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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-1784-P. Medicare and Medicaid Programs; CY 2024 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) 2024 Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Medicare Physician Payment Schedule (MFS) and Quality Payment Program (QPP), published in the *Federal Register* on August 7, 2023 (88 Fed. Reg. 52262).

The AMA's comments were developed on the framework of AMA policy as established by our House of Delegates, as well as our commitment to health equity. Our comments also draw upon and reflect the work of the AMA/Specialty Society RVS Update Committee (RUC), particularly those comments addressing specific Current Procedural Terminology® (CPT®) codes. We support the RUC recommendations and urge CMS to thoroughly consider the Relative Value Units (RVUs), direct expense inputs, and the comprehensive set of additional comments and recommendations put forth by the RUC. This collaborative approach reflects our commitment to advocating for policies that foster the quality of health care delivery and the equitable well-being of patients and physicians alike.

# Calendar Year 2024 Physician Payment Schedule and Quality Payment Program Proposed Rule Detailed Comments of the American Medical Association

I.	EXECUTIVE SUMMARY	Page 3										
II.	CY 2024 MEDICARE PHYSICIAN PAYMENT SCHEDULE – UPDATES TO PAYMENT PROVISIONS											
	A. Conversion Factor	Page 6										
	B. Determination of Practice Expense (PE) Relative Value Units (RVUs)											
	C. Evaluation and Management (E/M) Visits											
	D. Telehealth Services.											
	E. Clarifications for Remote Monitoring Services											
	F. Supervision of Residents in Teaching Settings											
	G. Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health (SDOH) Risk	8 -										
	Assessment, and Principal Illness Navigation (PIN) Services	. Page 34										
	H. Skin Substitutes											
	I. Additional Payment for In-Home Preventive Vaccine Administration	$\mathcal{E}$										
	Services	Page 45										
	J. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging	S										
	Program	Page 46										
	K. Medicare/Medicaid Enrollment											
	L. Dental Services.											
	M. Diabetes Services	-										
	N. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and	S										
	Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising											
	Practitioners	Page 58										
	O. Advancing Access to Behavioral Health Services	Page 61										
	P. Treatment of Opioid Use Disorder (OUD)											
	Q. Intensive Outpatient Treatment for Substance Use Disorder (SUD)	C										
	Treatment	Page 63										
	R. Electronic Prescribing of Controlled Substances (EPCS)	•										
	S. Coding and Payment for Administration of Complex Non-Chemotherap											
	Drugs											
	T. Medicare Shared Savings Program (MSSP) Accountable Care	C										
	Organizations (ACOs)	Page 65										
III.	CY 2024 MEDICARE PHYSICIAN PAYMENT SCHEDULE - UPDATES TO THE QUALITY PAYMENT PROGRAM (QPP)											
		S										
	A. Quality Payment Program Improvement Request For Information (RFI)	Page 81										
	B. MIPS Value Pathways (MVPs)	Page 88										
	C. Merit-based Incentive Payment System (MIPS)											
	D. Public Reporting- Compare Tools	Page 115										
	E. Advanced Alternative Payment Models (AAPMs)	Page 118										
IV.	CONCLUSION	Page 122										

## I. EXECUTIVE SUMMARY

The following executive summary offers a clear overview of our primary comments, emphasizing our positions, the evidence supporting them, and our overarching goals.

# **Medicare Physician Payment**

The AMA continues to underscore our concerns regarding ongoing conversion factor reductions, specifically the proposed 3.36 percent reduction in the 2024 Medicare conversion factor (CF), with corresponding reductions in anesthesia CF rates. We are deeply concerned that these proposed cuts will have far-reaching implications for both physicians and the patients they serve.

The proposed payment reductions are attributable to two factors, including a -1.25 percent reduction stemming from a temporary update and a negative budget neutrality adjustment linked to the introduction of an office visit add-on code. It is evident that these payment cuts are counterproductive to our shared goal of providing high-quality care to Medicare beneficiaries, and simultaneously eroding the financial sustainability of physician practices.

The continued decline in payment rates is unsustainable. Over the period of 2001 to 2023, the cost of operating a medical practice has surged by 47 percent, while physician payment rates have increased by only nine percent. When adjusted for inflation, Medicare physician payment rates have plummeted by 26 percent, underscoring the magnitude of the discrepancy between costs and compensation, which is only projected to worsen next year. CMS estimates that the cost to practice medicine as measured by the government's Medicare Economic Index (MEI) is 4.5 percent. This imbalance poses a serious threat to the stability and vitality of medical practices across the nation and contributes to high rates of burnout among physicians.

Worse, the AMA is hearing that more physicians and group practices will be hit with a MIPS penalty in 2024 based on the newly released 2022 performance period feedback. These penalties can reduce Medicare payment by as much as -9 percent. The MIPS program was largely paused during the 2020 and 2021 performance periods due to the COVID-19 Public Health Emergency (PHE), and we have serious concerns that it may be unfairly penalizing physician practices—particularly small, independent, and rural practices—due to a lack of awareness of the expiration of the automatic COVID-19 flexibilities. Further, there is growing evidence that this program is unduly burdensome, completely divorced from quality improvement, and exacerbating health inequities. When finalizing its proposals, CMS must consider the totality of the payment reductions facing physicians in 2024.

Moreover, such reductions in physician payment rates will severely hamper access to care for Medicare patients. The Medicare Trustees have explicitly warned that access to Medicare-participating physicians could be seriously compromised in the long term if payment rates fail to adapt. Delays in care, particularly in underserved populations, are associated with worse health outcomes and inequitable health care delivery. It is our shared responsibility to take proactive measures to prevent such outcomes.

While we appreciate that Congress partially mitigated the 4.5 percent cut to the MFS rates that was supposed to take effect in January 2023 through passage of the Consolidated Appropriations Act (CAA) of 2023, the forthcoming -1.25 percent reduction in 2024 that was included in the CAA, compounded by a two percent reduction that took effect for 2023, amplifies the financial stress on physician practices. We urge both Congress and CMS to collaborate urgently to address this pressing issue and ensure that

# physician practices can continue to provide exceptional care without the strain of financial adversity.

# **Valuation of Specific Codes**

The AMA appreciates that CMS adopted 91 percent of the RUC recommendations, including a new code to capture the costs of providing a female pelvic exam. CMS also increased the valuation of hospital visits within maternity care codes, consistent with the RUC recommendation to increase visit valuation within all codes with a global period to be consistent with stand-alone evaluation and management visits. The AMA urges CMS to review the RUC and national specialty society comments on the specific codes for which CMS did not accept the relative value recommendations. We acknowledge CMS's efforts to adopt certain recommendations from the RUC. However, we believe it is imperative to exercise careful deliberation to ensure that the valuation of codes accurately reflects the complexity and value of medical services provided.

## **Practice Expense Data**

We also thank CMS for postponing the implementation of updated MEI weights and for acknowledging the AMA's current survey to collect practice cost data from physician practices. The MEI serves as a pivotal measure of practice cost inflation and forms the foundation for determining the proportion of payments allocated to physician earnings and practice costs. We are aligned with the necessity of basing MEI weights on reliable and contemporary data sources to ensure accuracy and fairness in rate-setting and urge the agency to continue to use AMA data for this purpose.

## Evaluation and Management (E/M) Add-On Code

The AMA greatly appreciates the reduction in the utilization assumption for the G2211 E/M add-on code from 90 percent under the previous administration to 38 percent in the current Proposed Rule. Nonetheless, we must strongly echo the concerns raised by various stakeholders regarding the utilization assumptions for G2211, which are driving nearly all of the 2024 budget neutrality reduction proposed by CMS. The lack of clarity surrounding the appropriate circumstances for reporting this code, combined with potential implications for patient cost-sharing, has created significant ambiguity among health care practitioners. We urge the agency to further refine these assumptions to prevent unwarranted reductions in the Medicare conversion factor.

## Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Program

We are appreciative of CMS's responsiveness to the concerns raised by the AMA and other stakeholders regarding the AUC Program. We support CMS's proposal to pause the implementation of the AUC Program and to rescind current program regulations until the necessary modifications can be made. The concerns surrounding the burden, technical challenges, and workflow disruptions associated with the AUC Program are well-founded, and we believe that physicians need flexibility in consulting physician-developed, evidence-based, and transparent AUC or advanced diagnostic imaging guidelines. We urge CMS to finalize its proposal to pause implementation and to work collaboratively with Congress to address the challenges posed by the AUC Program.

# **Supervision of Residents in Teaching Settings**

The AMA appreciates CMS's consideration of remote resident supervision and the proposed expansion of virtual presence options for teaching physicians. The ability to maintain virtual supervision of residents in all settings after the COVID-19 PHE is of significant importance to the medical community. CMS's proposed alignment with Accreditation Council for Graduate Medical Education (ACGME) guidelines is commendable, and we support the individual tailoring of virtual supervision to accommodate the competency, training, and specialty of each resident.

We support the inclusion of guardrails to ensure the efficacy of virtual supervision and mitigate potential risks. The recommendations put forth by the AMA in our comments below represent our concerns regarding the need for clear implementation, communication, and oversight mechanisms. We believe that the permanent expansion of supervision of residents via audio/video real-time communication technology, beyond non-metropolitan areas, is essential to maintaining high-quality patient care and resident education.

## **Telehealth and Remote Monitoring**

The AMA supports CMS's proposals to continue paying for telehealth services provided nationwide and to patients in their homes, as well as the continuation of payment for the CPT codes for audio-only visits and all Medicare telehealth services covered in 2022 through the end of 2024. The value of telehealth services, particularly during the COVID-19 PHE, has been abundantly clear, and these flexibilities have enhanced patient access to care. We urge CMS to join efforts in supporting legislation for the permanent extension of Medicare telehealth policies. With regard to the policy clarifications on the reporting of codes for remote monitoring, we have outlined several recommendations to make the Medicare guidance more accurate and consistent with CPT, as well as to avoid imposing inappropriate restrictions on the use of these services.

# Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs)

The AMA commends the multitude of proposed alterations in this rule, many of which demonstrate responsiveness to prior concerns expressed by the AMA. These modifications predominantly aim to alleviate potential unintended consequences for specific ACO types, better address the needs of certain patient subpopulations, and uphold the participation of legacy ACOs while fostering program growth. We encourage CMS to finalize these proposals and further offer several recommendations that can augment these efforts. Of particular note, we applaud the proposals to postpone the transition to electronic clinical quality measures (eCQMs) due to logistical considerations, align financial benchmark risk adjustment methodologies across performance and benchmark years, and counteract the adverse effects of regional benchmark adjustments.

However, we oppose proposals that would counteract CMS's objective of encouraging more physicians to shift to Alternative Payment Models (APMs). In particular, the AMA strongly opposes CMS's proposal to mandate that all MSSP participating clinicians, regardless of their track, meet the MIPS Promoting Interoperability (PI) measures. CMS should be actively seeking opportunities to alleviate regulatory burdens for ACOs that have already taken the responsibility to be accountable for outcomes and costs. Moreover, we believe this proposal to require qualifying APM participants to participate in MIPS violates statute.

# **Diabetes Screening**

The AMA applauds CMS's decision to include coverage of the Hemoglobin A1C (HbA1c) test for diabetes screening, marking a significant step forward in addressing diabetes and prediabetes. The AMA commends CMS for its collaboration and responsiveness to vital voices within the industry, including the Diabetes Advocacy Alliance (DAA), which the AMA actively engages with. By adopting this coverage, CMS ensures Medicare's alignment with contemporary clinical standards, fostering more frequent screenings and early interventions for diabetes among Medicare beneficiaries. We strongly endorse the proposal to cover HbA1c tests for screening purposes and urge CMS to finalize this change as outlined. Going beyond, we encourage the agency to waive patient deductibles for HbA1c tests to encourage their utilization and eliminate cost barriers, especially for historically marginalized communities.

# **Merit-based Incentive Payment System (MIPS)**

The AMA strongly recommends that CMS take steps to alleviate the burden on MIPS eligible physicians during the 2024 performance period and at a minimum, CMS should maintain the current performance threshold at 75 points to prevent undue penalties. This is particularly important given the cumulative impact of five years of hardship exceptions and disruptions caused by the COVID-19PHE.

The AMA is concerned about CMS's proposal to raise the performance threshold to 82 points for the 2024 period, based on a three-year average of performance data from 2017 to 2019. Estimations reveal that about 54 percent of MIPS eligible clinicians might face penalties averaging 2.4 percent if the proposed 82-point threshold is implemented. The AMA is alarmed by the financial strain this could place on physicians, especially in light of a proposed 3.36 percent reduction to the Medicare conversion factor. The resulting higher MIPS penalties under such circumstances would jeopardize the stability of physician practices and impede patient access to care.

Increasing the performance threshold has distinct repercussions for smaller practices and certain specialists, as well as reveals the potential to increase and exacerbate health inequities. Studies indicate that physicians with a higher proportion of patients dually eligible for Medicare and Medicaid, as well as those caring for medically and socially vulnerable patients, could receive lower MIPS scores. Such dynamics could result in transferring resources from physicians serving disadvantaged patients to those caring for more affluent patients.

# II. CY 2024 MEDICARE PHYSICIAN PAYMENT SCHEDULE – UPDATES TO PAYMENT PROVISIONS

## A. Conversion Factor

## **Recommendation:**

• To ensure Medicare patients maintain or improve their access to care and to preserve the financial viability of physician practices, CMS should use every policy lever available to reduce the proposed 2024 physician payment cut.

The 2024 Medicare conversion factor is proposed to be reduced by 3.36 percent from \$33.8872 to \$32.7476. Similarly, the anesthesia conversion factor is proposed to be reduced from \$21.1249 to

\$20.4370. These cuts result from a -1.25 percent reduction in the temporary update to the conversion factor under current law and a negative budget neutrality adjustment stemming in large part from the adoption of an office visit add-on code, discussed below. Unfortunately, these cuts coincide with ongoing growth in the cost to practice medicine as CMS projects the increase in the MEI for 2024 will be 4.5 percent.

Physician practices cannot continue to absorb increasing costs while their payment rates dwindle. We already know how that story ends, and it is not a happy ending. According to the Medicare Trustees, if physician payment does not change, access to Medicare-participating physicians will become a significant issue in the long term. Some Medicare patients are already experiencing inequitable delays in care, and we know that when care is delayed, health outcomes worsen. These problems particularly impact minoritized and marginalized patients<sup>1</sup> and those who live in rural areas.<sup>2</sup> Will patients with Medicare have to wait six months to see a neurologist when they can no longer remember what day of the week it is? Will they have to wait eight months for an appointment with an oncologist about a persistent lump? Will they forego an endoscopy or mammography because the nearest gastroenterologist or radiologist who accepts Medicare is more than an hour away? We are urging both Congress and CMS to intervene before these problems get any worse.

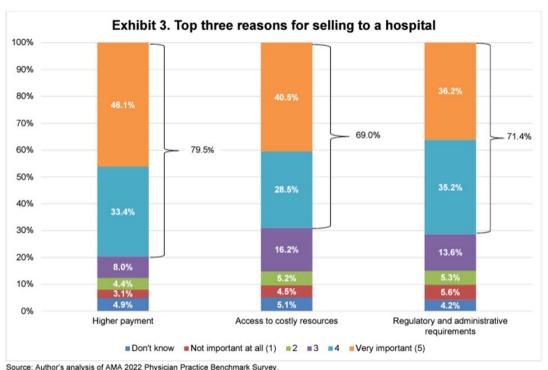
We appreciate that in the Consolidated Appropriations Act of 2023, Congress partially mitigated a 4.5 percent cut to Medicare physician payment rates, but physicians still endured a two percent pay cut this year and for 2024, physicians are facing another 1.25 percent cut, once again confronting the grim task of reconciling how to keep their lights on while getting paid less, while their expenses continue to rise. In fact, between 2001 and 2023, the cost of running a medical practice increased 47 percent, or 1.8 percent per year. In striking contrast, physician payment rates have increased just nine percent over the last 22 years, or 0.4 percent per year, according to data from the Medicare Trustees. Adjusted for inflation, Medicare physician payment rates declined 26 percent from 2001 to 2023, or by 1.3 percent per year.

Hospitals, skilled nursing facilities, and nearly every other Medicare provider receive an annual update. Physicians compete in the same marketplaces as these providers for clinical and administrative staff, equipment, and supplies. Yet physicians are at a significant disadvantage due to payment cuts and because their payments have failed to keep up with inflation. It is no wonder that these trends are driving consolidation, which is highly likely to increase future Medicare costs as these other providers receive increasingly higher payments than the diminishing number of independent medical practices. This Administration has <u>acknowledged</u> that health care consolidation is leaving many areas, particularly rural communities, with inadequate or more expensive health care options.

A new AMA analysis shows that by far, the most cited reason that independent physicians sell their practices to hospitals or health systems had to do with inadequate payment. Next were the need to better manage payers' regulatory and administrative requirements and the need to improve access to costly resources. Included below is an excerpted figure with more detail. The AMA strongly supports policies that promote market competition and patient choice. Payment adequacy is necessary for physicians to continue to have the ability to practice independently.

<sup>&</sup>lt;sup>1</sup> See e.g., Johnston KJ, Hammond G, Meyers DJ, Joynt Maddox KE. Association of Race and Ethnicity and Medicare Program Type With Ambulatory Care Access and Quality Measures. *JAMA*. 2021;326(7):628–636. doi:10.1001/jama.2021.10413

<sup>&</sup>lt;sup>2</sup> https://rhrc.umn.edu/wp-content/uploads/2019/12/UMN-Access-to-Specialty-Care 12.4.pdf.



Source: Author's analysis of AMA 2022 Physician Practice Benchmark Survey.

Note: These estimates are based on physicians whose practices had been acquired by a hospital or health system after 2012 and who were practice members at the time of that acquisition (N=282). The bracketed percentage is the sum of important (4) and very important (5).

Earlier this year, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress increase 2024 Medicare physician payments above current law by linking the payment update to the MEI, something the AMA and organized medicine have long <u>supported</u>. MedPAC raised concerns about the growing gap between what it costs to run a medical practice and what Medicare pays. While we recognize that CMS does not have the authority to provide an inflation-based update for physicians, we strongly urge the agency to use every policy lever available to reduce the proposed budget neutrality reduction for physician services in 2024 and to close the gap between the Medicare physician payment update and the rising cost of practicing medicine, which is estimated to increase by 4.5 percent next year. As discussed below, we believe CMS should lower the utilization estimate for the office visit add-on code, which would lower the budget neutrality cut to the conversion factor.

The AMA and organized medicine are also pursuing legislative relief from the unsustainable trajectory of Medicare physician payment. Specifically, we <u>strongly support</u> H.R. 2474, the "Strengthening Medicare for Patients and Providers Act," which provides a permanent annual update equal to the increase in the MEI. Such an update would allow physicians to invest in their practices and implement new strategies to provide high-value, patient-centered care. We hope the agency will work with the AMA and Congress to seek this legislative relief. This would enable CMS to prioritize advancing high-quality care for Medicare beneficiaries without the constant specter of market consolidation or inadequate access to care. These concerns stem from the disparity between Medicare physician payment rates and the actual costs associated with delivering high-quality care.

# B. Determination of Practice Expense (PE) Relative Value Units (RVUs)

## **Recommendation:**

• The AMA strongly supports the CMS proposal to postpone implementation of new MEI relative value weights. The AMA is engaged in a significant effort to collect practice costs data and urges CMS to continue to base MEI weights on AMA data sources.

MEI and the Physician Practice Information (PPI) Survey

The MEI, first implemented in 1975, has long served as a measure of practice cost inflation and a mechanism to determine the proportion of payments attributed to physician earnings and practice costs. In the nearly 50 years since the initial establishment of the MEI, data collected by the AMA has served as the standard and a consistent source of information about physicians' earnings and practice costs. The MEI weights that are the basis for current CMS rate setting were based on data obtained from the AMA's PPI Survey. This survey was last conducted in 2007/2008 and collected 2006 data.

In last year's Final Rule, CMS finalized updated MEI weights for the different cost components of the MEI for CY 2023 using a new methodology based primarily on a subset of data from the 2017 US Census Bureau's Service Annual Survey (SAS). However, CMS also noted that they postponed implementation of the proposed MEI changes until time uncertain, referencing the need for continued public comment due to the significant impact to physician payments.

# **MEI History**

	1975-1992	1993	Currently Used	Updated MEI Weights (Postponed)
Physician Work	60%	54.2%	50.9%	47.3%
Practice Expense	40%	41.0%	44.8%	51.3%
<b>Professional Liability Insurance</b>	(incl. with PE)	4.8%	4.3%	1.4%

In the CY 2024 Proposed Rule, CMS announced that they will continue to postpone implementation of the updated MEI weights, referencing the AMA's national study to collect representative data on physician practice expenses, the AMA PPI Survey. The AMA applauds CMS for recognizing the PPI Survey effort and postponing implementation of the updated MEI relative value weights.

"In light of the AMA's intended data collection efforts in the near future and because the methodological and data source changes to the MEI finalized in the CY 2023 PFS Final Rule would have significant impacts on PFS payments, we continue to believe that delaying the implementation of the finalized 2017-based MEI cost weights for the RVUs is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. Therefore, we are not proposing to incorporate the 2017-based MEI in PFS [rate setting] for CY 2024."

The AMA and Mathematica formally launched the PPI Survey on July 31, 2023. <u>The PPI Survey</u>, supported by <u>173 health care organizations</u>, will provide more than 10,000 physician practices with the

opportunity to share their practice cost data and number of direct patient care hours provided by both physicians and qualified health care professionals.

A coalition of other non-MD/DO organizations is also working with Mathematica to administer a similar study of their respective professions. These physician and qualified health care professional (QHP) surveys will be in the field through April 2024. Data would be shared with CMS in early 2025 for the 2026 MFS rulemaking process.

Major Flaw with Updated MEI Weight Methodology

CMS used data from the US Census Bureau's Service Annual Survey (SAS) as the primary source for the proposed MEI cost-component weights. The changes lead to substantial increases in the weights for many of the key components of physician practice expense and would greatly reduce the MEI weights for physician work and professional liability insurance.

If the implementation of the MEI weights is budget neutral, overall physician work payment would be cut by 7 percent and practice liability insurance (PLI) payment would be reduced severalfold. The weight of non-physician compensation would increase from 16.6 percent to 24.7 percent under the new MEI. These large shifts are principally due to a substantial error in CMS analysis, which omitted nearly 200,000 facility-based physicians. After correcting for this major omission, the physician work MEI weight would instead increase and PLI would likely experience a much smaller reduction.

CMS relied on US Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) data to split out the US Census SAS data using only the "Offices of Physicians" North American Industry Classification System (NAICS) category 6211. However, only 64 percent of employed physicians are in this category. CMS-updated MEI erroneously excluded 36 percent of physicians who are employed in other health care settings, such as hospitals. For example, the "General Medical and Surgical Hospitals" category (NAICS 6221) was not included in the CMS analysis and this category includes 158,880 employed physicians according to the 2017 BLS OEWS data.

In the CY2023 MFS Final Rule, in responses to the AMA and RUC pointing out this omission of data in the CMS analysis, CMS responded that "for physicians who are employed in other health care settings directly, such as hospitals, we do not believe that including costs for physicians that do not incur any operating expenses associated with running a practice would be technically appropriate." However, this fails to consider that the MEI weights also cover physician compensation and professional liability insurance. By excluding NAICS 6221 *General Medical and Surgical Hospitals* in the CMS MEI weights analysis, CMS inadvertently omitted over \$30 billion in physician compensation and over \$7 billion in professional liability insurance compensation. Also, physician practices do still have some indirect practice expense costs even for providers who are solely facility-based (coding, billing, scheduling, etc.).

The CMS analysis of the US Census SAS data captured a large majority of practice expense covered by the MFS but only a subset of the physician compensation and professional liability insurance premiums. For facility-based services, the MFS includes the payment for physician work, professional liability insurance, and the practice expense associated with the physician (e.g., billing costs) only. A separate facility payment (e.g., Hospital Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center) covers the cost of the service when performed in that setting. With the omission of over \$30 billion in physician compensation and over \$7 billion in professional liability insurance premiums for most facility-based physicians, the CMS-updated MEI greatly underrepresented the actual proportion of work and PLI costs that practices incur when performing services paid for by the MFS. **The AMA** 

strongly urges CMS to correct the substantial error in their updated MEI weights and to postpone implementation of the updated MEI weights until after the AMA completes its national study to collect representative data on physician practice expenses.

Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection Methodology

In the Proposed Rule, CMS included five questions related to the AMA PPI Survey:

a. If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPI survey data would be less likely to overallocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?

The AMA PPI survey uses stratification to control the distribution of sampled cases, either to match the distribution of the population or to differ from it in a controlled way. The use of stratification will improve the precision of estimates, both overall and within subgroups defined by the stratification. The AMA recommends that CMS postpone any consideration of the level of granularity of specialty-level data until after the PPI demonstrates the differences and similarities of practice costs by specialty. The AMA and Mathematica could consider recommendations related to this question once the study is completed.

b. Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable, and accurate means to account for indirect PE across various specialties or practice types?

The AMA believes that it is important for the CMS practice expense methodology to have a sufficient level of granularity to reflect actual practice costs incurred by physician practices. Ambulatory payment classification (APC) codes from the OPPS, for example, would not represent a fair, stable, and accurate means to account for indirect practice expense for the MFS due to lack of granularity.

Resource costs in the MFS are developed through an extremely granular "bottom-up" methodology in which the necessary resource costs are added line-by-line to achieve the actual costs for the physician to provide the care. In contrast, payment to facilities under the OPPS is calculated on the geometric mean of the costs of services in the same APC codes. To equate the rigorously developed line-item costs associated with services performed in the non-facility setting, with charges that are intended to be an average of "similar" services when performed in the facility is severely flawed because the two systems are making payments under vastly different assumptions.

While hospital charge information is updated on a rolling basis, it does not mean that these cost data are more accurate. Under the OPPS, each APC is assigned a cost weight based on the geometric mean costs of all the procedures assigned to that APC. These estimated costs are derived from hospital charges adjusted to costs using each hospital's cost to charge ratio (CCR). Rather than estimating the costs of each resource on a per line-item basis, this ratio is an average at the hospital department level. Since the creation of the OPPS, this averaging mechanism has consistently resulted in charge compression. CMS defines charge compression as the "practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services." As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center.

For the over 8,000 CPT/Healthcare Common Procedure Coding System (HCPCS) codes that have "Active" or "Restricted Coverage" status the CY2024 MFS NPRM Addendum B, there are only 162 unique APC codes in the CY2024 OPPS NPRM addendum B. Over 3,000 of the CPT/HCPCS codes that are "Active" or have "Restricted Coverage" status do not even have an assigned APC code.

c. If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice specific characteristics (for example, practice size, patient population served)?

In the PPI study, the AMA and Mathematica are controlling the number of sampled practices within strata defined by (1) specialty, (2) proportion of time in the facility setting, (3) practice size, (4) ownership type (individual ownership vs. more complex ownership types), (5) geographic region, and among practices with complex ownership, whether (6) the practice is part of a vertically integrated health system, and (7) private equity ownership.

The AMA and Mathematica are using these criteria for our Initial sampling, and if there is variance in the response rates between different practice types, we will also use these criteria to adjust the sampling midway through the data collection period. Finally, the AMA and Mathematica will develop final analysis weights to adjust for the probability of selection, practice eligibility, and cooperation, ensuring selected weighted totals match marginal population totals from the sample frame. In the survey itself, participating practices are asked to split out their provider compensation and time, staffing and other direct and indirect practice expenses at the Medicare specialty level, if possible.

The AMA and Mathematica could provide recommendations related to this question once the PPI survey is completed. The PPI sampling and weighting methodology should account for most of these factors.

d. What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?

Medicare payment differentials between the MFS and the OPPS are significant and have been growing, and this may be a factor in the decline in private practice. In fact, physician survey data indicate that payment and practice costs are two of the three leading reasons for private practices selling to hospitals or health systems.<sup>3</sup> It is important to ensure that any potential changes to CMS practice expense methodology do not further exacerbate this relationship and instead work towards correcting site of service inconsistencies.

