much needed relief and flexibility.

Unfortunately, thousands of practices across the country still await similar guidance for other CMMI models. Furthermore, both guidance documents leave important unanswered questions. For example, the ACO REACH guidance stipulates that REACH ACOs that do not meet the CEHRT requirements "may be subject to compliance actions by CMS, which may include a corrective action plan (CAP) *or other remedial action*," but does not specify what type of corrective action, or for what scenarios such corrective actions would be applied. Similarly, the MSSP PI guidance states: "to be eligible to share in

savings, ACOs are required to comply with all Shared Savings Program requirements, including the requirement to report the MIPS PI performance category for the performance year." From both guidance documents, it is unclear how a situation would be handled if a single participating TIN fails to report PI data or meet CEHRT requirements. Would the entire ACO risk losing its shared savings or participation as a result? Or will CMS work with the ACO and participating practice toward full compliance? The AMA strongly advocates for the latter, and believes this is CMS' intent, but without clear guidance, ACOs will be forced to take a more conservative approach by not accepting practices that may not be as advanced in their CEHRT utilization journey so as not to jeopardize their program status. This would be unfortunate as integrating these types of practices into ACOs is one of the most viable paths forward to promoting CEHRT adoption and APM participation among practices. Furthermore, if program participation are indeed in jeopardy, we believe the magnitude of such changes would warrant proposed rulemaking under the Administrative Procedures Act.

More information is desperately needed as APM Entities are making final participation decisions ahead of 2025. The AMA urges CMS to leverage the flexibilities it has approved for MSSP and ACO REACH by applying the 90-day CEHRT requirement and MIPS exclusions, including the small practice exception, across all models. We further urge CMS to expediently produce more detailed guidance about the compliance actions it will take should a single TIN or minority of participating TINs fail to report all PI measures or use CEHRT, specifically whether shared savings or elimination from the program are on the table. The AMA welcomes further collaboration with the Agency to clarify both policies and develop additional exceptions to avoid potentially harmful effects on APM participation and CEHRT adoption.

Last year, CMS also finalized a policy to adopt model-specific CEHRT criteria, which the AMA supported. Unfortunately, CMS has made no progress on developing model-specific CEHRT criteria. Accordingly, the AMA also urges CMS to work with the AMA, specialty societies, and other interested parties to develop model-specific CEHRT criteria to mitigate CEHRT-related burden and expense on physician practices and promote further innovation in this area.

Prepaid Shared Savings

Recommendation:

• The AMA strongly supports offering ACOs the option of prepaid shared savings, but CMS should not restrict how funds are spent so as to increase uptake and utility of this option.

CMS proposes that eligible ACOs with a history of shared savings can obtain an advance on future shared savings payments, which they can use to invest in patient care, infrastructure, or staffing. The AMA strongly supports the creation of a prepaid savings option, which aligns with previous AMA advocacy to provide more opportunities for up-front investments to drive improvements in patient-centered care.

The AMA is concerned the restrictions on how prepaid shared savings are spent would limit their utility, particularly for small practices that may need to use the funds for staff and technology first to improve patient outcomes. Additionally, CMS already has sufficient guardrails in place to prevent inappropriate use of prepaid shared savings. First, ACOs are held accountable for performance through shared savings and losses, so they are incentivized to spend the money in a way that will yield the most effective outcome. Second, CMS proposes to require that ACOs applying for prepaid savings submit a detailed spending plan for approval by CMS that must include the total amount of prepaid shared savings, the ACO's spend plan, and an itemization of how the prepaid shared savings were spent during the performance period. This information would then be publicly reported. Third, because the funds will be

repaid through future reductions in shared savings payments, ACOs should not face more restrictive policies under this option than they would in spending their shared savings payments in general.

Finally, the AMA urges CMS to allow distribution of prepaid shared savings to ACO participants, as this is one of the eligible spending categories for distributing shared savings. We also oppose the requirement that ACOs calculate a percentage of staff time spent on "providing direct beneficiary services that are not otherwise covered by Traditional Medicare" as unnecessarily burdensome.

Benchmarking

Recommendations:

- CMS should finalize its proposed benchmark changes, including a new health equity benchmark adjustment (HEBA) and accounting for improper payments, and consider additional benchmark changes to broaden the impact of a HEBA.
- CMS should finalize its proposal to hold ACOs harmless from anomalous billing activity and is urged to develop a more expedient process to proactively investigate potential sources of this activity at early stages, including at the regional level.

CMS proposes to add a HEBA to upwardly adjust ACOs' historic benchmarks based on the proportion of assigned patients enrolled in the Medicare Part D low-income subsidy (LIS) program or dually eligible for Medicare and Medicaid. The HEBA would be limited to ACOs with at least 20 percent of their patients enrolled in the Part D LIS or who are dual eligibles and would be capped at five percent of national assignable per capita expenditures, like regional and prior savings adjustments.

The AMA strongly supports adding a HEBA, which we agree would help promote MSSP participation and success by practices in rural and underserved communities, thereby advancing CMS' health equity goals, which are also an AMA priority. We especially support that it is not budget neutral so that other ACOs are not effectively penalized. However, as designed, the HEBA would only impact five percent of ACOs and increase benchmarks by 1.57 percent on average. We recommend that CMS consider modifications to the proposed eligibility requirements and methodology to increase its impact, including increasing the per beneficiary adjustment.

CMS proposes to hold ACOs harmless from significant, anomalous, and highly suspect (SAHS) billing activity by recalculating expenditures and payment amounts to account for improper payments upon reopening a payment determination and excluding SAHS billing activity from expenditure and revenue calculations for the relevant calendar year, as well as from historical benchmarks. The AMA strongly supports these proposals. Accounting for improper payments in benchmarks is a welcome change and significant improvement. We urge CMS to further protect ACOs from inappropriate financial penalties by collaborating with them to address these issues early. CMS should establish an expedited process for ACOs to report and CMS to investigate potential cases of fraud or suspicious billing. As discussed later in this letter, we are also urging CMS to apply these hold harmless policies to MIPS eligible clinicians (ECs) whose performance on cost measures is adversely impacted by anomalous spending outside of their control.

Beneficiary Assignment

Recommendation:

• CMS should finalize its proposals to not terminate ACO participation agreements if the ACO falls below 5,000 attributed patients and work with ACOs to comply before taking remedial action.

CMS proposes to no longer terminate an ACO's existing participation agreement if its population falls below 5,000. ACOs would still be subject to possible compliance action and be required to meet the minimum threshold of 5,000 assigned beneficiaries to begin a new participation agreement. The AMA supports this proposal and urges CMS to consider several factors on a case-by-case basis before deploying compliance actions or blocking an ACO from rejoining the program, including: how far below 5,000 the ACO falls; whether the ACO is serving a rural or underserved population; whether the ACO is the only ACO serving that region or population; and potential causes for the drop in Medicare FFS population, such as a new Medicare Advantage plan starting in the market. While appreciating the importance of maintaining statistical stability of the program's expenditure calculations, we also recognize that this threshold is a bigger barrier for certain ACOs, such as rural ACOs. As CMS notes, "given additional time, more ACOs likely would be able to increase their beneficiary assignment, keeping more beneficiaries in accountable care relationships." We agree this is a laudable goal and urge CMS to work with individual ACOs to maintain program compliance.

Beneficiary Notification

Recommendations:

- CMS should finalize proposed changes limiting beneficiary notification requirements to patients
 who received at least one primary care service from an ACO clinician during the relevant
 assignment window for ACOs with prospective assignment.
- Regarding follow-up beneficiary communications, CMS should consider an alternative requirement for ACOs to send follow-up communications up to 30 days <u>after</u> a patient's next primary care appointment instead of at arbitrary intervals unrelated to patient visits.

For ACOs that select preliminary prospective beneficiary assignment with retrospective reconciliation, CMS proposes to limit mandatory beneficiary notifications to a population subset that is more likely to be assigned to the ACO (i.e., those who received at least one primary care service during the assignment window from an eligible primary care clinician in the ACO), rather than all Traditional Medicare beneficiaries. The AMA supports this proposal, which will both reduce burden on ACOs and lead to less confusion among the potentially assignable Medicare beneficiary population. We encourage the Agency to finalize this policy as proposed.

CMS also proposes to no longer require ACOs to send follow-up communications to beneficiaries by their next primary care visit. Rather, all follow-up communications would be sent within 180 days of the standardized notice to all beneficiaries. The AMA acknowledges points raised in the rule that ACOs do not always know when a patient's next visit is and that this can often result in additional administrative burden for the ACO. Timing follow-up communications around a patient's visit with their physician may be more effective at engaging the patient, however, so we suggest an alternative of allowing ACOs to send follow-up communications to the patient up to 30 days *after* their primary care visit. This interval better balances aligning notices with physician visits, which is optimal for patient-centered care and likely

more effective at initiating a patient-provider conversation than blanket notices sent biannually, while avoiding problems that can arise due to the existing requirement to send this notice *in advance of* primary care visits, such as cancelled appointments.

We also urge CMS to monitor the effectiveness of beneficiary notifications, such as patients opting out of notifications after receiving standardized communications, to ensure that communications are achieving their goal of engaging patients as opposed to overwhelming or confusing them. CMS should work with ACOs and participating practices to help ensure the verbiage is patient friendly and allow practices to customize it to be most useful to their patients. Required MSSP follow-up notification language could be incorporated into regular post-visit communications, which may reduce ACO burden, align more naturally with care delivery protocols, and reduce the likelihood of spurring confusion or concern among Medicare patients due to being notified at an arbitrary time interval or ignoring it altogether. We appreciate that CMS is making this proposal in response to concerns raised by ACOs and encourage the Agency to continue being receptive to feedback from ACOs, physicians, and patients, and to continue working with interested parties to optimize patient communications.

Request for Information: Establishing Higher Risk and Potential Reward under the ENHANCED Track

Recommendations:

- CMS should <u>not</u> advance any model or track that mandates participation or that is built on baseline reductions to the MPFS, which do not prioritize advancing patient care.
- We urge CMS to retain the existing ENHANCED track to promote program continuity and maintain a gradual pathway to higher risk while it explores potentially establishing a new voluntary higher risk track.

CMS solicits comments on a potential higher risk-reward track that would replace the current ENHANCED track. Forcing ACOs (or other APM participants) into mandatory models and imposing so-called "discounts" is not a successful path forward and reinforces a dangerous precedent that prioritizes short-term savings over sustainable, long-term improvements to patient care and health outcomes. Models should be designed around what services and supports lead to optimal care outcomes, and arming practices with the resources needed to achieve those outcomes. The AMA strongly opposes mandatory models. Requiring physicians to assume financial risk, often for utilization and spending over which they have no influence or control, can lead to patient harm and/or reduced patient access to care when physicians stop seeing Medicare patients. If payment models are designed to sustainably improve patient care while maintaining or lowering costs, physicians will inherently be driven to participate in APMs, as evidenced by the growth in participation in MSSP, CMS' largest model, and one that is voluntary.

While the AMA agrees that a voluntary higher risk track could be attractive to some ACOs that might otherwise leave MSSP, this option should be available in addition to the ENHANCED track, not in lieu of it. Predictability and stability are important to ACOs. It is difficult to have confidence in the program or view CMS as a reliable partner when model features are terminated. Adding a new track instead of replacing an existing track would allow legacy ACOs to continue to grow within the program and attract new participants to a higher risk option while maintaining a more gradual glidepath for other ACOs still building up to that point.

We disagree with CMS' concern about "self-selection issues" wherein only the highest performing ACOs would self-select into the higher of the two risk tracks. The gradual glidepath to risk in MSSP as a

voluntary program has made it the largest Medicare APM to date. Furthermore, because an ACO will only share in savings if it achieves savings relative to its benchmark, there is no downside to offering variable risk options. Both in the interest of achieving greater gross savings and attracting and retaining as many ACOs as possible to advance CMS' goal of moving more physicians and beneficiaries into accountable care relationships, creating a new higher risk track in addition to, not in lieu of, the current ENHANCED track is the clear path forward.

APM Performance Pathway (APP)

Recommendation:

• The AMA strongly urges CMS to reconsider sunsetting the Web Interface and removal of the MIPS clinical quality measure (CQM) reporting option for ACOs starting in 2025. CMS must also specifically outline in the final rule that the Medicare CQM reporting tool for MSSP participants will remain in the program for the foreseeable future.

In the 2025 MPFS, CMS proposes to eliminate the option to allow ACOs to report quality measures through the MIPS COM option starting in 2025 and previously finalized sunsetting the Web Interface in 2025. The AMA strongly urges CMS to reconsider sunsetting the Web Interface and removal of the MIPS CQM reporting tools because not all ACOs are ready to adopt such a costly and burdensome technical change. The constant change related to ACO quality requirements and lack of technology readiness threatens program participation and jeopardizes the transition to APMs. As we have mentioned in previous letters, we are extremely concerned at the speed with which ACOs must shift to reporting on MIPS CQMs or electronic clinical quality measures (eCQMs), and once again being asked to shift how they are reporting quality in the MSSP program. To remove two options while CMS continues to release additional guidance and moves toward broadening the measures on which ACOs will be evaluated further increases the challenges and barriers that ACOs must address to successfully participate in this program. The unintended consequences of these policy changes have a direct impact on patients and providers and compel ACOs to divert shared savings into temporary technologies, diverting resources from patient care. Additionally, ACOs feel forced to remove practices that may need more time to adopt new technologies, and these practices tend to be smaller, independent practices, creating even more barriers for these types of practices to join APMs. These changes are also counter to CMS' goal to have 100 percent of Original Medicare beneficiaries in an accountable care relationship by 2030.

MIPS CQMs and eCQMs are significantly more burdensome than the Web Interface in that they expand the population on which quality is evaluated from Medicare beneficiaries to all-payer data. Also, ACOs must aggregate these data across all participating practices, frequently across multiple electronic health record (EHR) systems, including EHRs for employed and independent practices and clinicians. While the open source FHIR tool recently released by CMS will assist in their aggregation and de-duplication efforts, its first iteration is not comprehensive and requires refinements. Therefore, ACOs need more time to determine the best approaches to collecting and reporting these data, and the continued changes further increase this work's complexity. For more specific information on the challenges of pulling data from multiple sites, see Quality Payment Program, Quality Section Category- Data Completeness Criteria in the Quality Performance Category section of our comments below.

The all-payer requirement with these two reporting options also puts ACOs with higher proportions of underserved patients at a disadvantage and, to an extent, measures ACOs on payer mix rather than quality of care provided. In addition, there is an increased risk of unintended consequences for those ACOs with higher proportions of specialty practices, which tend to treat more complex patients. Many ACOs report

they are considering dropping specialty practices from ACOs, or have already done so, due to the impact of these requirements. These policies lead to lost opportunities to engage specialists in value-based care, further hindering CMS' goal to transition all practices to value-based care.

ACOs that moved to MIPS CQMs and invested significant time and resources must make another decision yet again. CMS provided no indication through previous rulemaking that the MIPS CQM option would be removed and ACOs and vendors have very little time to accommodate such a significant change. Now, ACOs will have only two months to quickly pivot to another option if this change is finalized Nov. 1. We also believe that the removal of MIPS CQMs is contrary to the overall goal of shifting to digital quality measures (dQMs) since this reporting option allows ACOs to leverage additional digital data sources such as clinical registries and claims data. While digital quality measurement should allow for seamless quality reporting that reduces burden and provides real time performance data that can be used to improve patient care, much work remains to achieve the broader goals of a more cohesive, thoughtful approach, e.g., one that does not prematurely push ACOs and participating practices to adopt new data sharing technologies before interoperability standards have caught up, thus risking potential disruptions to patient care.

While we continue to support the addition of Medicare CQMs as they address many of the concerns around the all-payer approach discussed above, CMS has not stated how long this reporting option will remain available. As a result, ACOs and EHR vendors are reluctant to invest time and resources in an option that may be removed with little to no warning, just like CMS has now done with the MIPS CQM reporting tool option for MSSP. We recommend that CMS make the Medicare CQM option available for the foreseeable future and specifically state so in the final rule. Without such an assurance in a rule, vendors have specifically stated they do not see return on investment to develop a temporary reporting tool only available to MSSP participants that can be eliminated by CMS.

APP Plus Measure Set

Recommendation:

We urge CMS to re-evaluate its proposal for an APP Plus measure set and the additional
administrative burden of reporting on the measures. Proposing such measures is premature, given
CMS is already asking ACOs to adopt a new reporting tool and is not considering the complexity
of the measures.

We urge CMS to re-consider the creation of APP Plus with the associated proposed measures. We believe the proposal is premature given it is being proposed at the same time the Web Interface and MIPS CQM reporting options are removed from the program. Only two of the measures (Colorectal Cancer Screening and Breast Cancer Screening) are available as both an eCQM and MIPS CQM. While we are aware of the development of an eCQM for the Screening for Social Drivers of Health (SDOH) measure, based on the drafts released for public comment, this eCQM will be broadened to include an intervention and specified differently than the existing MIPS CQM version. As a result, CMS must release information on its plans to make both versions available for ACO reporting, including how the specifications will be developed and tested and whether the new eCQM version will be reviewed during an upcoming Pre-Rulemaking Review (PRMR) cycle. We also urge CMS to evaluate whether the expansion to the additional measures in the set should be finalized, particularly given the increased complexity of some of the measures. While at a high-level review, it appears that CMS is only adding five measures over the next four years, several evaluate multiple components, which increases the data collection burden and reporting. For example, the Screening for SDOH measure

requires evaluation of four very different social needs and the *Adult Immunization Status measure* would require ACOs to report performance on four vaccines with varying age ranges.

We offer the following measure specific comments on the APP Quality Measure set:

Screening for social drivers of health: As the AMA has highlighted in previous comments, the measure has yet to be tested at the ACO-level, including the multiple standardized survey tools and determine that the specifications produce scores that are reliable and valid. The measure also needs to be further specified to align with data standards such as the HL7 Gravity Project and United States Core Data for Interoperability (USCDI). In addition, it is imperative that CMS reduce the measure's complexity and evaluate if it has any demonstrated links to directly improving patient outcome without any unintended consequence of creating patient harm. A recent article in *JAMA* specifically points out the inadequacy of the measure and a "well intentioned mandate will impede progress in health equity and have the potential to increase long-standing racial and socioeconomic inequities." CMS is also requiring collection of this data across multiple setting-specific programs, which could result in duplicative efforts and potentially having to share this sensitive information numerous times. CMS should explore how this data can be shared across providers to also better assist in care coordination.

Substance Use Disorder Treatment (SUD): The AMA continues to support measures that address the importance of ensuring that patients with an SUD receive appropriate and timely treatment. We encourage CMS to consider the challenges around the lack of access to these services in some locations as the overall low rates of performance may be more indicative of the lack of availability of services rather than the quality of care provided to these individuals. We also continue to recommend that CMS and the measure developer ensure that the measure is specified in alignment with the American Society of Addiction Medicine's 2023 publication on buprenorphine treatment of opioid use disorder for individuals using high-potency synthetic opioids. It is critical that treatment is individualized to the patient, and the measure should not prohibit clinically appropriate care.

Scoring Medicare CQMs

Recommendation:

• The AMA supports CMS' proposal to apply a flat benchmark for Medicare CQM reported measures for the first two years the measures are in the program but urges CMS to retroactively apply the policy to 2024.

CMS proposes to use flat benchmarks for measures reported through the Medicare CQM tool for the first two performance periods in MIPS starting in 2025. The AMA supports the proposal but urges CMS to retroactively apply the policy to 2024. ACOs are actively collecting data on this reporting option beginning this year (2024) so CMS should retroactively apply this policy to any ACO that successfully reports Medicare CQMs for the 2024 performance period. Otherwise, these measures will not have historical or flat benchmarks available, and it potentially creates a disincentive to report Medicare CQMs

¹ Garg A, LeBlanc A, Raphael JL. Inadequacy of Current Screening Measures for Health-Related Social Needs. *JAMA*. Published online August 21, 2023. doi:10.1001/jama.2023.13948.

² Weimer MB, Herring AA, Kawasaki SS, Meyer M, Kleykamp BA, Ramsey KS. ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids J Addict Med. 2023;17(6):632-639. doi:10.1097/ADM.000000000001202.

by not allowing this benchmarking approach to apply to the first year of this reporting option. In addition, we encourage CMS to publicly post the data for the performance period during which the flat benchmarks are used, as it will allow ACOs to understand how they performed against their peers and prepare for future years when they will be evaluated against a historical benchmark.

K. Medicare Part B Payment for Preventive Services (Section III.H.)

Recommendation:

• The AMA appreciates the steps that CMS is taking to preserve and expand access to adult vaccines and supports CMS' proposal to pay for pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV) prevention. We encourage CMS to consider potential consequences of removing the need for a physician's order for hepatitis B vaccine.

Medicare Part B covers preventive vaccines for influenza, pneumonia, hepatitis B, and COVID-19, and there is no patient cost-sharing. For CY 2025, CMS proposes to expand 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. In addition, CMS would allow roster billing for this vaccine by mass immunizers such that a physician's order would no longer be required. Also, for the first time since the law allowing coverage of drugs as "additional preventive services" was enacted in 2008, CMS is proposing to pay for a drug in this benefit category which, like other Medicare preventive services, would have no cost-sharing. Specifically, CMS proposes to pay for PrEP for HIV infection prevention once Medicare finalizes its national coverage policy.

AMA policy supports a strong adult immunization program in the United States, including improving utilization of recommended adult vaccines by patients with Medicare and securing appropriate Medicare payments for vaccine administration. The AMA appreciates that CMS is updating these payment rates by the annual increase in the MEI and supports the proposal to expand Medicare coverage of hepatitis B vaccinations.

As part of the revisions to the payment policies surrounding hepatitis B vaccines, CMS proposes to remove the requirement that the administration of the hepatitis B vaccine be preceded by a physician's order. This would mean that an assessment of an individual's vaccination status could now be made without the clinical expertise of a physician. The AMA encourages CMS to consider the potential consequences of removing the requirement for a physician order before administration of the hepatitis B vaccine, including the patient's physician not being aware of the administration of the hepatitis B vaccine and as such not being able to holistically assess and care for the patient.

The AMA strongly advocates for plans to end the HIV epidemic that incorporate a focus on preventing atrisk individuals from acquiring HIV infection, including with PrEP. We support inclusion of PrEP for HIV as an essential preventive health benefit and are committed to educating physicians and the public about its effective use. We support the CMS proposal to use its authority to pay for drugs covered as additional preventive services to pay for this important service.

L. Expand Colorectal Cancer (CRC) Screening (Section III.K.)

Recommendation:

 The AMA supports CMS' proposal to update and expand Medicare Part B coverage for CRC screening tests.

CMS is proposing to exercise its authority under section 1861(pp)(1)(D) to make significant adjustments in CRC screening to promote access and remove barriers for much needed cancer prevention and early detection within rural and communities of color that are especially impacted by the incidence of CRC. In response to evidence supporting its efficacy and recommendations by the United States Preventive Services Task Force, CMS proposes to introduce coverage for Computed Tomography Colonography (CTC). CMS also proposes broadening the definition of complete CRC screening in § 410.37(k) to include a follow-on screening colonoscopy after a positive result from a Medicare-covered blood-based biomarker test.

The AMA supports CMS' proposal to update and expand Medicare Part B coverage for CRC screening tests. This proposal includes the addition of coverage for CTC and expanded definition of a "complete colorectal cancer screening" to include a follow-up on screening colonoscopy after a Medicare-covered blood-based biomarker CRC screening test. The inclusion of CTC and blood-based biomarker tests as part of the CRC screening process provides patients with more effective and less invasive screening options.

The AMA strongly supports the proposal to eliminate patient cost-sharing for CTC when it is used as a CRC screening method. By reducing or eliminating financial barriers, this approach significantly enhances patient access to these important cancer screening tools while also ensuring that all Medicare beneficiaries, including those in underserved and rural communities, can access life-saving preventive services without the burden of out-of-pocket costs.

M. Requirements for Electronic Prescribing for Controlled Substances (EPCS) (Section III.L.)

Recommendation:

• The AMA strongly supports the proposal to extend the compliance date for long-term care (LTC) facilities to implement EPCS for Medicare Part D prescriptions until January 1, 2028.

CMS proposes extending the requirement for LTC patients' controlled substance prescriptions to comply with EPCS rules by three years, from 2025 to 2028. At that time, National Council for Prescription Drug Programs SCRIPT standard version 2023011, which includes three-way communication functionality to improve communication between pharmacies and LTC facilities, will also be required.

The AMA deeply appreciates this proposed extension of the EPCS compliance date for controlled substance prescriptions issued to patients in LTC facilities. CMS correctly identifies the barriers that physicians with patients in LTC facilities currently face in adopting EPCS. Physicians may be responsible for covering multiple LTC facilities, each with different electronic medical record systems, and they need to rely on LTC nursing professionals to communicate prescriptions to the pharmacist on behalf of the physician. Under SCRIPT version 2017071, physicians can submit EPCS to the pharmacy but would need to then contact the LTC facility to separately give an order for the facility staff to administer the

medication to the patient. As SCRIPT version 2023011 is expected to resolve these issues and this standard version will be required by January 1, 2028, it makes sense to align the LTC compliance date with the SCRIPT requirement.

N. Overpayment Provisions of the Affordable Care Act (ACA) (Section III.O.)

Recommendation:

• The AMA strongly supports modifying the standard 60-day repayment deadline to allow time to investigate and calculate overpayments and urges CMS to clarify that practices will have adequate time to organize funds and make payment once an aggregate repayment amount is determined. Regarding the 180-day maximum repayment window, CMS should allow for extensions on a case-by-case basis based on case complexity and demonstration of progress toward a resolution.

CMS is proposing to revise the repayment deadlines for overpayments under Medicare Parts A and B. Specifically, the proposal would modify the standard 60-day repayment deadline by allowing it to be suspended under certain conditions. If a provider identifies an overpayment but needs additional time to investigate and determine the full extent of related overpayments, the deadline for reporting and returning the overpayment could be extended. CMS proposes that this suspension could last up to 180 days from the date the initial overpayment was identified, giving practices more time to conduct a thorough investigation and calculate the aggregate amount of the overpayment. Once the investigation is completed or the 180-day period expires, whichever occurs first, the provider would then be required to report and return the overpayment within 60 days. This proposal would reduce the burden on providers, particularly in complex cases where identifying and quantifying overpayments requires more time. Overall, the AMA strongly supports CMS' efforts to reform the 60-day repayment requirement, which the AMA has previously advocated for as it will help to reduce burden on physician practices since 60 days is a short time to execute this laborious process, particularly for physicians who utilize external billing services and need to obtain records from third parties. However, under the proposal, since payment would be due on "the date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated," it is unclear whether practices would have any time to organize funds for making overpayments once an aggregate repayment amount is determined. Accordingly, we request additional clarification and confirmation from CMS that there will be sufficient time for practices to organize funds and make payment once an aggregate overpayment amount is determined, recognizing that in many cases these repayment amounts can be substantial, particularly for small, safety-net, and other practices with limited resources.

We understand CMS' objective to ensure investigations are progressing in a timely fashion and appreciate that the 180-day maximum timeframe is three times longer than the standard 60-day repayment window. We request that CMS allow practices an opportunity to request deadline extensions on a case-by-case basis based on the complexity of the case and demonstration of progress being made towards a resolution. We believe these modifications would balance the need to bring about timely resolutions of overpayments while allowing time for robust investigations to be conducted, all evidence to be considered, and accurate conclusions to be reached in complex cases.

II. UPDATES TO THE QUALITY PAYMENT PROGRAM – (SECTION IV.)

O. MIPS Value Pathways

MVP Adoption and Subgroup Participation Request for Information

The AMA appreciates the ongoing dialogue with CMS on MIPS Value Pathways (MVPs), and reiterates our <u>recommendation</u> of an alternative framework, which we call the Condition-Stratified MVP Framework and outline in more detail below. This alternative framework addresses many of the pitfalls of the current CMS approach to MVP and is based on direct conversations we have had with specialty societies and CMS in the Winter and Spring of 2024. We are hopeful CMS will finally address our concerns and recommendations in response to this RFI.

The AMA and medical specialty societies continue to believe that the best way to address the problems with CMS' existing MVP approach is to create separate MVPs for individual health conditions, episodes of care, and major procedures, specifically for areas that are high volume conditions and procedures—like the current MVP for Lower Extremity Joint Repair. However, based on ongoing conversations and meetings we have had with CMS, including hosting an MVP roundtable with CMS and the specialty societies in the winter of 2024, as well as CMS stating that it does not want a large portfolio of MVPs, we have developed an alternative MVP framework. This alternative framework categorizes quality and cost measures into condition-specific subdivisions within a broader MVP. Physicians who specialize in treating a particular condition would be able to clearly identify the available measures for that condition and register to be held accountable for those condition-specific quality and cost measures within the MVP. By creating MVPs through the proposed framework, CMS and physicians could also more easily identify and remedy gaps in measurement and scoring challenges, such as no or limited condition specific measures or measures without a benchmark. We believe this framework helps address many of the problems with the current MVPs for many specialists, is feasible for CMS to implement, and helps inform patient decision-making.

Our proposed framework will better ensure that there are applicable MVPs available for all clinicians and takes into consideration specialties with limited quality and cost measures. With the exception of the Surgical Care MVP Candidate, which we continue to not support, the AMA believes that CMS and the specialties can work together to modify the existing or proposed MVPs within this framework. AMA's goal is to have MVPs that work for patients, physicians, and CMS.

However, the AMA strongly opposes making MVPs mandatory and urges the agency to retain traditional MIPS. The MIPS program is already overly burdensome, as research shows compliance costs \$12,800 per physician per year and physicians spend 53 hours per year on MIPS-related costs, e.g., the equivalent of a full week of patient visits. We are concerned that requiring group practices, which is the largest participation method in MIPS, to form subgroups to report MVPs will add significantly to the burden of compliance. We are also concerned that there are not sufficient MVPs for all physicians, including subspecialists, to report as illustrated by this RFI. Worse, many of the MVPs currently available to physicians do not reflect the input of the AMA and national medical specialty societies who have tried through countless methods to offer constructive feedback to improve the MVPs which has been dismissed by the agency, often without sufficient rationale. Finally, as discussed in more detail below, we do not believe mandating subgroup reporting for MVPs is consistent with the best interpretation of the group practice provisions of the statute.

We continue to urge CMS to incentivize reporting of MVPs, rather than mandate it. One way to do this would be by providing more frequent, actionable performance feedback and claims data to physicians and groups that opt to report MVPs. While Congress recognized the critical importance of data sharing with physicians in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) statute, which requires timely MIPS performance feedback, CMS has dragged its feet in meeting its statutory obligations to provide timely (e.g., quarterly) MIPS feedback reports and has never provided Medicare claims data to physicians despite this requirement going into effect in 2018. For the growing set of administrative claims measures in MIPS, including every cost measure, physicians do not currently know which patients are attributed to them, which measures they are scored on, and how their scores compare to their peers and the benchmark until six months after the performance period ends. Without this information at any point during the actual performance year, physicians have no way to monitor their performance, identify opportunities for efficiencies in care delivery, and avoid unnecessary costs. The lack of timely and actionable feedback contributes to physicians' frustration with MIPS, which they experience as another check-the-box exercise rather than an effort to meaningfully improve quality of care and reduce unnecessary costs. CMS could incentivize reporting of MVPs by making Medicare claims data and meaningful MIPS attribution, measure, and performance data available on a rolling basis or, at a minimum, on a quarterly basis during the actual performance period for MVP participants.

Understanding clinician readiness to report MVPs

Condition-Stratified Framework for Aligning Quality and Cost in Specialty MVPs

While there is no one-size-fits-all approach to MVPs that will work for every medical specialty, we believe that an MVP Framework that prioritizes alignment of quality and cost measures will alleviate many of the concerns with the existing MVP approach that ignores the variation in care provided by subspecialists and to different patient populations. Our proposed framework also takes into consideration independent and small physician practices, as it is premised on maintaining the finalized flexibilities for small practice scoring.

Instead of the current approach of having a long list of quality measures in the MVP ordered by Measure ID, we suggest that CMS organize the quality measures into categories, each of which is relevant to a particular patient condition or an episode of a particular type of treatment. If applicable, cross-cutting quality measures, such as depression screening and advance care planning, would be in a separate category. The available cost measures, and the relevant improvement activities, would then be placed into the same condition or procedure categories, i.e., an episode-based cost measure specific to a particular condition or procedure would be shown in the same category as the quality measures for that condition/procedure.

For example:

• In the *Advancing Care for Heart Disease MVP*, the quality measures would be grouped based on whether they applied to coronary artery disease, heart failure, atrial fibrillation, or other heart conditions.

The measures could be further subdivided based on whether they relate to medical management of the condition or an interventional procedure (e.g., percutaneous coronary intervention (PCI) or ablation). The heart failure cost measure would be placed in the same category as the quality measures applicable to heart failure, and the PCI cost measures would be placed in the category for intervention related to coronary artery disease. This is shown in the attached table.

• In the proposed candidate MVP for *Comprehensive Ocular Care MVP Candidate*, we recommend CMS restructure it into subcategories of measures related to cataract, glaucoma, retina and vitreous conditions, or other eye conditions. The cataract episode-based cost measure would be grouped with the cataract quality measures. Please see attached table.

We also would like to see CMS develop MVPs that involve multiple specialists who coordinate care for patients with a particular condition, during an episode of care, or for a procedure. CMS should work closely with the national medical specialty societies to identify opportunities to reflect real-world, multi-disciplinary, and team-based care in MVPs, such as anesthesiology and surgery.

Quality Measure Scoring

This approach would also enable modifications to the scoring rules for MVPs to achieve more appropriate quality scores for MVP participants, including:

- Few relevant measures: If there are fewer than four quality measures in the MVP category for the specific type of condition that a physician manages or the specific procedure the physician performs (subcategory), then the physician would only be required to report those measures, rather than being forced to use generic measures in the MVP that are not relevant to their care or to not participate in the MVP at all.
- *Topped out measures*: To ensure equitable scoring rules and incentivize participation in MVPs, topped-out measures would not be capped.
- New or existing measures or measures without a benchmark: If there are few or no benchmarked
 outcome measures or high priority measures relevant to the condition(s)/procedures the physician
 manages/delivers, then the physician could be given maximum credit for submitting the
 unbenchmarked measures for a longer period to encourage submission of enough cases to
 develop a benchmark.
- Measures with substantive changes: The current approach to truncate the performance period to nine months may not yield sufficient data to establish reliable measure scores and/or benchmarks. Alternatively, if CMS cannot calculate a benchmark from truncated performance data, CMS creates a performance period benchmark. The scoring rule would lead to uncertainty and potential inequities with achieving the performance threshold. To encourage reporting on measures with substantive changes that need a new benchmark, physicians should be given maximum credit for submitting the measures to encourage submission of enough cases to allow CMS to develop a benchmark for future years, just as with the new or existing measure recommendation discussed previously. The current approach to truncate the performance period to nine months may not yield sufficient data to establish reliable measure scores and/or benchmarks.

Cost Measures

The AMA remains extremely concerned about the MIPS cost measures. We have long opposed inclusion of the Total Per Capita Cost (TPCC) in MIPS as it holds physicians accountable for costs over which they have no control because the services are ordered, provided, and priced by others, and for which they receive no data that might allow them to understand and influence their performance on the measure. As described later in our comment letter, the AMA is urging CMS to remove TPCC from MIPS as it meets and, in fact, exceeds the Agency's proposed removal criteria. If CMS does not remove TPCC from MIPS, it should at a minimum remove TPCC from all MVPs that include episode-based cost measures. If CMS continues to use TPCC in MVPs, we continue to recommend that it be modified in several ways:

- Eliminate inappropriate attribution to specialists due to QHP billing by (a) incorporating patient relationship codes/modifiers, (b) using place of service codes, and/or (c) identifying TINs that should otherwise be excluded if not for billing by QHPs.
- Exclude the cost of all preventive services from the measure in order to avoid penalizing physicians, including those who provide primary care, for delivering this high-value care, especially since any savings from preventive services are highly unlikely to be realized during the same performance year that the preventive services are provided.
- Disaggregate the total costs into subsets that are related to the conditions managed by different types of specialists, since it is those costs that each specialist can actually control. The disaggregated amounts would provide more meaningful and reliable measures of differences in practice than the current specialty adjustment and avoid holding specialists accountable for costs they cannot reasonably influence or control.

Finally, we are concerned about the Cost Performance Category resulting in MIPS scores that are inequitable for physicians and misleading for patients because of the limited portfolio of specialty-specific cost measures. For example, since only a subset of ophthalmologists is scored on the cataract surgery episode-based cost measure, other ophthalmologists will have more weight assigned to the Quality and Promoting Interoperability Performance Categories, which means that the MIPS scores for different ophthalmologists will reflect different components of value-based care. While we support CMS' proposed cost measure scoring methodology that would increase cost measure scores as outlined below, CMS must also prioritize development of additional episode-based cost measures.

Population Health Measures

While it is important to measure improvements in population health, adding one-size-fits-all requirements without considering how they can be integrated into existing criteria and tailored to each MVP introduces unnecessary complexity and is less effective at improving patient outcomes. For example, the population health measures are focused on hospital care that is not clinically relevant to ophthalmologists. While ophthalmologists and other specialists, including primary care, may be exempt from some of the measures, inclusion of these measures as a foundational layer would result in confusion and concern about the applicability of those measures and MVP. It also adds an additional category into the program with burdensome and uneven scoring rules that were never intended or required by Congress in the MACRA statute. Maintaining the foundational requirement just adds additional quality measure requirements and standards into the program and increases administrative burden. Because CMS has added this new foundational category, we believe it is not accurate to say that MVPs reduce the number of quality measures that a physician or group must report. In addition, given the measures are based solely on administrative claims, CMS is potentially introducing the same flaws we have repeatedly highlighted with the global cost measures into this new category. Therefore, we urge CMS to remove the flawed population health measures and category as a foundational requirement as it fails to accurately capture quality.

Given the number of problems the AMA has highlighted about CMS' current approach to designing MVPs, whether existing or proposed, we do not support CMS sunsetting traditional MIPS starting in the 2029 performance year/2031 MIPS payment year. MVPs MUST remain an option, along with subgroup reporting within the QPP. CMS should not force practices into a box by requiring them to report on a measure structure that may not make sense to them. It is also premature to propose such a timeline given CMS is continuing to seek feedback on MVPs by issuing an RFI in the 2025 MPFS proposed rule.

We offer the following feedback on outstanding RFI questions:

• For those clinicians who submitted an MVP for the CY 2023 performance period/2025 MIPS payment year, what practice level barriers did you overcome to successfully submit an MVP? How did you overcome any stated barriers? For those who did not submit an MVP, what key barriers impacted your decision to continue to report traditional MIPS?

We recommend CMS reach out to the practices directly that registered to submit an MVP to learn about any practice level barriers to successfully submit an MVP. If a practice registered and did not submit, we also recommend CMS reach out to those specific practices to learn why in the end they chose not to submit an MVP for the 2023 performance period.

We also recommend CMS review the data submitted on 2023 MVPs to see whether it skews towards a certain specialty, like anesthesiology. If there is a dominant specialty, we recommend CMS also reach out to the national specialty society to learn why MVPs may have resonated with a particular specialty. The AMA assumes it could be an indication that the MVP CMS designed for that specialty was relevant and reduced reporting burden over current MIPS. CMS should also reach out to other national specialty societies with existing MVPs in the program to learn why the physicians in their specialty chose not to report an MVP in 2023.

• We are interested to hear the technological barriers, if any, that impacted the ability to successfully submit subgroup level data. We are also interested to hear feedback from groups on any technical issues with de-aggregating data (specifically, the eCQM quality measure data) at the subgroup level.

As we have repeatedly highlighted to CMS, an ongoing problem in the MIPS program, whether MVP or traditional MIPS, as well as MSSP, is the high data completeness threshold CMS has set for successful reporting on a quality measure. The threshold is particularly problematic for physicians who practice at multiple sites of services and report on an eCQM or registry measure. We believe there is a lack of understanding about the maturity of health information technology (health IT) standards to seamlessly aggregate data from EHRs or registries. Challenges include lack of agreed upon semantic and syntactic standards, data privacy concerns, and patient misidentification. Many physician practices also lack knowledge on how to access providers' "digital endpoints" to collect the data needed for aggregation. For more specific details on the problem, see Quality Payment Program comments, Data Completeness Criteria in the Quality Performance Category section.

• What does meaningful MIPS participation look like for clinicians who in the future with the sunset of traditional MIPS may not have an applicable MVP, e.g., clinician types without an MVP due to having less than four applicable quality performance measures and less than one cost measure identified in the 2025 MVP Needs and Priorities.

As previously mentioned, we do not support sunsetting traditional MIPS. MVP must remain an option. In medicine, physician practice structure and design are not homogenous, and we have yet to see an MVP program that works for all of the specialties within medicine. We also believe CMS is too hyperfocused on the number of measures a physician must report. As we stated above, the emphasis should be on ensuring the measures are relevant and follow a clinical condition or episode, not hard numbers. If there are fewer than four quality measures in the MVP category for the specific type of condition that a physician manages or the specific procedure the physician performs (subcategory), then the physician

would only be required to report those measures, rather than being forced to use generic measures in the MVP that are not relevant to their care or to not participate in the MVP at all. As outlined above, we believe CMS should incentivize MVP reporting instead of mandating it. One way to do this is by providing more timely, actionable data and performance feedback.

• As subgroup participation becomes mandatory for multispecialty groups reporting an MVP beginning in CY 2026, how can we balance the increase in burden for groups while allowing comprehensive reporting on the diverse range of services provided by the clinicians in a group? For example, should we consider limiting the number of subgroups that a group must form based on group size and composition?

The AMA continues to oppose mandatory subgroup reporting. While we support a subgroup reporting option to allow specialists in a multi-specialty group to report and be evaluated on relevant measures, we strongly believe this participation method should remain voluntary. Practices should have the option to determine which MVP or MIPS measures are most relevant to the physicians in the practice.

The structure of physician practices is not homogenous. Physicians may practice in an independent practice or be employed by a hospital. They may be in a single specialty practice or a multi-specialty practice. The trend, however, is toward larger practice sizes and multi-specialty groups. In the AMA's report, "Recent Changes in Physician Practice Arrangements: Shifts Away from Private Practice and Towards Larger Practice Size Continue Through 2022," we found that the percentage of physicians in practices with 10 or fewer physicians fell from 61.4 percent in 2012 to 51.8 percent in 2022. In comparison, the percentage in practices with 50 or more physicians grew from 12.2 percent to 18.3 percent. The report also found that over the last 10 years the shares of physicians in multi-specialty practices and who have a direct employment or contracting relationship with a hospital have each grown by about 4 percentage points. In contrast, the shares of physicians in solo practices and in single specialty group practices each decreased by around 4 percentage points.

We are concerned that the growing number of large, multi-specialty practices will face numerous operational challenges to implement mandatory subgroup reporting for MVPs, which will disincentivize reporting on MVPs. Large groups would need to manage multiple applications to form subgroups, which would be time-consuming and administratively burdensome. They would also need to invest in tracking different measures and data submission mechanisms for subsets of physicians and figure out how to manage multiple Medicare physician payment schedule payment adjustments and compensation.

Furthermore, the AMA believes that mandatory subgroup reporting is inconsistent with MACRA, which provides significant flexibility to MIPS eligible clinicians regarding participation types to the extent that CMS invented the "MIPS APM" participant option. Where the statute is prescriptive, it states that CMS must establish a process to assess group practices on the quality performance category of MIPS and enables the Secretary to establish processes for assessing group practices on the other categories of MIPS (Section 1848(q)(1)(D)). This provision of MACRA cannot reasonably be read as requiring subgroup reporting. Additionally, the statute encourages MIPS participation by groups via combining tax identification numbers (TINS) rather than participation by subgroups, which involves subdividing TINs. Under 1848(q)(5)(I)(iii), the process for creating a virtual group includes combinations of TINs: "provide that a virtual group be a combination of tax identification numbers...."

Finally, CMS should also be aware of the challenges with designing a physician quality program that sets up different rules for different practice sizes. It attempted to do so with the legacy physician quality

programs and had to reverse policy. CMS quickly learned it was not technically feasible. Medicine is diverse and the program must continue to provide options.

MVP Development, Maintenance, Scoring and Subgroups

Development of New MVPs

Recommendation:

CMS should modify the proposed ophthalmologic care, dermatologic care, gastroenterology care, optimal care for patients with urologic conditions, and pulmonology care MVPs to be more meaningful to physicians and patients, remedy flaws with the cost measures, test new scoring policies, and remove the population health category. CMS should not finalize the surgical care MVP.

The AMA appreciates the ongoing dialogue and detailed discussions we have had with CMS on MVPs, including during sub-rulemaking when CMS initially released the 2025 candidate MVPs in the winter of 2024. Unfortunately, the six MVPs proposed in the 2025 MPFS (complete ophthalmologic care, dermatologic care, gastroenterology care, optimal care for patients with urologic conditions, pulmonology care and surgical care) completely ignore the detailed oral and written feedback the AMA along with specialty societies provided to CMS, including hosting a roundtable with CMS and the specialty societies to go over extensive feedback to improve the candidate MVPs and overall program. Therefore, we are extremely disappointed in the MVPs proposed for addition to the program given they do not reflect any of the recommended changes.

We recommend CMS revise the proposed 2025 MVPs and not move forwarded as drafted. The AMA strongly urges CMS to consider the following key recommendations for enhancing the MVPs:

- Ensure the MVPs are revised to be more meaningful and directly beneficial to both physicians and their patients, reflecting the real-world clinical scenarios and challenges faced in practice;
- Remedy flaws in the cost measures that are included in the proposed 2025 MVPs;
- Use the MVP framework as a testing ground for new scoring policies that effectively address existing shortcomings in both quality and cost measures, especially for subspecialists, including "topped out" measures and cost measures with little variation; and
- Remove the new population health category from MVP, as the MACRA statute does not specifically call for a population health category—only Quality, Cost, Improvement Activities (IA), and Promoting Interoperability (PI). Alternatively, adopt population health measures specifically for each MVP Candidate, ensuring they are relevant and contribute to meaningful improvements in patient care outcomes.

Please find below our detailed recommendations and specific comments regarding the proposed 2025 MVPs.

1. CMS should revise the proposed 2025 MVPs, so they are meaningful to physicians and their patients rather than moving forward with the 2025 MVPs as written.

The Achilles heel in each of the proposed 2025 MVPs, as well as the vast majority of the MVPs developed to date, is CMS' proposition that specialists who provide different services to different patients

with different conditions or clinical episodes should be held accountable against one another. This diverges from the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) statute's emphasis on episode-based cost measures and patient condition codes, as well as the premise of bundled payment models being tested by the CMS Innovation Center and other payers, which examine condition-specific or acute inpatient/outpatient episodes that typically last up to 90 days. CMS believes that MVPs should offer participants a window into their potential performance in Advanced Payment Models (APMs). To achieve this aim, we urge CMS to better align MVPs and bundled payment APMs by focusing on conditions or episodes of care, more specifically condition-specific subdivisions within a broader MVP. Therefore, physicians who specialize in treating a particular condition would be able to clearly identify the available measures for that condition and register to be held accountable for those condition-specific quality and cost measures within the MVP.

Furthermore, the proposed 2025 MVPs are counter to physicians' practice and person-centered care as they do not link quality and cost for the same patient or the same type of care. The AMA and organized medicine have previously written to CMS about our opposition to organizing MVPs at the broad specialty level, and the AMA continues to urge CMS to propose MVPs that are more clinically relevant by focusing on a discrete condition or clinical episode, even if they are only provided by a subset of the specialty's members or by a particular subspecialty. Alternatively, CMS should follow our proposed framework, which would continue to allow for broad specialty MVPs, but broken out by sub-clinical conditions.

For example, it is misleading for patients and physician practices to suggest the Gastroenterology (GI) Care MVP Candidate reflects a comprehensive measurement and evaluation of "GI Care" with only a label while omitting the full spectrum of care under the purview of gastroenterologists. With six quality measures assessing screening colonoscopy, two quality measures assessing Hepatitis C, one quality measure assessing Inflammatory Bowel Disease, and one episode-based cost measure focused on screening/surveillance colonoscopy, the measure set has limited, specialty-specific measures, which could disadvantage the many providers who subspecialize in conditions such as: motility and functional GI disease, Inflammatory Bowel Disease (a term for two distinctly different conditions: Crohn's disease and ulcerative colitis), interventional/advanced endoscopy, nutrition/obesity, and hepatology/transplant hepatology.

Instead, the AMA echoes the recommendation of the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), American Society for Gastrointestinal Endoscopy (ASGE), and GI Quality Improvement Consortium (GIQuIC) that this MVP should have a narrower focus on colorectal cancer prevention since the proposed MVP does not account for the full spectrum of GI care. A singular clinical condition will offer the granularity needed to be meaningful to both patients and clinicians and enhance comparative reporting and quality improvement. A GI Care MVP initially centered on colorectal cancer prevention is an opportunity to present a clinically coherent MVP for a subset of GI Care providers that can be grown as new reliable quality and episode-based cost measures are added to the QPP. There is also growing evidence that colorectal cancer rates are increasing in younger patients so this would be an opportunity to highlight the importance of tackling this disease, consistent with the White House Cancer Moonshot.