In last year's NPRM, CMS provided an impact table related to the initiative of rebasing and revising the MEI weights. CMS noted that implementation of that change in the PE methodology would have shifted payment weights from physician work to practice expense principally favoring Diagnostic Testing Facility (+13 percent), Portable X-Ray Supplier (+13 percent), Independent Laboratory (+10 percent), and Radiation Therapy Centers (+6 percent) to the detriment of Cardiothoracic Surgery (-8 percent), Neurosurgery (-8 percent), Emergency Medicine (-8 percent), and Anesthesiology (-5 percent). Modest increases occur to specialties who provide services in the office with extremely expensive disposable supplies embedded into physician payment. Primary Care would face decreases (Family Medicine (-1

<sup>&</sup>lt;sup>3</sup> Kane CK. Recent Changes in Physician Practice Arrangements: Shifts Away from Private Practice and Towards Larger Practice Size Continue Through 2022. Chicago (IL): American Medical Association; 2023. Policy Research Perspective 2023. <a href="https://www.ama-assn.org/system/files/2022-prp-practice-arrangement.pdf">https://www.ama-assn.org/system/files/2022-prp-practice-arrangement.pdf</a>

percent), Geriatrics (-2 percent), Internal Medicine (-2 percent) and Pediatrics (-2 percent)). Similar to that separate policy change, other changes to the PE methodology would cause massive shifts between specialties, as well as within specialties, and put the solvency of many physician practices and other health care organizations in jeopardy. Any changes that are considered should be made carefully to ensure they reflect actual practice costs incurred by physician practices. All changes that impact physician practices should be phased in.

e. Whether specific types of outliers or non-response bias may require different analytical approaches and methodological adjustments to integrate refreshed data?

The AMA and Mathematica will develop final analysis weights to adjust for probability of selection, practice eligibility, and cooperation, ensuring selected weighted totals match marginal population totals from the sample frame. The AMA and Mathematica will evaluate the potential for nonresponse bias by conducting a nonresponse bias analysis. The AMA and Mathematica are using strata for our initial sampling, as described above. Also, if there is variance in the response rates between different practice types, these criteria will be utilized to adjust the sampling midway through the data collection period.<sup>4</sup>

# Caregiver Training Services

The AMA appreciates CMS for accepting the RUC/HCPAC values as recommended for Caregiver Training Services, a series of three new CPT codes established to capture functional caregiver training services provided to caregivers without the patient present. These new codes will enhance communication between therapy practitioners, physicians, and caregivers, and reduce risk of patient injury and increase patient outcomes. CMS coverage of these services acknowledges the importance of caregiver training to alleviate the significant burden that falls greatest on caregivers in lower socioeconomic groups and diverse populations and supports both CMS and HHS initiatives on diversity, equity, and inclusion for family caregivers.

# C. Evaluation and Management (E/M) Visits

Office/Outpatient (O/O) E/M Visit Complexity Add-on Code Implementation

## **Recommendation:**

• The AMA greatly appreciates CMS's proposed reassessment of G2211 Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition utilization in 2024. We strongly urge the agency to further refine its utilization assumption to reflect the significant ambiguity about when to appropriately use this code and to avert an unwarranted permanent reduction to the Medicare conversion factor.

The AMA greatly appreciates CMS's proposed reassessment of G2211 utilization in 2024 in response to AMA advocacy. CMS proposes to mitigate anticipated cuts due to the budget neutrality impact of adding the new E/M add-on code, G2211, which was finalized in 2021 but then delayed for three years by Congress. Specifically, CMS has lowered the estimated utilization assumption of the add-on code from 90 percent in its 2021 rule to 38 percent when initially implemented in 2024 and 54 percent

<sup>&</sup>lt;sup>4</sup> *Id*.

once the code has been fully adopted. Unfortunately, despite these revisions, G2211 continues to drive a significant payment reduction to the MPS overall. CMS notes that approximately 90 percent of the -2.17 percent budget neutrality adjustment is attributable to G2211.

The AMA has raised several considerations that will reduce physicians' readiness and willingness to report G2211. This code was initially proposed to offset the payment cuts facing certain specialists who more often bill higher-level E/M visits as part of CMS's 2019 MFS proposal to collapse Levels 2-5 and subsequently Levels 2-4. However, in response to blanket opposition from organized medicine about the proposal to collapse the office visits, CMS ultimately abandoned that approach and instead adopted the CPT Editorial Panel's revised coding guidelines for O/O E/M visits, as well as the RUC's recommended increased valuation of those codes. This effort was the result of substantial collaboration among all of medicine.

Despite this shift in policy, CMS retained G2211. However, the agency has not clearly explained how G2211 works within the revised O/O E/M coding framework. With physicians now billing a higher-level E/M code for more complex patient counters, it is not clear when an add-on code would be a substitute for billing a higher-level E/M visit. Should physicians bill the add-on code when they determine the E/M code level based on time, medical decision-making, or both? How do physicians ensure that the add-on code does not duplicate work or time already counted for in higher-level E/M codes?

We also believe patient cost-sharing may be a barrier to uptake of this code as physicians will understandably be hesitant to label patients as "complex" and potentially cause them to incur an additional out-of-pocket cost for their office visits as a result. We have seen this with the other Medicare care management codes. Further, the expense will have a disproportionate impact on low-income patients. In addition, in a prior comment letter, the Medicare Payment Advisory Commission (MedPAC) raised the important question of how physicians will document that they are reporting G2211 appropriately without a more detailed description of the code. We have heard questions from physicians about how a single, serious condition will be defined. Without further clarity, physicians will be less likely to report this code, and it calls into serious question CMS's assumption that more than one-in-three office visits will include this add-on code in 2024.

CMS has previously overestimated physicians' readiness and willingness to report new codes that were not revaluations of existing codes. For example, the utilization estimates for TCM services are a cautionary tale. In 2013, CMS overestimated utilization for new TCM codes 99495 and 99496, resulting in a budget offset of \$773 million in 2013. This reduction was permanently removed from the MPS, reducing annual physician spending significantly each year since implementation. As shown in the chart below, this overestimate has resulted in a cumulative reduction of \$5.23 billion through 2021. CMS must not repeat this mistake with G2211.

	Medium Descriptor	Utilization for		2021 Actual Medicare Utilization	Charges	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed	2021 Actual Allowed Charges	Cumulative Net Overestimate in TCM Allowed Charges - CY 2013-CY2021
1	Transitional care management within 14 days of discharge	4,244,533	162,104	625,395	\$491 million	\$25,778,187	\$ 47,238,337	\$ 60,283,896	\$ 76,312,331	\$ 90,047,070	\$ 105,043,161	\$ 116,634,135	\$ 102,841,339	\$ 120,690,672	\$ 3,672,916,049
99496	Transitional care management within 7 days of discharge	1,398,767	136,160	613,997	\$282 million	\$30,696,021	\$ 57,920,377	\$ 75,718,617	\$ 101,725,254	\$ 122,150,936	\$ 138,234,085	\$ 151,173,222	\$ 137,835,385	\$ 161,517,681	\$ 1,558,634,875
										Total Over	estimate (CY20	13-CY2021):	\$5,231,550,923		

The AMA is not alone in raising concerns about potential overestimates about how often physicians and other practitioners will use G2211. The RUC <u>comment letter</u> includes a detailed analysis of the outstanding questions and ambiguities about the add-on code. We urge CMS to address the issues raised by the RUC and their impact on the utilization of G2211, including the following:

- There is a lack of clarity about the exact additional resources that CMS intends to capture by creating G2211, and the typical patient to receive G2211 services is not well-defined.
- Medicare contractors, compliance officers and other stakeholders will face significant challenges in effectively educating and auditing health care practitioners on the proper reporting of this code.
- The CMS method to predict these precise estimates was not published. It appears that CMS excluded the claims with modifier -25 and then assumed 50 percent of the remaining visits would include the reporting of G2211. However, CMS should confirm its method and share this information publicly.

In addition, the <u>American College of Physicians</u> (ACP) and the <u>American Academy of Family Physicians</u> (AAFP), whose members will use G2211, have both urged CMS to revise downward the utilization estimates for G2211. ACP argued that utilization should be less than 10 percent of all office visit codes, stating the following:

An equivalent in the surgical setting is modifier 22, appended when a procedure exceeds the normal range of complexity, which is only used in specific instances where the procedure is unusually challenging. CMS should reevaluate the utilization estimates, including an examination of actual utilization of similar codes implemented in recent years, such as chronic care management (CCM) and transitional care management (TCM) services, which has been lower than expected. Although two-thirds of Medicare beneficiaries are eligible for CCM services, these codes account for only 2.3 percent of all claims. Similarly, TCM services were only found on 9.3 percent of claims for the total eligible population of 22 percent. This report suggested that a more accurate estimate for G2211 would be far below CMS original projection.

In addition, to inform CMS's utilization estimate, we urge the agency to look at its own data on the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Patient Relationship modifiers,

which were established for voluntary reporting in 2018. Two of the modifiers – X1 and X2 – are used to indicate a longitudinal, continuous physician-patient relationship at the time of the service, which is consistent with the G2211 code description. For example, X1 is to be reported for primary care services and specialists providing comprehensive care to patients in addition to specialty care. For X2, a reporting clinician service example is a rheumatologist taking care of a patient's rheumatoid arthritis longitudinally but not providing general primary care services. By looking at the use of these two modifiers, CMS would have a more data-driven method to estimate the likely use of G2211.

Furthermore, CMS is proposing to codify its prior guidance that it would not be appropriate to bill G2211 with an E/M visit that includes modifier -25. In <u>subregulatory guidance</u> about G2211, the agency states that it would not expect G2211 to be reported with other payment modifiers, such as -24 and -53. The AMA urges CMS to further codify these instructions against reporting the E/M add-on code with a payment modifier and incorporate them into the utilization estimate. In addition, this CMS guidance describes G2211 as a service that results in "a comprehensive, longitudinal, and continuous relationship with the patient and involve[s] delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape." This guidance indicates that G2211 would involve team-based care and care coordination for the patient, both elements that go beyond the code descriptor and indicate that reporting of this code should be more discerning than CMS otherwise considers in this rule.

The AMA and others have highlighted several likely barriers to uptake of this code, including ambiguity about when to use it and how to document it, as well as concerns about patient cost-sharing obligations. Unfortunately, as noted above, although the utilization assumption has been greatly reduced, the add-on code will still lead to an additional across-the-board cut to the conversion factor due to budget neutrality requirements. The AMA strongly urges CMS to further refine its utilization assumptions for G2211 to avert an unwarranted permanent reduction to the conversion factor.

Global Surgical Codes

## Recommendation:

• CMS should reconsider its decision and increase the office visit E/M bundled into the global surgery payment consistent with the 2021 O/O E/M revaluations.

In our discussion of the E/M changes, the AMA would be remiss not to mention our long-standing request that CMS apply the office visit increases to the visits bundled into global surgery payment. As we have stated previously, the surgical specialties participated in the RUC survey and their data were the same as, and often greater than, primary care and other specialties. CMS has emphasized the robust survey utilized in the valuation of office visits and this survey demonstrates what the law requires, all physicians should receive the same payment for the same service.

Increasing the visits bundled into the surgical global payment would increase spending by approximately \$440 million, requiring an approximate 0.4 percent reduction to the Medicare conversion factor but it would help mitigate the redistributive impacts of G2211.

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

CMS responds to comments by consultants and others by asking a series of questions about the process used to value physician services. The CMS questions, and corresponding AMA responses, are listed below.

a. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?

The current E/M codes accurately define the full range of E/M services as they exist today. However, the CPT and RUC processes strive to identify new technology and gaps in coding and valuation as the practice of medicine evolves. Also, anyone may submit a coding application if they perceive any gaps in E/M coding. The CPT Editorial Panel and the RUC will continue to describe and evaluate new E/M services as they arise.

The recent extensive revisions of the E/M services specifically addressed the granularity of services by allowing for reporting by medical decision making or time on the date of the encounter (straightforward, low, moderate, and high), which was enhanced by the development of coding for prolonged services. The CPT Editorial Panel and the RUC have a long history of addressing coding and payment for primary care services. CMS has not always accepted the RUC recommendations for these types of services, sometimes only partially accepting RUC recommendations to increase valuation. For example, in the first Five-Year Review of the RBRVS, CMS did not fully implement the RUC recommended increases to office visits. Codes were also created by the CPT Editorial Panel, and CMS classified them as bundled into existing services. For example, in the immediate months of the PHE, the CPT Editorial Panel and the RUC urged CMS to pay for a new code 99072 Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease. However, the CPT Editorial Panel and the RUC persisted in defining and valuing primary care and E/M services. Some examples of the CPT Editorial Panel and RUC work, include:

- 1. Medical Home The RUC engaged in an extensive process, involving several stakeholders in developing a recommendation regarding the monthly resource costs of engaging in a medical home model of care. CMS did not implement these recommendations, resulting in medical home monthly payments that are significantly lower than the costs estimated by the RUC.
- 2. Care Management More than a decade ago, the CPT Editorial Panel and the RUC developed chronic care management and transitional care management codes to describe services that have long been performed, but never compensated. The number and scope of care management codes has grown as the CPT Editorial Panel considered coding applications for these services.
- 3. Immunization Administration The RUC strongly advocated for physician work valuation for immunization administration to reflect the counseling that physicians and qualified health care professionals must provide to encourage vaccination. The CPT Editorial Panel and RUC's work on COVID-19 immunization codes during the recent PHE was critical to public health efforts in the US.
- 4. Evaluation & Management (E/M) The CPT/RUC Workgroup on E/M, with significant specialty society involvement, revised the E/M office visit code descriptors and documentation guidelines that directly address administrative burden by simplifying the reporting and documentation process. Changes included allowing physicians to choose

whether their selection is based on medical decision-making or total time on the date of the encounter. The RUC recommendations to increase valuation were accepted and implemented by CMS in 2021. CMS implemented similar revisions and valuation improvements, created, and recommended by the CPT Editorial Panel and the RUC, to other E/M visit code sets, including inpatient and observation visits, emergency medicine visits, nursing facility visits, and home visits in 2023.

- 5. Telemedicine E/M Services As telemedicine and remote monitoring services surged during the COVID-19 PHE, the CPT Editorial Panel and the RUC have responded to these new technology needs with coding and valuation solutions.
- b. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?

Yes, the methods used by the RUC and CMS are appropriate to accurately value E/M and other HCPCS codes. The underlying methodology developed by Harvard University and CMS (formerly, the Health Care Financing Administration) in the late 1980s remains relevant today. Harvard conducted surveys of practicing physicians to measure time and the relativity of physician services utilizing magnitude estimation. All improvements since this time have been open to public comment via rulemaking. The RUC and CMS have developed numerous standards/policies/conventions to improve relativity and ensure consistency. Standard packages for pre-service time, post-service time, practice expense direct input benchmarks, and pre-service clinical staff time packages have been implemented, allowing for enhanced relativity and comparison among all services.

The RUC is engaged and eager to offer process improvement, both in its survey process and its use of extant data sources. More than 100 national medical specialty societies and other health care organizations participate in the RUC process. These organizations devote significant resources and expertise to conducting physician surveys. In recent years, the median number of survey respondents is 70, with surveys for high volume services having more than 100 physician respondents. As noted, the recent office visit RUC survey yielded the highest number of responses in the history of the RUC process, with 1,700 physicians completing the survey. The survey was the concerted effort of 51 specialty societies and other health care professional organizations who represented 95 percent of Medicare claims for E/M office visits. The RUC incorporates extant data when possible, such as data from the Society of Thoracic Surgeons, American College of Cardiology, and National Surgical Quality Improvement Program (NSQIP).

One methodological improvement that CMS should consider is to restore the Refinement Panel process, which served as an appeal process for those commenting on CMS proposed relative values. The refinement panel was comprised of physicians and contractor medical directors. In 2016, the AMA, with over 90 specialty societies, requested the restoration of the refinement panel. The AMA again requests that CMS reinstate the Refinement Panel process.

c. Are the current Non-E/M HCPCS codes accurately defined?

Yes, the current non-E/M HCPCS codes are accurately defined through the CPT Editorial Process. The CPT Editorial Panel process benefits from a collaborative and transparent process comprising many national medical specialty societies, private health care insurers, hospital associations, and government affiliates. Further, medical specialty societies, individual physicians, hospitals, third-party payers, and other interested parties may submit applications for changes to CPT for consideration by the CPT

Editorial Panel. The RUC also submits recommendations to CPT for coding changes resulting from its Relativity Assessment Workgroup (RAW) process. The CPT Editorial Panel considers applications using objective criteria, including stringent literature requirements. In addition to structured criteria for CPT code change applications that maintain consistency, the CPT Editorial Panel also works with Panel members, CPT Advisors, and applicants during the preparation and consideration of each proposal. Over a minimum of three meetings per year, the CPT Editorial Panel addresses over 200 major topics, each reviewed and discussed with careful consideration. The CPT Editorial Panel and those that participate in the process have maintained a respected method that is best suited to preserve accurately defined medical codes.

d. Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?

The MFS is a resource-based <u>relative</u> value scale, and it is important that all services be examined via the same methodology. The fact that this question distinguishes "non-E/M services" from "E/M services" is problematic, as all services should be valued using the same methodology to ensure fairness, consistency, and relativity. The benefit of the Resource Based Relative Value Scale (RBRVS) is that it measures resources in determining relativity, versus introducing bias or politics into the valuation process. As stated earlier, the RUC, CPT, HCPAC, and CMS continuously evolve to provide process improvement, but statutory and regulatory rules cannot be unwound instantaneously. For instance, the physician work definition cannot be modified by the RUC.

e. What are the consequences if services described by HCPCS codes are not accurately defined?

There are HCPCS I (CPT) and HCPCS II (CMS) codes. CPT Category I non-vaccine codes are created three times a year by the CPT Editorial Panel at open meetings. The process begins with an application that is open to review by all the specialty advisors, including non-physician health care professionals. CPT Editorial Panel reviewers interact with applicants as needed to refine applications. The interactive process promotes coding clarity with descriptors, readily accessible guidelines and parentheticals that direct correct coding in potentially confusing circumstances and exclusionary parentheticals. At the CPT Editorial Panel meetings, if not before, CPT Editorial Panel experts seek to amend any shortcomings or to defer the application decision until essential questions are resolved. At the CPT Editorial Panel table are a diverse group of specialties and professions, payer representatives, coding professionals and RUC representatives. Attendees may comment. The CPT Editorial Panel process is highly interactive and efficient with a high probability of producing accurately defined services. When there is concern about accuracy of definition, the CPT Assistant Editorial Board, the CPT Editorial Panel Executive Committee and/or the CPT Editorial Panel provide clarity and may revise CPT text as needed. The RAW process helps to identify lack of clarity or the need for change in descriptions due to changing technology. The CPT Editorial Panel recognizes that services must be accurately defined so they may be accurately valued, so program integrity is supported, so health services utilization can be monitored, and so public health can be advanced.

HCPCS II codes are developed by CMS with application periods twice per year. HCPCS II codes are generally used to report services, supplies, and services not included in CPT codes. However, there are some instances where CMS creates codes that almost mirror CPT codes for the purpose of changing the reporting requirements. For example, add-on code 99417 for prolonged E/M services was added to the CPT 2021 code set, effective January 1, 2021. In lieu of covering code 99417 for Medicare, CMS elected to create similar code G2212. For CPT 2023, code 99418 was created for prolonged services in the inpatient setting. However, in the 2023 Final Rule, CMS affirmed that CPT codes for prolonged services will not be payable and created G0316 to report prolonged inpatient or observation care services, G0317

to report prolonged nursing facility services, and G0318 for prolonged home or residence services. The result of these differing coding methodologies for reporting prolonged services further deepens the administrative burden for health care professionals and increases the potential for improper coding. Further, the CMS developed HCPCS II G-code descriptors for prolonged services created in lieu of the CPT code set that was thoroughly refined via the CPT Editorial Panel process, which included multispecialty input by expert physicians and QHPs.

It is imperative that physicians have one set of clear codes and guidelines to report medical procedures and services. If other HCPCS II codes are created that are not accurately defined, it could lead to improper reporting of medical services by Medicare and other insurers. For these clearly outlined reasons, code descriptors should be properly vetted via an established, consistent process that includes physician and QHP input when developing the code to assure that no two codes are alike. Moreover, codes should be consistent without variation to increase clarity for all payers. It is critical to ensure consistency and the validity of expertly defined medical codes by aligning CMS coding policy and CPT coding requirements.

f. What are the consequences if services described by HCPCS codes are not accurately valued?

The intent of the RBRVS is to ensure that the payment of one service is relative to the payment of another when accounting for the resources consumed in the provision of the service. If the relativity of one service is undervalued, physicians may not be able to sustain the practice of providing that service in an office setting. Likewise, a significant overvaluation of a service may provide financial incentive to perform the service. The RUC created RAW to develop objective and fair screens to identify potentially misvalued services and address these issues. This process is transparent, and <u>information is publicly available</u>. CMS also considers public nomination of potentially misvalued services. Those that continuously criticize the valuation process might instead publicly comment on specific codes believed to be potentially misvalued, with objective data and rationale articulated.

g. Should CMS consider valuation changes to other codes like the approach in section II.J.5. of this rule?

CMS should NOT consider valuation changes like the approach in section II.J.5. of the *Proposed Rule*. The calculation proposed for the increase in the behavioral health services is not resource-based and has the potential to distort the RBRVS. The statute that created the RBRVS (Omnibus Budget Reconciliation Act of 1989, Public-Law 101-239, section 6102) requires that the relative values be based on resource costs.

It is understandable that policymakers wish to improve access to behavioral health care and address shortages in behavioral health workforce capacity. However, these initiatives should occur via legislation and are best addressed via transparent bonus payments, grants, loan forgiveness or other programs. Distorting relativity within the RBRVS is not appropriate. **CMS should not use arbitrary calculations to adjust specific services performed by one specialty to address issues outside of the scope of the RBRVS payment system.** Access and shortage issues should be addressed through legislative solutions and properly funded.

h. We are particularly interested in ways that CMS could potentially improve processes and methodologies, and we request that commenters provide specific recommendations on ways that we can improve data collection and to make better evidence-based and more accurate payments for E/M and other services.

It is important to clarify that the RUC submits recommendations to CMS regarding resources required to provide a service. Congress and CMS determine the payment amount.

The RUC is continuously improving its processes to ensure it is best utilizing reliable, extant data. In 2013, the RUC increased the minimum number of respondents required for each survey of commonly performed codes:

- For services performed one million or more times per year in the Medicare population, at least 75 physicians must complete the survey.
- For services performed from 100,000 to 999,999 times annually, at least 50 physicians will be required.

Further strengthening its methodology in 2014, specialty societies moved to a centralized online survey process, which is coordinated by the AMA and utilized external expertise to ensure survey and reporting improvements. Over the last decade, the RUC has created and improved standard packages, such as preservice time, post-service time, practice expense direct input benchmarks, and pre-service clinical staff time packages. These packages have been implemented, allowing for enhanced relativity and comparison among all services. The RUC also incorporates extant data when possible, such as data from the Society of Thoracic Surgeons, American College of Cardiology, and NSQIP.

i. We are particularly interested in recommendations on ways that we can make more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines and new technologies that represent standards of care.

CPT and the RUC effectively respond to service description and resource-based valuation changes. New benefit categories, new practitioner or provider entity types, and codes that are program specific of necessity are not part of the CPT and RUC scope but may be addressed through legislation. CPT is an open process where any individual may make a code change application. It seeks to be responsive to changes in services and new technology. Treatment guidelines and standards of care commonly evolve more slowly than coding, but not always. CPT created Category III codes which are released twice a year and have permissive criteria for creation, while being clearly defined. CPT has a strong history of responding to changes, most recently with the creation of coding related to COVID-19 vaccination.

The RUC identifies, maintains, and reviews a list of new services and services that use new technology, develops objective screens to identify potentially misvalued services, and examines all services in which utilization estimates are more than expected.

As the RUC identifies new technology services that should be re-reviewed, a list of these services is maintained and forwarded to CMS. Currently, codes are identified as new technology based on recommendations from the appropriate specialty society and consensus among RUC members at the time of the RUC review. The RUC considers several factors to evaluate potential new technology services, including recent FDA-approval, newness or novelty of the service, use of an existing service in a new or novel way, and migration of the service from a Category III to Category I CPT code. The RUC new technology/new services list currently contains 817 services. In September 2010, the re-review cycle began and since then the RUC has recommended 59 services to be re-examined. The remaining services are rarely performed (i.e., less than 500 times per year in the Medicare population) and will not be further examined. The Workgroup will continue to review the remaining 296 services every April after three years of Medicare claims data are available for each service.

Since the inception of the RAW in 2006, it and CMS have identified over 2,700 services through over 20 different screening criteria for further review by the RUC. To provide Medicare with reliable data on how physician work has changed over time, the RUC, with more than 300 experts in medicine and research, is examining 2,717 potentially misvalued services accounting for \$45 billion in Medicare spending. The RUC has recommended reductions and deletions to 1,593 services, redistributing \$5 billion annually.

For every CPT code recommendation and family, the RUC submits utilization assumptions based on the specialty societies estimate for the next year of Medicare utilization. Starting with CPT 2009, the RAW began assessing all services for work neutrality. The RUC immediately examines the utilization assumptions as soon as actual Medicare utilization data is available. In 2012, the RUC confirmed that the RUC and specialty societies work neutrality calculation expectation is a zero-change target. However, if actual work RVUs results in 10 percent or greater than the former work RVUs for the family, the family will undergo review by the RAW. The Workgroup has examined eight code families for work neutrality. The RUC has either identified incorrect utilization assumptions, identified potential misreporting of services, recommended revisions to services via the CPT Editorial Panel, recommended extensive educational efforts, and/or recommended resurvey and review of services.

CMS may improve their methodologies by improving access to Medicare and Medicaid data. Disseminating Medicare utilization data earlier would be particularly helpful to immediately understand if the utilization of this service is as anticipated. The first quarter of Medicare claims data should be available by July 1st of each year. A full year of claims data should be available by April each year (example, 2023 data should be publicly available by April 2024). Availability of Medicaid utilization data is also necessary to examine trends in services in the non-Medicare population. The RUC has requested that CMS share recent Medicaid data to identify potentially misvalued services, and we urge the release of this information. The RUC also notes the absence of Medicare Advantage claims data. Since the number of patients in this program has increased, it is important to investigate mechanisms to collect this information.

j. We are also interested in recommendations that would ensure that data collection from, and documentation requirements for, physician practices are as least burdensome as possible while also maintaining strong program integrity requirements.

We support efforts to address the significant administrative burden that plague physicians and other health care professionals today. For this reason, the RUC was active in the effort to redefine the E/M descriptors and guidelines to ensure that documentation is utilized for clinical purposes and does not burden physicians to satisfy administrative or billing requirements.

Physicians and other health care professionals have limited time and other resources to participate in data collection efforts. The support of the national medical specialties and other health care professional organizations is imperative in obtaining adequate data on the resources required in the provision of services.

k. Finally, we are also interested in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide -recommendations to CMS on resource inputs for work and PE (Practice Expense) valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations.

The AMA strongly objects to this specific question. While we are supportive of the CMS queries related to process improvement to ensure that the RBRVS is accurate, to specifically call out the RUC in this manner is perplexing and unwarranted. Most importantly, the RUC is an independent entity, comprised of volunteer physicians and staffed and funded by the AMA, national medical specialty societies and other health care professional organizations. The RUC has a Constitutional Right to provide recommendations to the CMS on resource inputs for work and practice expense valuation. The First Amendment provides the freedom for individuals and entities to petition the government.

The RUC process operates with full transparency. Detailed minutes, recommendations, and voting records are publicly <u>available</u>, courtesy of the AMA. The RUC convenes three times annually, and these meetings are accessible to registered observers through advanced sign-up via the AMA platform.

The RUC's recommendations contain granular data to describe the physician time, work relativity, clinical staff time, medical supplies and medical equipment used in providing services to patients. This information is collected by national specialty societies and other health care professional organizations with the involvement of hundreds of dedicated volunteers. The staff in each of the more than 100 organizations involved are experts in coding and the RBRVS. The clinical input and expertise of these individuals is imperative to ensure a fair, consistent, and resource-based payment system. CMS, at one time, attempted to retain consultants to determine practice expense direct inputs for each service described by CPT codes. The effort was riddled with inconsistency in methodology and produced data that was not resource-based. The RUC, initially formed by organized medicine to review physician work, quickly realized that it was necessary for physicians and other health care professionals to lead an effort to submit direct practice expense inputs to CMS to restore relativity and trust in the RBRVS.

Simply stated, despite the efforts of others to foster division within medicine and minimize the influence of the RUC, we will continue to represent physicians and other health care professionals as we have every right and responsibility to do so.

Split or Shared Visits

## **Recommendation:**

• The AMA recommends CMS adopt the CPT guidelines for determining when a physician may report a split or shared E/M visit and to implement this policy following the proposed one-year delay, effective Jan. 1, 2025, to ensure physicians and other practitioners have sufficient time to incorporate this guidance into their practice.

The AMA supports the proposed delay, through Jan. 1, 2025, of the requirement that only the physician or practitioner who spends more than half of the total time with the patient during a split or shared visit can bill for the visit. In its rationale for a delay, CMS cited <u>concerns</u> raised by the AMA and organized medicine about the disruptions to team-based care in the facility setting that would result from this policy. CMS also noted that the AMA CPT Editorial Panel is considering revisions to aspects of split or shared visits, which are final as of Sept. 1, 2023. Therefore, we strongly urge CMS to adopt the CPT guidelines for determining when a physician may report the E/M service and to implement this policy following the one-year delay, effective Jan. 1, 2025, to give physicians and practitioners sufficient time to incorporate this guidance into their clinical practice.

The new CPT guidance states:

> Physician(s) and other qualified health care professional(s) (OHP[s]) may act as a team in providing care for the patient, working together during a single E/M service. The split or shared visits guidelines are applied to determine which professional may report the service. If the physician or other QHP performs a substantive portion of the encounter, the physician or other OHP may report the service. If code selection is based on total time on the date of the encounter, the service is reported by the professional who spent the majority of the face-to-face or non-faceto-face time performing the service. For the purpose of reporting E/M services within the context of team-based care, performance of a substantive part of the MDM requires that the physician(s) or other OHP(s) made or approved the management plan for the number and complexity of problems addressed at the encounter and takes responsibility for that plan with its inherent risk of complications and/or morbidity or mortality of patient management. By doing so, a physician or other OHP has performed two of the three elements used in the selection of the code level based on MDM. If the amount and/or complexity of data to be reviewed and analyzed is used by the physician or other OHP to determine the reported code level, assessing an independent historian's narrative and the ordering or review of tests or documents do not have to be personally performed by the physician or other OHP, because the relevant items would be considered in formulating the management plan. Independent interpretation of tests and discussion of management plan or test interpretation must be personally performed by the physician or other OHP if these are used to determine the reported code level by the physician or other QHP.

These guidelines were developed by the CPT Editorial Panel with input from the CPT/RUC Workgroup on E/M, which is comprised of current and former members of both the CPT Editorial Panel and RUC and has a distinguished track record of significant collaboration among state medical and specialty societies in developing a framework for the revised E/M services that have been implemented by Medicare across health care settings. CPT terminology is the most widely accepted medical nomenclature used across the country for E/M and all other medical services under public and private health insurance programs. Adoption of CPT guidelines for split or shared visits would reduce the ambiguity around how to report these codes since CMS revoked its previous definition of "substantive portion" and would ensure consistency and uniformity across the health care system.

Importantly, adoption of this guidance would allow physicians or QHPs to report split or shared visits based on time or medical decision-making. The AMA supports physician-led, team-based patient care. Patients benefit from the collaboration of physicians and QHPs who care for patients in hospitals, skilled nursing facilities, and other facilities, where they work hand-in-hand. However, reporting only based on the physician or QHP who performs more than 50 percent of the total time of the visit will disincentivize the continuation of these care relationships. There is significant variability in how much time it takes to perform elements of the visit based on the level of training and expertise of the physician and QHP. For many patient visits, the medical decision making involved in directing the management of the patient's care determines the course of treatment for the patient but may not require the most time. Just as is the case now, the physician or QHP who performs these critical elements of the visit should be able to adequately report the scenario that is best for their patient. For these reasons, we strongly urge CMS to adopt the CPT guidelines for reporting split or shared visits.

#### D. Telehealth Services

Extension of Current Policies through 2024

#### **Recommendation:**

The AMA strongly supports CMS's proposals to continue paying for telehealth services provided
nationwide and to patients in their homes, and to continue paying for all Medicare telehealth
services that were covered in 2022 through the end of 2024, including the CPT codes for audioonly telephone visits. We urge the Biden Administration to support legislation to permanently
extend Medicare telehealth policies.

CMS proposes to implement the telehealth flexibilities that were included in the Consolidated Appropriations Act (CAA), 2023, by waiving the geographic and originating site requirements for Medicare telehealth services through the end of CY 2024. By doing so, patients nationwide in both urban and rural areas will retain the ability to access telehealth services, particularly from their own homes. Based on the CAA, 2023, CMS is also extending payment for the CPT codes for audio-only telephone visits, 99441-99443 and 98966-98968, through 2024. CMS further proposes to continue payment for all other services that were on the 2022 Medicare Telehealth Services List in any category through 2024 when they are provided via telehealth and to delay in-person visit requirements for telehealth services for patients with mental health conditions.

The AMA deeply appreciates and strongly supports these policy proposals and urges that they be finalized. 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, including audio-only services, and that they can continue receiving them in their homes. The AMA strongly urges the Biden Administration to join us in supporting legislation to permanently extend these Medicare telehealth policies.

Modifying Telehealth Service Categories

CMS proposes to change the way it categorizes services on the Medicare Telehealth List by replacing the Category 1-3 designations and instead defining telehealth services as either Permanent or Provisional. Under the previous system, services in Category 1 or 2 were permanently on the Medicare Telehealth List and those in Category 3, which were added during the COVID-19 PHE, were to remain on the list on an interim basis through 2023, at which time CMS would determine if it would remove them from the telehealth list or add them to one of the permanent categories. The AMA agrees with the agency that the new proposed categories of Provisional and Permanent are clearer and less likely to cause confusion.

Frequency Limits on Subsequent Nursing Facility Telehealth Visits

## **Recommendation:**

• The AMA recommends that CMS permanently remove the frequency limit on physicians furnishing subsequent nursing facility visits via telehealth.

In comments on the 2023 Proposed Rule, the AMA raised concerns about the frequency limits of once every 14 days on subsequent nursing facility visits provided via telehealth and recommended that these frequency limits be lifted permanently. CMS previously determined that it is not enforcing these limits during 2023. The current rule proposes to lift the frequency limits during 2024 and seeks information to guide future policy beyond 2024.

As we previously noted, the discussion in the 2021 rule regarding the reason for increasing the allowed frequency of subsequent visits from once every 30 days to once every 14 days failed to note that federal regulations at 42 CFR 483.30 already require that patients in a nursing facility "must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter." Effective May 7, 2022, one year prior to the expiration of the COVID-19 PHE, CMS reinstated the requirement that the nursing facility patient visits required by these federal regulations must be provided by the physician in-person and cannot be provided via telehealth. Given that these regulatory visits are already required to be provided in-person, the AMA again recommends that CMS remove the frequency limit on physicians furnishing subsequent nursing facility visits via telehealth.

When a patient in a nursing facility develops a new problem or their condition is exacerbated such that they need to see a physician, the visit should be provided in the most expeditious manner. If the physician cannot quickly be in-person at the facility but could provide the visit via telehealth, that should be permitted. In addition, it is possible that the rapid availability of a telehealth visit in the nursing facility could help prevent avoidable patient transfers from nursing facilities to emergency departments.

# Continuation of Non-Facility Payment Rate

CMS proposes that telehealth services provided to patients in their homes should be reported with place of service (POS) code 10, which was established in the 2022 final rule. CMS established policy in the 2023 final rule that, for calendar year 2023, Medicare would continue paying for telehealth services at the non-facility payment rate instead of returning to its pre-PHE policy of paying for these services at the reduced facility payment rates that apply to services provided in hospital settings. (Although the facility rates are lower than the non-facility rates, for services provided in hospitals and other facility settings, Medicare makes a separate payment to the facility in addition to the payment for the physician service.) In the current rule, CMS proposes to align with the telehealth-related flexibilities that were extended via the CAA, 2023, by continuing to pay for telehealth services provided to patients in their homes at the non-facility payment rate for 2024 when the services are reported with POS 10. The AMA appreciates CMS's recognition that physicians who provide both in-person office services and telehealth services need to receive sufficient compensation to cover the expense of maintaining their medical office.

Direct Supervision

# **Recommendation:**

• The AMA recommends that CMS permanently allow the supervising physician to be present and immediately available through real-time audio and visual interactive telecommunications.

During the PHE and continuing through calendar year 2023, CMS has modified the definition of Direct Supervision to allow this supervision to be provided through the presence and immediate availability of the supervising practitioner through real-time audio and visual interactive telecommunications. In the current rule, CMS proposes to extend this definition of Direct Supervision through the end of calendar year 2024 and seeks information about future policy on virtual Direct Supervision for 2025 and beyond.

The AMA supports the proposal to continue the current policy through 2024 allowing the supervising physician to be present or immediately available through real-time audio and visual interactive telecommunications and, as we have previously stated, the AMA recommends that this policy be made permanent. 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 has to supervise or deliver services at multiple locations and may not be available to supervise services in-person when all patients need them. Failure to allow supervision via interactive telecommunications 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; the same principle should apply to how supervision is provided.

Reporting Home Address for Telemedicine Visits

#### Recommendation

• The AMA urges CMS to consider allowing physicians to continue to render telehealth visits as needed from locations other than their primary practice setting <u>without</u> having to add their home address to their Medicare enrollment form. In the alternative and at a minimum, we recommend that CMS announce changes that will occur related to a physician's address being publicly available on websites such as Care Compare so there is sufficient time to make the appropriate changes to the address listed or have their home address suppressed.

The AMA has concerns related to the public display of a physician's home address on Medicare websites that include a physician lookup feature. Specifically, we advise CMS to continue to 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. CMS allowed this during the COVID-19 PHE, and we urge the agency to consider permanently extending this flexibility beyond December 31, 2023, when it is set to expire. 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 only conduct telemedicine visits from their home. The nature of this physician's population of patients introduces a heightened level of safety concerns, that we find outweigh the perceived benefits of having the physician's address listed publicly.

Concerns for privacy and safety are not new, and escalating trends in violence towards physicians and other health care providers demonstrate that these professionals have never been at a greater risk of injury due to workplace violence. According to the U.S. Bureau of Labor Statistics, the rate of injuries from violent attacks against medical professionals grew by 63 percent from 2011 to 2018, and hospital safety directors say that aggression against staff escalated as the COVID-19 PHE intensified in 2020.<sup>5</sup> Notably, hospitals have turned to intensifying security protocols that have become more pronounced since the beginning of the COVID-19 PHE.<sup>6</sup> However, while hospital settings are attempting to respond with investments to protect the safety of staff and patients, reasons for aggression may vary and ultimately

<sup>&</sup>lt;sup>5</sup> U.S. Bureau of Labor Statistics, "Injuries, Illnesses, and Fatalities: Fact Sheet, Workplace Violence in Healthcare," 2018, <a href="https://www.bls.gov/iif/factsheets/workplace-violence-healthcare-2018.htm">https://www.bls.gov/iif/factsheets/workplace-violence-healthcare-2018.htm</a>; see also AAMC News, "Threats against health care workers are rising. Here's how hospitals are protecting their staffs", Aug. 18, 2022

<sup>&</sup>lt;sup>6</sup> Kara Hartnett, "As violence worsens, providers seek to balance security, patient care," Modern Healthcare, Aug. 10, 2023, https://www.modernhealthcare.com/providers/violence-in-healthcare-security-solutions

become targeted towards an individual, outside the walls of a secure hospital. We stress that any effort towards preserving the privacy and safety of a health care professional must be a top priority for CMS.

Should CMS decide to allow the flexibility to lapse, an announcement must be made in advance of December 31, 2023, to allow physicians who may have their home address listed, sufficient time to provide an alternate address or have their home address suppressed if they desire.

# E. Clarifications for Remote Monitoring Services

## **Recommendation:**

• The AMA recommends that this section be modified in the final rule as we are concerned that many of the statements in the Proposed Rule that are intended only to clarify CMS policy on reporting of remote monitoring services actually create new restrictions on the use of these codes that go beyond the intended guardrails adopted by the CPT Editorial Panel.

The AMA commends CMS for its efforts to increase patient access to remote monitoring services and thanks CMS for responding to questions and requests for clarification from remote monitoring interested parties. While some of the clarifications are helpful, the AMA is concerned that many of the statements reinforce or create new restrictions which go beyond the intended guardrails of the CPT Editorial Panel. The AMA acknowledges that CMS has the authority to implement more stringent restrictions on how CPT codes can be reported for Medicare beneficiaries, but we fear that if implemented as outlined in this Proposed Rule, the clarifications will increase administrative burden and discourage appropriate reporting of these services. Further, the clarifications have the potential to create unnecessary complexity in an innovative and rapidly evolving area of digital medicine and may prevent physicians from being able to access necessary services for their patients that could greatly improve patient outcomes. We also remind CMS that the CPT Editorial Panel process is a transparent, rigorous process that very deliberately and thoughtfully develops coding and guidelines that foster appropriate reporting. The CPT Editorial Panel delivers codes and guidelines that are well reasoned and vetted; if CMS wants to ensure appropriate access to remote monitoring services with the goal of higher quality patient care, there is no reason to implement clarifications that will limit use beyond what is stipulated in the CPT guidelines.

As it will be relevant to our comments on this section and to alleviate further confusion, the AMA would like to clarify the codes defined as remote physiologic monitoring (RPM), remote physiologic monitoring treatment management (RPMTM), remote therapeutic monitoring (RTM) and remote therapeutic monitoring treatment management (RTMTM). Often stakeholders, CMS, and even the AMA group these services together and refer to them with the shorthand RPM and RTM, however, there are distinctions that impact appropriate coding that seem to be overlooked in CMS clarifications. The distinctions are especially relevant to the 16-day monitoring requirement addressed by CMS in clarification three.

#### RPM

• 99453 Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment

<sup>&</sup>lt;sup>7</sup> Sachin H. Jain, "Violence Against Healthcare Workers Is Rising: Here's How We Can Protect Them," Forbes, Aug. 2, 2023, <a href="https://www.forbes.com/sites/sachinjain/2023/08/02/violence-against-healthcare-workers-is-rising-heres-how-we-can-protect-them/?sh=6f576de73940">https://www.forbes.com/sites/sachinjain/2023/08/02/violence-against-healthcare-workers-is-rising-heres-how-we-can-protect-them/?sh=6f576de73940</a>

• 99454 Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days

## RPMTM

- 99457 Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
- 99458 Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)

#### **RTM**

- 98975 Remote therapeutic monitoring (eg, therapy adherence, therapy response); initial set-up and patient education on use of equipment
- **98976** Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
- **98977** Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
- **98978** Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days

## RTMTM

- **98980** Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
- 98981 Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)

New vs. Established Patient Requirements

## **Recommendation:**

• The AMA recommends that CMS allow physicians and other qualified health care professionals (QHPs) to furnish remote monitoring services to new and established patients.

The AMA appreciates CMS's flexibility during the COVID-19 PHE in allowing for new patients to receive remote monitoring services. While the AMA is encouraged that patients who received initial remote monitoring services during the PHE are considered established patients for purposes of the CMS new patient requirement, we disagree that the new patient requirement is necessary. While some codes specify if a patient is new or established, these codes do not, and the AMA encourages CMS to eliminate the requirement.

Although CMS initially limited RPM services to patients with chronic conditions, the agency clarified in the 2021 Proposed Rule (<a href="https://www.federalregister.gov/d/2020-17127/p-400">https://www.federalregister.gov/d/2020-17127/p-400</a>) that remote monitoring can be furnished to patients with both acute and chronic conditions. Since CMS offered this clarification, it is logical that physicians should be able to utilize remote monitoring services for a new patient who presents with an acute illness. Limiting remote monitoring to only established patients is not only unnecessary but potentially dangerous. There is a wide range of acute symptoms that a new patient could present with from COVID-19 to heart failure and, in many cases, RPM is an important element of high-quality care and can also reduce the likelihood of additional costly care. In addition, a policy of excluding new patients assumes that the patient's primary care physician is providing remote monitoring services themselves when we know that at many large health systems the primary care physician partners with a remote monitoring team. If the patient is required to be an established patient with the physician leading the remote patient monitoring program, that could create a separate and unnecessary intake visit after the patient's primary care physician has already identified the need for remote monitoring services.

Data Collection Requirements

## **Recommendations:**

The AMA urges CMS to remove RTMTM services (98980, 98981) from its' clarification as CPT guidelines do not require 16 days of monitoring to report these services. CMS should reconsider the limitation that only one physician or other QHP may report CPT codes 99453 and 99454, or CPT codes 98976, 98977, 98980, and 98981, during a 30-day period.

The AMA appreciates CMS's temporary exception to the 16-day monitoring requirement for remote monitoring services during the COVID-19 PHE. CPT guidelines do specify a requirement for at least 16 days of monitoring *over an episode of care* to report the education and set up codes (99453, 98975) for both RPM and RTM and at least 16 days *over a 30-day period* to report the device supply codes (99454, 98976, 98977, 98978) for both RPM and RTM. This aspect of the CMS requirement is consistent with the current CPT guidelines and was intentional on the part of the CPT Editorial Panel when the codes were developed.

We strongly disagree with the CMS clarification requiring 16 days of monitoring for the RTMTM services (98980, 98981). As explained above, within the CPT code set, RPMTM and RTMTM services are distinct from RPM and RTM, respectively. The CPT guidelines are clear that the 16-day monitoring requirement only applies to RPM and RTM, which are the CPT codes for the practice expense of the clinical staff time to set-up and educate the patient on the device and the practice expense of the equipment to supply the patient with the remote monitoring device. RTMTM services are for the physician work and associated clinical staff time to analyze and implement the data collected from the patient through monitoring. CPT guidelines state that "remote therapeutic monitoring treatment management services are provided when a physician or other OHP uses the results of remote therapeutic monitoring to manage a patient under a specific treatment plan." The CPT Editorial Panel carefully outlined the requirements to report treatment management services and they do not include at least 16 days of monitoring. This flexibility is intentional so that the physician or other QHP can provide the appropriate care to the patient and report the time that they spent on the patients care even when the physician practice does not provide the device and/or less than 16 days of monitoring takes place. Simply not meeting the requirements to report the device supply code should not prohibit the physician from reporting services performed when they spend at least 20 minutes of time in a calendar month on remote therapeutic monitoring treatment management.

CMS goes on to state, "As a clarification for either RPM or RTM, only one practitioner can bill CPT codes 99453 and 99454, or CPT codes 98976, 98977, 98980, and 98981, during a 30-day period, and only when at least 16 days of data have been collected." The AMA contends that this is a misinterpretation of CPT guidelines. First, 98980 and 98981 should not be included in this statement for all the reasons stated previously. Second, the CPT guidelines are careful to set the framework that remote monitoring is provided for an episode of care and is part of a patient's treatment plan. The AMA agrees with CMS that only one monitoring device should be reported regardless of the number of devices provided to the patient and the number of parameters monitored, however, this is for an episode of care for a specific condition, it is not intended to limit treatment for patients who see separate physicians for separate episodes of care and would benefit from medical device(s) to monitor separate and distinct episodes of care. CPT guidelines are not intended to interfere with the physician's ability to use their independent clinical judgement in deciding the best course of treatment for their patients. There may be a situation where a patient has comorbidities and would benefit from remote monitoring for two episodes of care. For example:

- Comorbid patient is under the simultaneous care and supervision of the following:
  - Specialist 1 (Cardiologist) who is remotely monitoring heart failure via various digital medical devices as defined by FDA including a weight scale, a blood pressure cuff monitor, and/or a single lead personal ECG monitor.
  - Specialist 2 (Endocrinologist) who is remotely monitoring diabetes mellitus via various digital medical devices as defined by FDA including a glucose monitor, and a stand-on temperature monitoring system to assess inflammatory changes associated with foot ulcers.

Use of RPM and RTM in Conjunction with Other Services

## **Recommendation:**

• A patient can receive RPM *and* RTM services if they are reported by separate physicians or other QHPs for separate and distinct episodes of care.

The AMA thanks CMS for aligning with CPT guidelines and clarifying that RPM or RTM can be reported with care management services such as chronic care management and transitional care management if no time is double counted. We also agree that RPM and RTM should not be reported in conjunction as the CPT guidelines indicate. The AMA disagrees, however, with the CMS statement that "...services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected...." The AMA contends that this represents another misinterpretation of CPT guidelines. CPT guidelines are careful to set the framework that remote monitoring is provided for an episode of care and is part of a patient's treatment plan. As referenced in comments for clarification two, separate physicians should be able to report remote monitoring for separate and distinct episodes of care.

Other Clarifications for Appropriate Billing

## **Recommendation:**

• CMS should clarify that a physician or other QHP can report remote monitoring services separately from the global service period even if the service is related to the diagnosis and episode of care for the global procedure as long as the work described is distinct.

The AMA strongly urges CMS to reconsider this proposal, which would seriously limit the physician or other QHPs ability to use remote monitoring services based on their clinical judgment. CMS's final clarification introduces a new concept to the discussion of appropriate reporting of remote monitoring services. While we agree with CMS that remote monitoring may be furnished separately from a global service payment for a procedure or surgery, we strongly disagree that the diagnosis must be "...unrelated to the diagnosis for which the global procedure is performed...." or that the remote monitoring must be for "...an episode of care that is separate and distinct from the episode of care for the global procedure...." RPM, RPMTM, RTM and RTMTM services are not included in the services provided as part of the surgical global period and can be incredibly useful in post-surgical care. CMS should allow the diagnosis to be the same, if the work described by the CPT code is separate from the work described in the global period.

For example, one study found that monitoring vital parameters with professional medical devices and using the findings to address postoperative medical issues following cardiac surgery reduced hospitalizations and potentially life-threatening complications. Another example is RTM and RTMTM services to monitor a therapeutic response to physical therapy (PT). This type of service is typically excluded from the CMS global period for joint replacement surgery because the surgeon does not provide PT services. However, it is related to the diagnosis for which the global surgical period is applied and is part of the episode of care. Remote therapeutic monitoring of PT should be separately reportable even though it is related to the underlying condition that the global procedure addressed.

# F. Supervision of Residents in Teaching Settings

#### **Recommendation:**

As CMS considers how teaching physician's virtual presence could continue post COVD-19
 PHE, we urge CMS to maintain virtual supervision of residents in all settings permanently.

The AMA applauds CMS for its consideration of the expansion of remote resident physician supervision. Originally, CMS was only going to allow remote resident supervision to occur post the COVID-19 PHE for teaching physicians when they were present for the key or critical portions of services involving residents through audio/video real-time communications technology (virtual presence), for services furnished in residency training sites that are located outside of an Office of Management and Budget (OMB)-defined metropolitan statistical area (MSA). However, CMS is considering expanding this remote supervision option. CMS is now proposing to allow the teaching physician to have a virtual presence in all teaching settings when the service is furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations) through December 31, 2024. CMS is seeking comments and information to

<sup>&</sup>lt;sup>8</sup> Atilgan, K, Onuk, BE, Coşkun, PK, et al. Remote patient monitoring after cardiac surgery: The utility of a novel telemedicine system. J Card Surg. 2021; 36: 4226-4234. <a href="https://doi.org/10.1111/jocs.15962">https://doi.org/10.1111/jocs.15962</a>.

help them consider how telehealth services can be furnished in all residency training locations beyond December 31, 2024, and what other clinical treatment situations are appropriate to permit the virtual presence of the teaching physician. Additionally, CMS is seeking information on how the teaching physician's virtual presence could continue to support patient safety, while meeting the clinical needs for all patients, and ensure burden reduction without creating risks to patient care or increasing opportunities for fraud.

The AMA appreciates CMS's decision in the 2021 MFS to permanently allow virtual supervision of residents for certain types of services in non-metropolitan areas; however, we have been hearing from multiple physician groups within our Federation of Medicine, as well as the Association of American Medical Colleges (AAMC), how important the virtual supervision of residents has become post the COVID-19 PHE and how vital it is to permanently continue this additional supervision option regardless of location. Therefore, as CMS considers how teaching physician's virtual presence could continue post the COVD-19 PHE, we urge CMS to maintain virtual supervision of residents in all settings permanently.

While we commend CMS for recognizing the importance of access to care in rural areas, it is important to recognize that significant workforce shortages are also impacting access to care in other regions of the country. According to data from the Health Resources and Services Administration (HRSA), as of April 24, 2023, 160 million people currently reside in a Mental Health Professional Shortage Area (HPSA) and there are 8,200 fewer practitioners than are needed. Approximately 25 percent of mental health HPSAs are located in urban areas and 24 percent span both rural and non-rural areas. Currently, 99 million people reside in a Primary Care Shortage Area and there are 17,199 primary care practitioners that are needed. Additionally, a June 2021 report from the AAMC predicts a shortage of up to 124,000 physicians by 2034. These shortages have a real impact on access to care for patients.

In addition, the Accreditation Council for Graduate Medical Education (ACGME) recently amended its rules to allow for audio/visual supervision of residents and its guidelines now 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." Therefore, 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.

However, guardrails should be included in order to ensure virtual supervision is delivered efficaciously and to mitigate risk. As such, the AMA recommends:

 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.<sup>13</sup>

<sup>&</sup>lt;sup>9</sup> HRSA data on health professional shortage areas by discipline can be found here: https://data.hrsa.gov/topics/health-workforce/shortage-areas.

<sup>&</sup>lt;sup>10</sup> Designated Health professional shortage areas statistics, Bureau of health Workforce, HRSA (March 31, 2023) <a href="https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport">https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport</a>.

<sup>&</sup>lt;sup>11</sup> AAMC, The complexities of physician supply and demand: projections from 2019-2034 (June 2021) can be found here https://www.aamc.org/media/54681/download.

<sup>12</sup> https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency 2023v3.pdf.

<sup>13</sup> https://www.acgme.org/What-We-Do/Accreditation/Common-Program-Requirements/.

- Training programs should lay out 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.

Since a teaching physician will still be required to review the resident physician's interpretations and services, and ACGME has strict limits concerning supervision via interactive telecommunications technology, the AMA believes that the appropriate level 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 which would still be required to monitor programs' supervision of residents and ensure that supervision is consistent with the provision of safe and effective patient care, the educational needs of residents, the progressive responsibility appropriate to residents' level of education, competence, and experience, and any other applicable common and specialty/subspecialty specific program requirements.

The AMA believes that—if ACGME rules are adhered to, and the use of audio/visual real time communication equipment is individualized to support the needs of residents, teaching physicians, and their patients—this tool will be effective and will provide appropriate supervision, frequent evaluation, and open discussion. Therefore, in alignment with AAMC and ACGME, the AMA believes that there should be a permanent expansion of supervision of residents via audio/video real-time communications technology, beyond non-metropolitan areas, especially since these methods of supervision were successfully employed for multiple years throughout COVID-19 PHE.

G. Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health (SDOH) Risk Assessment, and Principal Illness Navigation (PIN) Services

Community Health Integration (CHI) Services

## **Recommendations:**

• The AMA supports CMS's proposal to further incentivize screening for SDOH and referral to community support systems to improve health outcomes and reduce avoidable inpatient, emergency department, and long-term care utilization. The AMA urges CMS to waive patient cost-sharing for CHI services, exclude these services from budget neutrality, expand the types of services that qualify as initiating visits, finalize the provision of these services under general supervision of a physician, and better define the services and personnel who can provide the service.

CMS proposes to establish two new Healthcare Common Procedure Coding System (HCPCS) G-codes and payment rates for time-based monthly CHI services under the general supervision of a physician to

address SDOH that are significantly limiting the ability to diagnose or treat problems identified in an initiating E/M visit. Studies have found substantial evidence linking social circumstances, including access to healthy food, stable housing, and transportation, to health and to health outcomes. It is now understood that non-medical factors, such as SDOH, account for as much as 50 percent of a person's health outcomes. When one or more of these conditions pose challenges, such conditions can become risk factors for poor health outcomes, as well as for inequitable health outcomes, particularly for Black, Latino, American Indian and Alaska Native (AI/AN), Asian American, Native Hawaiian, and Pacific Islanders (AANHPI), and LGBTQ+ individuals, people who live in rural areas, and people with disabilities. The AMA supports CMS's proposal to further incentivize screening for SDOH and referral to community support systems to improve health outcomes and reduce avoidable inpatient, emergency department, and long-term care utilization. The AMA urges CMS to waive patient costsharing for CHI services, exclude these services from budget neutrality, expand the types of services that qualify as initiating visits, finalize the provision of these services under general supervision of a physician, and better define the services and personnel who can provide the service.