As a second example, we share the concerns of the American Academy of Dermatology Association (AADA) that the Dermatological Care MVP Candidate uses an excessively broad measure set that lacks alignment and is incapable of offering meaningful feedback to enhance patient care as it encompasses both inflammatory and neoplastic disease processes. These distinct disease processes are treated by different subspecialties of dermatology and the overly broad measure set in the candidate MVP will lead

to unfair comparisons among dermatologists with varying sub-specializations and patient populations. Dermatologists who treat psoriasis (currently accounted for in the quality measures) do not treat melanoma (currently the only cost measure). If CMS decides to move forward with combining a cost measure of an oncologic disease with quality measures related to inflammatory disease, it uncouples the important nexus of cost and quality to determine value for patient care. Failing to address these distinctions could lead to misleading comparisons that do not reflect the nuances of each subspecialty's practice, potentially compromising the quality of care for patients. The AMA joins the AADA and recommends narrowing the scope of this MVP to focus on skin cancer, a neoplastic disease, which has a cost measure and clinically relevant quality measures, allowing for meaningful measurement.

As a third example, the Surgical Care MVP Candidate attempts to lump numerous, unrelated surgical specialties (e.g., general surgery, neurosurgery, cardiac surgery, and breast surgery) into a single MVP without any consideration to how care is delivered to patients. This is not only inappropriate from a clinical perspective, but it provides little added value—beyond the current MIPS specialty quality measure sets—in terms of assisting surgical specialists with identifying the most relevant MIPS measures. Therefore, we do not recommend CMS move forward with the Surgical Care MVP.

According to CMS' MVP guiding principles, "MVPs should consist of limited, connected, complementary sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, align scoring, and lead to sufficient comparative data." The Surgical Care MVP, as currently constructed, will not satisfy any of those goals. Instead, it will create confusion and discourage movement into MVPs among surgeons, who might assume that CMS plans to evaluate their performance against other unrelated surgical specialties, pitting one specialty against another. It is also inconsistent since CMS has proposed standalone MVPs for some surgical specialties (urology and orthopedic surgery). At a minimum, CMS should work with the national medical specialty societies to develop one MVP for each specialty using the alternative framework outlined above in the MVP RFI section that groups measures by the major conditions that specialty treats.

We understand that CMS believes developing condition-focused or clinical episode focused MVPs would result in a thousand MVPs blooming, so to speak. We disagree and firmly believe that the Agency has numerous options at its disposal to prevent such an outcome, such as by creating condition specific MVPs that are broken out by sub-conditions. With the exception of the surgical care MVP, the AMA believes that CMS and the specialties can work together to modify the other existing or proposed MVPs within our proposed framework. AMA's goal is to have MVPs that work for patients, physicians, and CMS.

For example, CMS previously established the Improving Care for Lower Extremity Joint Repair MVP, which includes quality and cost measures that evaluate care for patients needing lower extremity surgical repair, such as fractures and total joint replacements. Unlike a broad MVP that would include orthopedic surgeries from multiple, significantly different anatomic regions, this MVP has the potential to provide physicians with actionable performance feedback about patient outcomes and avoidable costs, as well as useful information to patients who may be able to shop around for this surgery. With this MVP as a precedent, CMS should work with national medical specialty societies to develop MVPs around targeted episodes of care or conditions and with appropriate measures moving us closer towards patient-centered care.

Alternatively, CMS could develop MVPs around the episode-based cost measures, such as by adopting the Cataract Surgery MVP put forward by the American Academy of Ophthalmology, the American Society of Cataract and Refractive Surgery, and the American Society of Retina Specialists. This would give CMS a means of limiting the number of MVPs, and MVPs developed under this approach could

grow over time as new episode-based cost measures are added. The AMA and national medical specialty societies stand ready to work with CMS to develop MVPs that are more clinically relevant to physicians and their patients.

2. CMS should remedy the problems with the cost measures included in the 2025 MVP Candidates prior to or in the same rulemaking as the proposed MVPs.

Since CMS made the most recent cost performance category information available to physicians in August 2023, the AMA has heard a growing chorus of concerns about the cost measures. These problems were outlined in detail in December 18, 2023 and October 27, 2023 letters to the Agency. Most relevant to the proposed 2025 MVPs are the problems with the Cataract Removal with Intraocular Lens (IOL) Implantation, Melanoma Resection, and TPCC measures.

First, the AMA has raised its concerns that the cataract surgery cost measure benchmark is based on incomplete data. We heard that a cataract surgeon scored in the 10th decile for the cataract surgery measure and, upon further investigation, realized that their patient level data file shows missing operating room fees. Clearly, there should be operating room charges because the measure captures surgeries done in the hospital outpatient department or ambulatory surgery center. Ophthalmologists cannot and should not be held accountable for the facility's billing practices. If the facility chooses not to bill their claim in a timely manner or has claim errors, it should not be reflected in the ophthalmologist's cost score. If episodes with clearly incomplete billing are being factored into the average cost per episode, then the benchmarks and deciles are wrong. Incorrect benchmarks and deciles hurt the physicians with accurate and complete billing because those physicians appear to be more costly and get pushed to lower deciles. CMS should conduct a study to examine the extent of the problem for this specific measure and seek input from the relevant national medical specialty societies on a policy to exclude from benchmarks any episodes that are missing critical elements, such as operating room charges.

Second, the AMA remains concerned that the melanoma resection measure is making apples-to-oranges comparisons. We learned that dermatologists who are receiving referrals appear to be higher spenders due to a difference in diagnosis coding for the pre-operative services. Dermatologists who see a patient with a suspicious mark will conduct a pre-op visit and biopsy while coding as Neoplasm of Unspecified Behavior (NUB) as it is not yet known whether the lesion is melanoma or not. Because these services are billed with the NUB diagnosis code, they are not included in the cost measure. However, once the lesion has been confirmed as melanoma and referred to a specialist, the specialist then uses a melanoma-specific diagnosis code for the pre-op visit and any related testing, such as bloodwork. Thus, the specialist who receives referrals following a melanoma diagnosis artificially appears to have higher spending due solely to differences in diagnosis coding. CMS should seek input from the relevant national medical specialty societies on creating additional subgroups within this measure based on whether the attributed physician is the physician making the diagnosis or providing care based on a referral.

Third, we continue to strongly believe that physicians should not be measured on the TPCC measure as it holds them accountable for all Medicare Parts A and B spending, the vast majority of which they cannot influence and are likely not even aware of, particularly as CMS still does not provide physicians with information on claims submitted by other physicians and facilities from which their patients receive services. Furthermore, we are concerned that including TPCC in MVPs designed to promote investments in preventive services, such as the Gastroenterology Care MVP, may unfairly penalize physicians for successfully improving the utilization of recommended preventive services as total costs are measured in the same year as those services are provided. While higher utilization of preventive services may reduce costs in the long term, neither the Gastroenterology Care MVP nor TPCC are designed to capture those

services and therefore does not account for the value of preventive services. CMS is essentially penalizing physicians for keeping their patients healthy. Therefore, we strongly oppose inclusion of the TPCC overall, but particularly in MVPs with preventive care measures such as the Gastroenterology Care MVP, which also includes a relevant episode-based cost measure.

Given the combined magnitude of these concerns with the Cost Category, we reiterate our comments below to implement the cost measure scoring methodology beginning with the 2023 performance period or, if that is not possible, reweight the 2023 cost performance category to zero to nullify the negative financial impact of these flawed measures on physician practices. In addition, CMS should fix these problems in subregulatory guidance, like the change that CMS made to the attribution methodology for the chronic condition episode-based cost measures, which should result in fewer misattributed episodes. All changes should be retroactively applied to the 2023 and 2024 performance periods prior to the corresponding payment adjustments taking effect in 2025 and 2026, respectively.

3. CMS should use MVPs as an opportunity to test new alternative scoring methodologies that address existing problems with quality and cost measures, including "topped out" quality measures and cost measures with little variation.

While the AMA is supportive of the proposed cost measure scoring methodology changes, we continue to have concerns about cost measures with little variation among the ten deciles. For example, the variation in cost is extremely limited among the ten deciles in the Screening/Surveillance Colonoscopy measure. The difference between a score in the tenth versus the fifth decile is less than \$200. For the cost measures, we recommend that CMS consider establishing a range of reasonable costs for physicians who provide high-quality care.

As CMS has acknowledged, some MVPs feature "topped out" quality measures which are limited to a maximum of seven points or subject to a flat benchmark (as proposed). Some subspecialties in particular have a limited selection of quality measures to choose from and may have no choice but to select topped out measures, inherently limiting their chances at a high-quality score compared to their peers. This effect is compounded when the same subspecialists do not have a relevant cost measure to report as part of the MVP, and therefore have their cost category reweighted to quality. Physicians are very concerned about having a diversity of physicians in the same broad specialty MVP, wherein some subspecialists who provide the service for which there is an episode cost measure are scored on it and others have no weight for cost at all. Although CMS will not compare performance among MVP participants, there could be a perception that these comparisons will take place, which would lower interest in participating in an MVP. Further, this would not provide meaningful feedback among subspecialists in the MVP. Therefore, we implore CMS to revisit capping the scores of topped out quality measures when there are no alternative or limited measures to report. As the AMA has previously recommended, this would also be a good opportunity to encourage the testing of new measures by awarding physicians full credit for reporting of a new measure for the first two reporting periods, which will promote the development of new quality and cost measures, which will in turn promote the growth of MVPs. For more details on CMS' proposal on topped out measures, see Quality Payment Program, Quality Performance Category, Scoring for Topped Out Measures in Specialty Measure Sets with Limited Measure Choice section comments.

These innovative solutions to current scoring issues would advance the goal of MVPs to improve the accuracy and clinical relevancy of cost and quality evaluations.

Scoring-Calculating population health measures

Recommendation:

• The AMA urges CMS to remove the population health measures requirement for MVPs.

While measuring improvement on population health is important, introducing additional, one-size-fits-all requirements, rather than considering the measures for potential use in existing criteria and tailoring them to each MVP, adds unnecessary complexity and is less effective at improving patient outcomes. We further question the relevancy and impact the measures can have on improving patient care given CMS now proposes to just calculate the best population health measure a practice scores on, regardless of whether it is the most relevant or relevant at all. We appreciate the favorable scoring rules, but administrative claims measures are rife with attribution issues and do not provide information to practices on their patient population in real-time or near real-time. Therefore, practices are essentially at the whim of CMS to dictate which measures they are scored on from year to year and have no opportunity to engage in quality improvement.

While ophthalmologists and other specialists may be exempt from some of the measures, inclusion of these measures as a foundational layer results in confusion and concern about the applicability of those measures and MVP. For example, the population health measures are focused on hospital care which is not clinically relevant to ophthalmologists. However, if they are part of a multi-specialty practice they still will be attributed and scored on the measures.

It also adds an additional category into the program with burdensome and uneven scoring rules that were never intended or required by Congress in the MACRA statue. Maintaining the foundational requirement just adds additional quality measure requirements and standards into the program and increases administrative burden. Because CMS has added this new foundational category, we believe it is not accurate to say that MVPs reduce the number of quality measures that a physician or group must report. In addition, given the measures are based solely on administrative claims, CMS is potentially introducing the same flaws we have repeatedly highlighted with the global cost measures into this new category. Therefore, we urge CMS to remove the flawed population health measures and category as a foundational requirement as it fails to accurately capture quality.

P. Merit-based Incentive Payment System (MIPS)

Performance Threshold

Recommendation:

• The AMA supports maintaining the performance threshold at 75 points in 2025 and is advocating for statutory changes that would freeze it at 60 points for at least three years.

The AMA recommends CMS do everything in its authority to correct the well-documented problems with the MIPS program, including establishing a performance threshold that will not disproportionately penalize small practices and solo practitioners. While the AMA supports maintaining the performance threshold at 75 points during the 2025 performance period, we are urging Congress to go farther and freeze the performance threshold at 60 points for at least three years. A three-year, 60-point performance threshold would introduce much-needed stability into the program, affording all eligible

clinicians flexibility following the five-year disruption of the COVID-19 PHE and Change Healthcare Cyberattack.

In the regulatory impact analysis, CMS estimates there will be 686,645 MIPS eligible clinicians (ECs) in the 2025 performance period, the median final score will be 86.42, and 78 percent of MIPS eligible clinicians will avoid a penalty. The increase in estimated final scores is largely due to CMS' proposal to modify the cost measure scoring methodology. For example, the median cost score increases from 59.16 under current policies to 73.85 based on proposed policies. However, even under the proposed policies, solo practitioners and small practices remain more likely to be penalized. CMS estimates 46 percent of solo practitioners and 21 percent of small practices will receive a penalty compared to 15 percent of MIPS ECs overall. This is also true for solo practitioners and small practices that qualify as safety net physicians, and those in rural areas. See the following table.

	Estimated median final score	Estimated percent receiving a penalty
All MIPS eligible clinicians	86.42	15%
All solo practitioners	75.00	46%
All small practices	86.02	21%
All rural practitioners	85.41	16%
Rural solo practitioners	75.00	46%
Rural small practices	87.34	20%
All safety net practitioners	88.59	14%
Safety net solo practitioners	65.78	52%
Safety net small practices	84.50	27%

CMS projects the median positive payment adjustment in the 2027 payment year based on 2025 performance will be 1.31 percent while the median penalty will be -1.48 percent. However, CMS expects that the median penalty will be -6.42 percent for solo practitioners and -5.88 percent for small practices because more solo practitioners and small groups are expected to receive the maximum negative nine percent MIPS penalty.

Considering these projections, the AMA remains gravely concerned about the impact of the MIPS policies on small practices and solo practitioners and their ability to continue to see Medicare beneficiaries while paying rent, compensating staff, and purchasing supplies and equipment. As discussed above, the gap between what Medicare pays physicians and what it costs to provide care continues to widen every year. Currently, when adjusted for inflation in practice costs, physician pay declined by 29 percent since 2001. Worse, for 2025, CMS proposes to further cut physician payment by 2.8 percent while the costs of practicing medicine are expected to rise by 3.6 percent. It is preposterous to believe physician practices can continue to absorb cuts of this magnitude while investing in the resources necessary to participate in the administratively burdensome MIPS program. The AMA supports maintaining the performance threshold at 75 points. We also believe the Agency should encourage Congress to prevent steep penalties on small practices and solo practitioners, particularly those who provide care in underserved areas and to patients with health-related social needs.

Quality Performance Category

<u>Data Submission in the Quality Performance Category - Multiple Data Submission in the Quality Performance Category</u>

Recommendation:

• The AMA does not support CMS' proposal to codify existing policy on the treatment of multiple data submissions for the quality category when multiple submissions are received from the same organization. CMS should maintain its existing policy to assign the highest score.

CMS proposes to codify its existing policies on the treatment of multiple data submissions received for the quality and IA performance categories. That is, CMS proposes to codify that if the agency receives multiple submissions for an individual clinician, group, subgroup, or virtual group for the quality or IA performance from submitters from separate organizations, the agency scores each and assigns the highest of the scores for the performance category. If multiple submissions are received from the same organization, then CMS will use the most recent submission. The AMA supports CMS' long-standing policy to score the highest of the scores received. To have two separate policies for an almost identical issue is confusing. We also know that there are many shortcomings with CMS' data submission tool, which does not allow for corrections once data has been submitted, so it is best to maintain the policy of giving practices the benefit of the doubt. It is also consistent with CMS' proposal for the PI and IA categories on multiple data submissions. Therefore, CMS should maintain uniform policy across the program on multiple data submission, regardless of whether external or internal.

Data Completeness Criteria in the Quality Performance Category

Recommendation:

 The AMA appreciates CMS maintaining the data completeness criteria at 75 percent but continues to urge CMS to re-think the policy and reduce the data completeness criteria back to 60 percent. The policy does not take into consideration administrative burdens or technology challenges.

As the AMA has stated in previous comments, the increased reporting requirement runs counter to CMS' goal of reducing administrative burden within the MIPS program and CMS has not yet adequately addressed our concerns. Since 2020, CMS has required physicians to successfully report on a quality measure for 70 percent of all eligible patients (otherwise known as the data completeness requirement within the MIPS program). Starting in 2024, CMS increased the data completeness requirement to 75 percent of all eligible patients and we continue to question the feasibility and necessity for such a high threshold. The challenges will further be exacerbated for participants in the MSSP program since ALL MIPS quality policy now applies to the MSSP quality requirements.

We believe there is a lack of understanding about the maturity of health information technology (health IT) standards to seamlessly aggregate data from EHRs or registries from physicians who practice at multiple sites or as a part of an ACO to meet this increased bar. We urge CMS to work with the physician, ACOs and the EHR vendor communities to find solutions to these data aggregation problems. Until the technology standards are more mature, CMS should reduce the quality measure data completeness requirement within MIPS and delay mandatory eCQM adoption for ACOs.

We reiterate the need for CMS to re-open the finalized policy for 2024-2026 and provide an opportunity for stakeholders to weigh-in on the interoperability challenges. Challenges include lack of agreed upon semantic and syntactic standards, data privacy concerns, and patient misidentification. Many physician practices also lack knowledge on how to access providers' "digital endpoints" to collect the data needed for aggregation.

To justify the increased requirement, it is our understanding that there is a perception within CMS that the reporting rates it is receiving for many of the eCOMs within MIPS are 100 percent.³ This may be the case for physicians who practice at one site of service and bill under a single TIN. However, we do not believe that vendors truly understand what is intended with data completeness and therefore the percentage received by CMS does not accurately capture the eligible population for each TIN. Some physicians and almost all ACOs provide services across multiple sites using the same National Provider Identifier or TIN combination, but not all sites (including across sites of service) may participate in MIPS, the registry, or EHR that the physician opts to use for MIPS reporting. Therefore, vendors or practices are just capturing the cases within a single EHR/site, which appears to be 100 percent, but excluding the eligible encounters from other sites of service. This may be the case for physicians who practice at one site of service and bill under a single taxpayer identification number. However, we do not believe that vendors truly understand what is intended with data completeness and therefore the percentage received by CMS does not accurately capture the eligible population for each TIN. Some physicians and almost all ACOs provide services across multiple sites using the same National Provider Identifier or TIN combination, but not all sites (including across sites of service) may participate in MIPS, the registry, or EHR that the physician opts to use for MIPS reporting. Therefore, vendors or practices are just capturing the cases within a single EHR/site, which appears to be 100 percent, but excluding the eligible encounters from other sites of service.

Therefore, we also request that CMS validate its assumption that it is possible to keep increasing the percentage when interoperability and seamless transfer of data are not yet universally available. Accordingly, we request that CMS work with a few registries and practices to compare which patients/data they are able to capture from the practice and/or EHR against what CMS sees for the TIN or NPI in claims. The analysis should also include data from a few specialties such as GI or radiology, as well as internal medicine and family physicians.

We offer the following examples to illustrate the issue:

• Example 1 - Specialty practice with Vendor X as their EHR

The specialty practice uses the Vendor X EHR to report their quality measures. Several physicians at the practice also provide care at two local skilled nursing facilities (SNFs).

Because one of the SNFs also uses Vendor X and has systems set up to enable data sharing with this TIN, Vendor X can include the data in what is reported for MIPS. The other SNF uses Vendor Y and is unable to share data with the practice. Data sharing roadblocks include lack of agreed upon semantic and syntactic standards, data privacy concerns, and patient misidentification. Many physician practices also lack knowledge on how to access providers' "digital endpoints" to collect the data needed for aggregation. To be clear, purposeful information blocking is unlikely the cause in this instance. Lack of technical capability and awareness are the main culprits.

³ Center for Medicare and Medicaid Services (CMS). Medicare Shared Savings Program Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP) Guidance. Posted 12/12/2022.

As a result, Vendor X is not aware of how many patients from that SNF could be eligible for the measure and they do not include the SNF's data from Vendor Y when aggregating the data for MIPS reporting. In addition, the vendor has interpreted the data completeness requirement to mean that they must report all of the cases that are captured in the EHR system. Because of this misinterpretation of the data completeness requirements, the vendor reports a data completeness rate of 100 percent while unknowingly omitting the cases from the SNF from the denominator.

• Example 2 - MSSP Participants

Interpretation of Guidance - ACO A

An ACO has one CEHRT system (Vendor A) used across most participating TINs; however, a small number of the participating TINs are specialty practices and Federally Qualified Health Centers FQHCs, which use different CEHRT systems (Vendors B-D).

The ACO is able to collect data from all participant TINs on Vendor A so the ACO can aggregate the data and complete patient de-duplication before submitting a file to CMS. The ACO was unable to successfully extract and aggregate the data from the other TINs using Vendor B due to data privacy concerns. In addition, although the ACO practices are using CEHRT (Vendors C and D), some of the systems were only able to produce Quality Reporting Document Architecture (QRDA) III files so they are unable to de-duplicate patients. The ACO is also attempting to use billing claims for those practices that are still on paper. Using all these various methods, the ACO estimates a data completeness rate of at least 70 percent, based on the patient volumes. Here again, unaligned implementation of standards and unique customization choices made by CEHRT impact data completeness.

Interpretation of Guidance - ACO B

An ACO has 10 CEHRT EHR systems used across all participating TINs, including several small practices. The ACO is using an external vendor to assist with the data aggregation.

The ACO can collect data from most of the participant TINs. The small practices are unable to submit data to the ACO in the format needed to enable the de-duplication and aggregation steps that ACOs must complete before submitting a file to CMS, because the vendor system used by them will charge an additional fee to support the eCQMs on which the ACO must report that they cannot afford. In addition, one practice changed vendors midyear and as a result is unable to produce the needed files for the reporting year. The ACO is not able to determine the number of individuals who could be included in the eCQMs' eligible populations, so the ACO can either estimate the data completeness and report the measure without data from these practices or remove them from the ACO.

Furthermore, physicians are being held to a higher bar than any other CMS quality program. For example, health plans report on a sample of patients for each of the measures that require clinical data beyond administrative claims in the Medicare Part C and D Star ratings. Hospitals also abstract clinical data on a sample of patients for the clinical process of care measures. None of these sample sizes, which are based on the number of plan participants or individuals admitted to the hospital for a specific diagnosis or procedure, comes close to the current 70 percent data completeness requirement in MIPS. If CMS determined that smaller sample sizes provide sufficient information on which CMS and others can make informed decisions on the quality of care delivered for health plans and hospitals, we believe that this same logic should also apply to MIPS.

Until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings and providers, it is premature to continue increasing data completeness and encourage reporting through a registry or EHR (or require eCQMs/MIPS CQMs under MSSP). Current policy levers such as MIPS Promoting Interoperability requirements or Information Blocking regulations cannot alone resolve data completeness issues. Technology, standards, costs, and implementation decisions made by CEHRT developers will continue to impact the completeness of quality reporting. As previously stated, varying interpretations and assumptions about policy play a key role. Therefore, we urge CMS to work with physicians and developers to solve the data completeness factors we have outlined.

Scoring for Topped-Out Measures in Specialty Measure Sets with Limited Measure Choice

Recommendation:

The AMA supports CMS' proposal for scoring topped-out measures but urges CMS to expand
the policy to ALL topped-out measures. Limiting it to a select set of measures is confusing and
arbitrary.

The AMA appreciates CMS' recognition of the ongoing challenges physicians encounter when reporting on relevant but topped-out quality measures. We support the use of a flat benchmark methodology but recommend that if CMS is going to omit one decile, that it should be the 1st rather than the 9th as the distribution across the deciles appears to be somewhat arbitrary. Clinicians should be able to achieve the highest number of points possible and we do not believe that CMS adequately justified why the 9th percentile was chosen to be removed.

In addition, we urge CMS to apply the policy to ALL topped-out measures. Limiting to a select set of measures adds complexity to the program, is subjective, and favors some specialties over others. For example, the hospitalist specialty measure set includes four measures, and all of the measures are topped-out, but none of the measures are on the flat benchmark eligibility list:

- Advance Care Plan (Measure 047)
- Documentation of Current Medications in the Medical Record (Measure 130)
- HF: ACE or ARB or ARNI Therapy for LVSD (Measure 005)
- HR: Beta-blocker Therapy for LVSD (Measure 008)

Therefore, due to the continued scoring cap on the measures they report on they are unable to meet the 2025 performance threshold. A hospitalist along with other specialties can participate in the program and meet the reporting requirements but will automatically be subject to a negative payment adjustment.

Complex Organization Adjustment for Virtual Groups and APM Entities

Recommendation:

• We appreciate CMS recognizing the complexities with reporting eCQMs for APMs and Virtual Groups by providing additional measure achievement points, but the policy does not provide sufficient safeguards or incentives for reporting eCQMs or address the underlying technology limitations with reporting eCQMs. We urge CMS to score eCQM measures as pay-for-reporting and re-instate the web-interface and ability for ACOs to report MIPS CQMs.