The AMA has incorporated work to address SDOH, which is already being performed, and encouraged it through changes to coding and payment. As CMS notes, the CPT Editorial Panel recognized in the revised CPT E/M Guidelines that SDOH needs can increase the complexity of a physician's medical decision-making for an E/M visit and increase risk to the patient, when diagnosis or treatment is significantly limited by SDOH. CMS adopted these guidelines, effective in 2021. For example, with use of E/M codes 99204 and 99205, which are used for moderate and high levels of medical decision-making (MDM) for a new patient, and 99214 and 99215 for established patients, SDOH factors may raise the risk of complications, morbidity, or mortality by limiting treatment options and diagnosis capability. We appreciate that CMS wishes to build on these efforts by establishing separate G-codes to promote Medicare beneficiary access to community-based social services (e.g., housing, utility, food assistance, and transportation) to address a patient's health-related social needs (HRSN), the individual-level corollaries of community-level social determinants of health.

First, to ensure that these services are accessible to the patients who need them the most, the AMA strongly urges CMS to explore all authorities, including working with the states and with Congress, to waive patient cost-sharing for these services. Under current policy, Medicare beneficiaries would be subject to a 20 percent co-insurance requirement to receive CHI services. Particularly for Medicare patients who are experiencing a HRSN, a majority of which are driven by financial hardship, out-of-pocket expenses can lead to delaying or foregoing these services. While research in this area is still growing and mixed for some interventions, there is promising evidence that well-designed and funded interventions lead to reduced health care utilization and costs. The Medicare program should reinvest these savings into waiving patient cost-sharing. Importantly, we believe CMS can also ensure greater access to these services by partnering with states to provide coverage of these services in their state Medicaid plans or coverage of cost-sharing for dual-eligible beneficiaries. Waiving patient cost-sharing would remove a significant barrier to uptake of care management services, including CHI.

If patient cost-sharing is not waived, the AMA supports a requirement to obtain patient consent during the CHI initiating visit. Unfortunately, patient cost-sharing is a barrier to care for other care management services that CMS has previously established as beneficiaries are not accustomed to out-of-pocket costs for this type of care. Obtaining patient consent will help ensure patients are aware of their cost-sharing responsibilities, and we believe providing this clarity to patients outweighs the additional burden imposed on physician practices to obtain informed consent.

Second, CMS should not apply budget neutrality to the CHI services as these codes establish a new benefit for beneficiaries. CMS believes there is a gap in the current care management code set for integration of community services provided by auxiliary personnel, including community health workers or peers. As this is a new service being provided by a new set of personnel who were not previously eligible to provide billable services under Medicare, we believe this falls outside the scope of budget neutrality as a change in law or regulation.

As the AMA has <u>argued</u> with respect to other CMS-developed new services, such as G2211, we believe CMS has the authority to exclude changes in law and regulation, including SDOH risk assessment services, which affect spending from the calculation of budget neutrality, analogous to its treatment under the Medicare Sustainable Growth Rate (SGR) system of certain new benefits that increased spending but were outside the control of the physician community. Specifically, Section 4503 of the Bipartisan Budget Act of 1997 states that one of the four factors used to set the SGR is (emphasis added):

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the fiscal year (compared with the previous fiscal year) which will result from *changes in law and regulations*, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B) ....

At a minimum, the AMA urges CMS to maintain a low utilization assumption for these services. As mentioned above regarding implementation of TCM, the uptake of these codes has historically been low and increasing the utilization assumption would result in a greater budget neutrality cut that physician practices cannot absorb given the proposed -3.36 percent reduction to the Medicare conversion factor and projected 4.5 percent increase in practice costs as measured by the MEI.

Third, the AMA agrees with CMS that the Annual Wellness Visit (AWV) should be included in the list of CHI initiating services but only when the physician or other practitioner bills for the service in order to meet "incident to" requirements and ensure care coordination. We also urge CMS to expand the list of CHI initiating services beyond office/outpatient E/M services and the AWV. Like the Biden Administration, the AMA is committed to tackling the issues surrounding maternal mortality and morbidity. Providing postpartum insurance coverage is crucial as it ensures new mothers receive necessary medical care and support during a vulnerable period, promoting their physical and mental well-being. This coverage also facilitates early detection and management of potential complications, contributing to healthier outcomes for mothers and newborns. To this end, we believe postpartum community service integration will be an important use of these new services but requiring an E/M or AWV to initiate the service would create a barrier to access as those codes are bundled into the maternity care codes. While Medicare does not cover many births, it is an industry leader, and public and private plans regularly follow its determinations on coverage, coding, and payment. Therefore, we believe CMS should include the maternal care CPT codes, describing a bundle of services, on the list of CHI initiating visit codes.

Similarly, we believe any visits by children qualifying for Medicare based on disability should also be included under CHI initiating visit codes, as these children often face particular challenges that are time-sensitive in a child's development. Further, we believe emergency department visits and observation status inpatient discharges should be included under CHI initiating visit codes, as HRSNs substantially contribute to these visits. Consideration should be given to including visits where there has been a substantial or sudden decline in medical (e.g., diabetes, cancer, end-stage renal disease, cardiovascular disease) or behavioral health (e.g., substance use disorder, serious mental illness) status or change in

incarceration status. We also believe patients undergoing major surgery would benefit from CHI services and urge CMS to include global surgical services, which also bundle the E/M visits into the code, on the list of CHI initiating visits list.

Fourth, we support CMS's proposal to designate CHI services as care management services that may be furnished when the "incident to" billing requirements are met and under general supervision of the physician, which means the service is furnished under the physician's overall direction and control, but the physician's physical presence is not required. Critical to the success of CHI services will be the establishment of procedures to ensure direct communication between the community health worker and the patient's medical team. We believe general supervision is the appropriate level of supervision to facilitate this communication.

Fifth, the AMA urges CMS to clarify the difference between non-clinical CHI services and clinical care management services, as well as adopt CPT guidance on when it is appropriate to bill for both PIN and other care management services. We believe Principal Care Management (PCM) codes would be the appropriate service to report when community health integration is provided by a nurse, social worker, or other clinical staff. Further, we believe CMS's proposal to allow a physician to bill separately for other care management services during the same month as CHI could lead to ambiguity and audit risk. To reduce these concerns, we urge CMS to adopt CPT guidance that "each minute of service time is counted toward only one service. Do not count any time and activities used to meet criteria for another reported service. However, time of clinical staff and time of a physician or other qualified health care professional are reported separately when each provides distinct services to the same patient at different times during the same calendar month." Physicians and their coding professionals are already familiar with this CPT guidance, thus adopting it will reduce confusion and help ensure uniformity in billing guidelines.

Finally, we urge CMS to better define the role of the auxiliary staff permitted to perform CHI services. To ensure patients understand the role of the community health worker (CHW) or other auxiliary staff providing CHI within the care team, we urge CMS to clarify that these staff should refrain from any activity that could be construed as clinical in nature, including interpreting test results or medical symptoms, offering second opinions, or making treatment recommendations. CHWs or peers should provide a supportive role for patients and, when necessary, help them understand medical information provided by physicians and other members of their medical care team. CHWs or peers should fully disclose relevant training, experience, and credentials, in order to help patients understand the scope of services the navigator is qualified to provide. They should also fully disclose potential conflicts of interest to those whom they service, including employment arrangements. As mentioned above, we believe CHI services provided by nurses, social workers or clinical staff would be more appropriately billed using the PCM codes.

Social Determinants of Health (SDOH) Risk Assessment

## **Recommendations:**

• The AMA supports CMS's proposal to further incentivize screening for SDOH and referral to community support systems to improve health outcomes and reduce avoidable inpatient, emergency department, and long-term care utilization. The AMA urges CMS to waive patient cost-sharing for SDOH risk assessment services, exclude these services from budget neutrality calculations, and address the potential negative implications of collecting SDOH data. We make several additional recommendations to ensure these services reach the patients most in need of

SDOH interventions and to ensure that the information collected is standardized and can be used to address SDOH risks.

CMS proposes to establish a new HCPCS G-code and payment rate for administering a SDOH risk assessment as part of a comprehensive social history when medically reasonable and necessary in relation to an E/M visit. CMS proposes this risk assessment could be billed no more than every six months and must be furnished on the same date as an E/M visit. The risk assessment tool would have to be tested and validated and include, at a minimum, the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties. Many physicians have begun screening patients for SDOH as evidence has grown that these social factors contribute to up to 50 percent of health outcomes, particularly as the CPT Editorial Panel added SDOH to the revised E/M Guidelines that were implemented in 2021, as discussed above. The AMA supports CMS's proposal to further incentivize screening for SDOH and referral to community support systems to improve health outcomes and reduce avoidable inpatient, emergency department, and long-term care utilization. The AMA urges CMS to waive patient cost-sharing for SDOH risk assessment services, exclude these services from budget neutrality calculations, expand coverage to Emergency Department (ED) E/M visits, clarify that they may be provided via telecommunications platforms and allow the SDOH risk assessment tool to also be completed prior to the date of the E/M visit as part of the patient intake.

The AMA strongly urges CMS to explore all authorities including working with the states and with Congress, to waive patient cost-sharing for these services. Under current policy, Medicare beneficiaries would be subject to a 20 percent co-insurance requirement to receive this service. Particularly for Medicare patients who are experiencing an HRSN, a majority of which are driven by financial hardship, out-of-pocket expenses can lead to delaying or foregoing these services. While research in this area is still growing and mixed for some interventions, there is promising evidence that well-designed and funded interventions lead to reduced health care utilization and costs. The Medicare program should reinvest these savings into waiving patient cost-sharing. Importantly, we believe CMS can also ensure greater access to these services by partnering with states to provide coverage of these services in their state Medicaid plans or coverage of cost-sharing for dual-eligible beneficiaries. Waiving patient cost-sharing would remove a significant barrier to uptake of care management services, including SDOH risk assessment.

CMS should not apply budget neutrality to the SDOH Risk Assessment services as these codes establish a new benefit for beneficiaries. CMS believes there is a gap in the code set for administering a SDOH screening tool to Medicare beneficiaries, which we believe falls outside the scope of budget neutrality as a change in law or regulation. As the AMA has <u>argued</u> with respect to other CMS-developed new services, such as G2211, we believe CMS has the authority to exclude changes in law and regulation, including SDOH risk assessment services, which affect spending from the calculation of budget neutrality, analogous to its treatment under the Medicare Sustainable Growth Rate (SGR) system of certain new benefits that increased spending but were outside the control of the physician community. Specifically, Section 4503 of the Bipartisan Budget Act of 1997 states that one of the four factors used to set the SGR is (emphasis added):

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the fiscal year (compared with the previous fiscal year) which will result from *changes in law and regulations*, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B) ...

At a minimum, the AMA urges CMS to maintain a low utilization assumption for these services. As mentioned above regarding implementation of TCM, the uptake of these codes has historically been low and increasing the utilization assumption would result in a greater budget neutrality cut that physician practices cannot absorb given the proposed -3.36 percent reduction to the Medicare conversion factor and projected 4.5 percent increase in practice costs as measured by the MEI.

CMS should address the potential negative implications of collecting SDOH data. Formally documenting SDOH risks in the medical record is a somewhat new undertaking. SDOH data could be considered as a pre-existing condition or become part of an evaluation of the patient record in other contexts (e.g., a life insurance application), where we do not yet fully know the possible impact of these social risks and needs, even if resolved. Patients should consent to being screened, understand the possible social risks that the given screener may detect (e.g., transportation insecurity, homelessness, victim of domestic abuse, etc.), and be aware that their screening results will appear in their medical record. A possible approach to mitigate potential negative implications might be to outsource screening and social care to organizations specializing in detecting social risks and offering referrals or interventions. With the consent of the patient, the minimum social care data required to improve the care of the patient could then be accessed by, or communicated to, the physician and documented in the patient's medical records, if appropriate. Additionally, regulations should be considered to protect social risk and needs data outside of covered entities (e.g., community-based organizations). Regardless of how the data is collected, to protect patients from discrimination and other unintended consequences of collecting this data, consideration should be given to recording the minimum social care data required.

We also urge CMS to permit SDOH risk assessments to be billed with emergency department (ED) E/M visits, in addition to office/outpatient E/M visits. CMS states that ED visits would not typically serve as SDOH risk assessment initiating visits because the practitioners furnishing the E/M services in those settings would not typically be the ones to provide continuing care to the patient. However, research has shown that individuals with SDOH needs have a higher rate of ED visits. <sup>14</sup> 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.

The AMA recommends allowing a SDOH risk assessment tool to be administered as part of the patient's pre-visit preparation or patient intake. As physician offices have moved away from paper forms to electronic records and patient portals, they often ask patients to complete or update their information up to three days prior to the visit to ensure the information is properly recorded and reviewed prior to the E/M visit to ensure the patient's clinical and, in this case, non-clinical needs are addressed during the visit. Because CMS proposes that this service would be available to all Medicare beneficiaries, many patients will need only a standard screening tool to rule out any unmet social needs. This could be completed prior to the visit and free up time for physicians to do a deeper dive with those patients who are identified as having a HRSN that is unaddressed. Allowing screening to be done in advance of a visit would also allow personnel to line up referral options in advance of the E/M visit so that they can be discussed more efficiently at the time of the visit. Additionally, screening is like a test and test results that

<sup>&</sup>lt;sup>14</sup> 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 <a href="https://www.cdc.gov/pcd/issues/2020/19">https://www.cdc.gov/pcd/issues/2020/19</a> 0339.htm.

may impact a visit are often available in advance of the visit. At the same time, however, we acknowledge that disparities in access to mobile devices and broadband can exacerbate issues, as those without access might miss out on crucial opportunities, such as access to an SDOH assessment ahead of their office visit. They must be afforded the option to complete the assessment in the office, but this may impact physicians' ability to do a deeper dive. Therefore, we believe that the requirement to furnish the SDOH risk assessment tool on the same day as the E/M visit may be an impediment to expanding this service.

The AMA does not believe it is prudent to limit risk assessments to once every six months for all patients at this juncture. We do not agree that "there are generally not significant, measurable changes to health outcomes impacted by a patient's SDOH in intervals shorter than 6 months." For example, transportation for health care needs (e.g., getting to dialysis or other critical appointments) can impact health outcomes in less than six months. It may also be the case that three negative screens six months apart warrant changing to a "not more often than yearly" screening schedule.

Additionally, we agree with CMS that these services could be conducted via telecommunications as appropriate and not necessarily in-person. Self-administered, online screening with automated detection of negative and positive screening results, which are reviewed by the physician or practitioner, is efficient and should be allowed.

Regarding the duration of the visit, we believe the time required to administer the screening that adheres exactly to questions on a screener should be fairly easy to estimate. However, for screenings with positive results, further time may be required for post-screening questioning and assessment (e.g., asking additional questions to understand the correct referral or intervention). We do not yet know enough to gauge the amount of time that might be appropriate for the latter and it may vary with complexity of the patient and their needs.

Regarding the domains to be screened, we feel the domains selected should be those where the evidence supports the best return on investment related to health outcomes. Where possible, we recommend aligning the selected domains with Gravity Project approved terms. Therefore, we suggest either: (1) replacing "house insecurity" with "housing instability, homelessness, and inadequate housing" or (2) clarifying that "housing insecurity" includes housing instability, homelessness, and inadequate housing. Further, CMS states "the billing practitioner may choose to assess for additional domains beyond those listed above if there are other prevalent or culturally salient social determinations in the community being treated by the practitioner" (emphasis added). The physician treats the patient, not the community. At times, patients are not even from the exact community in which a physician practices. We recommend replacing this language with: "the billing practitioner may choose to assess for additional domains beyond those listed above if, based on their knowledge of the patient, the practitioner determines that there are additional SDOH domains of concern."

We also recommend that CMS clarify the role of ICD-10-CM coding of screening data. For patients who screen positive, any associated ICD-10-CM codes should be required to be submitted to receive payment. Because addressing SDOH risks is the objective, standardized ICD-10-CM codes will be key in tracking SDOH risks and outcomes. To maximize consistency, interoperability, and value of the data from the selected screeners, it would be ideal if the instrument owner or steward or some other authoritative source, such as the Gravity Project, specify a single set of rules for mapping screening questions and responses to ICD-10-CM codes.

Regarding the risk assessment tool, we believe that specifying a set of allowed, evidence-based, standardized screening instruments should help reduce data variability and improve interoperability. As

discussed above, screening tools that can be self-administered online and support the automated detection of negative and positive screening results are optimal for integrating this service into the clinical workflow.

Finally, CMS seeks comment on whether to require as a condition of payment for SDOH risk assessment that the billing practitioner also have the capacity to furnish CHI, PIN, or other care management services, or have partnerships with community-based organizations to address identified SDOH needs. The AMA believes that it is too early to determine whether to require navigation or community integration services for SDOH screening. Some physician practices, particularly those who are serving low-income, uninsured, or underinsured beneficiaries, may not have the resources to offer CHI services, or CHI services for all of the screened social needs. There are also challenges to accessing community-based services, including limited capacity and long wait lists. Therefore, we believe this condition of payment may limit access to SDOH risk assessment and referrals to community-based organizations outside of formal CHI or PIN services. We urge CMS to revisit this question after more evidence is available about the best SDOH interventions for Medicare beneficiaries. Furthermore, we believe a government-hosted platform or service is needed that makes it easier for physicians to refer patients for social care screening and services.

Principal Illness Navigation (PIN) Services

### **Recommendations:**

• The AMA supports the White House Cancer Moonshot and recognizes the importance of patient navigators to support patients with cancer and other high-risk, serious illnesses in managing the complex aspects of the health care system. We urge CMS to waive patient cost-sharing for PIN services, exempt these services from budget neutrality requirements, expand the types of services that qualify as initiating visits, finalize the provision of these services under general supervision of a physician, and better define the services and personnel who can provide the service.

CMS proposes to establish two new HCPCS G-codes and payment rates for time-based monthly patient navigation services under the general supervision of a physician addressing a serious high-risk condition, illness, or disease expected to last at least three months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death. The AMA recognizes the importance of patient navigators to help improve access to care and to help patients with cancer and other high-risk, serious illnesses manage the complex aspects of the health care system. The AMA supports the White House Cancer Moonshot, which has a goal to ensure covered patient navigation services for every cancer patient as they face overwhelming decisions and challenges when they receive a new or recurrent diagnosis. The AMA urges CMS to waive patient cost-sharing for PIN services, exempt these services from budget neutrality requirements, expand the types of services that qualify as initiating visits, finalize the provision of these services under general supervision of a physician, and better define the services and personnel who can provide the service.

First, the AMA strongly urges the White House and CMS to explore all authorities, including working with the states and with Congress, to waive patient cost-sharing for these services. Under current policy, Medicare beneficiaries would be subject to a 20 percent co-insurance requirement to receive this service. Particularly for Medicare patients who are older and more likely to be on a fixed income, out-of-pocket expenses can lead to delaying or foregoing care. Further, CMS notes navigation services have proven to be especially effective for patients with socioeconomic disadvantages – the same

patients who are less likely to be able to afford a copay. This is the reason that the AMA strongly supports H.R. 2829, the Chronic Care Management Improvement Act of 2023, which would remove the patient cost-sharing obligations for chronic care management (CCM) services. The latest data reveals that only four percent of Medicare beneficiaries potentially eligible for CCM received these services. That amounts to 882,000 out of a potential pool of 22.5 million eligible CCM beneficiaries. Importantly, we believe CMS can also ensure greater access to these services by partnering with states to provide coverage of these services in their state Medicaid plans or coverage of cost-sharing for dual-eligible beneficiaries. Waiving patient cost-sharing would remove a significant barrier to uptake of care management services, including PIN.

If patient cost-sharing is not waived, the AMA supports a requirement to obtain patient consent during the PIN initiating visit. Unfortunately, as discussed above, patient cost-sharing is a barrier to care for other care management services that CMS has previously established as beneficiaries are not accustomed to out-of-pocket costs for this type of care. Obtaining patient consent will help ensure patients are aware of their cost-sharing responsibilities, and we believe providing this clarity to patients outweighs the additional burden imposed on physician practices to obtain informed consent.

Second, CMS should not apply budget neutrality to PIN services as these codes establish a new benefit for beneficiaries. CMS believes there is a gap in the current care management code set for services provided by a patient navigator or certified peer specialist to focus on the social aspects of accessing care as opposed to the clinical focus of the other Medicare care management codes. As this is a new service being provided by a new set of personnel who were not previously eligible to provide billable services under Medicare, we believe this falls outside the scope of budget neutrality as a change in law or regulation.

As the AMA has <u>argued</u> with respect to other CMS-developed new services, such as G2211, we believe CMS has the authority to exclude changes in law and regulation, including PIN services, which affect spending from the calculation of budget neutrality, analogous to its treatment under the Medicare Sustainable Growth Rate (SGR) system of certain new benefits that increased spending but were outside the control of the physician community. Specifically, Section 4503 of the Bipartisan Budget Act of 1997 states that one of the four factors used to set the SGR is (emphasis added):

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the fiscal year (compared with the previous fiscal year) which will result from *changes in law and regulations*, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B) ....

At a minimum, the AMA urges CMS to maintain a low utilization assumption for these services. As mentioned above regarding implementation of CCM, the uptake of these codes has historically been low and increasing the utilization assumption would result in a greater budget neutrality cut that physician practices cannot absorb given the proposed -3.36 percent reduction to the Medicare conversion factor and projected 4.5 percent increase in practice costs as measured by the MEI.

Third, the AMA agrees with CMS that the AWV should be included in the list of PIN initiating services but only when the physician or other practitioner bills for the service in order to meet "incident to" requirements and ensure care coordination. We also urge CMS to expand the list of PIN initiating services beyond office/outpatient E/M services and the AWV. As mentioned above, we share the Biden Administration's commitment to tackling the issues surrounding maternal mortality and

morbidity. Providing postpartum insurance coverage is crucial as it ensures new mothers receive necessary medical care and support during a vulnerable period, promoting their physical and mental well-being. This coverage also facilitates early detection and management of potential complications, contributing to healthier outcomes for mothers and newborns. To this end, we believe postpartum navigation will be an important use of these new services but requiring an E/M or AWV to initiate the service would create a barrier to access as those codes are bundled into the maternity care codes. While Medicare does not cover many births, it is an industry leader, and public and private plans regularly follow its determinations on coverage, coding, and payment. Therefore, we believe CMS should include the maternal care bundles on the list of PIN initiating visit codes.

Similarly, we believe any visits by children qualifying for Medicare based on disability should also be included under PIN initiating visit codes, as these children often face particular challenges that are time-sensitive in a child's development. Further, we believe emergency department visits and observation status inpatient discharges should be included under PIN initiating visit codes, as HRSNs substantially contribute to these visits. Consideration should be given to including visits where there has been a substantial or sudden decline in medical (e.g., diabetes, cancer, end-stage renal disease, cardiovascular disease) or behavioral health (e.g., substance use disorder, serious mental illness) status or change in incarceration status. We also believe patients undergoing major surgery would benefit from PIN services and urge CMS to include global surgical services, which also bundle the E/M visits into the code, on the list of PIN initiating visits list.

Fourth, the AMA supports CMS's proposal to designate PIN services as care management services that may be furnished when the "incident to" billing requirements are met under general supervision of the physician, which means the service is furnished under the physician's overall direction and control, but the physician's physical presence is not required. One of the critical functions of a successful patient navigator program is to establish procedures to ensure direct communication between the navigator and the patient's medical team. We believe general supervision is the appropriate level of supervision to facilitate this communication.

Fifth, the AMA urges CMS to clarify the difference between non-clinical PIN services and clinical care management services, as well as adopt CPT guidance on when it is appropriate to bill for both PIN and other care management services. Similar to our comments regarding CHI services, we believe PCM codes would be the appropriate service to report when patient navigation is provided by a nurse or other clinical staff. Further, we believe CMS's proposal to allow a physician to bill separately for other care management services during the same month as PIN could lead to ambiguity and audit risk. To reduce these concerns, we urge CMS to adopt CPT guidance that "each minute of service time is counted toward only one service. Do not count any time and activities used to meet criteria for another reported service. However, time of clinical staff and time of a physician or other qualified health care professional are reported separately when each provides distinct services to the same patient at different times during the same calendar month." Physicians and their coding professionals are already familiar with this CPT guidance, thus adopting it will reduce confusion and help ensure uniformity in billing guidelines.

Finally, we urge CMS to better define the role of the patient navigator. To ensure that patients understand how a patient navigator fits into their care team, we urge CMS to clarify that these navigators should refrain from any activity that could be construed as clinical in nature, including interpreting test results or medical symptoms, offering second opinions, or making treatment recommendations. Patient navigators should provide a supportive role for patients and, when necessary, help them understand medical information provided by physicians and other members of their medical care team. Patient navigators should fully disclose relevant training, experience, and credentials, in order to help patients

understand the scope of services the navigator is qualified to provide. They should also fully disclose potential conflicts of interest to those whom they service, including employment arrangements. As mentioned above, we believe navigation services provided by nurses or clinical staff would be more appropriately billed using the PCM codes.

### H. Skin Substitutes

### **Recommendation:**

 CMS should separately identify and pay for high-cost disposable supplies, including skin substitutes, priced at more than \$500 using appropriate HCPCS codes. The pricing of these supplies should be based on a transparent process, where items are annually reviewed and updated.

In the 2023 MPS Proposed Rule, CMS had initially proposed to bundle skin substitutes into its MPS practice expense payments with the graft application procedures. However, due to substantial push back, it did not finalize this policy. In this Proposed Rule, CMS indicates that it would be appropriate to take a phased approach over multiple rulemaking cycles to examine how to appropriately incorporate skin substitutes as supplies under the MPS rate setting methodology.

To this end, CMS is seeking comments about how best to establish appropriate payment for skin substitute products under the MFS. In addition, CMS is seeking comments about cost-gathering approaches to establish direct PE input for skin substitute products and to develop payment rates for physician services that involve furnishing skin substitute products. The agency is also considering how to account for these products' variability and resource costs, especially as new products increasingly become available.

As the AMA understands it, the issue is primarily around the granularity in costs between separate supplies in this area, and there are more appropriate mechanisms for CMS to address the underlying issue than bundling skin substitutes into MPS practice expense payments. The AMA and the RUC have consistently over many years requested that CMS pay separately for high-cost supplies that are greater than \$500. High variability in supply costs can create distortions and inadequate payment under the existing practice expense model of the RBRVS. The AMA recommends that CMS separately identify and pay for high-cost disposable supplies priced at more than \$500 using appropriate HCPCS codes. The pricing of these supplies should be based on a transparent process, where items are annually reviewed and updated.

An analogy in this area is CMS's current payment policy for paying separately for splint and cast supplies. Under current CMS policy, HCPCS Q-codes are utilized for separate payment of necessary supplies along with the CPT codes for cast/strapping procedures. This allows for price granularity across many different types of supplies, while maintaining consistency for the actual procedure reporting.

The AMA is pleased that CMS is not proposing to change the terminology of these products to "wound management," as we previously raised concerns that this would differ from established, consensus-driven CPT nomenclature and cause confusion and inconsistent reporting. We believe that the definitions listed in the CPT code set guidelines adequately describe skin substitute services. Creating deviation for these definitions, especially for primarily cost-related reasons, would create confusion across health care.

# I. Additional Payment for In-Home Preventive Vaccine Administration Services

### **Recommendations:**

- The AMA supports CMS's proposal to maintain the additional payment for in-home administration of the COVID-19 vaccine and to extend the additional payment for in-home administration to three additional preventive vaccines. We urge CMS to finalize its proposal to increase the payment annually based on the increase to the MEI.
- CMS should consider an additional payment for an extended visit with the patient or an extended commute to the patient.
- We urge CMS to clarify that billing for additional unexpected services at the same visit is permitted.

CMS is proposing to maintain the additional payment for in-home administration of the COVID-19 vaccine (HCPCS code M0201) and to extend the payment for in-home administration of three additional preventive vaccines – the pneumococcal, influenza, and hepatitis B vaccines. The in-home additional payment amount is \$36.85 in 2023, and CMS has previously finalized that it will be updated annually by the percentage increase in MEI, which is projected to be 4.5 percent for 2024, and geographically adjusted. The AMA supports CMS's proposals as they would improve access to immunizations for Medicare beneficiaries. We also urge CMS to finalize its proposal to increase the in-home additional payment for vaccine administration based on the MEI, consistent with the increasing costs of providing vaccinations.

We note, however, that CMS's proposal does not appear to fully account for the unique needs and disparities faced by specific patient populations. People from marginalized communities and/or with more complex circumstances (e.g., rare diseases, disabilities) might require more time (in travel and during the visit) and resources (e.g., vehicle gas and mileage) expended by the clinician, which a flat payment might not cover, potentially exacerbating existing health inequities. In these cases, the payment rate may be inadequate to ensure access to in-home vaccines, preventing patients who need such services and are unable to or have difficulty commuting to a physician office or facility from getting the care they need. This could contribute to fragmented care and compromised patient outcomes. CMS should consider an additional payment for an extended visit with the patient or an extended commute to the patient.

CMS's analysis of the use of this code found that it was being billed significantly more frequently for patients who are harder to reach and that may be less likely to otherwise receive these preventive benefits. Between June 2021-June 2022, those 85 years of age and older were over three times more likely than younger beneficiaries to have received an in-home COVID-19 vaccination, and persons who are dual eligible for both Medicare and Medicaid were more than twice as likely than those who are not dual eligible to have received a COVID-19 vaccine provided in their home. The AMA applauds CMS for expanding access to life-saving preventive vaccines to historically minoritized and marginalized patients, as well as older Americans who experience greater barriers to care.

The agency is proposing to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit. CMS emphasized that every vaccine dose that is furnished would still receive its own unique vaccine administration payment. The agency would also extend the requirements for billing HCPCS code M0201, including that the patient has difficulty leaving the home, to the administration of the additional preventive vaccines, though the agency will broaden the requirements that currently reference COVID-19 specifically. We urge CMS to clarify that billing for

**additional unexpected services at the same visit is permitted.** For example, there may be cases where there is an adverse reaction to vaccination, or the clinician observes an unrelated acute condition needing immediate attention when the visit was initially intended only for vaccination. This would encourage adequate payment for unanticipated more intensive services and encourage physicians to address acute issues during that visit rather than scheduling a separate visit.

# J. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Program

### **Recommendation:**

• The AMA supports CMS's proposal to pause implementation of the AUC Program and rescind current program regulations until modifications can be made via regulation or statute that exempt care mandated by EMTALA; adequately address technical and workflow challenges that add to clinicians' administrative burden and practice expenses; maximize alignment with the Quality Payment Program; and create flexibility for the consultation of physician-developed, evidence-based and transparent AUC or advanced diagnostic imaging guidelines using a mechanism best suited for their practice, specialty, and workflow. Similarly, the AMA supports CMS's proposal to end the educational and operations testing period.

In response to concerns raised by the AMA, CMS is proposing to pause implementation of the AUC program and rescind the current program regulations due to issues with the claims-based reporting requirements for ordering and furnishing physicians. We are glad that CMS heard the AMA's concerns about the burden of these requirements and their potential negative impact on beneficiary access to care. CMS also cited concerns that claims would be inappropriately denied, data integrity and accuracy would be lacking, and beneficiaries would potentially be financially liable for advanced diagnostic imaging services. CMS acknowledged that many of the goals of the AUC program have been met by the QPP and other value-based care initiatives, including the Medicare Shared Savings Program, advances in electronic clinical quality measures (eCQMs), and interoperability requirements of the Certified Electronic Health Record Technology (CEHRT). The agency is also proposing to end the educational and operations testing period.

The AMA agrees that the AUC Program should be permanently delayed until it can be modified to reduce burden, increase flexibility, and maximize alignment with the QPP. The AMA has repeatedly raised fundamental concerns about the burden of AUC and the workflow challenges it creates, including the procedures for transmitting information from the ordering to the rendering provider, efficient reporting of the required data on claims, and understanding the complicated program requirements and exceptions. For instance, ordering physicians must be able to easily identify the diagnoses and specific advanced diagnostic imaging services to which the AUC requirements apply so that they can consult the clinical decision support mechanism (CDSM) at the time of ordering. Ideally, they would be prompted to consult the CDSM upon ordering a service to which the requirements apply. Information regarding the CDSM consultation will then somehow need to be communicated between ordering and furnishing providers, as the physician ordering the imaging service in most cases will be different than the physician performing the imaging. Thus, not only must the claim change but also all methods used to send an order (electronically or otherwise).

Moreover, a standard and technological solution for transferring this information from ordering to furnishing providers (Integrating the Healthcare Enterprise Radiology Technical Framework Supplement Clinical Decision Support Order Appropriateness Tracking) is only in a trial implementation status and being used on a limited scale or as part of pilots, so physicians will most likely need to rely on manual

workflows to exchange these data during the implementation of the AUC program. Additionally, providers will need to determine optimal procedures for these communications. For example, will ordering providers send the applicable G-codes and modifiers to the furnishing physician, or will they simply send the information in text format that the furnishing provider will need to translate into the code and modifier? These communications and reporting burdens will be further compounded when different providers are responsible for the technical and professional components of the imaging service, as the ordering physician will need to send the CDSM consultation information to two separate providers to be reported on the technical and professional claims.

In addition to the burden and workflow challenges, the AMA has raised numerous other concerns about the AUC Program, including:

- Medicare beneficiaries' imaging services would be delayed by at least the time needed for the
  furnishing provider to contact the ordering provider for AUC consultation data. Patients' wait
  times could be further—and significantly—extended in situations where the ordering provider
  does not have a CDSM or is unaware of the AUC program requirements.
- In fact, most physicians remain unaware of the underlying program requirements. Our concerns are underscored by CMS's prior claims analysis finding that only 9-10 percent of claims would have been paid in 2020 had AUC been in effect. Put differently, 90-91 percent of Medicare claims for advanced diagnostic images would have been rejected and unpaid. If the AUC program had been fully implemented in 2020, the impact on furnishing providers would have been nothing short of disastrous from the resulting massive cash shortfall and the administrative hassles of resubmitting denied claims.
- The AUC Program is not aligned with the QPP. For instance, participants in APMs who are at financial risk for their spending and quality performance should be exempt from AUC requirements.
- Further, the lack of alignment between the AUC and QPP Programs extends to their differing definitions and requirements. For example, the two programs established different hardship exception circumstances, which only add to the confusion and complexity of complying with both programs, and the AUC program requires claims-based reporting whereas MIPS and APMs are moving toward digital measures captured and reported through CEHRT.
- The AUC exception for suspected or confirmed medical emergencies is too narrow and subjective, and, as a result, is being interpreted to require emergency physicians to consult AUC.

For these reasons, we urge the agency to finalize its proposal to pause implementation of the AUC program, rescind current program regulations, and end the education and operations testing period. It is imperative that CMS work with Congress to resolve the problems stemming from the complicated AUC claims-based reporting requirements prior to un-pausing implementation.

Finally, we agree with the agency that clinical decision support tools can be beneficial in assisting with clinical decision making and their continued use in a manner that best serves physicians and their patients should be encouraged. For this reason, as discussed in more detail later in this letter, the AMA is urging CMS to retain and modify MIPS Improvement Activity (IA) #29 Consulting AUC Using CDS When Ordering Advanced Diagnostic Imaging. Specifically, the AMA recommends that the IA provide flexibility for the consultation of physician-developed, evidence-based, and transparent AUC or advanced diagnostic imaging guidelines using a mechanism best suited for their practice, specialty, and workflow.

### K. Medicare/Medicaid Enrollment

### **Recommendations:**

- The AMA urges CMS to consider the implications of the post-Dobbs landscape and the increasing criminalization of gender affirming care have on this proposal and include explicit language that would exempt providers who have been prosecuted for providing evidence-based reproductive services from potential Medicare revocation.
- The AMA does not support the agency's proposal to shorten the current 30-day revocation reversal window.
- The AMA does not support Medicare's proposal not to pay providers or suppliers for services or items furnished to Medicare patients during the "stay of enrollment." At a minimum, we believe that a process should be in place for providers or suppliers who submit the proper paperwork within the 60-day time frame to dispute Medicare non-payment decisions made during the "stay of enrollment."
- The AMA supports the proposal to align the maximum Medicare enrollment bar with the maximum period that a provider can remain in the Medicare termination database following revocation from a state Medicaid program.
- The AMA urges CMS not to finalize new revocation authority for an FCA civil judgement.

### Misdemeanor Convictions

To ensure program integrity and patient safety, CMS seeks new authority to revoke provider or supplier status due to a misdemeanor conviction within the previous 10 years that the agency deems detrimental to the best interests of the Medicare program and its beneficiaries. Current law requires a federal or state felony conviction in this regard.

CMS explains its reasoning for proposing the addition of misdemeanor convictions as a basis for exclusion, noting two cases in which different physicians were convicted of misdemeanor offenses, one convicted of attempting to obtain controlled substances by fraud, and the other, assault with a dangerous weapon. AMA agrees that both convictions, albeit misdemeanor offenses, are appropriate grounds for exclusion and this is consistent with the authorizing statute, which provides that conviction of a misdemeanor relating to a controlled substance is grounds for exclusion at the discretion of CMS. Further, the statute provides that any conviction relating to patient abuse is a basis for mandatory exclusion; AMA supports the CMS proposal that would implement these statutory criteria in their regulations.

<sup>&</sup>lt;sup>15</sup> Medicare and Medicaid Programs; CY 2024 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, 88 Fed. Reg. 52262, 52516 (proposed August 7, 2023).

<sup>&</sup>lt;sup>16</sup> 42 U.S. Code§ 1320a-7 - Exclusion of certain individuals and entities from participation in Medicare and State health care programs, specifically provides for exclusion on the basis of a misdemeanor only in certain cases relating to fraud or controlled substances, as discussed below. See §§(b)(1)(A) and (b)(3).

<sup>17</sup> *Id*.

AMA has serious concerns, however, about additional proposals that would widen the scope of misdemeanor offenses that could disqualify a provider. The proposal that a provider may be excluded based on any misdemeanor conviction that CMS "deems detrimental to the best interests of the Medicare program and its beneficiaries," effectively removes all limits from the types of misdemeanors that may subject a provider to exclusion. Similarly, proposing that any misdemeanor "that places the Medicare program or its beneficiaries at immediate risk," could subject a provider to exclusion, is so subjective as to create uncertainty in the regulated community. The necessity of defending against every misdemeanor charge, which would now have the potential to exclude a provider from Medicare participation, would create a significant burden for enrolled providers.

Many physicians are small business owners who cannot afford the expense or reputational harm required to contest more serious charges, the merit of which have not been determined, and may make the difficult decision to accept a misdemeanor conviction for the sake of their personal and professional survival. Under the proposals, even misdemeanor charges would require a vigorous defense. Surely Congress also bore such scenarios in mind when it specifically provided, as noted above, that only misdemeanor convictions that are narrowly tailored to specific infractions, should disqualify a provider from Medicare enrollment. To expand the range of potential disqualification criteria to any misdemeanor which, in the sole judgement of CMS, "deems detrimental," is a significant departure from the Will of Congress with the potential for significant unintended, negative consequences.

In contrast to these proposals that significantly broaden the range of excludable offenses, the authorizing statute very specifically states which types of felonies will constitute grounds for exclusion, and narrowly tailors the scenarios in which certain misdemeanor convictions may result in exclusion. The proposals which fail to consider the limitations that Congress imposed on permissible bases for exclusion, call into question the agency's authority to enact these proposals.

AMA is also concerned with the CMS proposal in § 424.535(a)(16)(i), that it may revoke a provider's enrollment for any state of federal misdemeanor within the past 10 years. This proposal would allow the revocation of a provider's enrollment status for such minor infractions as a traffic citation or trespassing, both misdemeanor offenses. We recommend that CMS further modify the proposed regulation to limit the look-back period, and to limit the types of misdemeanors for which a provider may be disqualified, to those specified in § 424.535(a)(16)(i)(A) and (B), fraud and patient abuse, as discussed above.

Despite the anomalies noted above with regard to congressional intent, the proposals could be brought into alignment with the authorizing statute by limiting the types of misdemeanors described in § 424.535(a)(16)(i), to those specified in § 424.535(a)(16)(ii) (A) and (B), and deleting proposed § 424.535(a)(16)(i)(C). For the reasons noted above, AMA urges CMS not to implement the addition of unspecified misdemeanor convictions as a basis for provider exclusion from Medicare enrollment.

AMA recognizes the importance of imposing uniform penalties across legal jurisdictions. However, we have serious concerns about the potential unanticipated impacts of this proposal when it comes to the provision of reproductive health care services following the 2022 Supreme Court decision handed down in the Dobbs v. Jackson Women's Health Organization. The radically altered legal landscape for reproductive health care followings Dobbs, including vast swaths of the country with near-total abortion bans, has created a credible fear among providers that they could be prosecuted for providing essential reproductive health care services and, in some states, prosecution for counseling about abortion. AMA is similarly concerned about the growing movement to criminalize gender affirming care. Providers should not fear that their status within the Medicare program hinges upon whether they provide needed

reproductive health care services or whether they do harm to their patients by following state law. We urge CMS to consider the implications of the post-Dobbs landscape and the increasing criminalization of gender affirming care have on this proposal and include explicit language that would exempt providers who have been prosecuted for providing evidence-based reproductive services from potential Medicare revocation.

Timeframe for reversing a revocation under §424.535 (e)

Under current statute, a revocation resulting from an adverse action can be reversed if the provider or supplier terminates its relationship with the offending party and submits proof to CMS within 30 days of notification. The agency is concerned that this window is too long and opens the Medicare Trust Fund to unnecessary risk. CMS proposes to reduce the 30-day period to 15 days.

AMA believes that it may be unnecessarily burdensome to require providers to terminate a contract with an offending party and provide documentation of such action to CMS within 15 days of them receiving a revocation notification. Often, providers or suppliers are required to go through administrative channels to terminate a contract with a vendor or employee. Further, since the 15-day window would include the termination of contract and providing documentation to CMS, this shortened period may not be possible for providers and suppliers who are acting in good faith to sever contractual relationships with an offending party. In addition, it is not clear whether the notification window begins on the day that the offending provider was notified of the adverse action or when the organization seeking Medicare reimbursement was notified. For these reasons, the AMA does not support the agency's proposal to shorten the current 30-day revocation reversal window.

## Stay of Enrollment

The AMA supports the proposed 60-day "stay of enrollment" that would delay for 60 days the deactivation or revocation of Medicare billing privileges for simple paperwork mistakes or missed deadlines. We believe that the two preconditions proposed by the agency—that the provider or supplier must be non-compliant with at least one enrollment requirement and CMS must ascertain that the provider or supplier can remedy the non-compliance via the submission of the appropriate paperwork (e.g. Form CMS-855)—are reasonable given the potential benefits to providers and suppliers who are currently deactivated or revoked for no other reason than missing a revalidation deadline, as one example.

While we support the "stay of enrollment," we do not support Medicare's proposal not to pay providers or suppliers for services or items furnished to Medicare patients during the "stay of enrollment." At a minimum, we believe that a process should be in place for providers or suppliers who submit the proper paperwork within the 60-day time frame to dispute Medicare non-payment decisions made during the "stay of enrollment."

### Medicaid and CHIP Enrollment

There is confusion and nebulous standards around the length of time that a provider remains active in the Medicare termination database following revocation from a state Medicaid program. If a Medicare provider or supplier is revoked from Medicaid, they are barred from participating in the program for a period of 1-10 years. Many states have a similar reenrollment bar period for terminated Medicaid and CHIP providers, however, the periods vary greatly between states. The variability between state reenrollment bars for the same transgression has created confusion among states and within the provider community.

This Proposed Rule would stipulate that the provider would remain in the database for either the length of the termination period imposed by the initially terminating Medicaid or CHIP program or 10 years, whichever is shorter. Setting the maximum period for the termination database to ten years will address situations where a state imposes an extremely long or lifetime termination that far surpasses that which would be imposed by other states for the same conduct while also aligning with the maximum Medicare enrollment bar. Accordingly, the AMA supports the proposal to align the maximum Medicare enrollment bar with the maximum period that a provider can remain in the Medicare termination database following revocation from a state Medicaid program.

## False Claims Act Civil Judgements

The False Claims Act (FCA) uses stiff civil monetary penalties (ranging between \$5000 and \$10,000 for each false claim) to address and prevent Medicare fraud. CMS seeks new authority to revoke the enrollment of a provider or supplier if the provider or supplier, or any owner, managing employee, officer or director has had an FCA civil judgement imposed against them within the last 10 years. The agency would take several considerations into account including the number of actions that the judgement incorporates, the type of provider or supplier actions involved, the monetary amount of the judgement, when the judgement occurred, and the history of adverse actions held by the provider or supplier.

AMA is concerned that this authority would harm good faith Medicare providers and suppliers who have inadvertently submitted false claims. Participation in the Medicare program requires providers and suppliers to navigate extraordinarily complex statutory, regulatory, and sub-regulatory requirements. This authority may do inadvertent harm by requiring providers, the vast majority of whom make a good faith effort to fully comply, to take resources away from patient care to ensure their standing in the Medicare program. Further, situations in which false claims merit revocation will be identified by existing revocation criteria, which requires malicious intent and a pattern of abuse. Accordingly, we urge the agency not to finalize new revocation authority for an FCA civil judgement.

*Scope of §424.535(a)(17)* 

CMS views a failure to fulfill financial obligations to the Medicare program as a programmatic vulnerability that could increase the likelihood of future unpaid debts. To help address this vulnerability, CMS proposes to clarify that its existing revocation authority, which allows the agency to revoke providers or suppliers who have unpaid debts that are referred to the U.S. Department of Treasury, would also include debts that have not been fully adjudicated through bankruptcy or on appeal and debts that are classified as uncollectible.

AMA has concerns that this proposal is overly broad and will result in providers and suppliers being revoked unfairly. CMS acknowledges this possibility but assures stakeholders that they will carefully consider the factual circumstances behind unpaid debts. While we appreciate that CMS intends to fairly evaluate each situation, AMA requests further clarification of the circumstances which would lead to provider revocation under this proposal. In addition, we request further clarification of the duration of time that providers would have until they fall into the category of "failure to repay a debt" and how many points of contact CMS will attempt before moving a provider into such a status.

### L. Dental Services

Publication of Impact Data on Outcomes for Related Medicare-Covered Services

### **Recommendation:**

• CMS should regularly publish data on the impact of Medicare covered dental services on Medicare expenditures and outcomes for inextricably linked Medicare-covered clinical services.

The AMA strongly supports and agrees with CMS's prior interpretation that it is not appropriate to incorporate budget neutrality adjustments for coverage of additional dental services into the Medicare conversion factor as CMS is merely updating existing Medicare payment policies with additional clinical scenarios. We further appreciate CMS's clarification in the 2023 final rule that it intends to "closely study the trends in utilization and payment for these services and make refinements to the payment policy as needed in future rulemaking" (87 FR 69680). The AMA recognizes that the Medicare Trust Funds are under significant budgetary pressure and paying for more dental services may further add to concerns about the future financing of Medicare. As such, should CMS continue to add more Medicare-covered dental services each year, it is incumbent on the agency to establish a process to provide the public with regular updates on how existing and proposed services would impact Medicare expenditures.

The AMA appreciates CMS's clarification in the 2023 Final MFS that to receive payment for professional services, medical professionals and dentists would need to be enrolled in Medicare and meet all other enrollment, compliance, and other administrative requirements for billing under the PFS, including being subject to MIPS quality reporting requirements. However, given that dental services are only covered by Medicare if they are inextricably linked and substantially related and integral to the clinical success of Medicare-covered services, the AMA believes that it is incumbent on CMS to regularly monitor and evaluate the quality and outcomes not only of newly covered dental services in their own right, but also their impact on clinical outcomes for the relevant Medicare-covered services that they are considered inextricably linked to for purposes of justifying their coverage in the first place, and to make these findings available to the public. This type of evidence might include, but is not limited to, clinically significant improvements in quality and safety outcomes, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient.

It is critical that CMS establish a system for regularly publishing this information and understanding the implications of already finalized services <u>before</u> it further expands the scope of Medicare-covered dental services by adding new services.

Clarifying Guidance Regarding Coordination with Patient's Physician

## **Recommendation:**

• CMS should issue clarifying guidance that any Medicare-covered dental services must: 1) be ordered by the physician primarily responsible for managing that patient's care for the relevant Medicare-covered medical service; and 2) require follow-up by the dentist with the patient's physician.

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's clarification in the 2023 Final MFS in response to concerns raised by the AMA 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. However, it remains unclear what would qualify as "an exchange of information." The AMA urges CMS to release clarifying guidance expressly stating that in order to be covered by Medicare, any dental service must: 1) be ordered by the physician primarily responsible for managing that patient's care for their Medicare-covered medical service; and 2) require follow-up by the dentist with the patient's physician regarding outcomes of the relevant dental procedure. This ensures appropriate coordination with multiple members of patient care teams across settings which improves patient outcomes, helps to ensure the patient's medical record remains appropriately updated, and helps to ensure that dental services are in fact contributing to improved outcomes for Medicare-covered clinical services as required.

Clarification Regarding Tangential Dental Services

## **Recommendation:**

• The AMA strongly supports CMS's proposed clarification that Medicare will not cover dental services that are not expressly approved by CMS and considered inextricably linked to and substantially related to the clinical success of Medicare-covered procedures.

Specifically, CMS proposes to specify that dental services not immediately necessary to eliminate or eradicate infections prior to chemotherapy or administration of CAR-T therapy or necessary to the success of antiresorptive therapy would not be covered by Medicare, including implants, crowns, or dentures. The AMA strongly supports this proposal. We believe it is important CMS maintain strict adherence to statutory criteria that Medicare may only reimburse dental services when they are inextricably linked and substantially integral to the outcomes of Medicare covered services, which were put in place to protect the Medicare trust funds, and we encourage the agency to finalize this proposed policy.

RFI: Coordination of Dental Benefits Across Payers

### **Recommendation:**

• CMS should study and make available to the public information regarding the proportion of Medicare-covered dental services covered by other payers, including private dental insurance plans, that would be shifted to Medicare, verses those that had not previously been covered and that therefore represent an expansion in coverage and access.

The AMA appreciates CMS's request for information regarding coordination of benefits with other payers, including state Medicaid and private insurance plans. The AMA believes the Medicare trust funds should be closely protected. As such, we urge the agency to conduct a formal study into the proportion of Medicare-covered dental services that are already covered by other payers that would represent a cost-shifting to Medicare, verses those that were previously uncovered and would represent an expansion in coverage and access to new populations. We believe this will provide important insights into coverage and access expansions, particularly for underserved populations, while also offering important insights into shifting cost sharing responsibilities between the federal government, state governments, and private

dental insurers, which will help to guide future policies in such way that maximizes access expansions while preserving and protecting the Medicare trust funds. We encourage the agency to make the results of these findings available to the public, with a breakdown by payer type, and to evaluate dental services that have already been approved for Medicare coverage, as well as those proposed to be added.

### M. Diabetes Services

Diabetes Screening and Definitions

## **Recommendation:**

• CMS should finalize proposals to cover the Hemoglobin A1C (HbA1c) test for diabetes screening purposes and expand frequency limitations for diabetes screening to twice within a rolling 12-month period. Expand on these proposals by waiving the patient deductible for HbA1c tests to encourage their uptake.

The AMA has long advocated for and strongly supports Medicare coverage of the HbA1c test for diabetes and prediabetes screening purposes. Previously, HbA1c was approved for managing, but not screening for diabetes even though it has long been used as an effective screening method and the United States Preventive Services Task Force updated their 2015 and 2021 final recommendations statements to include the HbA1c test for diabetes screening purposes. The AMA is pleased to see this proposed change to ensure Medicare coverage remains current with the latest clinical standards and believes this change will lead to more frequent and earlier screenings, and therefore more effective diabetes treatments and clinical outcomes for Medicare beneficiaries.

In addition, the HbA1c test does not require fasting and has fewer day-to-day variations due to stress or other illness. It is therefore often both more convenient for patients and more reliable than a fasting plasma level or oral glucose tolerance test. Importantly, covering this test would also improve referrals to Medicare's Diabetes Prevention Program (MDPP) given the HbA1c test is already a qualifier for that program. Lastly, the majority of commercial payers cover the HbA1c test for screening purposes so covering this test for diabetes screening will bring Medicare coverage in closer alignment and thereby improve equity of access for Medicare beneficiaries.

The AMA appreciates CMS consulting with and being responsive to key industry voices on this issue, including the DAA, in which the AMA participates. We strongly support this proposal to cover HbA1c tests for screening purposes and urge the agency to finalize this change as proposed. Furthermore, we urge the agency to expand on this proposal by waiving the patient deductible for HbA1c tests to further encourage the test for screening purposes and reduce cost barriers for Medicare beneficiaries, particularly those from historically minoritized and disenfranchised communities.

The AMA likewise supports the proposal to expand frequency limitations for screenings to remove barriers and allow clinicians and patients to decide the appropriate interval for screening based on that individual's clinical history and circumstances. Regular screening for diabetes is critical to early and effective diagnosis and treatment and improved outcomes. Accordingly, we support removing regulatory barriers, including frequency limitations, for diabetes screening services.

### **Recommendation:**

• CMS should finalize proposals to streamline the definition of diabetes by removing codified clinical test requirements, which are currently required for diabetes screening, Medical Nutrition Therapy (MNT), and Diabetes Self-Management Training (DSMT) services.

The AMA supports this change, which would align the definition of diabetes across lines of service and create more flexibility to adapt to evolving clinical standards in the future.

Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) Services

### **Recommendations:**

- CMS should finalize proposals to extend telehealth flexibilities, including permanently allowing
  one-hour trainings required for insulin-dependent beneficiaries to be provided via telehealth,
  permanently allowing distant site DSMT practitioners to report DSMT services that are furnished
  via telehealth (including when performed by others within the DSMT entity), and allowing
  institutional providers to continue to bill for DSMT and MNT services when furnished remotely
  through the end of CY 2024.
- In addition, the agency should finalize additional changes to further strengthen and expand access
  to DSMT and MNT services, including allowing MNT and DSMT to be delivered on the same
  day, eliminating patient cost-sharing, and reimbursing for MNT services for individuals with
  prediabetes.

The AMA supports regulatory changes that mitigate barriers and improve access to DSMT and MNT services while ensuring services are appropriately performed via telehealth given the patient's individual needs and the latest clinical standards, guidelines, and best practices. In this case, we believe these flexibilities are appropriate and will not adversely impact patient safety or quality outcomes, while expanding access to these critical services which help to prevent obesity, diabetes, heart disease, and other diet-related conditions. Accordingly, we strongly support the proposed changes to expand telehealth flexibilities for DSMT and MNT services.

In addition to these proposed flexibilities, we urge the agency to consider making the afore-mentioned improvements to improve overall and more equitable uptake of these critical services. Reimbursing for MNT services for individuals with prediabetes for example has been shown in numerous studies to decrease fasting blood glucose, body weight, blood pressure, and waist circumference for patients who received the intervention for at least 3 months.

Medicare Diabetes Prevention Program (MDDP)

### **Recommendations:**

- CMS should finalize proposals to extend several COVID-19 PHE flexibilities an additional four years, including allowing alternatives for in-person weight measurements and eliminating the cap on the number of services that may be provided via distance learning.
- The agency should remove the requirement to maintain in-person recognition to allow virtual-only suppliers <u>for closer alignment with CDC</u> recognition standards and continue to look for ways to continue to align with CDC standards for its National Diabetes Prevention Program.

The AMA strongly supports proposals to eliminate the cap on the number of services that may be provided via distance learning and to continue to allow alternatives for in-person weight requirements, including via scales that report weights electronically and/or self-reported weight measurements. We believe these critical flexibilities will encourage more widespread participation in the MDPP, which has been drastically underutilized to date with only 551 claims filed for an initial MDPP session nationwide in 2022.

The positive impact of CMS's proposed changes to extend certain telehealth flexibilities for an additional four years could be multiplied several times over by allowing service providers who deliver the service solely via distance learning to participate as suppliers. The COVID-19 PHE provided a forced natural experiment in which we learned that distance learning MDPP services are no less effective than those provided in-person. CMS explains: "to date, there have been no preliminary indications that the synchronous virtual delivery of MDPP has limited supplier instruction or beneficiary success." In fact, "evaluation data confirm significantly increased weight loss accompanied with a higher number of sessions attended by participants completing the expanded model in 2021, with these participants attending primarily virtual sessions or a mixture of virtual and in-person sessions." Distance learning service offerings actually improved program performance because beneficiaries were able to more easily access services.

The AMA has also long advocated for MDPP to better align to CDC's National Diabetes Prevention Program recognition standards. The CDC already recognizes four standard modes of delivering the service, including distance learning, online, and combination in addition to in-person, and recognizes program delivery organizations that deliver via all of these modalities, including virtual-only providers. We encourage CMS to further align with CDC's standards by allowing online-only providers to become MDPP suppliers and to consider allowing online, asynchronous services.

By allowing distance learning-only service providers in particular, suppliers would be able to drastically scale down costs required to deliver in-person services such as maintaining an office space, which would make the program more cost-effective and greatly expand the number of suppliers without a drastic increase in payment levels. Accordingly, adding distance learning-only providers would directly result in expanding access to MDPP services for Medicare beneficiaries that live in more remote areas, have mobility issues, lack access to reliable transportation, or face other barriers to seeking in-person care. This has important health equity implications, which is a serious issue for the MDPP given that more than three quarters of the participants to date <a href="heave-been white females">have been white females</a> and that "MDPP supplier locations have traditionally clustered proximate to large metropolitan areas, leaving significant gaps throughout rural communities."