To account for the organizational complexities faced by Virtual Groups and APM Entities, including ACOs in the Shared Savings Program, CMS is proposing to establish a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS Payment Year. Virtual Group and APM Entities would receive one measure achievement point. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment would be added for each measure submitted at the individual measure level. We appreciate CMS acknowledging the complexities of obtaining data across practice sites, but the policy should not be limited to just Virtual Groups or APM entities. It must be applied across MIPS.

As we highlighted in our data completeness section, any physician who practices at multiple sites, including sites of service, has challenges with collecting and reporting data. See *Data Completeness Criteria in the Quality Performance Category* for more specific details on the challenges with collecting and reporting data across multiple sites. If CMS is concerned with verifying eligibility, CMS has the ability to clarify during the data submission period through the QPP portal whether the practice utilizes multiple EHRs or practices at multiple sites. As part of PI data submission requirements, practices already must include their CEHRT CHPL number. For the site of service issue, the information is documented on Medicare claims and given CMS calculates administrative claims measures for all MIPS participants, it can review this information as part of calculating administrative claims measures.

In addition, the additional points do not address the underlying challenges with submitting data and provide sufficient safeguards for reporting electronic measures. There is great concern among ACOs on the ability to successfully pull, package, and submit eCQMs to CMS. As a result, they are worried that the data they submit will be incomplete, rife with errors, and then inappropriately scored, which will impact their quality score and overall eligibility for shared savings. Therefore, given the flexibilities CMS has with implementing MSSP and APM programs, we urge CMS to score eCQM measures as pay-for-reporting measures until the underlying technology and interoperability challenges are resolved. We know CMS has the statutory authority to do so because prior to CMS implementing universal MIPS scoring policy to the MSSP, it scored new measures as pay-for-reporting.

Quality Measures with Substantive Changes

Recommendation:

 We urge CMS to re-evaluate and change its policy on how it scores quality measures with substantive changes. The current policy to truncate the performance period to nine months is problematic, as it may not yield sufficient data to establish reliable measure scores and/or benchmarks.

In the 2025 MPFS, CMS proposes substantive changes to 66 quality measures out of 196 total measures in the program. As a result of CMS' policy for scoring measures with substantive changes, 33 percent of measures in the program are subject to a new benchmark, which provides no certainty to physicians in terms of how they will be scored on the measure. The current policy to truncate the performance period to nine months is problematic, as it may not yield sufficient data to establish reliable measure scores and/or benchmarks. If CMS cannot calculate a benchmark from truncated performance data, CMS creates a performance period benchmark. Therefore, the scoring rule leads to uncertainty and potential inequities with achieving the performance threshold. To encourage reporting on measures with substantive changes that need a new benchmark, physicians should be given maximum credit for submitting the measures to

encourage submission of enough cases to allow CMS to develop a benchmark for future years, just as with the new or existing measure recommendations discussed in the MVP RFI section of our comments.

Ensuring that the scores used to evaluate physician performance and for benchmarking have sufficient denominator cases is critical. We encourage CMS to evaluate the potential impact on the measure score reliability due to any substantive change and/or the resulting truncation of data. We also encourage CMS to evaluate whether a coding update should be considered a substantive change based on whether changes in performance scores are due to the modifications to the measure construct or coding rather than actual performance. For example, if year-over-year comparisons could not be attributed to actual changes in performance, it should be considered a substantive change and may require reliability of the measures scores to be reassessed.

We offer the following measure-specific comments on measures proposed with substantive changes and new measures:

Preventive Care and Wellness (composite)

While we appreciate that the measure was updated to improve data capture and ensure that it is aligned with evidence, we remain extremely concerned that the complexity of the measure with seven numerators, denominators, and exclusions/exceptions will directly impact the feasibility of the measure for use in MIPS. We continue to request that CMS reconsider the removal of the seven individual measures as each addresses important preventive care activities. It also eliminated the ability of some specialties to select a subset of the measures, such as those around vaccinations on which they may be able to report. As a result, the AMA continues to oppose the inclusion of this measure in MIPS.

Connection to Community Service Provider

While we support this measure's intent, we continue to oppose its inclusion in MIPS. Measures must be evidence-based and facilitate improvements in patient care. Unfortunately, we continue to see a lack of any evidence supporting the measure, nor has any testing been provided to demonstrate the measure's reliability and validity. Even more concerning, CMS now proposes to expand the measure to be attributed to clinicians to more than 15 specialties.

We remain concerned that clinicians will be unable to address their patient needs due to the lack of resources and tools that are widely and readily available to clinicians and practices. The availability of resources will also be dependent on the patient's locality and the type of service needed. For example, the second evaluation report of the Accountable Health Communities (AHC) model found that there were several factors that contribute to whether a community service provider may offer services to individuals, including limited availability of affordable housing and transportation services and whether some patients were able to meet the eligibility requirements for a service. These gaps are not within the clinician's control and contribute to our concerns. These issues were also identified in a recent JAMA article, specifically that the inadequacy of the measure and "well intentioned mandate will impede progress in health equity and have the potential to increase long-standing racial and socioeconomic inequities." The article also highlights that there is a difference between social risk screening, which relies on validated screening measurement tools, and social need screening, which queries whether a patient desires assistance. This measure does not make a distinction and does not acknowledge that clinicians may not be

⁴ Garg A, LeBlanc A, Raphael JL. Inadequacy of current screening measures for health-related social needs. *JAMA*. Published online August 21, 2023. DOI:10.1001/jama.2023.13948.

able to adequately address a patient's needs due to persistent shortages in resources that are outside of their control, as well as patients' preferences.

At a minimum, the measure should continue to align with the work of the HL 7 Gravity Project and the USCDI. Specifically, there should be continued work to include additional health-related social needs (HSRN)-aligned interventions from the Gravity-curated intervention value sets. For example, while the performance is met using a HCPCS code, additional interventions from these value sets should be allowable and/or mapped to the required numerator coding to facilitate standardized data collection since "contact with a community health worker" does not provide sufficient detail to facilitate quality improvement at the point of care. Use of the Gravity Project-curated intervention value sets would enable clinicians to capture specific details such as "provision of food" or "enrollment in SNAP program" and while this measure is not yet specified for electronic health record systems, including guidance and mapping to these value sets would facilitate future digital data capture.

In addition, the measure itself must be tested to demonstrate reliability and validity since only data for two screening tools (which are not required) were provided. Most of the information outlined is based on CMMI's AHC project, which involved community health centers/health systems. Therefore, testing to date has been insufficient and it is unknown how the measure would perform at the individual clinician level. Furthermore, we believe that it is imperative that this process measure has demonstrated links to directly improving patient outcome without any unintended consequence of creating patient harm. By expanding to additional specialties without sufficient testing at the individual clinician level, we believe that CMS increases the potential for unintended negative consequences, and we do not support the measure or this expansion in MIPS or MVPs. Adding this measure along with continuing to include the problematic *Screening for Social Drivers of Health* measure in MIPS or MVP, which we continue to not support, will only exacerbate the problems on measures related to social needs. To continue to include social needs-related measures in the MIPS program along with ALL the CMS quality programs without a comprehensive strategy on the best approach for physicians and providers to address the problem will exacerbate inequities and runs the risk of deteriorating the physician-patient relationship.

Adult COVID Vaccination Status

The AMA continues to have concerns with this measure and strongly encourages CMS to clarify its numerator. Specifically, this numerator defines the vaccination status as whether a patient is up to date on his or her COVID-19 vaccinations as defined by the CDC, but this definition continues to change throughout the performance year. Therefore, it is inappropriate to hold physicians accountable for COVID vaccination rates when the recommendations keep changing. No other measure within the MIPS program relies on clinical recommendations that are known to change frequently. This vague and variable definition increases its complexity and could negatively impact the reliability and validity of the measure. It is also difficult to track since a large percentage of patients do not receive their COVID vaccinations from their primary care provider. As a result, it must be thoroughly tested prior to its implementation.

In addition, this measure has yet to receive support from the committees charged with determining whether a measure is appropriate for MIPS. First, it was not supported by the Measures Application Partnership in 2022 and during the most recent review by the Pre-Rulemaking Review (PRMR) Clinician Committee the measure did not achieve consensus on a recommendation. Until testing of the measure with precise specifications is completed and consensus is reached by PRMR, we believe that this measure should not be implemented in this program.

We offer the following measure-specific comments on measures proposed for removal:

Q439: Age-Appropriate Screening Colonoscopy

The AMA opposes removal of Q439, *Age-Appropriate Screening Colonoscopy* measure from MIPS. The goal of the measure is to eliminate inappropriate screening colonoscopies, and the measure assesses eligible clinicians routinely performing screening colonoscopy, including those doing lower volumes, to determine if unnecessary screening of the elderly is being performed. Therefore, we recommend maintaining the measure in this program as it focuses on a vulnerable population and specifically addresses overuse of colonoscopy, thereby improving cost and resource efficiency.

We also do not believe MIPS performance data is an accurate assessment to determine whether this measure was topped- out and CMS' analysis was insufficient to make the determination. CMS' analysis was based on one year of benchmarking data following the substantive changes made to the measure specification in PY2022. The amount of time to verify the extremely topped-out status should be based on multiple years, not one performance year cycle, and no other multi-year data was used to validate the topped-out status or extremely topped-out status, which typically occurs over multiple performance year cycles. Furthermore, Q439 has been designated by CMS as a high-priority measure and as the only colorectal cancer screening measure that specifically addresses the vulnerable population of older adults. Other more general conditions such as screening for Body Mass Index (BMI) and blood pressure are also standards of care where every patient is weighed and has their blood pressure checked at every eligible contact with a provider; however, CMS continues to include the measure in multiple specialty sets regardless of the performance rates.

Furthermore, the implications for removal of this measure are greater than just reducing the number of reportable measures in the MIPS program. Q439 is one of six measures included in the GIQuIC qualified clinical data registry (QCDR) measure set, three of which are QPP measures and three of which are GIQuIC QCDR measures. All six of these measures look at physician performance on screening and surveillance colonoscopy and support meaningful and feasible performance measurement of clinicians addressing colorectal cancer prevention. It is the six quality measures that make up the GIQuIC QCDR Measure set that balance the only specialty-specific cost measure included in the candidate GI Care MVP, the Screening/Surveillance Colonoscopy episode-based cost measure.

Q144: Oncology: Medical and Radiation - Plan of Care for Pain

The AMA strongly opposes the removal of *Q144: Oncology: Medical and Radiation – Plan of Care for Pain* from the MIPS Program and echoes the American Society of Clinical Oncology's (ASCO) concerns with removal of the measure. The measure is not duplicative of, but rather paired with, *Q143: Oncology: Medical and Radiation – Pain Intensity Quantified.* The measures should be implemented sequentially to achieve a comprehensive clinical quality outcome, with Q143 confirming that the patient's pain was evaluated and Q144 validating that a patient care plan for pain was developed based on that assessment. The intent is for applicable clinicians to report on *both* measures as a unit, while resulting in individual measure scores. Second, both measures were recently re-endorsed by CMS' consensus-based entity contractor, Battelle, as part of its Fall 2023 Endorsement and Maintenance cycle. In addition, a 2022 study evaluated patient and caregiver perspectives on cancer-related quality measures, to inform priorities for health system implementation. Measure concepts related to pain management plans and improvement in pain were nominated as part of the top five concepts. The study noted that the patient and caregiver panel emphasized the importance of routine pain screening, management, and follow-up. ⁵ Third, the

⁵ O'Hanlon, C. E., Giannitrapani, K. F., Lindvall, C., Gamboa, R. C., Canning, M., Asch, S. M., Garrido, M. M., ImPACS Patient and Caregiver Panel, Walling, A. M., & Lorenz, K. A. (2022). Patient and Caregiver Prioritization

observed performance rates of this measure within the MIPS-Quality Program from the 2019-2021 performance periods indicate opportunity for improvement at both the individual clinician and practice level.

Third-Party Intermediaries General Requirements - Requirements for CMS-approved Survey Vendors

Recommendation:

• The AMA supports CMS' proposal to require Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey vendors to include in their application to CMS the range of costs of their third-party intermediary services starting in the 2026 performance period. The proposal is consistent with requirements placed on other third-party intermediaries that participate in the MIPS program.

Survey Modes for the Administration of the CAHPS for MIPS Survey Request for Information

Recommendation:

• The AMA supports the addition of web administration of the CAHPS for MIPS survey but is concerned vendors will use it as an opportunity to increase their survey administration fees. For years organizations have highlighted the need for CMS to allow organizations the option to administer the CAHPS for MIPS surveys via more modern technology, such as email and do not see the downside, as long as it is an option. Practices should have the ability to determine whether administering via email or postal mail is most appropriate based on their patient population and any increase in cost is worth the return on investment. CMS' field testing demonstrated that allowing email increased response rates. However, we caution CMS on moving too quickly with the expansion because we are concerned that vendors will increase their survey administration fees. We do not believe that practices should be asked to shoulder the additional expense in an already costly and burdensome survey to administer, on top of the cost to participate in the MIPS or MSSP programs.

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

While we understand that CMS seeks to increase the number of measures that leverage patient-reported information in their programs and models and is a measurement focus we support, it remains unclear how the principles proposed in the RFI will create a meaningful pathway to achieve the implementation and use of patient-reported outcome measures (PROMs) and patient-reported outcome performance measures (PRO-PMs) without additional burden and costs to practices, health systems, and others. We believe that many of these principles are already addressed in current requirements for a measure to be included in CMS quality programs, including reliability and validity testing, feasibility of implementation without unnecessary costs or implementation burden, and patient engagement in measure development. The RFI also mentions that it is important to have a data infrastructure that "allows PROMs and PRO-PMs to be integrated into clinical workflow with minimal cost and administrative burden, with data seamlessly shared across different health care settings and systems." Other efforts including CMS' Digital Quality Measure (dQM) Roadmap⁶ seek to ensure that all measures including PRO-PMs are deployed using

of Palliative and End-of-Life Cancer Care Quality Measures. *Journal of General Internal Medicine*, 37(6), 1429–1435. https://doi.org/10.1007/s11606-021-07041-8

⁶ https://ecqi.healthit.gov/dqm?qt-tabs dqm=dqm-strategic-roadmap

interoperable data standards. As a result, we do not understand what additional value these principles provide or if they will further ensure that the PRO-PMs selected by CMS have minimal burden to implement and report and result in data that can inform patient decision-making and assist clinicians in their quality improvement efforts.

The RFI also proposes a potential path forward through a database, "the development of an accessible and unified database of PROMs/PRO-PMs." The proposed database would capture those tools and measures not only across federal programs but also states, commercial payers, and others. It also implies that multiple repositories of PROMs and PRO-PMs may discourage measure development and potentially create additional costs to clinicians and others. It is not clear how multiple repositories could discourage measure development as we are not aware of any examples where this has occurred nor are we able to determine how the presence of multiple options would lead to additional burden. CMS' potential repository appears to be like the previous National Guideline Clearinghouse (NGC) and National Quality Measures Clearinghouse (NQMC) that were sponsored by the Agency for Healthcare Research and Quality (AHRQ), but folded due to lack of funding. In addition, there is a similar resource currently available called the CMS Measures Inventory Tool (CMIT). These clearinghouses require significant funding and oversight to ensure that the information included remains up to date. HealthMeasures was also noted as a model for PROMs that are publicly available, yet there are still costs to end users if additional services such as scoring are needed, or a survey must be translated to another language. As a result, it is not clear what additional value a national repository would provide.

The AMA supports efforts to continue to bring the patient voice into measurement efforts but urges CMS to focus their efforts around reducing implementation burden of these PRO-PMs and thoughtfully approaching some of the potential unintended consequences that may be encountered with increased use of PRO-PMs. Each PROM and resulting PRO-PM requires careful evaluation by practices and others on whether the survey or its results should be captured within an electronic health record system (EHRs) or if another source should be leveraged. Even with the increased use of interoperable data standards, these tools and resulting performance measures require mapping of data within the EHRs and potentially with other external databases or systems. Practices must also spend significant time determining clinical workflows to optimize data capture and build quality improvement activities to ensure that the resulting information can be used to improve patient care. In addition, the potential for patient fatigue when asked to complete one or more surveys during every encounter and across health care settings is a real concern and CMS, practices, health systems, and others must identify strategies to ensure that we are prioritizing the collection of data that are most useful to inform clinical care and patient decision-making rather than trying to measure everything.

The potential unintended consequence of a broad, rather than selective, approach to selecting and implementing PRO-PMs is not adequately prioritized in CMS quality programs, and we are greatly concerned that in the future, disease-specific measures will not be approved for use within MIPS or an MVP. In a specialty like rheumatology where defining quality of care can be extremely dependent on the specific disease being treated, it may not be clinically appropriate to combine similar clinical assessments for different diseases into one measure. For example, the best tools to evaluate disease activity in rheumatoid arthritis are not appropriate to evaluate disease activity in psoriatic arthritis (PsA) and combining those concepts into one measure increases its complexity and implementation burden for practices. It also makes it more difficult for clinicians to have access to actionable data, truly understand their performance among those distinct populations, especially if performance among the larger patient population (e.g., rheumatoid arthritis patients) is already topped-out, and may give the false impression

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⁷ https://www.healthmeasures.net/resource-center/about-us/pricing-for-services

that performance among the smaller patient population (e.g., PsA) is better than it is. This problem will only be compounded by moving to one universal PROM or PRO-PMs. Therefore, we urge CMS to focus on creating a process that encourages evaluations of potential PRO-PMs based on strong clinical input and patient perspectives balanced with realistic assessments on whether the value of the patient-reported outcome (regardless of whether it is broad or condition-specific) outweighs the burden of data collection and reporting.

Lastly, to improve the measure development process, CMS must recognize that changes to measures, whether through a QCDR, registry or EHR, require significant financial resources and time to plan, incorporate, and test. This time-lag limitation becomes very challenging when CMS makes annual changes to quality requirements, measure specifications or technology functionality. In addition, changing the measure development and QCDR process and expectations of measure developers and QCDRs on a yearly basis creates the perception among specialty-led measure developers and QCDRs that the changes are arbitrary and lack evidence or reason. The annual changes are also administratively burdensome and do not allow sufficient time for implementation. Therefore, there must be consistency from year to year, especially if CMS would like to move to measuring improvement.

Furthermore, it is nearly impossible to create historic benchmarks if CMS changes or removes measures annually. For example, the Screening Colonoscopy Adenoma Detection Rate measure has been included in the program since its inception and is the only colonoscopy-focused outcome measure for gastroenterologists. In 2019, the measure was last reported as a MIPS Clinical Quality Measure and removed from the program through rulemaking that same year; however, in 2020, CMS allowed it to be reintroduced as a QCDR measure. Over the last five years, changes to the overall structure of the measure were made: from a single measure to one measure with multiple stratifications (multi-strata) to two separate measures back to one measure with multi-strata. All changes were made at CMS' request. While none of these changes impacted the intent or scope of the measure(s), it resulted in adding burden to physicians and their teams to modify workflows without any connection to quality improvement. In addition, it required resetting the benchmark every year until 2024. It is the AMA's belief that the only way to truly measure improvement and track data over time is to have a process in place that allows for longitudinal data collection and tracking.

There is a false belief within CMS and among its contractors that reducing the number of measures and limiting the number of MVPs will reduce the burden of the program. It is not the number of measures or MVPs that cause physician burden, but rather the many and frequently changing reporting requirements associated with the measures. Also, combining multiple measures into one measure increases complexity and adds additional burden to reporting. Physicians are still reporting multiple clinical processes or outcome measures, but now the individual measures are rolled into one bundled measure. Key to achieving MACRA's goals and improving the program is the availability of a robust portfolio of appropriate quality measures and MVPs that are harmonized with improvement to assist physicians with advancing the care of their patients. Moreover, as the Agency continues to introduce new episode-based cost measures into MIPS, it is essential that there are sufficient, clinically related quality measures to ensure that cost and quality can be evaluated in tandem and prevent stinting on care.

Cost Performance Category

Recommendations:

• CMS should introduce the six proposed episode-based cost measures on an information-only basis for at least two years due to concerns about unintended consequences, particularly related to

health equity and inclusion of Part D drug costs. Additionally, CMS should establish specialty exclusions for the proposed episode-based cost measures, along with all of the chronic condition cost measures.

- CMS should finalize its proposal to establish criteria for removing cost measures. Based on the removal criteria, CMS should immediately remove the TPCC measure from MIPS.
- CMS should finalize its proposed changes to the cost measure scoring methodology beginning with the 2023 performance period. If CMS cannot apply this policy retroactively, then it should zero out the cost performance category for the 2023 performance period.
- CMS should finalize its proposed changes to the cost measure exclusion policy beginning with the 2023 performance period.
- To align with the Medicare Shared Savings Program, CMS should mitigate the impact of significant, anomalous, and highly suspect (SAHS) billing activity on cost measures in MIPS.

Proposed Cost Measures Should be Informational - Only for at Least Two Years

CMS proposes to include five chronic condition cost measures related to outpatient treatment and ongoing management of chronic kidney disease (CKD), end-stage renal disease (ESRD), kidney transplant management, prostate cancer, and rheumatoid arthritis. CMS also proposes to add the Respiratory Infection Hospitalization measure which focuses on inpatient treatment of respiratory infection. **Due to ongoing concerns with the measures, we urge CMS to add the six proposed episode-based cost measures on an information-only basis for at least two years to allow tracking and feedback about these measures before they could potentially penalize physicians for caring for more patients from historically minoritized and marginalized communities or for care outside of the control of the physician.** The information-only period must be at least two years to allow sufficient time for physicians to receive feedback on the measures as feedback reports are not currently available until six months after the start of the year following the performance period.

In comments during field testing of these measures, the AMA raised numerous concerns about potential adverse consequences on health equity due to these measures and our concerns continue to remain unaddressed.

Kidney Disease Measures

Regarding the kidney disease measures, race has been included in kidney function (estimated glomerular filtration rate or eGFR) calculations based on flawed explanations of clinical trial data suggesting that Black patients have higher levels of creatinine in their blood. Unfortunately, this has led clinicians to underestimate the severity of kidney disease in many Black patients, delaying their access to medication, specialist referrals, nutrition therapy, disease education, dialysis, and transplants. Recent changes to eGFR calculations eliminate the race adjustment allowing for potentially better health outcomes for Black patients as more laboratories become aware of and adopt the new formula, but implementation is still in progress. For Black patients that have received late diagnoses or care as a result of the old eGFR formula, the cost to treat them will likely be more than for non-Black patients. Measures that fail to account for this may incentivize physicians to avoid these patients to have better cost scores or further skimp on or delay care for these patients in an effort to curb costs, further exacerbating existing inequities for patients. In addition, research has found that physicians who care for Black patients often have fewer resources, making the administrative burden of MIPS reporting less feasible, or have limited access to the specialists needed to complete assessments to get on the transplant list, resulting in all of these cases putting any incentive payments out of reach.

It is also unclear how past use of a race-based formula and the still inconsistent use of successor formulas are accounted for in the CKD, ESRD, and kidney transplant management measures. CMS must ensure these measures avoid penalizing physicians who are caring for patients who have previously had care delayed by use of the old formula. The Organ Procurement and Transplantation Network (OPTN) recently <u>called for</u> reassessing transplant waiting lists based on this issue and could serve as a model.

Prostate Cancer Cost Measure

Similar to the kidney-related issues expressed above, prostate cancer has many racial disparities that are present at every stage of the cancer continuum. Black men in the U.S. have 60 percent greater incidence, a higher proportion diagnosed at advanced stage, and two times the prostate cancer mortality than white men. Factors such as increased exposure to neighborhood deprivation and carcinogens, less access to care, lower prevalence of PSA screening, and lower quality care are related to Black men being diagnosed at a later stage and experiencing higher mortality. These exposures, delays, and missteps could lead to higher cost of care for advanced cancer or complications compared to non-Black patients. As a result, MIPS may incentivize physicians to prioritize patients expected to have better outcomes and avoid patients or services expected to cost more, which would exacerbate existing prostate cancer inequities. At the same time, the policy could discourage physicians from spending more time discussing options with patients who have historically been mistreated by the health care system and/or addressing social factors that are barriers to care. Stratifying cost measures separately within groups with local or metastatic cancer may be helpful in avoiding discrimination against Black men who are more likely to present with advanced disease, as long as the payments for caring for metastatic disease are sufficient to avoid incentivizing physicians to shift their care predominantly toward patients with localized disease.