The proposed new G-codes for MDPP services provided in a distance learning setting, which the AMA supports, will provide additional insights into the effectiveness of distance learning versus in-person services. We would argue that allowing distance learning-only courses would provide valuable insights into these effectiveness comparisons and is an additional reason to allow distance learning-only suppliers to participate in the MDPP. Importantly, there has also been a positive response to distance learning MDPP service offerings from beneficiaries. CMS states in the rule that "many beneficiaries have reported the desire to continue utilizing virtual delivery of MDPP for a wide range of reasons." The fact is distance learning services are both effective and are in many cases even preferred by beneficiaries reaffirms that CMS should allow distance learning-only suppliers to participate in the program. At the end of the day, having a service provided virtually is far better than having no services available at all in many regions of the country.

While we acknowledge the need to protect against fraud for virtual MDPP services is equally as important as to any other Medicare service, the robust program integrity safeguards CMS already has in place, including regular monitoring through an independent contractor, already alleviates many of these concerns. CMS's proposed creation of a new G-code specific to distance learning will go even further to protect against any potential fraud and abuse when it comes to virtual MDPP services.

Additionally, while we agree that patients should of course have access to in-person services if they wish, these concerns could be easily alleviated through certain protectionary measures, such as requiring distance learning-only suppliers to have local clinicians to refer patients for in-person consultations.

The case to expand the MDPP to distance learning-only suppliers is clear; the potential positive impact on program participation and expansion that would result from adding distance learning-only suppliers, particularly in certain areas of the country, far outweighs any potential risks.

### **Recommendations:**

- CMS should finalize proposals to strengthen and streamline the program, including allowing payment for up to 22 sessions during the 12-month core services period, converting to a hybrid fee-for-service and weight loss payment structure, and aligning recognition with CDC's Diabetes Prevention Recognition Program.
- CMS should also further these efforts by removing the once-per-lifetime benefit limit, classifying suppliers as medium fraud risk, and approving MDPP as a permanent covered Medicare benefit, all of which would help to improve uptake of the program by suppliers and Medicare beneficiaries.

The AMA appreciates the agency being responsive to feedback from current suppliers and relevant industry voices and strongly supports CMS's proposals to simplify and strengthen the payment structure, for which the AMA has previously advocated. More specifically, the AMA supports CMS proposals to align recognition with the CDC's Diabetes Prevention Program. The AMA has previously called on CMS to eliminate differences between the two programs to promote collaboration and alignment and we believe this change in recognition status is an important step. In addition, we support the proposal to base payments on a combination of weight loss and services, as opposed to making payment completely contingent on weight loss, which will reimburse suppliers more accurately based on resources expended in addition to simplifying the administrative burden of coding these services and will likely help to draw more suppliers to the program as a result. The AMA likewise supports CMS proposals to reform the payment structure and allow payment for up to 22 sessions, which ultimately increases the maximum attendance-based payments a supplier may receive. We encourage the agency to continue to monitor payment adequacy and look for additional ways to continue to grow and expand the program.

To that end, while the proposed changes will positively impact the MDPP, we question whether they go far enough. As already noted above, the program faces some serious challenges in that "MDPP supplier locations have traditionally clustered proximate to large metropolitan areas, leaving significant gaps throughout rural communities" and "white women account for the majority of MDPP participants to date," which has been "low" overall. In addition to allowing virtual-only suppliers, CMS should make MDPP a permanent Medicare covered benefit, remove the once-in-a-lifetime limit, and classify MDPP suppliers as medium, as opposed to high-risk, for fraud.

CMS points out in the rule that there are currently approximately 786 in-person organizations that are nationally eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes Prevention Recognition Program status. However, only 25 percent of eligible in-person organizations are participating in MDPP, and only one-third of MDPP suppliers have submitted MDPP-related claims. Clearly there is some sort of barrier preventing their participation in the MDPP. The AMA is aware that several would-be suppliers have repeatedly commented that the single largest barrier to their participation in the program is the stringent criteria that results from MDPP suppliers having to undergo screening for those considered a high-level risk for fraud, which requires Board members of organizations to submit to fingerprinting and submitting their social security numbers and other personally identifiable information. This can be a major barrier for non-clinical, community-based, often nonprofit organizations participating in the program. As noted earlier, the agency also already has several robust oversight mechanisms in place including regular monitoring by an independent third party. We strongly urge CMS to reclassify MDPP suppliers as medium fraud risk, which we believe will directly result in several reputable organizations with a national footprint reconsidering participating in the program as suppliers. Taken together, these changes would boost supplier confidence in the longevity of the program and mitigate unnecessarily burdensome barriers to entry, thereby expanding the number of suppliers willing to participate and expanding the program's national footprint, particularly in rural and underserved areas.

Removing the once-per-lifetime benefit limit would address major barriers to participation. Losing weight, a metric of the program, is difficult and often takes several attempts and Medicare beneficiaries should be supported in those efforts. In addition, CMS does not place this same limit on other lifestyle behavior change programs such as smoking cessation.

# N. Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Expansion of Supervising Practitioners

### **Recommendations:**

- The AMA strongly opposes the supervision of Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) by non-physician practitioners. The AMA strongly opposes removing the requirement that physicians supervise all PR, CR, and ICR and expanding supervision privileges to physician assistants, nurse practitioners, and clinical nurse specialists. As such, the AMA strongly opposes removing the requirement that physicians must supervise PR, CR, and ICR and requests CMS to not enact this proposed provision.
- Furthermore, we do not support the definition of nonphysician practitioner (NPP) being added to §§ 410.47(a) and 410.49(a). We believe that it is crucial that there not be an overarching term used, like nonphysician practitioner, but rather that the practitioners that are being referred to, in this case physician assistants, nurse practitioners, and clinical nurse specialists, be specifically referenced so that the full implications of the statutory language can be easily understood. The term nonphysician practitioner can lead to confusion and therefore, the AMA does not support the addition of this term to the statutory language.
- If CMS does continue on with implementation of this statutory change, we would strongly encourage that the language specify that the nonphysician practitioners must be licensed to practice medicine in the state where the PR, CR, or ICR program is located and where the patient is located when receiving care, and that the nonphysician practitioners must adhere to state scope of practice laws.

CMS is proposing to revise §§ 410.47 (PR) and 410.49 (CR/ICR) to add to the types of practitioners who may supervise PR, CR, and ICR programs to also include a physician assistant, nurse practitioner, or clinical nurse specialist. CMS argues that these changes are needed to fulfill the statutory requirement in section 51008 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123, enacted February 9, 2018) (BBA of 2018) effective January 1, 2024. Though the AMA acknowledges that CMS is implementing the statutory requirements from the Bipartisan Budget Act of 2018, the AMA is concerned about these proposed supervision changes.

The AMA strongly opposes the supervision of PR, CR, and ICR by non-physician practitioners. The AMA strongly opposes removing the requirement that physicians supervise all PR, CR, and ICR and expanding supervision privileges to physician assistants, nurse practitioners, and clinical nurse specialists.

In general, we are deeply concerned that this broad, sweeping statutory change endangers the care of Medicare patients by expanding the types of services nonphysician practitioners can perform and removing physician involvement in patient care. This change would also likely allow nonphysician practitioners to perform tasks and services outside their education and training and could result in increased utilization of services, increased costs, and lower quality of care for patients. In a recent survey of U.S. voters, 95 percent said it is important for a physician to be involved in their diagnosis and treatment decisions. <sup>18</sup> Patients expect the most qualified person—physician experts with unmatched training, education, and experience—to supervise care to individuals with severe cardiac conditions which often requires making complex clinical determinations. Unfortunately, the proposed statutory changes run counter to this preference by effectively removing physicians from important medical treatment decisions regarding a patient's care.

While all health care professionals play a critical role in providing care to patients, and nonphysician practitioners are important members of the care team, their skill sets are not interchangeable with those of fully educated and trained physicians. This is fundamentally evident based on the difference in education and training between the distinct professions.

- Physicians complete four years of medical school plus three to seven years of residency, including 10,000-16,000 hours of clinical training.<sup>19</sup>
- Nurse practitioners, however, complete only two to three years of graduate level education, have no residency requirement, and complete only 500-720 hours of clinical training.<sup>20</sup>
- Physician assistants complete two to two and half years of graduate level education with only 2,000 hours of clinical care and no residency requirement.
- Clinical nurse specialists complete a master's degree but there is no residency requirement and only 500 clinical hours of training are required.<sup>21</sup>

But it is more than the difference in hours and years of training—the depth and breadth of physicians' education is far beyond that of nonphysician practitioners. Equipped to handle any clinical scenario as the most highly trained health care professional, physicians are the appropriate leaders of the health care team. The reality is that nonphysician practitioners do not have the education and training needed to be the head of the care team and our nation's Medicare patients deserve physician-led care.

<sup>&</sup>lt;sup>18</sup> https://www.ama-assn.org/system/files/scope-of-practice-protect-access-physician-led-care.pdf.

<sup>&</sup>lt;sup>19</sup> https://www.ama-assn.org/system/files/scope-of-practice-physician-training.pdf.

 $<sup>^{20}</sup>$  Id.

<sup>&</sup>lt;sup>21</sup> https://www.gmercyu.edu/academics/learn/become-a-clinical-nurse-specialist.

Moreover, when nonphysician practitioners practice without supervision, the result is lower-quality, higher-cost care. There is strong evidence that increasing the scope of practice of nurse practitioners and physician assistants has resulted in increased health care costs. A high-quality study published as a working paper by the *National Bureau of Economic Research* in 2022 compared the productivity of nurse practitioners and physicians (MDs/DOs) practicing in the emergency department using Veterans Health Administration data. The study found that nurse practitioners practicing independently use more resources and achieve worse health outcomes than physicians. Nurse practitioners ordered more tests and formal consults than physicians and were more likely than physicians to seek information from external sources such as X-rays and CT scans.<sup>22</sup> They also saw worse health outcomes, raising 30-day preventable hospitalizations by 20 percent, and increasing length of stay in the emergency department. Altogether, nurse practitioners practicing independently increased health care costs by \$66 per emergency department visit.<sup>23</sup> The study found that these productivity differences make nurse practitioners more costly than physicians to employ, even accounting for differences in salary.<sup>24</sup> Not only does the increased resource use by nurse practitioners result in increased costs and longer lengths of stay, but it also means patients undergo unnecessary tests, procedures, and hospital admissions.

In addition, a recent study from the Hattiesburg Clinic in Mississippi found that allowing nurse practitioners and physician assistants to function with independent patient panels in the primary care setting resulted in higher costs, higher utilization of services, and lower quality of care compared to panels of patients with a primary care physician. Specifically, the study found that non-nursing home Medicare ACO patient spend was \$43 higher per member, per month for patients on a nurse practitioner/physician assistant panel compared to those with a primary care physician. Similarly, patients with a nurse practitioner/physician assistant as their primary care provider were 1.8 percent more likely to visit the ER and had an eight percent higher referral rate to specialists despite being younger and healthier than the cohort of patients in the primary care physician panel. On quality of care, the researchers examined 10 quality measures and found that physicians performed better on nine of the 10 measures compared to the nonphysicians.

Additionally, multiple studies have shown that nurse practitioners order more diagnostic imaging than physicians, which increases health care costs and threatens patient safety by exposing patients to unnecessary radiation. For example, ordering x-rays increased substantially—more than 400 percent—by nonphysicians, primarily nurse practitioners and physician assistants, between 2003 and 2015. Furthermore, a Mayo Clinic study compared the quality of physician referrals for patients with complex medical problems against referrals from nurse practitioners and physician assistants for patients with the same problems. Physician referrals were better articulated, better documented, better evaluated, better managed, and were more likely to be evaluated as medically necessary than nurse practitioner or physician assistant referrals, which were more likely to be evaluated as having little clinical value. This sampling of studies clearly shows that nurse practitioners and physician assistants tend to misuse health

<sup>&</sup>lt;sup>22</sup> Productivity of Professions: Lessons from the Emergency Department, Chan, David C. and Chen, Yiqun, NBER, Oct. 2022.

<sup>&</sup>lt;sup>23</sup> *Id*.

<sup>&</sup>lt;sup>24</sup> *Id*.

<sup>&</sup>lt;sup>25</sup> https://ejournal.msmaonline.com/publication/?m=63060&i=735364&view=contentsBrowser.

<sup>&</sup>lt;sup>26</sup> D.J. Mizrahi, et.al. "National Trends in the Utilization of Skeletal Radiography," Journal of the American College of Radiology 2018; 1408-1414.

<sup>&</sup>lt;sup>27</sup> Lohr RH, West CP, Beliveau M, et al. Comparison of the Quality of Patient Referrals from Physicians, Physician Assistants, and Nurse Practitioners. Mayo Clinic Proceedings. 2013;88:1266-1271.

care resources, and are less able to manage complex medical problems<sup>28</sup>—all which increases health care costs, threatens patient safety, and leads to poorer health care outcomes.

Without proper supervision, nonphysician practitioners' level of training can strain the health care system and endanger patients. PR, CR, and ICR programs care for patients who have serious health complications, including patients who have had an acute myocardial infraction within the past 12 months, a coronary bypass surgery, angina pectoris, a heart valve repair or replacement, a heart or heart-lung transplant, chronic heart failure, and more. <sup>29</sup> Due to the serious health conditions of the patients in these programs, physicians who supervise these programs must have expertise in the management of individuals with respiratory pathophysiology or cardiac pathophysiology depending on the program. Therefore, it is very important that physicians continue to supervise PR, CR, and ICR patients and that these patients are generally part of a physician-led care team.

If CMS does continue on with implementation of this statutory change, we would strongly encourage that the language specify that the nonphysician practitioners must be licensed to practice medicine in the state where the PR, CR, or ICR program is located and where the patient is located when receiving care, and that the nonphysician practitioners must adhere to state scope of practice laws. We believe that this clarification is especially important since CMS is proposing to add in the new term "nonphysician practitioner" into the statutory language. Furthermore, we do not support the definition of nonphysician practitioner (NPP) being added to §§ 410.47(a) and 410.49(a). We believe that it is crucial that there not be an overarching term used, like nonphysician practitioner, but rather that the practitioners that are being referred to, in this case physician assistants, nurse practitioners, and clinical nurse specialists, be specifically referenced so that the full implications of the statutory language can be easily understood. The term nonphysician practitioner can lead to confusion and therefore, the AMA does not support the addition of this term to the statutory language.

The AMA has long supported physician-led health care teams, with each member drawing on his or her specific strengths, working together, and sharing decisions and information for the benefit of the patient. This includes ensuring that the MFS promotes the appropriate standard of care, compensation, and acknowledgment of the valuable service that physicians provide especially in their role as supervisors of PR, CR, and ICR. As such, the AMA strongly opposes removing the requirement that physicians must supervise PR, CR, and ICR and requests CMS to not enact this proposed provision.

# O. Advancing Access to Behavioral Health Services

### **Recommendation:**

• Though we applaud CMS for requiring adherence to state law, we would like for the definitions of marriage and family therapists (MFT) and mental health counselors (MHC) to have a specific additional reference to the requirement that they must adhere to state scope of practice requirements. Additionally, the MFT and/or MHC should be licensed in the state in which the patient is receiving care, as well as the state in which the practitioner is located, to ensure that the

<sup>&</sup>lt;sup>28</sup> Sanchez GV, Hersh AL, Shapiro DJ, et al. Brief Report: Outpatient Antibiotic Prescribing Among United States Nurse Practitioners and Physician Assistants. Open Forum Infectious Diseases. 2016:1-4. Schmidt ML, Spencer MD, Davidson LE. Patient, Provider, and Practice Characteristics Associated with Inappropriate Antimicrobial Prescribing in Ambulatory Practices. Infection Control & Hospital Epidemiology. 2018:1-9.

<sup>&</sup>lt;sup>29</sup> https://www.law.cornell.edu/uscode/text/42/1395x.

patient has clear access to remedies should malpractice occur, especially with the increased use of telehealth in this space.

Section 4121(a)(1) of the Consolidated Appropriations Act of 2023 amended section 1861(s)(2) of the Act by adding a new benefit category under Medicare Part B to include marriage and family therapist (MFT) services and mental health counselor services (MHC).

To further incorporate these additional services, CMS is proposing to define a marriage and family therapist at § 410.53 as an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;
- After obtaining such degree, has performed at least 2 years or 3,000 hours of post master's degree supervised clinical experience in marriage and family therapy in an appropriate setting such as a hospital, skilled nursing facility (SNF), private practice, or clinic; and
- Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

CMS would define "Marriage and family therapist services" at § 410.53(b)(1) as services furnished by a marriage and family therapist for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under laws (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. CMS is also proposing that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

CMS is also proposing to define a mental health counselor at § 410.54 as an individual who:

- Possesses a master's or doctorate degree which qualifies for licensure or certification as a mental
  health counselor, clinical professional counselor, or professional counselor under the State law of
  the State in which such individual furnishes the services defined as mental health counselor
  services;
- After obtaining such a degree, has performed at least two years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and
- Is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are performed.

CMS is proposing to define "mental health counselor services" at § 410.54(b)(1) as services furnished by a mental health counselor for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under laws (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. CMS is also proposing that the services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service.

The AMA strongly supports the team-based approach to care. Though, per the proffered definitions, MFTs and MHCs would complete a master's or doctorate degree plus two years of training, these requirements are not equivalent to the training that physicians must complete. Physicians complete four

years of medical school plus three to seven years of residency, including 10,000-16,000 hours of clinical training. MFTs and MHCs are an essential part of a physician led patient care team, however, they lack the requisite medical education, medication management training, and clinical training that is critical for the diagnosis and treatment of certain mental illnesses. As such, though we applaud CMS for requiring adherence to state law, we would like for the definitions of MFTs and MHCs to have a specific additional reference to the requirement that they must adhere to state scope of practice requirements. Additionally, the MFT and/or MHC should be licensed in the state in which the patient is receiving care, as well as the state in which the practitioner is located, to ensure that the patient has clear access to remedies should malpractice occur, especially with the increased use of telehealth in this space.

# P. Treatment of Opioid Use Disorder (OUD)

### **Recommendation:**

The AMA supports the proposals to continue allowing Opioid Treatment Programs (OTPs) to
furnish periodic assessments via audio-only technology through 2024 and to increase resources
for psychotherapy services in the office-based OUD monthly bundled payments. The AMA also
urges CMS to continue paying for OTP provision of take-home naloxone whether for prescription
or over-the-counter products.

In previous rulemaking, CMS extended the ability for OTPs to furnish periodic assessments via audio-only communication technology through 2023. To align the OTP policies with the telehealth provisions of the CAA, 2023, CMS is proposing to extend this policy on audio-only periodic assessments through 2024. For all the reasons cited in the Proposed Rule supporting the 2023 extension, the AMA supports this further extension through 2024. The AMA also appreciates that the HCPCS codes for office-based treatment of opioid use disorder (G2086, G2087, and G2088) are permanently on the Medicare Telehealth List and that the list indicates that these services may be provided via audio-only communication technology.

In the 2023 MFS final rule, CMS finalized the rates for bundled episodes of care for OUD services provided through OTPs to reflect more resources devoted to psychotherapy, specifically by basing the payment rate on a 45-minute psychotherapy service instead of a 30-minute psychotherapy service. For 2024, CMS is proposing a parallel increase in the bundled monthly payments for office-based OUD treatment. The AMA appreciates the proposed alignment between these two families of services.

Finally, the AMA also calls to CMS's attention the need for Medicare to continue paying for take-home supplies naloxone to reverse the effects of opioid-related overdoses whether the medications are available over the counter or by prescription. Recent FDA approval of some naloxone products being available over the counter is an important means of increasing patient access to these lifesaving drugs. It is critical that CMS not discontinue paying for the take-home supplies provided by OTPs just because they may be available without a prescription.

# Q. Intensive Outpatient Treatment for Substance Use Disorder (SUD) Treatment

## **Recommendation:**

CMS should develop coverage and payment policies to allow SUD patients to access intensive outpatient treatment services.

CMS is soliciting comments on whether gaps in its coverage and payment policies exist for intensive outpatient SUD treatment furnished by intensive outpatient programs. In June 2021, the Legal Action Center published a paper in the journal Health Affairs that describes this gap in SUD treatment in the Medicare program. According to this paper, intermediate levels of SUD care are more intensive than office-based outpatient counseling but less intensive than inpatient hospitalization. This includes intensive outpatient, partial hospitalization, and residential treatment. The authors state that this type of care is often used as a step down for people who no longer need to be hospitalized but cannot be discharged safely, or as a step up for those who need more services and supports than can be provided in the office setting. The authors also note that Medicare does cover comparable rehabilitation programs for patients with other medical conditions, such as Comprehensive Outpatient Rehabilitation Facility services, but does not have comparable programs for SUD treatment. The AMA encourages CMS to fill this gap in care.

# R. Electronic Prescribing of Controlled Substances (EPCS)

### **Recommendation:**

The AMA supports the proposal to continue the current Medicare EPCS program compliance
policy of issuing a prescriber notice of noncompliance, which already has been adopted as the
CMS policy on non-compliance through the 2024 measurement year, as the non-compliance
action for subsequent measurement years.

CMS is proposing several administrative changes to the standards for the Medicare EPCS program for 2024, including better aligning its policies on recognized emergency circumstances with other programs administered by CMS, such as MIPS, and modifying the way it defines the prescriptions that are counted in calculations of the EPCS rate, for example, by excluding refills from the calculation. CMS previously finalized a policy, currently in effect through measurement year 2024, to enforce compliance with Medicare EPCS requirements by sending a letter to physicians who are not in compliance explaining the need for them to take action. The current rule indicates that CMS is proposing to continue this same enforcement policy in future years and the AMA supports this proposal. The AMA is also pleased that CMS is seeking applicants for a new EPCS Program Prescriber User Group to provide input on educational materials and the usability of the prescriber portal for the CMS EPCS program. The AMA welcomes this effort to seek input from physicians who prescribe drugs that are covered by Medicare Part D on the EPCS program user experience.

## S. Coding and Payment for Administration of Complex Non-Chemotherapy Drugs

## **Recommendation:**

The AMA strongly urges CMS to review and update reimbursement policies for the
administration of complex non-chemotherapeutic drugs, ensuring adequate payment, transparency
in coding and coverage guidance, and proper engagement with affected physician and patient
groups. This is to maintain the feasibility of administering these drugs in office-based settings,
preventing potential shifts to more expensive and less accessible hospital-affiliated infusion
centers.

Reimbursement Policies for Administration of Complex Non-Chemotherapeutic Drugs

The AMA is pleased to see the increased focus on appropriate reimbursement for complex non-chemotherapeutic drug administration. The AMA initially contacted CMS about this issue in July 2022,

when it came to our attention that several Medicare Administrative Contractors (MACs) were downcoding certain drug administrative services while also disallowing stakeholder input on the coding and reimbursement changes. It is critical that CMS provide both adequate reimbursement for these physician services while also providing adequate coding and coverage guidance. We also urge CMS to ensure that all MACs operate in a manner which ensures maximum transparency and clear opportunity for stakeholder input on actions that ultimately impact coverage and reimbursement for physician services.

The AMA has serious concerns that reimbursement policies for the administration of complex non-chemotherapeutic drug administration, including downcoding of these services by MACs, is medically inappropriate and will ultimately impact physician's ability to administer these critical therapeutics to patient in office-based settings. The therapeutics at issue require multiple staff with specialized training to administer, along with specialized equipment and systems. The coding and reimbursement policies proposed by many MACs last year would result in a situation where a number of practices would no longer be able to employ the staff or maintain the systems necessary to administer these treatments to patients, forcing them to other sites for care.

If payment, coding, and coverage guidance is not appropriately updated for these services, we may face a situation where it is no longer financially feasible for physicians to administer these therapeutics to patients in an office setting, forcing patients to receive care at what would likely be more expensive hospital-affiliated infusion centers. This is untenable for a number of reasons, including the additional significant burdens placed on patients to switch care settings and the significantly increased costs associated with hospital-based care. Additionally, not every hospital is well-equipped to provide these services. Should a patient reside in an area where there is no hospital-affiliated option, they may experience significant disruption to their care. The AMA strongly urges CMS to engage directly with impacted physician and patient groups to determine appropriate reimbursement policies that maintain access to these critical drug administration services.

In addition to providing clear reimbursement policies for these covered services, CMS should ensure that processes utilized by MACs in issuing local coverage determinations and local coverage articles are appropriate, transparent, and provide the necessary opportunity to stakeholder input. Last year, several problems arose with respect to these services after MACs issued Local Coverage Articles that directed the downcoding of these services then refused additional opportunity for discussion or evidence submission from interested parties, including physicians rendering these services. CMS must ensure that changes this impactful on physicians and patients are afforded appropriate and transparent processes by which those changed are made.

# T. Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs)

The AMA appreciates many of the proposed changes in this rule, many of which are in direct response to previous concerns raised by the AMA and other interested parties, and which primarily aim to mitigate potential negative and unintentional impacts on certain types of ACOs, better address unmet needs for certain patient subpopulations, and retain legacy participants and continue to grow the program. We generally encourage CMS to finalize these proposals, and offer several recommendations intended to expand on them. In particular, we appreciate proposals to delay the transition to eCQMs based on logistical concerns, align financial benchmark risk adjustment methodologies across the performance year and benchmark year, and mitigate the negative impacts of regional benchmark adjustments.

However, we have major concerns with proposals that seem to counter CMS's objective of encouraging more physicians to move to APMs by proposing to require MSSP participants meet burdensome MIPS

requirements, such as CMS's proposal to require all MSSP participating clinicians, regardless of track, to report PI measures. CMS should be looking for additional opportunities to lift regulatory burdens for ACOs already agreeing to be held responsible for outcomes and cost, not add to them. We worry these types of policies move in the opposite direction and risk the long-term viability of the MSSP, as well as the ultimate goal of transitioning more physicians to APMs.

We offer more specific feedback and recommendations on the MSSP proposals below.

Quality Performance Standard and Other Reporting Requirements

Medicare Clinical Quality Measure (CQM) Collection Tool

### **Recommendation:**

The AMA supports CMS's proposal to establish the Medicare Clinical Quality Measures (CQMs) ("Medicare CQMs") for ACOs Participating in the MSSP.

The AMA is very glad to see CMS recognize the concerns the AMA and other organizations have had with requiring ACOs to collect and report on quality measures that included all-payer data and eCQMs. We support CMS's proposal to add the Medicare CQM collection tool for ACOS participating in MSSP. The inclusion of the new collection tool will ease the concern with the state of readiness of reporting on eCQMs and reduce administrative burden.

CMS highlights that the Medicare CQM collection tool could be eliminated without advance notice, which the AMA does not support. CMS must ensure that interoperability challenges and health IT standards are mature before eliminating the Medicare CQM tool. Based on conversations with several large EHR vendors, they have stated that they have never supported ACOs quality (even if the ACO is utilizing CEHRT) because the health IT standards are insufficient, and the following issues must be resolved *before* advancing to eCQMs:

# 1. Data Gathering Challenges

- a. Health IT can generate the measures, *but* it is time or cost prohibitive/challenging to do
- b. Some parts of the health IT cannot generate the data (uncertified system, on paper).
- c. Some parts of the health IT cannot generate the required measures (certified but not to the ACO measures that are required).
- d. If health IT uses a "smoking gun" methodology and only generates data for patients qualifying for the measure, then data might not be available if the patient would only qualify for the measure across two systems.
- e. Someone must know to gather the data from all applicable locations.

# 2. Data Processing Challenges

- a. Need a central place to pull all the data together (sufficient hardware/processing power in one place).
- b. Need to be able to patient-match across all the data sources to deduplicate.
- c. No implementation guide for QRDA I import means there could be variation across how different systems have uploaded data.

# 3. Data Validation Challenges

a. Missing or a lack of methods to confirm data completeness. Additional data sources may be inadequate to confirm data completeness.

Even if ACOs and the health care systems transition to digital quality measures (dQMs) or the Fast Healthcare Interoperability Resources (FHIR) standard, we believe the same problems listed above will persist since it still does not resolve issues around data processing and validation. In terms of patient matching, some issues could be mitigated if more demographic data were captured in existing data requirements (QRDA I or FHIR). **CMS should include additional demographic requirements in the CMS Implementation Guide (IG) or in QRDA I specifications,** which will aid in improving data matching and validation. Additional time is needed before requiring the adoption of eCQMs or dQMs to make progress in addressing some of these challenges.