Rheumatoid Arthritis Cost Measure

Regarding the rheumatoid arthritis measure, research has shown that disparities exist in patients with rheumatoid arthritis that affect outcomes, prognosis, and management of the disease. Access to care is a major concern for many physicians, no matter the area of practice, but is so specifically with rheumatoid arthritis due to lack of access to a nearby rheumatologist and/or inadequate access due to narrow networks in coverage prior to eligibility for Medicare. As a result, it often leads to delayed diagnoses and care and more severe disease manifestations and irreversible bone destruction, disability, and loss of function. According to an NIH study, "Caucasians" with RA have the least amount of disability (HAQ-DI 1.24) compared with African Americans (HAQ-DI 1.28), which often results in greater need for physical, occupational, or speech therapy for Black patients relative to others. Given the access issues and contribution to the need of higher acuity of services, physicians' quality scores and cost scores are adversely impacted, especially physicians who treat a higher proportion of patients with social demographic factors.

Another contributing factor of concern for rheumatoid arthritis patients is pain, which was also reported as higher in African Americans (39.3/100) versus "Caucasians" (33.3/100). Again, this could lead to far worse, more expensive outcomes for Black patients. The same study saw high opioid prescriptions with more than 66 percent of Medicare/Medicaid beneficiaries receiving chronic opioids, which could suggest that Black rheumatoid arthritis patients present with more pain and joint deformities, subsequently having an increased need for/reliance on pain medications. This is particularly problematic as the measure includes Part D costs. If this disparity in need for medication is not taken into account, then physicians taking care of Black patients could be penalized for providing appropriate care based on higher relative costs.

Moreover, the Partnership for Quality Measurement Pre-Rulemaking Measure Review Measures Under Consideration Clinician Committee voted not to recommend the rheumatoid arthritis episode-based cost measure for use in MIPS due to concerns around how it impacts patient outcomes and wide differences in costs to manage rheumatoid arthritis by provider group. The Committee also did not reach consensus on the CKD, ESRD, kidney transplant management, and respiratory infection hospitalization measures with a majority of votes for do not recommend or recommend with conditions. The Committee also cited health equity concerns, as well as concerns with scientific acceptability and appropriateness of risk adjustment. Ultimately, the Committee urged CMS to provide stronger justification for the cost measures.

Inclusion of Part D Prescription Drugs in Cost Measures

We remain concerned that the addition of prescription drugs to the cost measures, which is not yet well understood, will only exacerbate current inequities in the program. Inclusion of medications would penalize physicians for something over which they have no control. Drug manufacturers and payers, in this case CMS and Medicare Prescription Drug Plans – rather than physicians – negotiate formularies, coverage, and price. To hold physicians accountable for transactions they are not responsible for negotiating is fundamentally problematic. In this scenario, one presumes that patients and physicians have information about coverage, formularies, out-of-pocket costs, and list prices at the point of care, which is not true in most cases. We believe this also assumes there is a viable, evidence-based, less expensive alternative option for patients. We strongly oppose including Part D prescription drug costs in Medicare cost measures.

Similar to the Diabetes, Asthma/COPD, and Sepsis measures in Wave 3 and Heart Failure, Low Back Pain, and Major Depressive Disorder in Wave 4, we were also unable to fully evaluate the impact of the addition of Part D prescription drug costs to the CKD, ESRD, Kidney Transplant, Prostate Cancer, and Rheumatoid Arthritis episode-based cost measures due to the lack of access to detailed, aggregate-level data about the variation in spending per drug class, per drug plan, and per drug tier with different copayments and thus different patient incentives. We urge CMS to release more information about how the payment standardization methodology distinguishes costs in a manner that is actionable for physicians to influence. Release of this vital information should be done prior to proposing inclusion of these measures in MIPS.

Due to these concerns, CMS should not move forward with the six new cost measures as proposed. Instead, CMS should introduce these measures on an information-only basis for at least two years to allow time for physicians to receive performance feedback on these measures and evaluate whether the measures are having any unintended consequences, such as penalizing physicians who care for more patients who are historically minoritized or marginalized. This information-only period would also give CMS time to provide more information about the impact of Part D drug costs on physicians' scores and payment adjustments in MIPS.

We were pleased that CMS' cost measure development contractor, Acumen, presented a measure concept that would be informational-only in the MIPS program during the March 2024 Technical Expert Panel meeting. The AMA has made this recommendation in the past and been told that CMS does not have statutory authority to include a measure that does not count toward the MIPS score and payment adjustment. We are glad that CMS has apparently reevaluated its legal analysis and determined that the Agency can adopt measures on an information-only basis.

Proposed and Existing Chronic Condition Cost Measures Should Include Specialty Exclusions

The AMA has heard concerns from several national medical specialty societies that the proposed chronic condition cost measures may be inadvertently attributed to physicians who are providing care to patients with CKD, ESRD, or rheumatoid arthritis but not managing the patient's chronic condition. If history is a guide, then we should expect that these concerns will come to fruition. As previously communicated to CMS, the existing chronic condition cost measures have been inappropriately attributed during the 2022 performance period. In particular, the AMA heard from an interventional cardiologist who was attributed the diabetes cost measure. Similarly, we heard that numerous ophthalmologists were inappropriately attributed the diabetes cost measure because they treat co-morbidities of diabetes, such as diabetic eye disease, and not the patient's underlying diabetic disease. We were pleased that CMS agreed to fix the attribution error for 2023 and beyond but extremely disappointed that CMS did not fix the problem for the 2022 performance period.

In a subsequent <u>letter</u>, the AMA highlighted more attribution problems with the chronic condition cost measures. Specifically, we heard that oncologists were inappropriately attributed both the diabetes and asthma/COPD cost measures. We heard from oncologists in oncology groups (including medical, surgical, radiation, and gynecologic oncologists, as well as urologists and hematologists) who have multiple visits with patients during the performance period and may include ICD-10 codes related to complications of these conditions as they impact and may alter the course of chemotherapy and other oncology treatments. However, an oncologist including significant complications of care in billing for oncology-related visits should not result in attribution of non-oncology cost episodes. This will result in skewed benchmarks and unfair penalties on oncologists who have much higher spending on cancer care than physicians who are managing patients' diabetes or COPD in the absence of cancer. We are further concerned that unfairly penalizing oncologists is detrimental to the Administration's Cancer Moonshot, as any MIPS penalty would cut cancer care.

Although CMS has taken steps to improve attribution of the diabetes cost measure, we remain concerned that inappropriate attribution of the chronic condition cost measures is ongoing and penalizing physicians for care outside of their control. Additionally, it is not an effective policy solution to respond retroactively when attribution issues become apparent in feedback reports six months after the end of the performance period. Instead, CMS should proactively prevent inappropriate attribution by seeking input from the national medical specialty societies and adding specialty exclusions to all chronic condition cost measures in MIPS. There is precedent for this approach in the TPCC measure.

Finalize Cost Measure Removal Criteria and Remove the TPCC Measure from MIPS

The AMA is pleased that CMS proposed objective factors for removal of cost measures, and we strongly urge CMS to immediately remove TPCC from MIPS based on these criteria. CMS proposes the following criteria for removal of a cost measure:

- It is not feasible to implement the measure specifications.
- A measure steward is no longer able to maintain the cost measure.
- The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- The measure specifications do not reflect current clinical practice or guidelines.

• The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

The problems with TPCC meet and, in fact, exceed the proposed criteria for measure removal. First, it is not feasible to implement the TPCC measure specifications. The measure includes specialty exclusions so that "clinicians who would not reasonably be responsible for providing primary care are excluded from attribution of the TPCC measure." However, CMS cannot currently implement the specialty exclusions as written in the measure specifications, and group practices that exclusively provide specialty care are being measured on TPCC based on billing by nurse practitioners, physician assistants, and clinical nurse specialists within the group practice. We have previously written to CMS expressing our concerns that TPCC was inappropriately attributed to radiologists and hospitalists in 2022 due to this problem.

There are other serious attribution problems with the TPCC measure. Physicians still have no way to indicate that they are the primary source of care for patients who are healthy and who may not need to be seen for another billable service within the next three months; these patients would not be attributed to the physician under the current methodology. Conversely, there is no way to indicate that the relationship between a patient and physician has ended, and that is also important to address since costs beyond that endpoint would no longer be within the control of the physician. Because all attribution remains retrospective, no physicians would have any certainty as to whether they would or would not be attributed patients until after the performance period ends. These attribution problems are at odds with the measure rationale, which is aimed at "capturing the broader health care costs influenced by primary care," because TPCC does not include patients that are effectively managed by a primary care physician and need few visits during a given period, nor does it identify the end of a primary care and patient relationship, in which case the primary care physician would have no influence over the patient's health care costs. Second, the negative unintended consequences associated with TPCC far outweigh the benefit of its continued use in the MIPS cost performance category. As the AMA has repeatedly said, TPCC is fundamentally flawed because it attempts to hold physicians accountable for costs associated with medical conditions that the physician did not treat, medical decisions made by another provider, or care that the physician had no involvement in. It also includes aspects and types of costs they cannot influence, such as changes in the prices of drugs, or coverage decisions for high priced drugs.

Worse, TPCC currently penalizes physicians for delivering services designed to prevent health problems or treat them at early stages, because it counts the costs of those services but does not account for the savings that will accrue in the future by preventing health problems from occurring or avoiding the higher costs associated with treating more advanced illnesses. For example, patients who enroll in a Diabetes Prevention Program (DPP) will have higher costs in the performance period but will have lower costs in future periods if they avoid or delay the onset of Type 2 diabetes. In this case, the physician would be attributed the costs of DPP under TPCC without recognition of the downstream savings to the Medicare program and patients. Thus, TPCC penalizes physicians for taking actions today that will reduce future spending in the Medicare program. By contrast, in the Maryland Total Cost of Care Model, the Center for Medicare & Medicaid Innovation provides credit in its total cost of care calculations for the estimated future savings from reducing diabetes incidence.

Furthermore, because the TPCC measure includes all Medicare Part A and B spending, not just the portions of spending that physicians can control, the TPCC measure provides physicians little or no actionable information about how to lower their spending, and it gives patients no useful information about how to lower their out-of-pocket costs or how to select physicians. TPCC does not enable

physicians to determine whether they are making referrals to other physicians who order unnecessary tests or procedures or whose treatments result in avoidable complications and adverse events. Nor does the TPCC help a patient determine whether a particular physician will treat that patient's specific health problems more cost-effectively than another physician would.

Third, TPCC does not reflect current clinical practice or guidelines because TPCC does not account for differences in cost related to the types of treatments the patient needed during the year. Moreover, the risk adjustment methodology is based only on chronic conditions in a prior year and does not consider current acute conditions or newly diagnosed chronic conditions that are treated for the first time during the current year. For example, a primary care physician who has a higher-than-average number of patients diagnosed with cancer during the year, particularly expensive-to-treat cancers, will be penalized by the TPCC because neither the risk adjustment methodology nor the specialty adjustment addresses this. Similarly when an oncology practice is attributed a patient under TPCC, it could also be penalized under the current methodology, as research has shown.

Fourth and finally, there are more applicable measures than TPCC in MIPS, including measures that apply across settings, across populations, and are more proximal in time to desired patient outcomes. Specifically, there are 27 episode-based cost measures in MIPS in 2024, and CMS proposes to add six more for 2025. While the AMA has expressed concerns about some of the episode-based cost measures, we also believe they have more promise to provide more actionable feedback to both physicians and patients and are more likely to be aligned with quality measures and quality initiatives. Moreover, in 2024, the episode-based cost measures accounted for 36.8 percent of all Medicare Parts A and B spending. For these reasons, we believe the proposed removal criteria support removal of the TPCC measure from the MIPS program beginning in 2025 at the latest.

Cost Measure Scoring Methodology Should Take Effect in 2023

Due to concerns from the AMA and others about the cost measure benchmark methodology, CMS proposes changes aimed at increasing the scores of MIPS eligible clinicians who deliver care at an average cost near the median. Specifically, CMS would score median cost performance at 10 percent of the performance threshold and the cut-offs for benchmark ranges would be calculated based on standard deviations, expressed in dollars, from the median. CMS proposes that these changes would be effective beginning with the 2024 performance period.

The AMA is encouraged that CMS is proposing a change that would address concerns about the low scores for the cost measures and in particular the unfairness of comparing physicians who are scored on cost measures against physicians who are not scored on cost measures. We remain concerned about using a single national benchmark for all the cost measures, but we believe this change is a step in the right direction.

We strongly urge CMS to implement this scoring improvement retroactively starting with the 2023 performance period. The AMA has pointed out how the cost performance category penalizes physicians who are measured on applicable cost measures and the inequality in scoring is exacerbated within MVPs when one subspecialty has an applicable cost measure (e.g., cataract surgery) while other subspecialists do not. This disadvantage is corroborated by CMS' own data. According to CMS, the average cost score in 2022 was 59, well below the performance threshold of 75 points and much lower than the average quality score of 74. The average scores for Improvement Activities and Promoting Interoperability were 94-95, nearly 30 points above the average cost score. The AMA agrees with CMS that physicians should

not be at a disadvantage simply because there are cost measures applicable to their specialty or because of their participation type of MIPS as MIPS APMs are exempt from the cost performance category.

If CMS cannot apply this proposed policy retroactively, then it should zero out the cost performance category for the 2023 performance period to avoid further unfair and unwarranted penalties due to the current faulty cost measure scoring methodology. In this proposed rule, CMS is acknowledging serious concerns with the cost performance category scoring methodology as it drags down the scores for eligible clinicians with applicable cost measures. Thus, the resolution CMS has proposed should apply immediately to prevent further unfair penalties from the faulty cost measure scoring methodology. Physician payment should not be reduced based on an arbitrary, problematic formula that does not have anything to do with their performance.

CMS has statutory and regulatory authority to reweight the cost performance category when there "are not sufficient measures... applicable and available to each type of eligible professional involved" (Section 1848(q)(5)(F) of the Social Security Act). In such cases, the "Secretary shall assign different scoring weights (including a weight of 0)...which may vary from the [specified] scoring weights...." Existing regulations further clarifying these circumstances include:

- "For the cost performance category, CMS cannot reliably calculate a score for the cost measures that adequately captures and reflects the performance of the MIPS eligible clinician." 42 CFR 414.1380(c)(2)(i)(A)(2)
- "Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, CMS determines, based on information known to the Agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its Agency." 42 CFR 414.1380(c)(2)(i)(A)(9)

These provisions require CMS to reweight the cost category based on the fact that flaws in the cost measure scoring methodology make it impossible to reliably calculate a score for any of the affected cost measures that "adequately captures and reflects the performance" of the MIPS eligible clinician. As a result, these measures are inherently insufficient, triggering the statutory reweighting provision.

Finalize Cost Measure Exclusion Policy for 2023 Performance Period

CMS proposes to exclude cost measures from a MIPS EC's or group's cost performance category score if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results. The AMA supports this proposed exclusion policy that would give CMS greater flexibility to be responsive to any errors or significant changes outside of the control of the physician that negatively impact their score. We urge the Agency to apply this policy retroactively to the 2023 performance period. At a minimum, it should be effective in the 2024 performance period.

The AMA has documented numerous problems with the cost measures during the 2022 performance period in <u>December 18, 2023</u> and <u>October 27, 2023</u> letters to CMS. For example, the cataract surgery cost measure benchmark may be based on flawed data as it included episodes that erroneously exclude operating room expenses. Moreover, the measure specifications for the TPCC and Medicare Spending per Beneficiary measures from 2022 used for 2024 physician payment include deleted 2022 CPT codes. We

have reason to believe that the 2023 cost measures will reveal similar and likely new problems, which should be addressed through this expanded exclusion policy before they negatively and arbitrarily impact physicians' payment.

Mitigate the Impact of Anomalous Billing Activity on MIPS Cost Measures

Elsewhere in this rule, CMS proposes numerous changes to reduce the financial impact of SAHS billing activity on MSSP ACOs in 2024 and beyond. CMS would exclude all Medicare Part A and B payment amounts associated with SAHS billing activity from the ACO's historical benchmark, performance year expenditures, and other MSSP calculations to ensure ACOs are not unfairly punished for assuming a substantial magnitude of financial risk outside of their control. These proposals stem from a joint letter sent by the AMA along with the National Association of ACOs and others that raised concerns about suspected fraudulent billing for catheters in 2023. Following that letter, CMS issued a separate proposed rule to mitigate SAHS billing activity in the 2023 performance period, which the AMA strongly supported, and announced it would apply similar policies for the ACO REACH model.

There is no reason to believe that the \$2 billion in SAHS payments for urinary catheters somehow affected only those physicians who participate in an MSSP ACO and not any of the hundreds of thousands of MIPS eligible clinicians. Rather, this alleged fraud likely negatively impacted physicians' cost measure scores in 2023 as well. For more context about the extent of the problem, the Institute for Accountable Care analyzed Medicare claims for two catheter codes from the CMS Virtual Research Data Center and discovered a nearly 20-fold increase in just two years, with spending increasing from \$153 million in 2021 to \$3.1 billion in 2023. Furthermore, almost all of the increase was attributed to just 10 suppliers, meaning the impact of the high catheter spending varied greatly from region to region. Because MIPS cost measures are based on a national average, physicians who were attributed patients in areas affected by the SAHS billing scheme may have been penalized due to the drastically increased catheter spending and not due to their own performance.

Unfortunately, unlike ACOs, physicians and group practices in MIPS do not receive claims data, nor do they receive timely and detailed feedback reports to identify the impact of the SAHS billing activity on their specific MIPS measures. However, because this scheme was so significant and its potential to negatively impact physicians is so severe, we believe CMS should establish the same protocols for excluding all Medicare Part A and B spending associated with SAHS billing activity from MIPS cost measures. Just like ACOs, physicians should be held harmless from SAHS spending that is outside their control.

Improvement Activities (IAs)

Weighting and Reporting of IAs

Recommendation:

• CMS should finalize its proposals to eliminate the "high" and "medium" weighting distinctions of IAs and to reduce the number of IAs that physicians must report.

The AMA supports this proposed policy and agrees this proposal would simplify scoring for this category and help reduce complexity and burden within the MIPS program.

Scoring

Recommendation:

• In lieu of CMS' proposal to only score the IA category if it receives at least one attestation for an improvement activity, CMS should adopt an alternative policy in which it scores the IA category and reweights the IA category and uses the higher of those two scores.

We believe this is the simplest solution to achieve the intended effect of not overriding a requested and approved reweighting, while also avoiding other unintended consequences such as not awarding due credit for clinicians that qualify for automatic credit within the IA category, such as those that participate in an eligible MIPS APM, or patient-centered medical home, for example. We believe the potential for unintended consequences would be even higher given CMS' concurrent proposal to reduce the number of activities required to earn a full score in this category, which the AMA does strongly support.

Additions to IA Inventory

Recommendation:

 CMS should finalize its proposals to add two new population health activities focused on increasing screenings for lung cancer and cardiovascular disease and modify the vaccine achievement for practice staff measure.

We agree with the Agency that finalizing these two new improvement activities will promote activities that should increase utilization of these important screenings. We likewise support the Agency's proposed modifications to IA_PM_XX "Vaccine Achievement for Practice Staff - COVID-19, Influenza, and Hepatitis B" to include vaccinations for Influenza and Hepatitis B along with COVID-19 to promote influenza and Hepatitis B vaccines among staff and align with the latest CDC recommendations. We encourage CMS to adopt these policies as proposed.

Streamlining the IA Inventory

Recommendations:

- CMS should reconsider its approach to streamline the IA category in the interest of maintaining a sufficiently diverse inventory of improvement activities.
- The Agency should also delay implementation of any deleted activities for an additional year to allow practices time to sufficiently plan and budget for reporting a new IA.
- CMS should reverse proposals to delete several activities and should retain them or consider modifying criteria in lieu of removing them for all practices.

The AMA has concerns with the overall reasoning behind CMS' plan to "streamline" the IA inventory, and we wish to underscore the importance of maintaining a robust, diverse inventory of improvement activities that applies to a wide range of practices and specialty types. While we appreciate the Agency's desire to focus on robust, clinically meaningful activities, we caution strongly against removing or restricting too many activities, especially in rapid succession. We note that the AMA understands the need to periodically remove activities no longer aligned with clinical practice standards or tied to events, such as the COVID-19 Public Health Emergency. We do not universally oppose all proposals to delete

activities in this NPRM. However, we do oppose removing activities that can drive meaningful clinical improvement for more subjective reasons, such as not being aligned with national priorities or simply for being commonly reported.

We disagree strongly with the logic that activities should be removed if they are commonly reported and are thus "overutilized" and "achieved." We would argue that the frequent reporting of these IAs speaks to their importance to improving patient care, not lack thereof, and bodes against removal. Moreover, the transition to value-based care cannot feature a one-size-fits all approach; practices are at varying points in their journey to value-based care and so a diverse inventory of measures is necessary to meet practices where they are and support them in their transition to APMs, a core goal of CMS. We urge CMS to consider its own policy of retaining activities when "the benefit of retaining outweighs the benefit of removing" and to err on the side of retaining activities if their clinical benefit is not in question. Practices should be able to select activities of the greatest clinical relevance and benefit to their patient populations, while minimizing burden.

At a minimum, rather than deleting several measures, CMS should look to amend the criteria or make them available to new reporters for a certain number of years. We believe this would more appropriately balance CMS' desire to drive continuous innovation while retaining an inventory of improvement activities that meet a diverse range of practice capabilities to support all practices in their transition to value-based care.

Proposing to delete or modify the two most commonly-reported IAs (IA_EPA_1 and IA_BE_4), which respectively account for 25 percent and 21 percent of clinicians reporting IAs, will cause significant disruptions to physicians, particularly given the short one-month timeframe practices have to make arrangements to report a new IA between the rule being finalized in early November 2024 and the start of the 2025 performance year. CMS indicates in the rule that it intends to move toward activities that are more robust, which will in turn require more robust coordination and investment. Practices relying on the existing IA inventory will need time to coordinate and budget resources to pivot to new improvement activities. We believe giving practices a minimum of one-year advance notice of deleted IAs is necessary. Therefore, we urge CMS to delay the effective date of any IAs finalized for deletion until January 1, 2026, to allow practices time to allocate appropriate resources and funding and coordinate an implementation strategy for a new IA.

We also take issue with the argument that IAs are duplicative of quality measures. The AMA continues to believe that alignment between the various MIPS performance categories is a benefit, not a weakness, as it promotes harmonization around key care improvement goals while reducing burden, as CMS itself has indicated in its creation of MVPs. Furthermore, IAs can supplement and strengthen quality measures and in some cases are applicable to a particular specialty when a "duplicative" quality measure is not. For example, Q374 (closing the referral loop; receipt of a specialist report) is seldom applicable to specialists as they are generally the physicians sending the specialist report, as opposed to receiving it. Since IA_CC_1 on the other hand also includes providing specialists reports back to the referring provider, it is generally much more applicable to specialists than Q374.

We oppose CMS' proposed removal of IA_PM_12 "patient empanelment" on the basis that it is widely accepted and therefore obsolete. As CMS indicates in its explanation, patient population empanelment is "important to driving patient-centered care and quality improvement" and "is the foundation for the relationship continuity between patient and MIPS eligible clinician or group /care team that is at the heart of comprehensive primary care." As noted above, practices are at different points in their journey to value-based care and patient empanelment is an integral step to transitioning to APMs.

Therefore, we believe this activity warrants retaining. CMS notes in its explanation that "this activity has no requirement for implementation or improvement beyond the empanelment." While we maintain that the existing activity is sufficiently beneficial to warrant retaining, as an alternative to deleting the activity, CMS should propose modifications that would continue to advance the activity or make the activity available to new reporters for a certain number of years.

We similarly oppose CMS' proposed removal of IA CC 1 (implementation of use of specialist reports back to referring clinician or group to close referral loop) on the basis that it is duplicative of some QCDR measures and does not align with the other MIPS categories. First, we find these two justifications contradictory. How can an IA not align with the quality category and be duplicative of OCDR measures? Moreover, the AMA continues to believe that synergy between the MIPS performance categories is a benefit, not a weakness, as it promotes harmonization around key care improvement goals while reducing burden, as CMS itself has indicated in its creation of MVPs. As noted above, the "duplicative" quality measure in question (Q374) is in fact largely not applicable to specialists since they are generally the physicians sending the specialist report, as opposed to receiving it. Since IA CC 1 on the other hand also includes providing specialists reports back to the referring provider, it is generally much more applicable to specialists than Q374. Furthermore, providing specialist reports back to the referring clinician to close the referral loop or documenting specialist reports within a patient's electronic medical record are both foundational to delivering well-coordinated, patient-centered care and are thus integral to any value-based care delivery system. CMS notes that this is the "standard of care" which in our mind only emphasizes its importance. While it is true and good that closing the referral loop is being recognized for its importance and becoming more widespread, it is by no means universal. Lastly, closing referral loops is another example of an activity that can be a critical steppingstone for many practices on their journey to more advanced value-based care delivery models. Accordingly, we urge CMS not to remove this important activity or, as an alternative to removal, CMS should consider modifications or limiting it to new reporters for a set number of years.