Furthermore, a lower and more flexible data completeness requirement would also assist with making eCQMs or dQMs a more realistic, viable and feasible quality measure requirement (*Please see MIPS*, 1. *Quality Performance Category, Data Completeness for specific details on our concerns MIPS data completeness requirements*).

We urge CMS to consider a sample methodology to satisfy data completeness. ACOs and 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, come close to the current 70 percent data completeness requirement in MIPS and MSSP. If CMS has already determined that smaller snapshots and sample sizes provide sufficient information to make informed assessments on the quality of care being delivered for health plans and hospitals, this same logic should also apply to individual Medicare physicians in MIPS.

CMS also highlights that with the Medicare CQM collection type it plans to follow existing MIPS policy for setting benchmarks. This means CMS must receive data from at least 20 ACOs reporting and meeting the case minimums and data completeness requirements in order to set a benchmark. However, CMS is vague in terms of what will happen if it receives insufficient data. For example, what if only 10 ACOs report Medicare CQMs? There is a risk that some ACOs would then receive zero points and not have a quality score above zero. In addition, there is an even higher chance that they would only be able to achieve at most seven points since all but one of the MIPS CQMs/eCQM benchmarks are distributed across the 10 deciles. In both cases, ACOs would have no idea how performance will be distributed across those deciles since there is no historical benchmark.

To mitigate this potential concern and uncertainty, we recommend CMS use the Web Interface benchmarks for the Medicare CQMs in the first two years of reporting. By using the historical data from the Web-Interface, which is only available to ACOs, ACOs will know where they may end up for quality and it reduces the risk of no benchmark being set due to the 20 ACO threshold not being achieved. If our recommendation is not feasible, we recommend CMS re-instate pay-for-reporting for the first two years a measure is reported on, which allows time for data to be collected on new measures, and measures that underwent significant changes or incorporated into a new collection mechanism. At a minimum, CMS needs to address what will happen if an insufficient number of ACOs report Medicare COMs.

## APP Measure Set

The AMA continues to question the value and connection of the APM Performance Pathway (APP) measure set to the design and intention of the MSSP. The quality measure set does not appropriately protect patients and it is unclear how CMS landed on the set of measures outside of trying to align with the CMS "Universal Foundation." As CMS continues to refine the Universal Foundation measure set, it must ensure there is not a significant growth in the number of measures ACOs must report. As a reminder, CMS started the MSSP with over 30 quality measures, and over time reduced the measure set to reduce burdens associated with reporting and allow ACOs to better focus and tailor their quality improvement strategies.

Another issue is that ACOs are being financially penalized for their failure to reduce spending or rewarded for quality improvements compared to their past performance under an FFS delivery and payment system, rather than based on independent, evidence-based best practice standards that reinforce innovative new care delivery models. One of the strengths of the set of quality measures within the Web-Interface is the inclusion of several measures related to preventive care, which incentivizes providers to deliver preventive care services to their patients. While it is expected that better preventive care will lead to better outcomes and therefore savings in the long term, it may lead to slight increases in spending in the short term if these high-value services were not previously being utilized. However, the current shared savings methodology does not account for this in any way and may actually penalize ACOs for short-term increases in spending for higher rates of preventive care services, despite this clearly being in the best interest of patients, as well as long-term savings for the Medicare program. As presently designed, these two cost and quality goals are set up to be competing priorities that are fundamentally incentivizing opposite goals and undercutting one another.

The program's ability to successfully drive higher quality care is contingent on the individual measures being clinically relevant and accurate. Accordingly, CMS must also only include measures within the ACO set that are required that have been tested for reliability, validity, and feasibility. Therefore, we have concerns with CMS including the following measures in the APP set:

- Screening for social drivers of health: As the AMA has highlighted, the measure has yet to be tested. 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), standardize which survey tools may be used, and determine that the specifications produce scores that are reliable and valid. In addition, it is imperative that CMS reduce the complexity of the measure and evaluate whether 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 a substance use disorder receive appropriate and

<sup>&</sup>lt;sup>30</sup> 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.

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 recommend that CMS and the measure developer ensure that the measure is specified in alignment with the American Society of Addiction Medicine's recent 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. In addition, we note that this measure is only currently supported as an eCQM. A MIPS CQM version does not appear to have been developed or tested. ACOs must also have the option to report this measure as a MIPS or Medicare CQM prior to any inclusion in the APP measure set.

Therefore, we do not believe that CMS has struck an appropriate balance between ensuring quality of care and minimizing administrative burden in a program that has a primary goal of reducing spending. We urge CMS to consult with the ACO community and patient representatives to determine the best-balanced measure set.

Quality Measure Scoring Methodology

### **Recommendation:**

CMS must revise methodologies for MIPS CQMs, eCQMs, and Medicare CQMs to recognize the inherent differences between ACOs and other providers, increase transparency, consider the impact of random fluctuation, and make adjustments for practical considerations of comparison and relative performance. We urge CMS to consider a methodology like the Web Interface benchmark that is based on pre-determined distributions of performance.

We are once again disappointed that CMS continues to move forward with its proposals to align MSSP quality scoring methodology with the MIPS methodology. As the AMA has repeatedly highlighted in comments, the MIPS scoring and benchmark methodology is flawed and CMS should not be expanding it into an additional program.

It is also inherently inappropriate to compare ACO quality performance to MIPS quality performance scores as this one-size-fits-all policy does not take into consideration the unique characteristics of the design of the ACO program or the inherent differences between MIPS and the MSSP. There are nuances specific to ACOs that must be considered and different incentives provided for performance on the same measure.

On review of the existing benchmarking process for MIPS CQMs, eCQMs, and now Medicare CQMs, we do not believe that the process for distributing performance across deciles is transparent nor does this approach as constructed produce information that is meaningful. For example, the current process of determining whether a benchmark can be created appears to be arbitrarily set based on 20 entities reporting at least 20 patients in the denominator, which is much too low to assure reliable

<sup>&</sup>lt;sup>31</sup> 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 [published online ahead of print, 2023 Jul 28]. *J Addict Med.* 2023;10.1097/ADM.000000000001202. doi:10.1097/ADM.0000000000001202.

results. Given this small sample size, there is also a significant risk of variation and instability in the benchmarks from year to year that may be due to changes in the number of entities reporting on a measure or other random variation rather than representing true differences in performance. The approach also assumes that all measures should be scored with the potential to achieve 100 percent (or 0 percent if it is an inverse measure) and while it may be a laudable goal, it may not reflect clinical knowledge or practical considerations of delivering high-quality care.

CMS could instead consider a process similar to benchmarking of the Web Interface measures in which thresholds are not dependent on random fluctuations in performance or because a measure is new to the program but are rather defined based on pre-determined distributions of performance based on clinical best practices and reasonable performance standards developed in collaboration with physicians. This approach would ensure that the benchmarking process is transparent and predictable and enable ACOs to participate in the program in a more meaningful way.

CMS must revise these methodologies for MIPS CQMs, eCQMs, and Medicare CQMs to recognize the inherent differences between ACOs and other providers, increase transparency, consider the impact of random fluctuation, and make adjustments for practical considerations of comparison and relative performance.

Quality Performance Standard

We continue to believe tying ACO quality performance thresholds to MIPS score is inappropriate and makes unfair comparisons. However, we support CMS's proposed changes to the MSSP Quality Performance Standard (QPS) calculations to move to a three-year average of historic performance data with a one-year lag for calculating the QPS as opposed to relying on one performance year of data. This proposal would provide ACOs with more certainty regarding what quality targets are in advance of the performance period starting and mitigates the potential impact of annual program changes affecting the QPS scores. We request CMS publish MIPS quality performance category scores in the Public Use Files to bring greater transparency to these calculations.

Scoring Policy for Excluded/Suppressed APP Measures

The AMA supports CMS's proposals to apply an MSSP-specific policy for measures suppressed from quality scoring, providing ACOs with the higher of their own score or the QPS if a measure is suppressed for a performance year. The changes will better ensure ACOs are not negatively impacted by measure changes or benchmark issues that occur mid-year and are outside of the ACO's control. *CEHRT* 

### **Recommendation:**

• The AMA recommends CMS adopt the proposed revisions to the CEHRT definitions in alignment with ONC with certain caveats. CMS must conduct an extensive and robust educational campaign to inform the physician community about its new approach to health IT certification.

The AMA supports CMS's proposed revisions to the CEHRT definitions in the Medicare Promoting Interoperability (PI) Program and the QPP, including the proposed transition from the historical state of year themed "editions" to the "edition-less state" that the Office of the National Coordinator for Health Information Technology (ONC) put forward in the *Health Data, Technology, and Interoperability*:

Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.<sup>32</sup>

We appreciate the alignment with and cross-references to ONC's regulations and terminology, as well as the simplified regulatory approach of updating certain criterion rather than publishing and finalizing an entire new edition of certification criteria. In addition, we embrace the additional flexibility granted in this regulation to allow eligible hospitals, Critical Access Hospitals (CAHs), and MIPS eligible clinicians to adopt, implement, and use ONC's updated certification criteria for health IT, including EHRs, as it becomes available from their chosen vendor, without the need for CMS to first amend the regulations.

However, in determining requirements for any potential new or revised measures, CMS should be able to consider factors such as implementation time and provider readiness to determine when to require participants to complete measures that require the use of certified health IT.

For example, CMS should have the flexibility to finalize updates when there is sufficient implementation time and when physicians are ready to adopt the changes. This point is especially important as we consider that the ONC HTI-1 Regulation is still in the Proposed Regulation stage and may not be finalized until late in 2023. If CMS does finalize these proposed revisions to the CEHRT definitions in the CY 2024 Regulation, the agency should not immediately require any changes to measures that require the use of updated certified health IT. The AMA strongly encourages CMS to consult with the provider and developer communities before putting forward changes to requirements for any potential new or revised measures.

If finalized, these CMS changes will require an extensive and robust educational campaign to ensure that eligible hospitals, CAHs, and MIPS eligible clinicians understand "The ONC Certification Criteria for Health IT," discontinuing year themed "editions," and any proposed revisions to the CEHRT definitions in the Medicare PI Program and QPP. In particular, physicians in small- to medium-sized practices will need guidance on the implications of declining an update of a certified criterion from their health IT developer.

The AMA noted several questions in our public comments on the ONC's HTI-1 Proposed Regulation that are particularly applicable for CMS. We encourage CMS to collaborate with ONC on an educational campaign around ONC's new Certification Criteria.

For example, our understanding is that if a physician were to decline an EHR update that includes changes to abide by any new ONC certification criterion it would result in a "decertified" EHR and therefore the physician would not be able to participate in MIPS or QPP. We are concerned that shifting the responsibility to the physician, rather than requiring explicit use of a specific certified edition as ONC and CMS have required for years, will disadvantage physicians. The AMA is aware that many EHR developers charge physicians for "upgrades" and software updates to support new certified editions. While largely unreasonable, these fees often signify a required change in EHR versions to support federal reporting requirements. Leaving it up to the EHR developer to "provide" ongoing certified EHRs to physicians will likely result in the EHR developer charging physicians for updates without sufficiently communicating why the update is necessary. This could result in physicians choosing to decline the

<sup>32 &</sup>lt;a href="https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program">https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program</a>

update as a reasonable attempt to save money without realizing this action would decertify their EHR and prevent them from successfully participating in MIPS.

As such, the AMA strongly urges, as part of a joint ONC-CMS educational campaign, that it is clearly communicated to physicians what an EHR developer's "provided product" means and what declining the product means for the EHR's certification status and the physician's ability to participate in federal reporting programs such as MIPS and QPP. We also recommend that certified health IT developers use written and verbal communication methods to reinforce the salient points in ONC-CMS communications and adequately inform physicians about the new approach to health IT certification. CMS should work with ONC to require the certified health IT developer document its written and verbal communications, their customer's response, and provide that documentation to ONC as well as its customer.

## MSSP CEHRT Changes

### **Recommendations:**

- CMS should reverse and replace its proposal to require MSSP participating clinicians regardless of qualifying APM participant (QP) status and model track to report MIPS Promoting Interoperability (PI) measures with a new proposal that would achieve alignment with Advanced APMs with less burden by applying the current 75 percent attestation-based CEHRT standard for QPs to all MSSP participating clinicians, regardless of track.
- CMS should look for opportunities to collaborate with other federal agency partners and leverage
  the information already being collected to advance certified EHR adoption while reducing the
  reporting burden on physicians.

The AMA strongly opposes CMS's proposal to require all clinicians, regardless of QP status or model track, to report MIPS PI measures and earn a PI score, and for ACOs to publicly report the number of clinicians in that ACO that earn a PI score, which moves the MSSP in the wrong direction. CMS argues in the rule that its proposal will "alleviate burden" on ACOs because ACOs will no longer have "the burden of managing compliance with two different CEHRT program requirements." However, this proposal would achieve the exact opposite of the intended effect and increase burden on MSSP ACOs because it forces all participants to meet the more burdensome MIPS criteria. Moreover, CMS's accompanying proposal for ACOs to publicly report the number of clinicians participating in the ACO that earn a MIPS PI score would increase reporting burden even further. As CMS well knows, increased reporting burden has a disproportionately negative impact on small, independent, rural, and safety net practices, making the already nearly insurmountable hurdles to them joining an APM even higher, and making the vulnerable patient populations they serve even less likely to participate in an accountable care relationship.

If CMS wants to create alignment across the MSSP, reduce burden for MSSP participants, and encourage participation in the MSSP and APMs more broadly, it should instead adopt the AMA's <u>prior recommendations</u> to apply an attestation-based CEHRT standard more broadly, in this case for all MSSP participants, regardless of track, or to award automatic CEHRT credit when it is used to report quality or other performance data, since that in and of itself demonstrates use of CEHRT. CMS has stated repeatedly its goal to move more physicians into APMs and create a glidepath to advanced APM participation. Yet, by proposing to require all MSSP participants to report the more burdensome MIPS measures, CMS is

moving in the opposite direction by removing incentives to participate in the advanced tracks of the MSSP and to potentially qualify as a partial QP or QP.

Most importantly, the MACRA statute expressly states that "the term MIPS eligible professional does not include... an eligible professional... who is a qualifying APM participant... [or] a partial qualifying APM participant." Accordingly, this proposal would be an open contradiction to existing law and needs to be reversed. From the time that the MACRA legislation was first drafted, a fundamental element of the program has been that participants in Advanced APMs who achieve QP status are exempt from MIPS. There were two major incentives included in MACRA for physicians to work to attain QP status: lump sum incentive payments and exemption from MIPS. Virtually every description of the program notes that QPs are exempt from MIPS, including the guidance developed by CMS, which states: "QPs receive the following benefits, which include burden reduction and financial incentives: Exclusion from MIPS reporting ..." Similarly, the Congressional Research Service report on MACRA said "Health care professionals excluded from the MIPS incentive payment program will include otherwise eligible professionals who (1) will be qualifying APM participants, (2) will be partial qualifying APM participants..." Based on the MACRA exclusion of QPs from MIPS eligibility, CMS does not have statutory authority to require QPs or Partial QPs to report the PI component of MIPS.

The AMA believes it is time to shift the paradigm of EHR reporting from largely on the backs of physicians. Today, physicians assume the vast majority of the burden of capturing, documenting, and reporting CMS MIPS PI requirements. The PI Program is designed to compel physicians to "use" their EHR and meet several MIPS interoperability requirements, including giving individuals' access to electronic health information, public health information reporting, and clinical care information exchange. However, the PI data being collected from physicians also attempts to track EHR functionalities and usage that is largely out of the physician's control. Physician-reported PI measures continue to be used as a proxy for actual EHR-EHR interoperability and patient access despite the fact that individual physicians have little to no control over how EHR systems are designed or whether patients are able to or choose to access their data. Furthermore, the MIPS data submission window does not open until the January following the performance year and does not close until April 1, and physicians are waiting up to 24 months or even longer to receive feedback on that data. Put simply, physician-reported PI data is often too out-of-date to inform policy changes or be leveraged to improve CEHRT usage practices for practices. MIPS has also been documented to be significantly administratively burdensome. A study of MIPS participation in 2019 showed that it cost \$12,800 per physician per year, with physicians spending 53 hours per year on MIPS-related tasks—equivalent to a full week of patient visitors.

The MIPS EHR data currently being collected measures capabilities that are totally out of physicians' control, is outdated, duplicative, and burdensome to collect. Therefore, the AMA believes it is both ineffective and inappropriate to continue to expect physicians to shoulder the cost and burden of data collection to measure national EHR interoperability through PI measures. CMS could easily collect more informative data on EHR adoption and interoperability while reducing burden on physicians by working more collaboratively with ONC and levering data that is already being collected and relying more on EHR developers to pull data automatically from CEHRT systems and report data themselves, particularly as it relates to EHR functionalities and interoperability between systems, which physicians have no control over. Instead of extending MIPS PI requirements to QPs and Partial QPs participating in ACOs, CMS should look for opportunities to collaborate with other federal agency partners and leverage information that is already being collected, which would collect more useful data regarding adoption, use, and interoperability of CEHRT while reporting burden on physicians, therefore incentivizing them to join APMs.

Specifically, the AMA proposes that CMS coordinate with ONC to leverage EHR developer-reported data to augment attestations from MSSP participating physicians regarding use of CEHRT. In previous public comments to CMS and ONC, the AMA expressed support for CMS's goal of thinking creatively to reduce burden and promote interoperability and leverage vendor-provided health IT utilization data to simplify physician reporting and we outlined opportunities to specifically utilize ONC's EHR Reporting Program as a supplemental data source for physician EHR data reporting. [4].[5] CMS officials have previously stated that PI numerator/denominator reporting by physicians is necessary to ensure they are using EHRs, providing patients with their electronic health information (EHI), reporting to public health agencies, and exchanging information, but we disagree. The AMA believes that the goals of reducing physician PI reporting burden and providing CMS and ONC insight into EHI access, exchange, or use can be jointly achieved by allowing physicians or ACOs to attest "yes/no" to meeting PI Objectives—rather than reporting a numerator/denominator—and supplementing that with automatically reported EHR developer-reported data.

Moreover, in ONC's HTI-1 Regulation, the agency is proposing a new Condition and Maintenance of Certification requirement associated with its EHR Reporting Program. The "Insights Conditions" would require certified health IT developers to report on four areas of interoperability, including individuals' access to EHI, public health information exchange, clinical care information exchange, and standards adoption and conformance. The proposed measure areas would use data derived from the certified health IT system itself and ONC would then generate metrics using numerator/denominator calculations based on the certified health IT's supplied data points. Moreover, since ONC is proposing that EHR developers report their Insights Conditions data semiannually, ONC has an opportunity to provide CMS better, more timely data about real-world CEHRT adoption and use. In the HTI-1 Proposed Regulation, ONC itself discusses how the Insights Conditions measure has the potential to improve informing and monitoring the implementation of key ONC policies, assess the impacts of these various efforts, and understand their uptake and use for future development and improvements.

The AMA strongly supports ONC's proposals to improve the efficiency and accuracy of CEHRT evaluations, and we believe this is the most effective path forward for advancing CEHRT adoption and interoperability, not requiring individual physicians to take time away from delivering care to report duplicative information. We believe that ONC's proposed Insights Conditions can and should play a major role in helping CMS evaluate CEHRT adoption and use and serve as a preferred alternative to extending MIPS PI reporting to ACO participants. The AMA urges CMS to work with ONC to leverage its more informative, timely data on CEHRT adoption, use, and interoperability while reducing physician burden and encouraging participation in the MSSP. The AMA stands ready to assist ONC and CMS in these efforts.

Moreover, CMS recently <u>announced</u> that the MSSP saved \$1.8 billion last year compared to spending targets, making it the sixth consecutive year of savings, while demonstrating superior quality care, which the agency accredited to superior care coordination. If the program is achieving its objectives and program participants are clearly already leveraging CEHRT to coordinate care under the program's existing structure and requirements, it is not clear why CMS would risk disrupting the program with burdensome new requirements. As CMS's "flagship" ACO program, CMS should be building off the success of the MSSP, not changing core elements a decade into the model.

For all of the above reasons, we strongly recommend that the agency withdraw this proposed policy and fully consider our concerns related to implementation logistics, statutory authority, available alternative data sources, and increased burden on MSSP participants. CMS should instead give full consideration to our alternative proposals, which would achieve the desired effect of reduced

burden and improved consistency across the MSSP while collecting meaningful data about EHR adoption and simultaneously incentivizing clinicians to move to APMs.

At the very least, the agency must not finalize this proposal for the 2024 performance year given that the deadline to finalize MSSP participant lists for the 2024 performance year has already passed, and the short 60-day window between finalization of the rule and the proposed effective date of this new policy. This proposed policy represents a substantive change from previous CEHRT requirements that would require a significant lift from ACOs, participating clinicians and practices, and vendors that would be extremely difficult to implement within that timeframe. Furthermore, because CMS releases QP and Partial QP determination information throughout the performance period, including as late as March of the year following the performance period, the timing would mean that some ACOs would have to meet the PI reporting requirements despite being QPs or partial QPs – and therefore excluded from MIPS under law – simply because they would not be aware of their QP status by the last date to begin collecting PI data. This would be especially true if CMS finalizes its separate proposal to extend the PI reporting period from 90 to 180 days.

We also oppose the proposed alternative, which by removing the option to report data at the individual, group, or virtual group level, would relegate MSSP participants to even less flexibility than non-MSSP MIPS reporters.

# **Beneficiary Assignment**

#### **Recommendation:**

• CMS should provide additional information on the anticipated impacts of this proposed change on minimum savings rates, payment limits, risk adjustment, high/low revenue status, and other impacted methodologies, including a breakdown by ACO and patient sub-population demographics, and solicit additional feedback from interested parties before finalizing beneficiary assignment changes related to adding a new third step to the attribution methodology.

The AMA appreciates that CMS is exploring ways to improve the accuracy of beneficiary assignment. CMS notes in the rule that their proposal to add a new third attribution step with an expanded assignment window of 24 months would result in slightly increased populations of both assigned and assignable beneficiary populations, and would therefore have downstream impacts on minimum savings rates, performance payment limits, and high/low revenue status, etc. However, it is unclear to us based on the information and analysis provided in the rule whether there could be any potential adverse unintended consequences, particularly on specific types of ACOs and patient subpopulations. CMS's observation that the newly captured patients have lower service utilization and higher mortality rates, suggests for example that this new patient population may be disproportionately patients who do not frequently engage with primary care physicians or who may be experiencing potential barriers to access and likely captured as a result of receiving follow-up care to an acute event. We request a more detailed breakdown of CMS's modeling showing how this policy would affect different types of ACOs, such as rural ACOs, smaller ACOs with smaller patient populations, and those treating large safety net populations. Furthermore, CMS provides modeling based on 2021 data, which was significantly impacted by the pandemic. While the AMA supports the spirit of the proposal to enhance attribution, we feel more detailed information, including modeling based on additional years of data, as well as a breakdown of any disparate impacts by ACO type and patient sub-populations, is necessary so consequences can be more fully evaluated and interested parties can provide more informed feedback before such a policy is finalized.

We appreciate CMS's efforts to improve the accuracy of beneficiary assignment, including as it relates to non-physician practitioners. The AMA recognizes that this is an ongoing challenge, and we support CMS working closely with ACOs and physicians to develop a workable approach. To this end, we urge CMS to consider using patient relationship codes that were established under MACRA. We refer you to our previous comments regarding implementation and use of these codes. We also reiterate our previous comments that the gold standard to assignment is always voluntary, prospective patient attribution, which both empowers patients at the center of their care decision making and allows providers to proactively manage care for the patients they know they are responsible for.

# Financial Benchmarks and Risk Adjustment

#### **Recommendations:**

- CMS should finalize benchmarking changes, including phasing in of a new risk model, capping
  regional risk score growth, eliminating negative regional adjustments on financial benchmarks,
  applying the more favorable of the two-way and three-blend if losses are owed, and aligning risk
  adjustment models across the performance year and benchmark year while continuing to monitor
  for potential unintended consequences and explore additional ways to further improve
  benchmarking and risk adjustment technologies.
- CMS should apply the proposed changes universally across ACOs beginning with the 2024 performance year to ensure consistency across the program regardless of an ACO's agreement period.

In the rule, CMS proposes several benchmarking refinements intended to improve the accuracy of benchmarks, encourage sustained participation in MSSP ACOs, and protect against disproportionate impacts on rural, small, safety net, and legacy ACOs. These proposed changes include phasing in a new risk model over three years, capping regional risk score growth to align with the overall risk score growth cap (while accounting for an ACO's Medicare FFS market share), eliminating the impact of negative regional adjustments on an ACO's financial benchmark altogether, applying the more favorable of the two-way or three-blend if shared losses are owed, and aligning risk adjustment models across the performance year and benchmark year to ensure symmetry with Medicare Advantage plan changes and to keep pace with MSSP policy changes.

The AMA appreciates CMS's continued efforts to be responsive to feedback from interested parties and evaluate program data to continuously improve the accuracy of benchmarks. We are generally supportive of these proposed changes, many of which are in direct response to feedback raised by the AMA and other interested parties. However, we do have concerns regarding CMS's proposed implementation plan, specifically that many of these changes would only apply to ACOs beginning new agreement periods. While we appreciate that CMS would allow ACOs to terminate their contracts and begin new agreement periods early, we believe this would be unnecessarily burdensome on ACOs and CMS and would risk disruption to the program, as well as large swings in cohort sizes. We urge CMS to instead apply these changes universally and synchronously in order to promote consistency across the program and avoid disparate impacts across ACOs.

We encourage the agency to continue to monitor for possible unintended consequences should these policies be finalized including any disproportionate impacts on certain types of ACOs or patient populations and to be receptive to feedback from industry partners and look for additional ways to continuously improve benchmarking and risk adjustment methodologies. In particular, we urge CMS to

look for additional ways to address the ratcheting effect and retain high-performing ACOs in the program, such as by raising the prior savings adjustment percentage and removing or addressing the cap, as discussed in our response to the New Higher Risk Track RFI below.

# Advance Investment Payments (AIPs)

#### **Recommendations:**

- CMS should finalize proposals to allow AIP ACOs to seek reconsiderations of AIPs and advance to risk-bearing tracks beginning in performance year three or opt to renew early after two years and carry forth their AIP balance into their new performance contract.
- We urge CMS to consider expanding on these proposals by revising eligibility criteria so that a more diverse network of ACOs can access AIPs and modifying existing AIP recovery policies so that AIP ACOs can retain a portion of their shared savings payments to facilitate their continued participation in the program.

The AMA generally supports proposed improved flexibilities for AIP ACOs, which include allowing AIP ACOs to seek reconsiderations of AIPs for the first time, advance to higher risk tracks beginning in performance year three, or renew early after two years and to carry forth their AIP balance into those new performance contracts in either of these cases. We agree these changes would help to make it easier for AIP ACOs to voluntarily transition to higher risk tracks and ensure more accurate AIP determinations and potentially empower more ACOs to join the program, as well as enhance transparency and credibility in AIP determinations and the program as a whole.

We encourage the agency to explore additional ways to leverage AIPs to strengthen and expand the MSSP even further, including expanding eligibility criteria so that a broader, more diverse network of practices and ACOs can take advantage of AIPs. Because ACOs are required to repay these payments in their entirety, we would support CMS making these types of payments as expansive as possible, provided CMS determines that the ACO is in a reasonable position to make repayment, as it already does with all AIP applicants.

We also urge CMS to consider modifications to AIP recoupment and recovery policies, which currently dictate that CMS recoup AIPs from any shared savings earned by an ACO until all those AIP funds are repaid. We worry that AIP ACOs may not receive shared savings payments for a significant period of time, which could jeopardize their ability to maintain the necessary infrastructure investments to support advanced care coordination and performance improvement efforts and remain in the program. We strongly recommend CMS recoup AIP funds more gradually from a portion of shared savings earned by the ACO so that ACOs can use the remaining portion of shared savings payments to continue to fund ongoing performance improvement initiatives and other investments necessary to remain in the program. Request for Information (RFI): New Higher Risk Track

#### **Recommendation:**

• The AMA recommends that CMS takes steps to expand participation options in APMs by introducing additional voluntary risk tracks. We appreciate CMS's commitment to exploring strategies to attract both new participants and legacy ACOs to the program, exemplified by the issuance of this RFI.

The AMA supports adding additional voluntary risk tracks to expand participation options and we appreciate CMS continuing to explore ways to attract new participants while retaining legacy ACOs in the program, including issuing this RFI.