We also disagree with the proposed removal of IA_CC_2 (timely identification of abnormal test results with timely follow-up) for similar reasons. We disagree that because the activity is widely used and reported it is obsolete. We believe it is important to maintain an inventory of activities for practices at different points in their transition to value-based care. Rather than delete the IA, CMS should consider modifications or making the activity available for new reporters.

The AMA opposes CMS' proposed deletion of IA_BMH_8 (EHR Enhancements for BH data capture). CMS explains that the activity is duplicative of IA_BMH_7 (Implementation of Integrated Patient Centered Behavioral Health Model) which includes use of a registry or health information technology (HIT) functionality to support active care management and outreach to patients in treatment. At the same time, CMS also explains that it intends, in future rulemaking, to develop a new activity (or to modify an existing activity) to promote the effective use of HIT in behavioral health, so clearly IA BMH 7 is not alone sufficient to cover use of HIT in behavioral health.

Further, the Office of the National Coordinator (ONC) and the Substance Abuse and Mental Health Services Administration (SAMSHA) are collaborating on a multi-year effort to improve HIT in the behavioral health space. Health IT adoption among behavioral health clinicians currently lags other clinicians. This is due in part to behavioral health-related facilities being ineligible to participate in the CMS Electronic Health Record (EHR) Incentive Program (also known as the Meaningful Use Program) that concluded several years ago. Lack of access to HIT and associated higher-level capabilities and efficiencies (e.g., patient access, notifications, clinical decision support, care planning, data exchange, analytics, and reporting) impact behavioral health clinicians' ability to provide access to treatment

through tools such as telehealth. ONC and SAMHSA's collaboration will also develop new certified HIT-specific behavioral health data elements. By removing IA_BMH_8, CMS is sending a message to the HIT industry, and physicians, that it no longer values or considers EHRs important components in behavioral health. It would undermine ONC and SAMHSA's efforts to bolster EHR functionality and hamstring behavioral health data capture. Therefore, we recommend that CMS not propose IA_BMH_8 for deletion until it has proposed a replacement activity specific to utilizing EHRs to capture BH data.

Rather than remove IA_ EPA_1 "Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record" for all practices, we recommend CMS make this IA available to practices newly reporting it. We believe having this activity available will help practices transition to CEHRT, and it is important to maintain an array of activities for practices at various points in their CEHRT transition.

Finally, we disagree with CMS' proposed modification to IA_BE_4, "Engagement of patients through implementation of improvements in patient portal," to limit the activity to only new implementations of a patient/caregiver portal. Maintaining a patient portal demonstrates a continued commitment and real-dollar investment in delivering high-value, patient-centered care and should continue to be recognized as an improvement activity by all practices who maintain patient portals, including those that have implemented a portal in previous reporting years. Patient portals provide several benefits. ONC and CMS' focus on information blocking disincentives and patient engagement efforts should clearly convey to CMS the importance of patient portal engagement and, as such, the importance of continuing to encourage the use of patient portals. This activity is a prime example of where CMS should instead broaden existing criteria to include deploying new functionalities in addition to deploying a portal itself, which would align with the activity's goal of driving continuous improvement in patient portals.

Multiple Data Submissions

Recommendation:

• The AMA opposes 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. Instead, CMS should use the highest of the scores received regardless of the timing of the data submission.

The AMA believes CMS' proposed policy would be confusing as it would be inconsistent with CMS' existing policy for scoring multiple data submissions and could lead to negative unintended consequences. For example, under this proposal, if a practice administrator submits a large amount of data on behalf of the entire practice, then a physician submits data for themselves, CMS would score the individual data submission as it was the most recent data submission for the physician. However, if the practice intended to be scored as a group, this could be detrimental to their score.

The only way to accurately credit practices for the data they submit and the work they are doing to improve patient care is to award the highest score in cases where multiple data submissions are received. Additionally, this would ensure a consistent policy across all scenarios in which data submissions may be received. Having two disparate policies for scoring multiple data submissions will result in unnecessary confusion and add additional, unnecessary complexity to the MIPS program.

Promoting Interoperability Performance Category

Recommendations:

- CMS should ensure that any future changes to the Promoting Interoperability (PI) performance period are evaluated and based on the administrative burdens placed on clinicians from EHR use.
- CMS should refrain from any further changes to the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure until the current update process for the guides is completed and physicians have had time to become educated on and implement any necessary changes.

In our CY 2024 MPFS Proposed Rule comment letter, the AMA disagreed with CMS' proposal to require a 180-day Promoting Interoperability performance period. Physicians, above all else, strive to do what is best for their patients. The AMA and its members, along with physicians and medical professionals across the country, hold strong convictions to always put their patient first. CMS' policies only serve to continue to inflame the physician burnout crisis. While the AMA has clearly stated that all options should be on the table to address this crisis, CMS' PI proposals seemingly turn a blind eye to our appeal. Without justification or reason, CMS is requiring physicians to produce more data and absorb more administrative tasks. CMS continues to ignore the clear evidence that physician administrative burden is linked to MIPS participation and electronic health record (EHR) use. **Relatedly, the AMA stresses that CMS should not consider or propose in future rulemaking extending the PI performance period beyond 180 days.** Extending this timeline would serve no benefit to physicians or patients. CMS should consider what is best for overworked and overburdened physicians and not its desire to capture more reporting data.

AHRQ <u>states</u> that "burnout can threaten patient safety and care quality when depersonalization leads to poor interactions with patients and when burned-out physicians suffer from impaired attention, memory, and executive function." It is well-documented that EHRs and MIPS significantly contribute to physician burnout. CMS' PI requirements for 2024 have doubled the administrative and EHR requirements for physicians. The AMA reiterates that CMS' policies should reduce administrative demands on physicians, not increase them.

CMS believes that requiring physicians to report more data for a longer duration will prove physicians are using EHRs. CMS has all the evidence it needs to be assured physicians are already using EHRs in a meaningful way. The AMA's 2022 Physician Practice Benchmark Survey shows that 71 percent of physicians cite regulatory and administrative requirements as their reason to leave independent medical practice. It is unclear how increasing administrative burdens associated with MIPS and EHR use will benefit physicians and their patients if those very physicians are driven out of medical practice due to increased regulatory and administrative requirements.

Each MIPS regulatory change or addition may have a small impact—but in the aggregate, along with the ongoing EHR burdens, the changes become overwhelming. As a result, clinicians will experience cognitive overload and burnout. Again, the AMA expresses significant concern with CMS' PI reporting requirements that doubled the administrative and EHR reporting requirements on physicians for 2024. The AMA strongly urges CMS to evaluate and base any future changes to the PI performance period on the administrative burdens placed on clinicians from EHR use.

In terms of the SAFER Guides, the AMA agrees that implementing safety practices for EHR use is important. However, the SAFER Guides need to be updated to meet the needs of today's physicians before any further changes to the SAFER Guides measure occur. We are encouraged that the process

is underway with the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) to update the guides.

CMS and ASTP/ONC should ensure that any update of the guides is informed by stakeholder input, as well as a notice and comment period before being finalized, in order to revise the guides based on stakeholder feedback. In addition, CMS and ASTP/ONC need to undertake a robust communication, education, engagement, and awareness campaign to disseminate information to the field on the revisions to the guides, including information tailored to small and medium-sized physician practices. The AMA wants to ensure that the community is fully educated on the changes to the guides before any changes are made to the SAFER Guides measure and physicians have had sufficient time to implement any changes in their practices.

Request for Information (RFI) Regarding Public Health Reporting and Data Exchange

The AMA appreciates the opportunity to respond to the RFI on public health reporting and data exchange.

We agree that the COVID-19 PHE highlighted the interdependencies of public health and health care, and the importance of timely, integrated, and interoperable data, especially the interoperability of data between health care providers and Public Health Agencies (PHAs). PHA data and systems are often siloed. They work independently of each other and do not always have an easy way to share information across state lines or even, at times, between agencies within a given state, preventing them from efficiently supporting each other.

Surveillance is a core public health function that is essential to inform decision making, identify underlying causes and etiologies, and respond to acute, chronic, and emerging health threats. Being on the front lines of patient care delivery, physicians play an essential role in public health surveillance through reporting diseases and conditions to PHAs. Physicians similarly expect that PHAs will communicate with health professionals in their jurisdiction about the status of the population's health and the health needs of the community based on this data. The AMA is uniquely positioned to comment on how CMS could advance public health infrastructure through more advanced use of HIT and data exchange standards. An HHS-wide approach is needed to realize this goal, including robust collaboration between CMS, ASTP/ONC, and CDC.

As described in more detail previously in this public comment letter, the MIPS program is broken. MIPS is well-intentioned, but its reporting requirements are burdensome to physician practices and often appear to be clinically irrelevant, with a focus on checking boxes rather than improving care. We recommend that CMS focus on HHS-wide collaborations and the gains in public health reporting capabilities that can be made there, rather than adding to the requirements in the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category of MIPS.

There are other ways for HHS to spur the development of public health infrastructure through collaborations across the Department, including capitalizing on CDC's Data Modernization Initiative (DMI) and ASTP/ONC's Health IT Certification Program.

The AMA supports DMI, including electronic case reporting (eCR), which alleviates the burden of case reporting on physicians through the automatic generation and transmission of case reports from EHRs to PHAs for review and action in accordance with applicable health care privacy and public health reporting laws. Hospitals play a critical role in public health surveillance—we encourage hospitals and other entities that collect patient encounter data to report syndromic data to PHAs to

facilitate syndromic surveillance, assess risks of local populations for disease, and develop comprehensive plans with stakeholders to enact actions for mitigation, preparedness, response, and recovery.

Another critical component is the sharing of immunization data. The AMA encourages physicians to participate in immunization registries for patients of all ages. EHR vendors should automate the exchange of vaccination information in the patient EHR to state immunization registries to improve and help ensure completeness and accuracy of vaccination records. EHR vendors and registry administrators need to work with physicians and other health professionals to facilitate the exchange of needed vaccination information by establishing seamless, bidirectional communication capabilities for physicians, other vaccine providers, and immunization registries. The AMA has also encouraged all states to move rapidly to provide comprehensive lifespan immunization registries that are interfaced with other state registries.

In addition, we believe that DMI is an appropriate vehicle for providing funding for the adoption and use of public health-related technology. The AMA supports positive financial incentives for physician practices to adopt technology for public health reporting and help ensure bidirectional information sharing. We advocate for positive incentives for physicians to upgrade their EHR and other health IT systems to support eCR as well as positive incentives to submit case reports that are timely and complete. The AMA works from the perspective that financial incentives are most effective when framed as a positive stimulus, as opposed to a penalty.

Incentives implemented with the goal of enhancing public health information sharing by physicians should ensure that physicians receive a meaningful positive stimulus to support the necessary practical technology enhancements required to bring about desired improvements. Moreover, the AMA recognizes the need for increased federal, state, and local funding to modernize our nation's public health data systems to improve the quality and timeliness of data. Positive financial incentives for physician practices should be coordinated with other financial investments in public health data systems for PHAs at the federal, state, and local levels. Aligned investments for all parts of the public health infrastructure ensure that the capabilities to transmit eCR and other data streams are supported along with the capabilities of public health partners to receive that data electronically and return the necessary data to physicians and other providers on the front lines of delivering patient care.

An important component of greater adoption and use of public health technology is aligned data standards through the ASTP/ONC Health IT Certification Program. Moving to standards-based requirements is an important step toward ensuring that public health programs have access to critical data. In addition, requiring the use of data standards will improve interoperability and implementation consistency that further enables the transmission of timely, granular, and accurate case data between physicians, other health providers, and PHAs. Adherence to required standards also helps with burden reduction by minimizing the work required for two systems to communicate with each other and effectively share data.

ASTP/ONC recently finalized a regulation that demonstrated the important connection between eCR certification and adoption and use of public health technology. The Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule included a new certification criterion for "Transmission to public health agencies — electronic case reporting" that required health IT modules to adopt consensus-based, industry-developed standards for eCR. Modules will also be required to create case reports for electronic transmission, consume and process case report responses, and consume and process eCR trigger codes using Health Level 7 (HL7®) standards, either the FHIR Implementation Guide (IG) or the Clinical Document Architecture (CDA) IG. Standardizing eCR will improve consistency and increase real-time

communication between health care and public health while adding little burden to physicians or other providers.

ASTP/ONC noted that it moved forward with this change because for nearly a decade, eCR program requirements have not been standards-based, and there are numerous examples that reveal deficiencies in nationwide eCR due to misaligned technical standards and implementations. eCR should serve as a model for the development of other standards-based public health surveillance data collection activities that rely on the automatic generation and transmission of data from EHRs rather than adding to the reporting burden on physicians.

We envision an opportunity for HHS to build on the use of ASTP/ONC health IT-certified technology by combining use of certified technology with CDC's DMI as a means to provide positive financial incentives for physicians as well as PHAs at the federal, state, and local levels. Since the COVID-19 PHE, the CDC has provided grants to PHAs as they modernize their data systems, offering direct support for new technology and adoption of data standards. Such programs could be expanded to include positive financial incentives for physician practices that adopt and use certified technology, amplifying the benefits of adherence to ASTP/ONC-certified standards for public health data sharing.

In addition, as ASTP/ONC's work on the Trusted Exchange Framework and Common Agreement (TEFCA) continues, we encourage HHS to look for opportunities to utilize TEFCA for additional public health exchange purposes. In July 2024, TEFCA launched its first two public health use cases, eCR and public health query. As TEFCA operations grow and recruit additional participants and sub-participants, more public health use cases may be applicable for sharing on the network. **However, and we stress this, HHS should not make TEFCA participation a requirement for physicians.** We have moved well past the belief that physicians cannot or will not adopt or use health IT unless forced or prodded. Rather, from the AMA's experience, and the experience of hundreds of thousands of physician members, physicians will voluntarily adopt health IT if provided a clear return on its investment, it serves their needs to care for patients, and benefits public health.

With increased public health data sharing also comes other considerations where HHS should focus. For example, PHAs do not need access to an individual's full medical record and medical history, but there are instances where a physician or other provider needs to report an individual's condition or disease to a PHA and cannot segment the data to remove sensitive personal health information that an individual may not necessarily want shared with a PHA.

There are times when an individual's condition or disease must be shared with PHAs, but in other instances there are a lack of meaningful controls for patients to express their preferences and direct the access, exchange, or use of their personal health information. Lacking adequate tools for granular segmentation of sensitive data, health care organizations resort to imprecise automated or manual processes to withhold sharing for broad patient populations. This can result in care inequities and the potential for information blocking. Lacking trust in data protection, patients with stigmatized conditions will be less likely to consent to having their data shared. As sensitive conditions are more prevalent in historically minoritized and marginalized populations, this can contribute to health disparities. The AMA seeks to advance an interoperable ecosystem with an eye toward ameliorating disparities using granular data segmentation—in other words, preserving trust while sharing data.

ASTP/ONC is working across HHS and with the community to address sensitive health data tagging, and particularly its impact on patient safety, mistrust, and compliance. There is also a heightened need for data privacy in public health due to the potential for bias or stigmatized care. These topics need to also be

addressed in a public health context to mitigate the risk of negative impacts on individuals resulting from the disclosure of their personal health information.

The AMA encourages HHS to continue to facilitate public health data reporting but look beyond adding to the requirements in the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category of MIPS. HHS can nurture the development of public health infrastructure through collaborations across the Department, such as with CDC and ASTP/ONC.

Q. Advanced Alternative Payment Models (APMs)

Qualifying APM Participant (QP) Determination and APM Incentive

Recommendation:

• CMS should advance physician participation in Advanced APMs by: 1) taking an active role in educating Congress on the urgent need to freeze QP thresholds and extend the Advanced APM bonus; 2) collaborating with interested parties to design and adopt more Advanced APMs, especially those that fill current gaps; 3) ramping up performance feedback and data sharing in MIPS to prepare physicians for moving to APMs; and 4) reversing policies set to take effect next year that move us backwards and will hinder physician participation in APMs.

In the 2022 performance year, the most recent year for which we have data, the total number of QPs in Advanced APMs was 386,263—a 41 percent increase from 2021. QPs accounted for 38 percent of overall QPP participants in 2022, more than ever before. We commend CMS for this important progress, which has been helped largely due to new models that began accepting new participants in 2022, including Primary Care First and the Kidney Care Choices Model. More MSSP participants also advanced to higher risk-bearing tracks, demonstrating the importance of models that offer gradual glidepaths to risk.

However, we have significant concerns that this important progress is about to take a significant step backward due to several major changes that are set to take effect January 1, 2025, under current law. First, Advanced APM lump sum bonuses are set to expire at the end of the 2024 performance year. Second, QP thresholds are set to increase in the 2025 performance year from 50 to 75 percent of payments and from 35 to 50 percent of patients. The partial QP thresholds will also increase from 40 to 50 percent of payments and 25 to 35 percent of patients. Based on the most recently available data from the 2022 performance year, physicians in non-primary care specialty models will significantly struggle to achieve QP status under those higher QP thresholds set to take effect next year.

The AMA recognizes these changes are set in statute. We urge CMS to leverage its expertise and authority to educate Congress on the adverse impact that allowing the QP thresholds to rise and the Advanced APM bonus to expire could have on Advanced APM participation. The AMA strongly supports S. 3503/H.R. 5013, the Value in Health Care (VALUE) Act, bipartisan legislation that would extend the original five percent APM incentive payments and freeze the 50 percent revenue threshold for an additional two years, among other changes that would stabilize and strengthen APMs.

The AMA appreciates important progress in the form of new voluntary models, including the Accountable Care Organization Primary Care Flex (ACO PC Flex) Model and the Making Care Primary Model. However, there are still many physicians who have no opportunity to voluntarily participate in an APM focused on the conditions that their patients have and/or the treatments they deliver, there is no

nationwide voluntary primary care medical home model, and small, rural and safety net physicians lack opportunities to transition to APMs.

Broadly speaking, models should be designed with the specific needs of these unique practices and their patient populations in mind. One-size-fits-all models will not work to encourage adoption among groups that have so far been left out of APM participation. In addition to a lack of available relevant models, low APM uptake is due to barriers such as high start-up costs and high levels of risk, which disproportionately hinder small, rural, and safety net practices. Physicians need innovative models that are designed around unique practice and patient needs, that are willing to make front-end investments in technology and other supports and pay for high-value services that have been proven to improve outcomes, and that have a long-term mindset and are sustainable over time. Models cannot simply transfer financial risk to physicians and prioritize short-term financial savings above all else.

As CMS looks to bridge the gap between MIPS and APMs, increasing data sharing and performance feedback is paramount for practices to monitor their performance and build confidence to move into APMs. Reducing the administrative burden of MIPS is also critical to allow practices to devote scarce resources to exploring APM opportunities, if available. Additional recommendations for improving APMs and physician participation in them are outlined in our response to the request for information on ambulatory specialty payment models.

Finally, as discussed above, CMS should not move forward with its previously finalized policies to extend the MIPS PI reporting requirements to MSSP participants, including QPs, nor its changes to the CEHRT requirement for all QPs.

Attribution

Recommendation:

• The AMA generally supports the proposal to broaden the definition of "attribution-eligible beneficiary" to be based on all covered professional services, not just E/M, but seeks more information about its likely impact on QP determinations.

CMS proposes changing its definition of an "attribution-eligible" beneficiary so that patients who receive any covered professional service from an Advanced APM participant can be attributed to that APM. Under current policy, most APM attribution relies only on E/M services, with exceptions for certain APMs that may focus on specific episodes of care and include services related to those episodes in patient attribution. CMS explains that changing the definition for all APMs to encompass all covered professional services may help to provide "equitable opportunities to achieve QP status for participants in Advanced APMs that have different focus areas, goals, scopes, and design features." The policy also aims to avoid perverse incentives for APM entities to exclude non-primary care specialists from their APM participation lists, as these specialists tend to deliver a lower proportion of E/M services than primary care physicians. On the other hand, it is not clear why CMS notes in the rule that "there still may be situations in which the proposed change in attribution policy would limit QP determinations in certain Advanced APMs, particularly in situations where an Advanced APM is focused on a limited set of services."

The AMA appreciates that CMS is working to identify proposals that would allow Advanced APMs to include meaningful participation by more non-primary care specialists, and we generally support the proposed policy change. Although this is the second time CMS has proposed this change, we are unclear about its likely impact, which is not discussed in the regulatory impact analysis. It would be helpful for

CMS to provide direct comparisons of the proportion of participants in each Advanced APM who are estimated to meet the thresholds required to achieve QP status under the current and proposed policies, and under both the performance year 2024 thresholds and the higher 2025 thresholds in current law.

III. ADDITIONAL REQUESTS FOR INFORMATION

R. Request for Information: Services Addressing Health-Related Social Needs

CMS seeks information regarding the recently established G-codes for Community Health Integration, Principal Illness Navigation, and Social Determinants of Health (SDOH) Risk Assessment services. The Agency also requests feedback about fracture care.

The AMA supports the use of a standardized code set to capture and report services that address and improve the needs of marginalized, minoritized, and underserved populations. The AMA, as a member of the Health IT End-Users Alliance, contributed to and signed on to a Consensus Statement on Data to Support Equity last year. The statement highlights the need for appropriate payment for the time and resources needed to identify social needs and other influences of health. In particular, the Alliance provides: "[i]ncreased discharge planning efforts to address health-related social needs documented during acute care and emergency department visits should also be factored into reimbursement." As such, the AMA urges CMS to revisit its decision not to allow the SDOH Risk Assessment service to be billed with Emergency Department E/M visits. As we stated in our comments on last year's proposed rule, "[r]esearch has shown that individuals with SDOH needs have a higher rate of ED visits. For this reason, screening can help physicians in these settings to formulate targeted interventions to facilitate referrals for patients (e.g., initiating primary care) with an unmet social need. In addition, expanding this service to the ED allows for the potential to reduce repeat ED use for patients by connecting them to navigation or community health integration services, improving their health outcomes and reducing costs to the Medicare program."

As stated earlier in our comment letter, the AMA strongly urges CMS to collaborate with the CPT Editorial Panel through their transparent review process to revise existing codes or create new CPT codes when CMS has specific programmatic needs. We believe the Agency may be seeing low uptake of these new G-codes because they are specific to the Medicare program, rather than CPT codes that are more likely to be supported across multiple payers. Additionally, these codes duplicate six existing G-codes, listed below, which may be causing confusion in physician practices.

- CPT code 96156, Health behavior assessment, or re-assessment (i.e., health-focused clinical interview, behavioral observations, clinical decision making)
- CPT code 96160, Administration of patient-focused health risk assessment instrument (e.g., health hazard appraisal) with scoring and documentation, per standardized instrument
- CPT code 96161, Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument

⁸ See e.g., McCarthy ML, Zheng Z, Wilder ME, Elmi A, Li Y, Zeger SL. The Influence of Social Determinants of Health on Emergency Departments Visits in a Medicaid Sample. Ann Emerg Med. 2021 May;77(5):511-522. doi: 10.1016/j.annemergmed.2020.11.010. Epub 2021 Mar 11. PMID: 33715829; PMCID: PMC9228973 and https://www.cdc.gov/pcd/issues/2020/19 0339.htm.

- CPT code 97802, Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes
- CPT code 97803, Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes
- CPT code 97804, Medical nutrition therapy; group (2 or more individuals), each 30 minutes

Regarding fracture care, there is extensive guidance on how to report those codes. Notably, in 2022, with input from the national medical specialty societies, the AMA developed a *CPT Assistant Online* article entitled, "Reporting Fracture and Restorative Care and Dislocations." The detailed article discusses how to report an initial cast, split, or strapping procedure performed as part of a restorative treatment for a fracture or dislocation; how to report an initial cast, splint, or strapping procedure performed without restorative treatment and applied only to temporarily stabilize or protect a fracture or dislocation, and/or to afford pain relief to a patient who has sustained a fracture, dislocation, and/or musculoskeletal sprain/strain; how to report an initial cast, splint, or strapping procedure when another physician will provide restorative treatment at a later time; and how to report a replacement cast, splint, or strapping procedure as follow-up care during or after the global period for fracture and/or dislocation care. For detailed guidance on coding fracture care, the AMA directs CMS to review the examples provided in the article, which offers comprehensive insights on correct coding practices.

S. Request for Information: Building Upon the MIPS Value Pathways Framework to Improve Ambulatory Specialty Care

Summary and Recommendations

The AMA strongly opposes creating a new pay-for-performance program for specialists based on MVPs and mandating their participation in it. CMS already has a mandatory pay-for-performance program for specialists in MIPS. There is widespread agreement that MIPS has failed to improve care for patients or reduce spending for Medicare, and that it has significantly increased administrative burdens on physicians, reduced the amount of time physicians are able to spend with patients, and made it more difficult for patients to receive the care they need in a timely fashion. The approach that CMS is proposing would not solve the current problems with MIPS, and it is likely that it would create significant additional problems.

CMS states that its goals in considering this approach are to improve clinical outcomes and control Medicare spending. We support these goals. However, providing physicians with financial incentives will not allow them to achieve these goals unless they are paid in a way that enables them to deliver timely, high-quality, coordinated care for their patients. Comparing specialists based on problematic quality and cost measures and threatening to make large payment cuts based on those comparisons, as CMS proposes, would be far more likely to reduce patients' access to care, particularly for those with the highest needs, than to improve patient outcomes.

If CMS and the CMS Innovation Center are truly committed to developing successful payment models for specialists that support meaningful improvements in care for patients, the AMA urges the Agency to adopt the following recommendations:

⁹ CPT® Assistant (May 2022): Clarify Musculoskeletal Coding Guidelines

- Actively engage with relevant physicians throughout all model development and
 implementation stages, including making sufficient data and methodological details available to
 physicians and other interested parties so they can understand, assess likely impacts, and provide
 feedback to CMS on proposed payment models.
- Seek public input on payment amounts, risk requirements, quality measures, and other key elements long before they are formalized in program guidelines or proposed rulemaking and respond publicly to all feedback that is provided.
- Ensure the payment model places physicians at the center of decision making about care delivery, gives them the resources and flexibility they need to deliver services that can achieve good outcomes for all types of patients, and does not place them at financial risk for outcomes or costs they cannot control. Include prospective payments designed to support the costs of high-quality care, not just future bonuses and penalties, and waive regulations that prevent delivering care in more effective ways.
- Provide adequate payments and flexibility that will ensure access to high-quality care for patients with higher levels of need. Current CMS risk adjustment systems were not designed for physician payment models and can exacerbate inequities for vulnerable and high-need patients. Physicians should be able to assign higher-need patients to different patient need categories and receive higher payments in exchange for delivering enhanced services for those patients.
- **Provide start-up funding to payment model participants** so they can invest in the data analytic capabilities, care managers, training, and/or other practice changes needed to improve care delivery and facilitate successful participation in the model, especially for small, independent, rural, and safety net practices.
- Increase payments annually to cover inflation, changes in technology, changes in evidence about the effectiveness of services, and changes in requirements imposed by CMS.
- Commit to providing Medicare claims data to participants in a timely manner and an easily
 accessible and usable format, consistent with the recommendations in the <u>Voluntary Best</u>
 <u>Practices in Data Sharing</u> report developed by AHIP, AMA, and NAACOS.
- Commit to continuing the model long enough to allow practices to make significant changes in care delivery and provide assurance that the payment model will not be terminated or changed abruptly. Investments in new or different teams, education for staff and patients, new equipment and other changes take time to implement and cannot be easily abandoned after a few years. When model requirements are changed midstream, it costs practices time and money, so CMS should only make changes after seeking participants' input and allowing adequate time.
- Make participation voluntary. Payment models that provide adequate support for high-quality care will attract physician participants without the need for mandates. Conversely, mandates can result in adverse consequences that can jeopardize the viability of small, rural, independent, and safety net practices and create access problems for the vulnerable patients they serve.
- Ensure that the payment model will help sustain high-quality, financially viable medical practices. A payment model can only improve care for patients if there are physicians who can

deliver that care, and there are growing concerns about whether there will be an adequate number of physicians to take care of patients in the future. Low payments for services and high administrative burdens under both current payment systems and current APMs are making it increasingly difficult for physicians to sustain their practices. Any new payment model must be designed to be sustainable.

In response to a request from CMS Innovation Center staff to help address concerns about APMs for specialists during its strategy refresh, the AMA developed a payment approach that has the above characteristics – <u>Payments for Accountable Specialty Care (PASC)</u>. We discussed PASC with CMS and Department staff multiple times but they never explained why CMS has not implemented this approach. CMS should abandon the concept described in this RFI and instead pursue a payment model such as PASC or the condition-specific payment models that were <u>recommended by the Physician-Focused Payment Model Technical Advisory Committee</u> that can facilitate true improvement in patient care and help control Medicare spending.

The balance of this section responds to the specific questions in the RFI and provides more detail on the problems with the approach CMS is considering and how we recommend modifying it.

Responses to RFI Questions

Participant Definition

No physician should be expected or required to participate in a payment model if they believe the model is not appropriate for their patients or will not support the delivery of high-quality patient care. The RFI's assertion that CMS "would need to rely on data sources to which CMS already has access" to determine whether a specialty-specific payment model is appropriate for a particular physician is not true. CMS can and should ask physicians to indicate which, if any, payment model is appropriate for their services and patients to be certain that they are using the most current, accurate, and relevant information. Conversely, it is highly likely that CMS will make incorrect determinations using its current data sources because its specialty designations do not accurately describe what many clinicians do. In addition, CMS should not require any physician to participate in a new model if the physician believes it would prevent them from delivering appropriate care to their patients or jeopardize the viability of their practice.

It is very important to give specialists more opportunities to participate in APMs, but an APM must be designed to support the specific types of care a specialist delivers to their patients. We strongly oppose forcing specialists into an APM that fails to provide that support and could result in harm to their patients or cause their practices to fail financially.

1. How should CMS identify single specialty and multispecialty groups while accounting for regular clinician turnover? Which data sources and methodology should CMS use to consider identifying specialists and sub-specialties that could potentially participate in an ambulatory specialty model?

The only accurate and reliable way to determine which types of health problems a particular physician specializes in diagnosing and treating is to ask them. The specialty designations CMS currently uses are based on a combination of information derived from the PECOS system and specialty codes assigned by Medicare Administrative Contractors based on past claims data. These assignments are not accurate for many physicians and often do not accurately describe the range of services a physician provides. CMS acknowledged these inaccuracies in the CY 2023 PFS Final Rule, where it stated, "there may not always

be a perfect match between the information on specialty included in Medicare Part B claims and the clinical focus of an individual clinician" (87 FR 70039). Moreover, CMS acknowledged that the categories used to record the physician's specialty are not sufficiently specific or comprehensive to enable identification of physicians who provide similar types of services to similar types of patients, but it stated, "we do not believe it is necessary to introduce a new data source at this point, given that subgroup reporting is voluntary at this time."

CMS also stated in the 2023 Final Rule that it was "not aware of an alternative data source that would provide a closer match" between specialty designations and the care physicians provide. However, there is an obvious alternative data source that CMS can and should use, namely, asking physicians to provide the information. In comments on the CY 2023 PFS Proposed Rule, we urged CMS to allow physicians and groups to attest to their specialties, but CMS refused because it "would require CMS to implement additional criteria for validating the specialty composition of a group." We see no reason why CMS would need to "validate" the specialty composition of a group if the physicians have stated which specialty is appropriate. Specialty designations in PECOS were chosen by the physicians, and we are not aware that they were validated by CMS beyond asking physicians to update their information.

In addition, CMS stated in the 2023 Final Rule that allowing physicians and groups to attest to their specialty "may cause confusion and add operational complexity." CMS assigning an incorrect specialty to a physician or group will cause more confusion than using the specialty the physician provides. It would be extremely problematic for CMS to assign an incorrect specialty or an overly broad category and then hold the physician financially accountable for the quality and costs of care for health conditions that they do not treat while ignoring the services that they do provide.

Some physicians are highly subspecialized, providing services for a specific subset of diseases or patients with specific characteristics. They are likely to have the same specialty designation as physicians with completely different subspecialties, simply because CMS does not have a specialty code that defines them more precisely. A quality or cost measure that is applicable to physicians in one subspecialty may not be applicable at all to physicians in another subspecialty, even though they have the same overarching specialty. Even if the measure is technically applicable to the subspecialist's patients, the characteristics of the patients treated by that physician may be so different from the average for the overall specialty that the scores on a quality or cost measure for those patients will be much lower or higher than average. As a result, comparisons of physicians with the same specialty designation in PECOS would be inappropriate and misleading because the services delivered by the physicians and/or the patients they treat are not comparable. Forcing physicians to report in groups or subgroups does not solve these problems. Most "single specialty" groups are a collection of physicians with different subspecialties. The subspecialty mix also may be different in two different "single specialty" groups. Consequently, it is also inappropriate to compare one group's performance to another on current "specialty-specific" measures.

At the other extreme, some physicians, particularly in rural areas and small communities, may provide a range of services that would typically be delivered in larger communities by multiple physicians from different subspecialties or even different specialties. This is a great benefit to the patients in these communities because they can receive services from more types of specialties and subspecialties than there are physicians practicing in the community. However, these physicians are not "single specialty" physicians, and no one specialty code accurately describes what they do. The PECOS system recognizes that many physicians are not single specialty physicians by allowing them to enter multiple specialty codes. While PECOS requires designation of a "primary" specialty, that does not mean that most services the physician delivers to Medicare patients are in that specialty. Similarly, a "primary" specialty code

assigned by a Medicare Administrative Contractor based on the physician's or group's plurality of services will not accurately reflect what they actually do for all their patients.

For these and other reasons, the AMA and the specialty societies have repeatedly urged that MVPs be designed to focus on specific types of *clinical conditions* rather than on physician *specialties*. Ideally, there should be a separate MVP for each health condition or disease. The quality and cost measures in each MVP could then be specific to services and outcomes that are directly related to that health condition, and the measures could assess aspects of care that physicians can influence. Each physician could then select the combination of MVPs that are most applicable to the types of patients they care for, rather than being forced to choose one MVP that only applies to a subset of their patients, or having CMS assign them to an MVP using arbitrary statistical rules. If CMS is unwilling to create condition-specific MVPs, it should at least structure the MVPs so that there are subcategories tied to individual clinical conditions, and that measures are grouped into those subcategories, so it is clear which measures, if any, are applicable to physicians who care for patients with specific clinical conditions. Comparisons of physicians could then be made for physicians who are reporting measures in the same condition-based subcategory, rather than to all physicians in the broad overall category.

The goal of a new payment model for specialists should be to enable them to improve care for their patients, not simply to change payments for the physicians. For a payment model based on MVPs to do this, MVPs will need to better align with patient health conditions rather than with physician specialties. The PTAC has also recommended that to support primary and specialty care integration, new payment models should be based on clinical conditions rather than physician specialties. In its September 22, 2023 report to the Secretary of HHS, the Committee said "disease-based models are preferable to specialty-specific models. Specialists often treat a range of conditions; therefore, it is not appropriate to adopt a payment model that can be applied universally across a given specialty."

2. Should CMS consider different identification approaches to identify individual clinician specialist type versus practice- or group-level specialty types? If so, how?

If the goal of the payment model is to improve patient care, what matters is which patients and health conditions each physician treats and which services they deliver, not what other physicians in the practice do for different patients. A patient treated by one physician in a group practice may or may not receive services from other physicians in the same practice, and if they do, those services may be for a different health condition. In many cases, a physician in one practice will work as part of a team with physicians from different specialties in other practices to manage patients with specific clinical conditions and combinations of conditions. For example, an endocrinologist may work with a cardiologist in one group to treat patients who have both diabetes and heart disease, while working with a pulmonologist from a different group to treat patients who have both diabetes and asthma or COPD. These multi-specialty relationships across practices will likely be more important for patient outcomes than specialty-specific relationships within each practice. If a payment model is going to be tied to specialty categories rather than patient conditions, then physicians should be able to participate under multiple specialty categories if there is not one category that is appropriate for all of the conditions they treat and services they deliver.

3. Are there certain characteristics of clinicians or practices or both that may warrant additional policy flexibilities or exemption from participation in a mandatory ambulatory specialty model? What flexibilities should CMS consider for these participants?

No physician should be mandated to participate in a new payment model, particularly one that has not been tested, evaluated, and shown to improve the care of patients. If CMS creates a new payment model

for physicians, every physician should be given the ability to opt out of participation if they believe that the model will harm their patients' care or jeopardize the viability of their practice. Congress recognized this concern when it provided for a "low volume threshold" exempting certain physicians from MIPS.

4. How should CMS collect unbiased comparison group data on quality and costs for evaluation purposes? Would mandating a control group to report MVPs be appropriate for model evaluation?

We strongly oppose creating payment models that require physicians in randomly selected geographic regions to participate while precluding those in the remaining regions from participating. If the payment model will better enable physicians to deliver high-quality care than the current system, physicians will want to participate and there will be no need to mandate participation. In that case, precluding a subset of physicians from participating solely based on their geographic location will inappropriately deny Medicare patients in those areas the benefits of the model that patients elsewhere are receiving. If physicians believe that the payment model will not enable them to deliver high-quality care to their patients, then forcing them to participate just to satisfy a CMS test design has potential to harm Medicare patients. Mandating participation in a problematic model does not guarantee physicians will participate because they could stop accepting Medicare patients or stop practicing, which would also harm patients. We also oppose creating a "control group" that requires physicians to report new or different information, which increases reporting burden for these physicians while denying them any benefits the model may provide. It could disadvantage patients in the "control group" communities by reducing the time physicians have for patient care or discouraging them from practicing in those communities.

5. How can CMS support a multispecialty group's ability to successfully participate in MIPS and the model if a portion of its clinicians are reporting separate measures pursuant to the model? What steps could CMS take to reduce any added administrative burden that might arise from such separate reporting?

The best way to support participation by a multispecialty group in a specialty payment model and avoid increasing administrative burdens is to (1) enable the group to decide whether participation in the model will help it deliver better care to its patients, and (2) directly involve physicians in the design of the model. This RFI is not an adequate way to obtain physician input on APM design, but we can help CMS organize meetings with physicians to discuss how to best design an effective APM for specialists.

MVP Performance Assessment

APMs are needed because current Medicare payment systems create barriers to the delivery of high-quality, affordable care. The goal of a payment model should be to *enable* delivery of the highest quality and most efficient care for patients, not to simply compare physicians' performance under the current payment system and then provide bonuses or penalties based on that. A physician who scores well today on performance measures could potentially provide even better quality or lower-cost care if they had the resources and flexibility to change the way they deliver services. A physician may score poorly on performance measures because of the types of patients they treat and their inability to deliver the most appropriate services to meet the needs of those patients. Neither physician will receive the resources or flexibility they need to improve care through a pay-for-performance program based on current MVPs.

Instead of creating bonuses and penalties based on current quality and cost measures, CMS should work with physicians to determine what changes in care delivery would help to improve quality and control spending, what barriers exist in current payment systems that prevent physicians from implementing

those changes in services, and what changes in payments should be made to overcome those barriers. Then appropriate measures should be used or created that assess whether the desired improvements have been made and the expected outcomes have been achieved.

6. If CMS were to reduce the number of measures and activities in an MVP for clinicians participating in the model to those measures and activities most relevant to a specified specialty or subspecialty, how should CMS select the measures and activities? Consider the following prioritization approaches: (a) measures with a performance gap; (b) measures with meaningful benchmarks that can be applied; (c) measures that are reliable in the model context given the expected sample size; (d) measures that are evidence-based and either strongly linked to outcomes or an outcome measure; (e) measures that capture an adequate number and representativeness of the clinicians intended by a possible ambulatory specialty model; (f) measures that drive specialty integration with primary care and meaningful involvement with accountable entities. Are there other measure selection principles that should be prioritized when narrowing measuring in an MVP?

One important way that CMS can and should reduce the number of problematic measures in MVPs is to eliminate the claims-based measures that CMS currently uses. We have <u>repeatedly pointed out</u> the serious problems with the TPCC measure being used in most MVPs and urged CMS to stop using it. The highest priority for reducing the number of measures in MVPs should be to eliminate TPCC and the claims-based "population health" measures.

Although we strongly support eliminating problematic measures in CMS payment models, the goal should not be to simply reduce the *number* of measures, but rather to select measures that *appropriately* assess the quality and cost of care for each clinical condition that the payment model is intended to support. As we have <u>stated previously</u>, it is not the number of measures that causes burden, but the many reporting requirements associated with the measures.

In addition, many current MVPs include lots of measures because the MVP is defined too broadly around an entire specialty or a wide spectrum of medical conditions. Reducing the number of measures without also narrowing the focus of the MVP could mean that the quality and cost of care for some medical conditions and types of patients are not measured at all. Using a small number of measures in an overly broad MVP is likely to result in performance scores that provide misleading information to patients with specific health problems and will inappropriately penalize physicians who specialize in treating challenging conditions and complex patients.

It is not sufficient to simply have measures that are "relevant" to a specialty or subspecialty or even a particular clinical condition. If the goal is to enable and encourage *higher-value care*, the quality and cost measures in the model need to be closely *aligned*, so that both the quality and the cost of care are being evaluated simultaneously for the same types of clinical conditions and patients. Most current MVPs fail to do this; the measures of quality and cost in the MVP are based on different types of patients and services.

Moreover, while an important goal of a payment model is to improve quality, the quality measures in a payment model should be designed to ensure that quality is maintained when spending is reduced. A measure should not be excluded simply because there is no current "performance gap" (e.g., a so-called "topped-out" measure), since a performance gap could reappear if the payment model creates too much pressure to reduce costs, and this would only be known if that aspect of quality continues to be evaluated.

If the payment model is going to base a physician's payment on their performance on quality measures, the measures must be evidence-based, reliable, and have meaningful benchmarks. Those are not just priorities, but minimum requirements. The goal of the payment model should be to enable physicians to deliver evidence-based care and achieve good outcomes for their patients without unnecessary use of resources, not for CMS to "drive" any particular form of organization or integration with other physicians or organizations. Current approaches to value-based payment have already resulted in problematic consolidation in the health care industry that has led to higher prices without improvements in quality, and new payment models should avoid doing the same thing.

A measure is not better simply because it "captures" more clinicians. If the measure applies to a clinical condition that affects large numbers of patients and it appropriately assesses the quality of care for those patients, then many clinicians will automatically report it. However, there are many serious medical conditions that only affect a small number of patients, and there may also be few specialists capable of treating them. The effectiveness and efficiency of the care delivered to these patients can have a disproportionate impact both on their quality of life and on Medicare spending. These patients should not be ignored by CMS when it creates improved payment models simply because their care involves only a small number of physicians. Due to the small numbers of patients and/or physicians, it will be challenging to reliably measure and assess quality of care through quality measures.

Therefore, the only way to ensure the right measures are used in a specialty payment model is to select the measures in collaboration with the physicians who provide the type of care that the payment model is intended to support. Many specialty societies have developed MVPs and submitted them to CMS, but CMS has refused to use them. If CMMI is going to pursue a payment model based on MVPs, it should use the MVPs that have been developed by the physicians who would be participating in the model.

7. Are there specific measure focus areas or objectives that should be prioritized across MVPs (such as equity, population health measures, or patient-reported outcome-based performance measures (PRO-PMs) and patient-reported experience measures)?

The priority in any new payment model and in all MVPs should be to:

- Shift the primary focus from reporting of disparate measures to meet reporting requirements to supporting quality improvement.
- Measures should focus on the care continuum that patients experience and focus on aspects of
 care quality, outcomes, and patient experience related to the particular clinical condition or
 combination of conditions the patients have that are within the control of the physician(s)
 managing the patients' care.
- 8. To support improvements in primary and specialty care integration, an ambulatory specialty model could initially focus on specialty types eligible to become rostered specialty care partner clinicians in the MCP model, which include general cardiologists and physical medicine and rehabilitation clinicians. Accordingly, which measures within the Advancing Care for Heart Disease MVP and the Rehabilitative Support for Musculoskeletal Care MVP might be subset to apply to general cardiology and physical medicine and rehabilitation, respectively?

It has been 10 years since the passage of MACRA, and most specialists still do not have the opportunity to participate in an APM that would support the types of clinical conditions and patients that they treat. The RFI indicates that the reason for pursuing a payment model using MVPs is to enable a wide range of

different specialties to participate in a single payment model approach, so CMS should make the model available to any specialists who wish to participate, rather than arbitrarily limiting the program to one or two specialties or MVPs. The Making Care Primary (MCP) model is only available to primary care physicians in eight states, and only a subset of the primary care practices in those states are participating, so it makes no sense to tie the design of a national specialty payment model to MCP.

9. Similar to how other Innovation Center models may test new measures during their implementation (for example, the Comprehensive Joint Replacement model (80 FR 73358 through 73382 and 86 FR 23543 through 23549) and the Guiding an Improved Dementia Experience (GUIDE) Model), what role could an ambulatory specialty model have in testing potential new measures, such as relevant PRO-PMs, by gathering data for consideration in future MVP measure sets?

A specialty payment model could serve as an excellent opportunity for developing and testing new measures, but only if CMS provides adequate resources to the physicians participating in the model to enable collecting the data needed for new measures, calculating the measures, and analyzing the results.

The best measures utilize clinical data collected and analyzed through clinical data registries, rather than claims data. By using a registry, physicians can ensure that all of the relevant information about patient characteristics, tests, and treatments are recorded, and they can regularly compare their performance to other physicians' outcomes for patients with similar characteristics. However, even with the best electronic health record systems, it requires time and resources to record and extract data needed to accurately measure quality and resource use.

CMS has promoted the use of claims-based measures because they do not require physicians to record or report additional data, but claims-based measures do not allow accurate assessments of the quality of care for specific types of patients, and physicians cannot receive prompt feedback on performance because of the delays in calculating claims-based measures. Because of the inherent superiority of registry-based measurement, Congress mandated that Qualified Clinical Data Registries (QCDRs) be included as a reporting option in MIPS, and many specialty societies established QCDRs and developed quality measures for specific types of clinical conditions and procedures through the QCDRs. Unfortunately, CMS payment policies and program design decisions have created numerous obstacles for using QCDRs. Moreover, the maintenance of the registry and the collection and submission of data to the registry is expensive. Specialty societies and participating physicians need financial assistance to support and expand this work. CMS should invest as much or more to support the use of QCDRs as it does to develop and calculate claims-based measures.

The MIPS scoring system also discourages development and use of registry measures. It takes multiple years to collect enough data to establish reliable benchmarks for a registry-based measure. As we have recommended in the past, MIPS scoring policies need to be changed to provide adequate time for physicians to begin using the measures and develop meaningful performance benchmarks, and this problem should not be repeated in the creation of new payment models for specialists.

10. What kinds of strategies could be tested to obtain patient and family feedback on how they experience care coordination between primary care and specialty care for the clinical focus areas of the model?

Physicians face many barriers in trying to coordinate patient care with other physicians, including lack of timely data about their patients and lack of payment to support communication with other physicians.

Rather than asking patients whether care coordination occurred *after* services have already been delivered, CMS should help physicians coordinate care while it is being delivered. This requires: (1) providing physicians with timely information about all of the services their patients are receiving, similar to what it currently provides to ACOs, in order to help the physicians coordinate their services with other physicians who are also providing care to the patients, and (2) providing adequate payments to primary care physicians and other specialists so that they can spend adequate time communicating and coordinating with each other during care planning and delivery.

11. What types of peer engagement would specialists consider valuable to enhance their performance within a given sub-specialty or clinical topic?

Most specialists are members of one or more medical societies, both at the state and national levels. These societies provide physicians with a wide range of opportunities for engagement with other physicians within their specialty and in other specialties, and they provide education and training programs designed to help physicians maintain and improve their knowledge and skills. Rather than creating duplicative or conflicting programs, CMS should provide medical societies with financial support for these programs.

Payment Methodology

The RFI states that CMS has heard from "interested parties" that the "current range of Medicare Part B payment adjustments resulting from MIPS participation may be insufficient to encourage meaningful specialty care transformation." It seems unlikely that these "interested parties" include the specialists who currently participate in MIPS. What specialists consistently tell us is that they need to receive adequate payments to support high-value services for their patients at the time those services are delivered, not "adjustments" to their payments two years in the future for services delivered to different patients.

Instead of creating bonuses and penalties based on current quality and cost measures, CMS should work with physicians to determine what changes in care delivery would help to improve quality and control spending, what barriers exist in current payment systems that prevent physicians from implementing those changes in services, and what changes in payments should be made to overcome those barriers. Then appropriate measures should be used or created that assess whether the desired improvements have been made and the expected outcomes have been achieved.

12. How could a model for applicable specialists improve the comparison of similar specialists to determine future Medicare Part B payment adjustments?

The goal of a specialty payment model should not be to "make comparisons" of specialists to determine "future payment ... adjustments." To be successful, the model should be designed to provide specialists with adequate resources for high value services when those services are delivered so that they can provide high quality care to patients and reduce avoidable spending. Most specialists want to deliver care to patients in different and better ways, but there are barriers in current Medicare payment systems that prevent them from doing so, such as a lack of payment for many types of care management, care coordination, and other high-value services. Making comparisons among physicians and adjusting their payments two years in the future based on those comparisons will not overcome these barriers; it just penalizes the physicians who already face the greatest barriers to delivering high-quality care. Both MIPS and most CMS APMs have demonstrated that measuring and comparing physicians and attaching rewards and penalties to the comparisons does not result in better quality or lower cost care. There is no reason to believe that variations on this approach, such as payment adjustments based on MVPs, will do any better.

13. What range of upside and downside risk (as measured by the range of possible payment adjustments to future Medicare Part B claims) could incentivize increased and meaningful participation of specialists in APMs, care transformation, and strengthened integration between primary and specialty care?

Specialists want their patients to receive care in the most effective and coordinated way possible. They do not need "incentives" or "risk" to do this; they need to receive adequate payments to support the delivery of high value patient care and spend the time necessary to coordinate care delivery with primary care physicians and other specialists. There is no evidence that a significant amount of financial risk results in better care for patients or significant savings for the Medicare program.

14. What model design features should CMS consider in designing an ambulatory specialty care model that increases risk over time to potentially qualify the model for Advanced APM (AAPM) status under the Quality Payment Program (see § 414.1415)?

MACRA does not require that an APM involve significant financial risk; Congress required only that an APM involve "more than nominal risk." The amount of risk that CMS has required in its regulations for a payment model to qualify as an "Advanced APM" is unreasonably high and should be reduced. Requiring this amount of risk in a specialty payment model, particularly if the model places physicians at risk for performance on problematic measures such as TPCC, will deter many specialists from participating in the model and prevent many Medicare patients from receiving improved specialty care.

<u>Care Delivery and Incentives for Partnerships with Accountable Care Entities and Integration with Primary Care</u>

Specialists want to focus their time on the subset of patients and services that require their unique skills and expertise and assist primary care practices when needed to help them manage their patients' care. Enabling specialists to practice in this way ensures that patients are managed in the most appropriate setting, reduces waiting time for access to specialty services, and reduces patient out-of-pocket costs. However, current payment systems do not support this approach. Also, because current CMS APMs put physicians at risk for total spending on all services their patients receive, these models can penalize specialists for involving other physicians in their patients' care. As part of any new payment model for specialists, CMS should make additional payments to support the time specialists and their practice staff spend coordinating care with primary care practices and ACOs.

15. Are there model design features not discussed here that would incentivize primary care and specialty care providers to improve how beneficiaries experience care coordination?

If a payment model is designed to support services that can best be delivered by specialists to the kinds of patients who need those services, specialists will want to coordinate with primary care practices and refer patients back to them when their care can safely and effectively be managed in primary care settings. Specialists do not need to be "incentivized" by CMS to coordinate their services with primary care physicians; instead, they need adequate Medicare payments to support the time required to do so. Because Medicare payments for physician services fall further behind inflation every year and there are growing shortages of physicians in every specialty, both primary care physicians and specialists are forced to see as many patients as possible every day. Spending time communicating with other physicians means seeing fewer patients and losing revenue, which can threaten the practice's financial viability.

This is one reason why it is essential for any new payment model to include new payments designed to enable physicians to deliver the types of services they cannot deliver today. CMS payment models for primary care physicians have included additional payments to support care coordination activities, but they only address half the problem, because coordination between primary care physicians and specialists also requires time from the specialist. MCP recognizes the need to provide additional payments to specialists as well as primary care physicians to support collaboration, but these payments are only available in "Track 3" of the model, MCP has only been implemented with a subset of primary care practices in eight states, and not all of them will be in Track 3. Payments to support coordinated care are needed for all primary care physicians and specialists, not just those involved in MCP.

16. How can CMS best encourage specialist clinicians and accountable care entities collaborate to establish clear care pathways and protocols that optimize patient outcomes while ensuring efficient resource utilization?

Many specialists want to deliver care in ways that would help ACOs to improve patient outcomes and reduce spending, but they cannot do so because of barriers in the current Medicare payment system. Since ACOs cannot change the way specialists are paid by Medicare, they cannot overcome these barriers. Creating a new pay-for-performance program that does not change current payments for specialists but merely adjusts their payments up or down two years in the future will also not overcome these barriers.

In response to a request from the CMS Innovation Center, the AMA developed the Payments for Accountable Specialty Care (PASC) program to address barriers preventing specialists and ACOs from collaborating. Under PASC, an ACO and a specialist or specialty practice would be able to enter into a voluntary PASC Agreement designed to improve services for ACO patients. The specialist would take accountability for delivering specific types of services to each patient in a way designed to improve outcomes and/or reduce avoidable spending, and the specialist would receive an Enhanced Condition Services (ECS) Payment from Medicare for each patient in addition to standard Medicare payments to support the improved approach to care delivery. More details on PASC are available in this summary and our letter to PTAC regarding specialty care integration. We believe PASC would facilitate greater collaboration between ACOs and specialists without creating the problems associated with a new pay-for-performance program based on MVPs. We urge CMS to implement PASC.

17. How may CMS identify specialists who are most engaged in care management, care coordination, and care improvement activities with an accountable care entity?

Only a limited number of specialists are currently collaborating with ACOs because of the barriers in the current payment system. Implementation of a payment model such as PASC is needed to rectify this. A key component of PASC is a PASC Agreement between an ACO and a specialist or specialty practice, which would provide a direct method of identifying specialists engaged in care management, care coordination, and care improvement activities with ACOs.

Another more recent barrier is the increasingly cumbersome and technologically challenging health IT and quality requirements CMS is placing on ACOs, which we outline in more detail below.

18. In what ways can the model define clear expectations and performance metrics for specialists, beyond what exists in the current MVP measure sets, to foster a collaborative environment with ACOs and primary care clinicians to enhance health care outcomes and reduce costs? What levers, such as the MIPS's Improvement Activities, could be used to support participants to close the care loop back to accountable care entities or primary care or both?

The PASC Agreement (see #17) would focus on one or more specific health conditions. This agreement would include (1) specific measures of quality and/or service utilization related to care of the condition(s) and target performance levels on the measures that the specialist would agree to meet or exceed. These components—a focus on a health condition, measures of quality and utilization related to the condition, and target performance levels—are similar to the components that MVPs should have, but the PASC Agreement would ensure that the components are more directly aligned with the goals and priorities of the ACO than would a general MVP. Moreover, the Enhanced Condition Services Payment tied to the PASC Agreement would directly support the services the specialist would need to deliver to achieve the goals in the Agreement, whereas a future pay-for-performance adjustment to the specialist's payments based on a general MVP would not.

19. What characteristics should CMS consider in the design of this model to account for variations between ACOs, such as whether the ACO is physician-owned versus hospital-owned (or a low revenue ACO versus a high revenue ACO), whether or not an ACO identifies as an integrated delivery system (IDS), and differences in regional health care landscapes and local dynamics? What other characteristics should we consider?

The PASC Agreement (see #17) would be customized to the specific goals and priorities of each ACO as well as the specific contributions that each specialist could make to achieving those goals. There would be no need for CMS to make arbitrary distinctions based on the structure, size, or location of the ACO.

20. How can the model proactively address concerns related to increased consolidation, ensuring that integration efforts do not lead to reduced competition and potential negative impacts on health care quality and costs?

The heavy administrative burden and prospect of significant financial losses in both MIPS and APMs has been one of the drivers of consolidation in health care in recent years, so CMS should do everything possible to minimize administrative burdens and financial risk in any new specialty payment model. The best way to ensure that a new payment model does not result in further consolidation is to not mandate a model and design it so that small, independent specialty physician practices would find it feasible and desirable to participate without merging with or being acquired by a larger practice or health system. To design a model in this way, CMS should invite physicians and practice managers from small specialty physician practices to assist in the development of the payment model and provide them with financial support to enable them to do so. The AMA would be pleased to assist CMS in organizing this process.

21. How might risk categorization of ACOs influence the design of incentive structures of model participants engaging with ACOs, and what adjustments might be necessary to accommodate different risk levels?

If specialists receive adequate payments to support delivery of high-quality services and are only held accountable for aspects of quality and cost that they can reasonably influence, they will be able to work effectively with all ACOs, regardless of the ACO's risk level, as well as working with primary care physicians and other specialists who are not part of an ACO. PASC Agreements (see #17) would be customized to the specific goals and priorities of each ACO as well as the specific contributions that each specialist could make to achieving those goals. There would be no need for CMS to make arbitrary distinctions based on the risk level of the ACO.

Health Information Technology and Data Sharing

Specialists want to use data and information that enables them to deliver better care to their patients. However, CMS has failed to provide timely, actionable information to physicians in the MIPS program that enables them to improve their performance. Any new payment model must do better. One of the most serious problems has been the lack of information regarding cost measures. MIPS cost measures are calculated by CMS using claims data. Physicians do not receive any feedback on their performance on the cost measures, including those used in MVPs, until well after the end of the performance year. This makes it impossible for physicians to identify opportunities for reducing costs and to implement them before the next performance year begins.

The QPP Experience Report Public Use File (PUF) is not released until the middle of the second year after the services it describes were delivered, so the data are as much as 2.5 years old at that point. For example, the PUF file released in May 2024 contains information about the quality and cost of services delivered in calendar year 2022. Because cost measures were not used in 2020 and 2021, this PUF was the first that contained any information about physicians' performance on costs. However, physicians had to deliver services in 2023 and through the first part of 2024 without the benefit of this information, and their payments in 2024 were adjusted based on their cost scores before the PUF was released. More importantly, there is no detail at all in the QPP PUF as to why some physicians' cost scores are lower than others. The data show that average cost scores are significantly lower for physicians in some states than others, but there is no way to determine the reasons using the information in the PUF.

22. What specific issues should CMS consider when determining whether additional requirements and objectives may be necessary beyond those currently specified in the MVP framework around the use of health IT by specialists participating in a potential model?

One of the many problematic aspects of both the MIPS program and MVPs is the burdensome requirements related to health IT. These requirements are particularly problematic for specialists because many commercial IT systems are not designed to support the types of services delivered by specialists, and it may be difficult or impossible for specialists to use them efficiently and effectively to manage their patients' care or to compare their performance to other practices. In addition, despite federal efforts to promote interoperability, physicians still face serious barriers to sharing information and coordinating services with other physicians. Moreover, most commercial IT systems are expensive, and many physicians cannot afford to purchase or upgrade them, particularly as Medicare payments fall farther behind inflation every year.

These problems will not be solved by CMS imposing additional requirements on specialists to use IT. As part of any new payment model, CMS should ensure that specialists' payments are adequate to support the costs involved in obtaining, maintaining, and using effective IT systems. CMS should not impose any additional IT requirements unless it (1) confirms that effective systems exist for the kinds of care the specialists provide, (2) determines the costs that physicians would incur to comply with these requirements, and (3) provides adequate payments to cover those costs.

23. What investments in health IT or information exchange would be most beneficial to helping specialists succeed in such a model?

One of the most effective forms of IT for physician practices is a clinical registry that is also used by other physicians who deliver similar types of care to similar patients. A clinical registry enables a physician to (1) proactively monitor patient care to ensure that patients are receiving all of the services

they need, (2) monitor patient outcomes to ensure that services are achieving the intended results, and (3) compare services and outcomes with other physician practices in order to improve performance and expand the evidence base regarding which approaches to care are most effective for specific kinds of patients. We urge that any new payment model created by CMS be designed in a way that encourages and supports the use of clinical registries managed by specialty physician organizations, and that payments to physicians in the model are set at levels adequate to support the maintenance and use of such registries.

In addition to the clinical data in registries, physicians need timely access to CMS claims data for their patients, so that they can determine what services their patients are receiving beyond those that the physician delivers directly. Not only do the cost measures used in the MIPS program inappropriately place physicians at financial risk for services and costs they cannot control, but CMS also does not provide timely information about a physician's performance on the measures that could enable them to try and influence those other costs.

24. What is your experience with the integration of health IT systems? Please highlight any inoperability issues or opportunities for seamless data exchange between different systems, such as electronic health records (EHRs) and telehealth platforms.

Despite federal requirements for interoperability, physicians still face serious barriers in sharing information and coordinating services with other physicians. In addition, one of the most serious gaps in the integration of health information is the inability of physicians to obtain claims data from CMS and other payers that can be used in conjunction with the physicians' clinical data in order to understand all aspects of a patient's care, identify opportunities for improvement, and assess the effectiveness of changes in care delivery.

Without unique patient identification, health IT interoperability faces significant challenges, leading to fragmented care and potential patient harm. When health systems cannot accurately match patients across different platforms, crucial medical data can be lost or misattributed, resulting in incomplete health records. This lack of cohesive information disrupts continuity of care, as health care providers may make decisions based on incomplete or incorrect data. Furthermore, the absence of unique patient identification complicates data sharing between institutions, stifling efforts to improve patient outcomes through integrated care and analytics. Consequently, the full potential of health IT interoperability to enhance patient safety and care efficiency remains unrealized.

25. How should CMS structure the model and any health IT and data sharing requirements to align with, build upon, and otherwise, leverage advances in Federal interoperability policy (for example, USCDI and USCDI+ or FHIR; TEFCA)?

The AMA recommends that CMS structure model and health IT data sharing requirements to promote and leverage existing federal interoperability frameworks while allowing flexibility for future innovations. The AMA emphasizes the importance of reducing the administrative burden on physicians by ensuring that these requirements are practical and do not impose excessive costs or complexities. By aligning with existing policies, CMS can facilitate a more integrated health IT ecosystem that supports improved patient care and data accuracy. The AMA also urges CMS to consider stakeholder feedback, particularly from frontline physicians, to ensure the model is both clinically effective and technologically feasible. Additionally, the AMA advocates for positive incentives to encourage adoption and use of these interoperability standards, ensuring that the model supports physicians in transitioning to new systems without disrupting care delivery, ultimately enhancing care coordination and improving patient outcomes.

26. What data or metrics or both are important to clinicians in terms of monitoring performance and improving patient outcomes? What data or metrics or both should CMS share publicly to help inform beneficiaries of clinician performance?

The AMA and most specialty societies have spent millions of dollars and devoted hundreds of hours to develop quality measures that will provide physicians with reliable and actionable information about services and outcomes for a wide range of patient conditions. However, rather than encouraging and supporting these efforts, CMS has resisted them, frequently rejecting evidence-based measures that would fill important gaps in the measures available for MVPs and creating obstacles to the use of measures derived from QCDRs. We described these problems in detail in a July 9, 2024 letter and in our response above to the Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs (RFI), as well as in numerous other meetings and correspondence.

We urge that any new specialty payment model enable specialists to utilize the measures they have developed to assess the quality of care for their patients, and that CMS proactively support the use of clinical registries as a primary way of monitoring performance and improving patient outcomes. Because measures derived from these registries can be risk adjusted using the most appropriate clinical variables, they are also more appropriate for public reporting than claims-based quality measures.

27. What additional resources or support mechanisms could CMS provide to help clinicians make sense of the data, enhancing the data's usability, effectiveness, and frequency of updates, so that clinicians acquire actionable insights for improving patient care and experience? And to enable data-driven referrals?

We urge that CMS encourage and support the use of QCDRs managed by specialty societies and set payments to support maintenance and use of such registries. In addition, we urge that CMS provide physicians with timely access to CMS claims data regarding the services their patients are receiving.

28. What supports can this new model provide for decreasing burden of data collection and measure reporting?

CMS should not impose any requirements for data collection or measure reporting unless it (1) determines the costs that physicians would incur to comply with these requirements, and (2) provides payments to the physician practices that are adequate to cover those costs.

Health Equity

One important way to reduce disparities in health care and outcomes is to pay adequately for the services that patients need, particularly patients who have multiple health issues with complex circumstances and patients who are best served by tailored services and treatments. Penalizing physicians for health disparities with root causes well outside the exam room and requiring physicians to develop plans for improving equity without giving them the resources needed to implement those plans may discourage physicians from serving patients who have historically been marginalized. This will exacerbate inequities rather than reduce them.

29. Similar to how other Innovation Center models may offer financial and technical supports to certain qualifying clinicians (for example, safety net clinicians) as part of a model's health equity strategy (for example, the GUIDE model), how might CMS support the participation of clinicians

in an ambulatory specialty model that may serve a higher proportion of underserved patients (for example, small practices or clinicians in rural areas)?

Many patients are underserved because they have complex needs and physicians cannot afford to spend the time and/or hire the staff required to successfully address those needs. The only way to ensure that all patients receive the services they need is to provide physicians with payments that are adequate to support delivery of high-quality care to patients with complex needs. Financial and technical assistance should not just go to physician practices who have a high *proportion* of complex patients; *every* practice should be able to receive the support needed to care for these patients regardless of the characteristics of the practice's other patients. In fact, practices that have small numbers of complex patients will likely need extra financial assistance because standard care management payments are usually not sufficient to enable a practice to hire care management staff unless there is a full caseload of patients. In a small, rural community, there may only be one physician providing specialty care services to the entire population, and that physician should not be precluded from receiving assistance simply because the proportion of their patients with specific characteristics falls below an arbitrary threshold. Supports should be structured to further desegregation of care rather than reinforcing segregation of care.

30. How could an ambulatory specialty model support participant efforts to identify health disparities within their practices, identify actionable equity goals, and design and implement strategies to improve identified disparities?

Identifying the existence of disparities in health care services involves determining whether patients who have similar clinical characteristics but different demographics are receiving different services and experiencing different outcomes as a result. Health disparities can be addressed when individuals are provided the additional or different services required to achieve the same outcomes as other patients. An effective way to identify disparities and progress in addressing them is through a clinical registry. Consequently, CMS can support identification of disparities by providing funding to specialty physician organizations to maintain clinical registries and providing payments to specialty physician practices that are adequate to support the use of the registries.

In cases where clinicians are using outdated tools, such as harmful race-based correction in clinical formulas and decision supports, CMS could be helpful in using supplemental payments to support identifying these usages and planning and implementing a transition away from them.

In many cases, patients with greater needs are not receiving the services they need because payments are inadequate to support delivery of those services. Reducing these types of disparities is not an *actionable* goal for a physician practice unless the practice can obtain the resources needed to deliver more or different services. If CMS wants to reduce health disparities through a new specialty payment model, it should first get input from physicians about the most important gaps in services and what is needed to fill those gaps. Then CMS should ensure that the payment model provides the resources needed to eliminate the gaps, either through additional payments to the physician practices and/or through funding for community social service organizations.

31. How could an ambulatory specialty focused model work synergistically with other primary care focused models to improve health disparities?

Disparities in outcomes can often occur when patients who have complex conditions or multiple health problems and patients who face barriers in receiving standard treatments or services do not receive the right services for their needs. These patients often need expertise or services that can only be provided by

one or more specialist physicians, but they may encounter challenges accessing those specialists. For example, the RFI quotes research showing that Medicare beneficiaries with complex chronic conditions in rural areas have comparable access to primary care physicians but significantly lower access to specialists and higher rates of avoidable hospitalizations as a result. Access to specialty physicians for these patients will not be improved by a pay-for-performance model based on MVPs; the specialty physicians need to receive adequate payment to support the resources required to deliver services to these patients, such as the time and cost of travel to rural communities to see patients needing specialty care.

Patients with multiple conditions may need to see multiple specialists to effectively address their needs. CMS should not label patient care as "fragmented" simply because multiple specialists are involved, and CMS payment models should not create barriers that prevent patients with complex needs from seeing all the specialists who have the expertise needed to treat them. Specialists should not be expected to coordinate the care of complex patients with multiple other physicians without adequate payment to support the significant time required to do so. Patients' primary care physicians also should be provided with adequate payment to support coordination of complex care from multiple specialists and optimize the use of specialty care to suit the patient's evolving needs.

32. How could an ambulatory specialty model encourage clinicians to collect and use HRSN screening and follow-up data collected on patients attributed to the model?

Although it is important for physicians to understand whether a patient's health-related social needs require adjustments to their treatment plans, screening and collection of data from patients can be burdensome for both the patients and physicians. CMS should not create requirements for collection of specific types of data unless it (1) determines the costs that physicians would incur to comply with collecting data and addressing the needs identified, and (2) provides payments to the physician practices that are adequate to cover those costs.

33. How can measure stratification among patient subgroups or use of composite health equity measures improve how participants identifies and quantifies potential disparities in care and outcomes related to ambulatory specialty care?

Anyone familiar with Simpson's Paradox will understand that stratification of measures based on simple patient subgroups can erroneously show the presence or absence of disparities because of the correlation between many clinical and sociodemographic characteristics of patients. Not all differences in services and outcomes represent true disparities in care, and in some cases, similarities in services or outcomes may hide genuine disparities in care. An effective way to identify disparities in care and outcomes is through a clinical registry that includes detailed data on demographics, the clinical characteristics of patients, the services they receive, and the outcomes they achieve.

Multi-Payer Alignment

It is very difficult for physicians to make significant changes in care delivery based on changes in payments from a single payer. Although the Medicare program typically represents a large percentage of a physician's patients, it is not the largest payer. Moreover, with half of Medicare beneficiaries now enrolled in Medicare Advantage plans, payments for Original Medicare beneficiaries represent a smaller percentage of a physician practice's revenues than in the past, and the impact of any changes in those payments is also smaller.

Most payers already have pay-for-performance programs for physicians, and many private health plans also have programs that compare specialists on cost and/or quality measures. It seems unlikely that these payers would make changes in their existing programs to align with a new pay-for-performance program based on MVPs, particularly when there is no evidence that such a program would result in any significant reduction in spending or improvement in the quality of patient care. Moreover, commercial insurance and Medicaid plans insure younger individuals and children, so they cannot use MVP measures that are primarily or solely focused on the elderly.

The best way for CMS to encourage greater alignment among payers is for CMS to implement payment models designed by physicians. If physicians believe that a payment model will help them deliver better care to patients, they will not only voluntarily participate in such a model for Medicare patients, but they will also be less likely to contract with payers who do not pay in a similar way for other patients. Moreover, if a payment model enables physicians to deliver care in a way that reduces or controls payer spending, then it will be in the best interest of all payers to implement that payment methodology.

34. Are there opportunities to reduce clinician burden between this model, other CMMI models, and beyond through multi-payer alignment, in areas such as performance measurement, quality measurement, and data/reporting requirements?

Differences in payment methodologies across payers create higher administrative burdens for physicians, and any change in one payer's approach that is not adopted by other payers will add to this administrative burden. Since it is unlikely that other payers will align their methodologies with a new Medicare pay-for-performance program, creating such a program will inherently increase administrative burdens for physicians. CMS should work with physicians to design a program that will enable them to improve care for patients and reduce spending. Both physicians and CMS can then encourage other payers to adopt it.

35. How could this model align with value-based care approaches in the Medicare Advantage, Medicaid, and commercial payer space that focus on specialty integration? What model components and payment incentives can be aligned with other payers to support improvement goals?

Most payers' "value-based" payment programs are simplistic pay-for-performance or shared savings models that do not enable specialty physicians to truly transform care. CMS should implement payment models developed by specialists to support value-based care.

36. How can CMS align with other payer approaches to equity and disparity reduction? This could include alignment on definitions, methods, and requirements for equity-related data collection, etc.

As discussed above, CMS should support the use of clinical registries and provide payments that enable the delivery of the services that complex patients need to reduce disparities in services and outcomes. Other payers should provide similar support.

37. What technical assistance can CMS provide to support alignment and reduce burden?

CMS should work with physicians to design a program that will enable them to improve care for patients and reduce spending without unnecessary administrative burdens. CMS can then assist other payers in adopting the same approach.

T. Request for Information: Advanced Primary Care

The AMA has championed the advancement of primary care through sustainable, physician-centered payment models that support high-quality care. In our recent <u>letter</u> to Congress, we emphasized the need for payment reforms that align with the realities of modern primary care, highlighting the importance of moving away from mandatory downside risk-bearing capitation models and instead advocate for a more flexible approach that allows primary care physicians to provide the full spectrum of services their patients need without facing undue financial risk or administrative burdens.

The AMA has a long history of working with CMS to develop and refine payment models that accurately reflect the work and resources required to deliver high-quality primary care. Our involvement in the overhaul of E/M coding guidelines, which successfully reduced documentation burdens and improved the relevance of coding criteria, is an example of the effectiveness of physician-led initiatives. The AMA believes that any new payment models, including the proposed Advanced Primary Care Hybrid Payment model, should build on these efforts by involving physicians to ensure that payment structures are clinically appropriate and practical for implementation across practice settings. The AMA recommends that any new payment model must prioritize the financial sustainability of primary care practices by ensuring that payments are adequate, predictable, and free from the constraints of budget neutrality. The AMA supports a model that integrates the flexibility of fee-for-service with the stability of prospective payments, all while reducing administrative burdens and safeguarding against unintended consequences that could undermine patient care.

For more information on the AMA's views and recommendations pertaining to hybrid payments for primary care physicians, please see our July 15, 2024, letter to Congress. ¹⁰

¹⁰ American Medical Association (AMA) response to (RFI) regarding S. 4338, the "Pay PCPs Act." Can be retrieved at: https://searchlf.ama-

assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2Flfscls.zip%2F202 4-7-15-Letter-to-Whitehouse-and-Cassidy-re-RFI-on-S-4338-Pay-PCPs-Act-v2.pdf.