To this end, we would like to reiterate some of our core themes for building APMs that attract and retain physicians while advancing quality of care and maintaining or reducing costs, which we recently reiterated in our comments in response to the episode-payment model RFI. In our letter, we highlight the importance advancing voluntary models with financial structures and accompanying regulatory flexibilities that are inherently sufficient to attract participants and support and sustain innovative new methods of delivering better patient care, rather than relying on models that compare financial performance to past spending. We also underscore the importance of prospective patient assignment and payments so physicians have the resources they need to proactively manage patients' care, performance measures that measure what is within physicians' control, regular and timely performance feedback, longer agreement periods, additional supports for practices serving high-needs patient populations to help address and overcome barriers to care, targeted incentives to encourage primary and specialty coordination, and automatic annual inflation-based payment updates to ensure payments keep pace with rising practice costs. Regarding specialty integration in particular, we encourage CMS to implement the AMA's PASC approach, which would work within the MSSP structure to engage specialists in a more targeted fashion for collaborating with primary care providers for caring for patients with acute or chronic health conditions requiring specialty care.

We look forward to continuing to collaborate closely with the agency throughout development of this and other new APM concepts, particularly those that address current gaps in participation, such as effectively engaging non-primary specialists and safety net practice serving historically minoritized and disenfranchised patient populations.

# Prior Savings Adjustment RFI

# **Recommendation:**

• The AMA appreciates CMS's efforts to develop effective incentives for retaining highperforming ACOs within the program over the long term and recognize the challenge posed by the "ratchet effect," which can diminish an ACO's ability to consistently generate shared savings over time.

The AMA appreciates that CMS is looking for ways to design appropriate incentives to retain high performing ACOs in the program long-term and recognizing the issue that the so-called "ratchet effect" (i.e., diminishing ability to continuously generate shared savings over time) creates. We strongly support the prior savings adjustment. However, we do not feel 50 percent is sufficient and will lead to ACOs exiting the program. Accordingly, we strongly support recognizing a higher portion of previously attained shared savings, particularly for ACOs in higher risk tracks. We would also support removing or raising the current cap on prior savings adjustments.

# Financial Benchmark Blend RFI

## **Recommendation:**

• The AMA appreciates CMS recognizing that with the addition of the prospective national trend factor the current benchmark formula now disproportionately reflects national trend factors to regional on a 2:1 basis and encourages CMS to continue to evaluate the data and explore ways to improve the accuracy of the financial benchmark blend and appropriately incorporate the ACPT in a way that does not unfairly disproportionately negatively impact certain subsets of ACOs.

The AMA appreciates CMS recognizing that with the addition of the prospective national trend factor (i.e., the "accountable care prospective trend" or "ACPT"), the current benchmark formula now disproportionately reflects national trend factors to regional on a 2:1 basis, which disfavors approximately one-third of ACOs in higher cost regions. Accordingly, we believe replacing the national trend factor with the ACPT and creating a new two-way blend that is evenly divided between the ACPT and the regional growth factor would help to mitigate this disparity and would therefore represent an improvement from the current formula for those ACOs in higher-cost regions. We believe it would be appropriate to calculate the blend both ways and apply the more advantageous, which would align with CMS's proposal to mitigate the negative impacts of regional adjustments when shared losses are owed.

This being said, it is unclear without additional information and modeling whether this proposed approach is the most optimal solution. For example, CMS could model an alternative in which the regional factor is weighted as 50 percent of the blend, and the national growth factor and ACPT each represent one quarter of the blend, respectively. Accordingly, we encourage CMS to continue to evaluate the data and explore ways to improve the accuracy of the financial benchmark blend and appropriately incorporate the ACPT in a way that does not unfairly disproportionately negatively impact certain subsets of ACOs.

Strategies to promote collaboration with community-based organizations to address health-related social needs RFI

#### **Recommendation:**

• To enable ACOs to effectively establish and maintain vital relationships, the AMA proposes several strategies and strongly encourages CMS to ensure that these services are properly integrated into financial benchmarks, preventing any potential disincentives for ACOs to embrace these high-value offerings.

The AMA appreciates CMS's interest in promoting collaboration with community-based organizations to address health related social needs, which we agree is critical to closing gaps in access to care, advancing health equity, and improving population outcomes. Recognizing this work will require additional infrastructure and support, we believe there are multiple ways CMS could give ACOs the necessary resources to be able to foster these types of relationships. Possible strategies include allowing ACOs with a high proportion of high-needs or underserved patient populations to retain a higher proportion of their shared savings payments, allocating separate, additional, dedicated funds specifically for coordinating community-based services that could be used to reimburse the community partners themselves, similar to specialty integration incentive payments under the new Making Care Primary Model. In addition, CMS could also revise and expand eligibility criteria for advance incentive payments, allow them to be repaid more gradually over time, and/or raise or remove the current cap on risk score growth, as noted earlier.

New reimbursable codes for community health integration and SDOH risk assessment proposed in this rule, which we comment on in more detail beginning on page 34 of this letter, are a helpful first step in supporting these enhanced collaborative efforts, and we encourage CMS to ensure these newly payable services are appropriately factored into financial benchmarks so that ACOs are not penalized for taking advantage of these new high-value services.

CMS could also provide in-kind support by acting as a facilitator and helping to establish relationships with community-based providers, particularly those with an expansive regional or national footprint, and connecting them with the MSSP community to streamline processes and benefit from efficiencies of scale so that individual ACOs are not having to independently take on all of the relationship-building groundwork in silos.

MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program Accountable Care Organizations (ACOs) – Request for Information (RFI)

#### **Recommendation:**

• The AMA strongly urges CMS to drive more specialty engagement in APMs by adopting more specialty-focused and integrated models, including implementing new episode-based payment models that reflect the AMA's comprehensive <u>feedback</u>, including models that have already been developed by physicians, rather than further miring APM participants in MIPS.

In this RFI, CMS is seeking comments about ways to encourage specialists in ACOs to report on MVPs, which it believes will lead to increased specialty engagement in the Shared Savings Program. The AMA agrees that it is essential to provide all physicians with incentives and opportunities to engage in alternative payment models (APMs) designed for the kinds of patients they treat. However, we do not believe requiring specialists to report MVPs in MSSP is an effective strategy to boost specialist engagement in ACOs. In the CMS Innovation Center (CMMI) <u>Strategic Refresh</u>, the Center set a goal that 100 percent of Medicare beneficiaries be in a care relationship with accountability for quality and total cost of care by 2030. To achieve this goal, CMMI acknowledged that it would need to create incentives for specialty, episodic care that is supported by or embedded into ACOs, or what CMMI describes as total cost of care models.

The AMA was pleased that CMMI recently released an RFI about episode-based payment models. In fact, that RFI (CMS-5540-NC) was published on July 18, just a few days after this NPRM was released on July 13. We believe these RFIs, issued within a week of one another, have a competing vision of how to engage specialists in APMs, including ACOs. We strongly urge CMS to drive more specialty engagement in APMs by adopting more specialty-focused and integrated models, including implementing new episode-based payment models that reflect the AMA's comprehensive feedback, including models that have already been developed by physicians, rather than further miring APM participants in MIPS.

Adopting physician-developed episode-based payment models will have a far greater impact on patient outcomes than encouraging specialists to report MVPs. A number of different medical specialties, such as allergy/immunology, neurology, and rheumatology, have developed payment models designed to support better care for patients with the chronic conditions they treat, such as asthma, headache, and rheumatoid arthritis. One of the components in all of these payment models is designed to give specialists and primary care physicians the resources and flexibility to more accurately diagnose a patient who is

experiencing new or unresolved symptoms and, if the patient does have the chronic condition that is the focus of the model, the payment model would enable the physicians to develop an effective plan for treating or managing that condition. Ensuring that a chronic condition is diagnosed accurately and that an effective treatment is found quickly not only benefits the patient but saves money by avoiding treating the wrong disease or delivering an ineffective treatment. CMS should be encouraging physicians to move to these innovative new models of delivering care, rather than funneling them into MVPs, which as currently designed are largely a repackaging of MIPS, which has yet to show improvement to quality or reduction to cost with a growing body of literature documenting its harms.

In addition, in response to a CMMI request about how to address the problems about the lack of specialty integration in APMs more generally, the AMA developed Payments for Accountable Specialty Care (PASC), a mechanism through which CMS could support the ability of physicians and Accountable Care Organizations to implement episode payments and other physician-focused payment models in a coordinated way. Details on PASC and how it could be used to improve the success of ACOs and other population-based payment models are included in the May 5, 2023 <a href="Letter">Letter</a> to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) that we sent in response to PTAC's request for input on this issue. Adoption of PASC would have a far bigger impact on improving specialty care, including generating a larger cumulative impact when combined with the quality improvement results of the ACO, than encouraging specialists to report MVPs.

We also wish to emphasize our comments made elsewhere in this letter that one of the statutory incentives under MACRA for joining an APM is exclusion from MIPS. We do not believe that it is appropriate to expand MIPS or MVPs into APMs, including ACOs. In fact, we strongly believe the Quality Payment Program would work more successfully if the opposite were true — if APM measures and data and flexibilities were better incorporated into MIPS as a way to begin preparing physicians to participate in an APM if and when the opportunity arises. MACRA is clear that APM participation, not MIPS participation, is the ultimate goal. APM participants should be exempt from all MIPS and MVP requirements, and if they do not reach the Qualifying APM Participant thresholds, their participation in the APM's quality and cost efforts should automatically count as their MIPS participation.

The AMA strongly supports the Value in Health Care Act (H.R. 5013), which would encourage more participation in ACOs and other APMs by, among other things, extending the APM incentive payments. The Act would also give CMS authority to lower the APM participation thresholds for episode models and similar APMs that, by definition, involve a lower percentage of the practice's patient population. We hope that CMS will work with the AMA and Congress to support this legislation that would help achieve CMS's aim of engaging more specialists in APMs, especially episode-based payment models.

# III. CY 2024 MEDICARE PHYSICIAN PAYMENT SCHEDULE UPDATES TO THE QUALITY PAYMENT PROGRAM (QPP)

# A. Quality Payment Program Improvement Request For Information (RFI)

• What potential policies in the MIPS program would provide opportunities for clinicians to continuously improve care?

Physicians and practices need program stability to allow them to focus on improvement. CMS's yearly changes to the MIPS program, increasingly stringent requirements, and individualistic approach to

measurement makes it impossible to measure year over year improvement and allow practices the opportunity to institute any sort of quality improvement strategies or align their MIPS participation with other quality or certification programs in which they may be engaged. CMS is incentivizing reporting for the sake of compliance with a payment incentive in the absence of true quality improvement frameworks.

We frequently hear from physicians that the amount of churn in the program, specifically around the availability of measures and associated benchmarks makes the program extremely difficult to track. They also feel that the program lacks meaning and does not track to clinical care pathways or promote teambased care. There is a constantly moving goal post, which does not allow for engagement in instituting any form of quality improvement protocols like plan, do, study, act (PDSA). This also applies to CMS's increasing insistence on combining measures. The measure list may look more efficient but then prohibits the ability to collect, report, and benchmark the individual components of a measure. Therefore, absent true reforms to the overall MIPS program, quality and cost categories, benchmark methodology, and overall MIPS program, we find CMS's efforts short sighted and not a true movement to improved quality of care.

Another frequent challenge is CMS continues to reject measures that physician specialty associations, including the AMA identify as evidenced-based measures with gaps, particularly Qualified Clinical Data Registry (QCDR) measures. There is a major risk that those groups who are the recognized experts in the field may decide that attempting to further expand the set of measures available for MIPS reporting is not worthwhile. Therefore, there is an increasing risk that the program will not have enough measures for which each specialty will be able to report in the near future, particularly if they are not able to meaningfully contribute to filling these gaps. For example, the AMA has been a recognized leader in diabetes prevention for the past 10 years. As part of our commitment to preventing diabetes, we sought to address the gap in quality measures related to diabetes prevention by developing a set of quality measures that would serve as a means of both assessing and incentivizing high-quality diabetes preventive care. To that end, we spent over six years and nearly \$1,000,000 working on developing a set of measures that would be adopted by CMS into a quality payment program. The results of our efforts are:

- Prediabetes quality measures aligned with CMS's focus on chronic conditions;
- A measure set that is based on clear and recently updated clinical guidelines;
- Each quality measure was developed as an eCQM to align with CMS's move toward electronic measures even though we could have developed the measures as MIPS CQMs instead;
- A Screening measure that shows a clear gap in care; and
- The Screening measure is more broadly applicable than the two screening measures for breast and colorectal cancers that CMS recently prioritized in the Universal Foundation.

Unfortunately, after two separate attempts of working through the CMS pre-rulemaking Measure Under Consideration process and numerous conversations with CMS staff updating them on our efforts to ensure alignment with CMS's goals and obtain support, our measures were rejected by CMS staff and not even proposed and considered as part of the formal rulemaking process.

We continue to view the development of measures in this area to be a valuable contribution to the quality measures available to MIPS participants since diabetes prevention is a priority, yet the program does not include any relevant quality measures. If our experience is representative of what other specialty societies experience, then we believe that there are significant flaws in the process that must be addressed. The AMA is unable to support a program that requires measure developers to spend extreme amounts of

money without any indication (or contradictory indications) that evidenced based and tested measures being developed will be adopted.

• Should we consider, in future rulemaking, changes in policies to assess performance to ensure ongoing opportunities for continuous performance improvement?

We urge CMS to create stability in the program, discontinue the practice of combining measures, and prioritize those measures developed by clinical specialties. In addition, we continue to propose that CMS enable a sampling approach to satisfy data completeness rather than the current data completeness requirements. A sampling methodology would make it easier for groups to participate and allow them to replicate traditional quality improvement activities.

We also once again reiterate the need for CMS to revise the quality and cost measure benchmarking scoring approach and methodology. There has been a lack of consideration of MIPS program policies and methodologies and the intersection with Care Compare (formerly Physician Compare), as well as a lack of solicitation for feedback and comment on the issue. The AMA first highlighted the policy disconnect in our 2017 MFS Interim Final Rule comments and have since repeatedly highlighted our concerns with the MIPS benchmarking methodology during the yearly MFS comment period. CMS has operated Care Compare in a silo and often proposes and finalizes methodological changes through sub-regulatory comment and webinars. Therefore, there are now multiple programs by which CMS attempts to rank and compare the quality-of-care physicians provide. MIPS involves awarding points to physicians based on where they fall in decile-based categories calculated from historical quality measure data (when available). Notably, this methodology differs from CMS's Care Compare star rating public reporting program. Care Compare uses the Achievable Benchmarks of Care (ABC) methodology to place physicians into one of five categories (each with a corresponding "star rating") for purposes of helping patients compare physicians to make more informed decisions about where they seek care. In contrast, the MIPS methodology uses nine categories (and point system) to score physicians on quality measure reporting to determine whether a physician will be subject to a MIPS penalty or eligible for an incentive. As a result, through our examination, the two methodologies (MIPS and 5-star) result in inconsistent ratings and comparisons.

# Our primary concerns related to the MIPS benchmark methodology are as follows:

- For topped-out or highly skewed data, thresholds are clustered close together (meaning that similar performance may not result in similar points awarded) and even relatively high performance can place a physician in one of the lower deciles. For example, a physician could score 88 percent and be in the 4th decile while another physician scores 92 percent and is in the 8th percentile. Therefore, on the same measure two physicians can perform very similarly on the measure but be awarded very different points. There is a lack of consideration of the role played by random fluctuation, especially for small denominators;
- Strictly data-driven thresholds may conflict with clinical knowledge and evidence of ideal performance or with practical considerations of quality;
- There may be significant changes to the population of physicians and groups between the time that the historical data represents (two years prior) to the time period to which the resulting thresholds are applied; and
- Under certain circumstances, physician performance score under MIPS may differ significantly from their performance under the Care Compare methodology, even for the same measure.

These concerns are further exacerbated when applied to the measures in the Cost Category as the distribution across the deciles assumes that lower costs in the absence of any evaluation of the quality of care is better. We fundamentally disagree with this premise and also question the usefulness of this decile approach when costs often differ by less than \$100.

Therefore, we urge CMS to revise the benchmark methodologies to allow measure thresholds to incorporate clinical knowledge, consider the impact of random fluctuation, and be adjusted for practical considerations of comparison and relative performance. To address the shortcomings of the existing benchmark methodologies, we suggest that CMS implement a methodology that allows for manual manipulation of thresholds. We acknowledge that this would add process to an already complex method, but we believe that what is most important is ensuring the fairness and clinical relevance of the measure benchmarks. We further acknowledge that there may be modifications to the methodology other than what we suggest which may also address our concerns and welcome the opportunity to discuss further with CMS.

At a minimum, we urge CMS to immediately align and move to one consistent data calculation policy between the two programs on the following issues:

- Only incorporate data used to calculate a physician's quality measure score: Under MIPS, a physician may report measures through multiple submission mechanisms or report more than the required number of measures. For purposes of avoiding a penalty CMS only considers the most successful method and measures. However, under Care Compare, as long as a physician successfully satisfies MIPS quality reporting requirements, ALL data, regardless of whether the data was used to calculate the physician's score, is publicly posted and included in the downloadable database.
- Individual vs. Group Reporting: Under MIPS, CMS calculates separate benchmarks and scores based on each reporting mechanism (eCQM, registry, QCDR) and combines individual, group, and MSSP data to calculate the benchmark and score. However, under Care Compare, CMS calculates and displays separate scores for measures reported as an individual and measures reported as a group.
- Create Separate Benchmarks for Each Reporting Mechanism: CMS is mixing various reporting mechanisms when developing the benchmarks for Care Compare, which CMS does not do when setting MIPS benchmarks. Therefore, CMS should create separate benchmarks for each reporting method instead of aggregating data from all reporting mechanisms.
  - Move to the same number of achievable points across programs: Care Compare places physicians into one of five categories to calculate star ratings, while the MIPS methodology uses nine categories (and point system) to score physicians on quality measure reporting to determine whether a physician will be subject to a MIPS penalty or eligible for an incentive.
  - Retain only the "successful" performance indicator for PI: CMS should limit the PI performance category indicator to that of only "successful."

The inconsistencies result in physician frustration and further dissatisfaction, and ultimately lead to a lack of confidence in the MIPS program. Further, these inconsistencies also send mixed signals to patients who might make incorrect assumptions about physician quality when deciding to seek care and leads to additional administrative burden and complexity.

• Should we consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?

Overall, a lighter touch is needed in evaluating quality with a greater emphasis on motivating physicians to internally track and evaluate where their own care gaps exist and how they can improve. This is opposed to the current heavy-handed approach by CMS and private payers. We continue to not see how MIPS or MVPs fall in the value equation and assist physicians with transitioning to APMs.

We recommend CMS enable the profession to identify care gaps, implement measures, and activities that promote high quality care, and track progress on addressing these gaps—as Congress intended with statutorily mandating the QCDR option in MACRA. Unfortunately, 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, current CMS physician payment policies and program design features have created obstacles for QCDRs to be engaged successfully in the program. The CMS QCDR approval process used in MIPS is complex and cumbersome, and the lack of accessible cost data inhibits progress toward true value-based care. As a result, most specialties that originally received QCDR certification have dropped out of MIPS because the CMS demands lacked clinical relevance or evidence and inhibited their ability to engage in true quality improvement efforts that often aligned with larger clinical lifelong learning goals, like maintenance of certification. Unfortunately, the short-sighted nature has now limited the ability of physicians to leverage their participation in these quality improvement efforts for MIPS and engage in continuous learning.

Another problem with the current thinking of CMS is it expects that everything can be measured and is appropriate for accountability, improvement, and public reporting. Unfortunately, some measures may meet all three characteristics and others may only meet reliability and validity when used for internal quality improvement. Quality measures may serve several purposes: provide comparative data for use in accountability programs, such as pay-for-performance and alternative payment models and support a patient's ability to participate in and make decisions about health care; or allocate resources toward identified gaps in community and population health needs. However, quality measures used for accountability and public reporting are not always the same as measures used for quality improvement, but they may overlap with those used to accelerate internal clinical improvement, patient outcomes, and health needs. Therefore, CMS needs to shift the focus from one where "successful reporting and participation" in a program is not based on whether an individual physician or practice reports a certain number of possibly disparate measures and achieves somewhat arbitrarily set targets. Rather we call for a measurement and improvement approach that leverages parsimonious and actionable measures that logically represent care along a clinical pathway based on evidence, is valid, reliable, and feasible and informs patients and caregivers (first and foremost) and payers.

To meet the goals to improve the care of individuals and their overall quality of life requires enhanced access to data—without this information, care cannot be evaluated and improved.

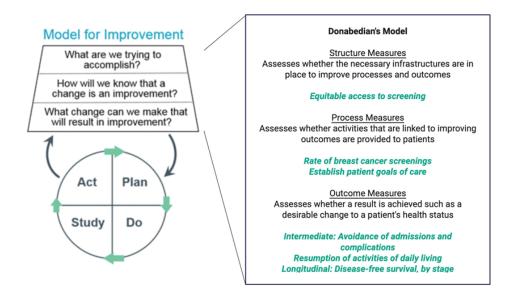


Figure 1. Interaction of Quality Improvement and Measurement<sup>33</sup>

Ideally, we recommend CMS leverage existing efforts (e.g., certification programs, registries) with demonstrated improvement in care, promote innovative digital technologies, and minimize reporting burden. This re-envisioned model would allow practices and care teams to certify/attest to many components to facilitate meaningful, actionable, and near real-time improvement. It will be less burdensome to implement this model that is verified by a registry or certification program, for example, than it is to measure a series of metrics tied to a clinical visit but not necessarily linked to improvement efforts. The intent is to have physicians and the care team focused on delivering optimal care over the lifecycle of a condition, procedure, or other health care need rather than solely focusing on meeting a payer's metric(s) during each visit. Our recommendation would also promote the use of innovative technologies by practices such as leveraging digitally enhanced data and interoperability to support their improvement cycles, inform near-real time decision-making and co-management, and to inform and engage patients. Practices would be incentivized to take steps to expand their digital capabilities beyond CEHRT functionalities and improvement activities are built into the overall model design and therefore would not require any additional documentation or reporting. The re-envisioned model, by its very nature, would use CEHRT as the foundation but promote the use of broader digital health tools to coordinate care, leverage knowledge to inform clinical decisions, engage patients where they are at, and address health disparities. It is no longer necessary or appropriate to require the use of specific technology; physicians' use of CEHRT is well above critical mass and incentives must focus on reducing burden and simplifying reporting. The registry or certification program would only provide data to CMS and other payers on the same measures appropriate for accountability and public reporting, along with identifiers of those entities participating.

• We acknowledge the potential increase in burden associated with increasing measure reporting or performance standards. How should we balance consideration of reporting burden with creating continuous opportunities for performance improvement?

<sup>&</sup>lt;sup>33</sup> Institute for Healthcare Improvement. How to Improve. https://www.ihi.org/resources/Pages/HowtoImprove/default.aspx.

CMS must shift the focus from one where "successful reporting and participation" in a program is not based on whether an individual physician or practice reports a certain number of possibly disparate measures and achieves somewhat arbitrarily set targets. Rather it calls for a measurement and improvement approach that leverages parsimonious and actionable measures that logically represent care along a clinical pathway based on evidence, is valid, reliable, and feasible, and informs patients and caregivers (first and foremost) and payers. Therefore, the primary focus of the MIPS program must shift from the reporting of disparate measures to meet reporting requirements to incentivizing quality improvement. To achieve this, we recommend CMS institute the following:

- Leverage existing efforts (e.g., certification programs, registries) with demonstrated improvement in care, promote innovative digital technologies, and minimize reporting burden:
- Define quality based on the care continuum that patients experience;
- Enable the profession to identify care gaps for improvement, implement measures and activities that promote high quality care, and track progress on addressing these gaps; and
- Evaluate the model's effectiveness periodically.
- While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement we are also mindful that this will result in an increasing challenge for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

Before moving to more rigorous policies and requirements on demonstrating improvement, CMS must enable the profession to identify care gaps, implement measures, and activities that promote high quality care, and track progress on addressing these gaps. Otherwise, MIPS participation will continue to be seen as a costly and burdensome exercise that does not truly measure improvement in care, but improvement from the perspective of avoiding a payment penalty. In addition, implementing stable measure benchmarks that utilizes a methodology that is more manual+data driven will more than likely mitigate any unintended consequences.

There is also a need for a phased implementation to encourage adoption of value-based care arrangements by transitioning from silos of care toward ultimately holding physicians accountable for patient outcomes, allowing specialties to focus efforts and apply uniform measures across payers. Any program MUST also facilitate and encourage flexibility and enable measurement to be aggregated to the level for which the clinical action is most appropriate (e.g., group, care team), while also promoting shared accountability across physicians, specialties, facilities, and other care settings.

Furthermore, physicians currently interact with a payer-mandated quality measurement and improvement system that is overly burdensome and increasingly complex and unstable. These program structures require significant manual data collection and what is often duplicative reporting to others (e.g., private payers, other CMS quality programs). This approach does not truly evaluate the profession's goals of improved patient care and overall quality of life. MIPS is also limited in its usefulness for informing a patient when making decisions about their care.

# B. MIPS Value Pathways (MVPs)

The AMA continues to believe that MVPs have the potential to remedy the well-documented <u>problems</u> with MIPS, including the undue administrative burden on physicians, the exacerbation of health inequities, and the disadvantages for small and independent practices. Currently, however, MVPs cannot fulfill this potential because they retain the same core rules and requirements of traditional MIPS. By carrying the flawed MIPS policies over into MVPs, CMS is doing the same thing and expecting a different result. CMS must try something new, and we offer several recommendations below about how to do just that that are within the agency's existing statutory authorities.

Make Meaningful Reductions in Burden for MVP Participants

# **Recommendations:**

• To be successful, MVPs should meaningfully reduce burden for participants by increasing scoring simplicity and predictability, removing the population health measures unless relevant to the MVP, aligning performance goals across the four MIPS categories, and increasing flexibility for CEHRT use and demonstration.

The AMA is disappointed that MVPs do not go further to streamline and simplify MIPS requirements. MVPs have the same four disparate performance categories with four unique scoring methodologies. Despite significant opportunities to reduce burden and tailor health IT use for different episodes of care or conditions, MIPS and MVPs have the same Promoting Interoperability requirements. Despite the availability of episode-based cost measures, MVPs continue to include the problematic Total Per Capita Cost measure. Furthermore, we are extremely concerned that the added burden of reporting MVPs, such as forming subgroups, will more than outweigh the modest changes finalized to date (e.g., reporting as few as four rather than six quality measures), and compound, not resolve, the burdens in the program.

Despite CMS's statements otherwise, merely limiting physicians' choice of measures by grouping quality measures and improvement activities together in an MVP will <u>not</u> remedy the substantial administrative burdens of MIPS. In a 2019-2020 <u>survey</u> of physician practice leaders from a variety of specialties, practice types and locations about their perception of MIPS, one of the key themes that emerged was that MIPS caused substantial administrative burden. Notably, the key contributing factors cited were constant programmatic changes, data collection and reporting, and interference with patient care. Nowhere was a surplus of measures mentioned.

Here are quotes from practice leaders:

- "Seems like CMS can't leave things the same ever..."
- "It's very hard to give CMS the info that they are looking for. It's complicated and time consuming. The docs are frustrated with the extra clicking and form filling out. The price that they are having to pay is burnout. It's just not rewarding."
- "Some doctors have retired instead of working part-time."
- "For us, the biggest part is that doctors can't see as many patients as they used to."

In a <u>study</u> evaluating the time and financial costs of MIPS, researchers found that it takes 201 hours per physician per year to comply with MIPS. The researchers found that the majority of the MIPS activities included reviewing medical records, collecting information from patients, and entering data into the EHR. Once again, measure selection was *not* mentioned as a time-consuming MIPS activity. Based on these

findings, we disagree that grouping existing MIPS measures and activities together effectively responds to the need for significant burden reduction in MIPS.

Instead, we believe CMS must make meaningful reductions in burdensome reporting requirements for MVP participants, and we offer the following recommendations to do so:

- Increase scoring simplicity and predictability by not imposing additional restrictions such as requiring reporting on a certain minimum number of measures across MVPs or assigning varying measure weights.
- Remove population health measures as a foundational requirement on top of the general quality measure requirements. While measuring improvement on population health is important, introducing additional, one-size-fits-all requirements rather than incorporating them into existing MVPs when appropriate adds unnecessary complexity.
- Align performance improvement goals through multi-category scoring for measures or activities that inherently cross multiple performance categories. We are pleased to see CMS's creation of an improvement activity (IA) for MVP participation. We urge CMS to increase the weight of this activity, so it is equivalent to the full IA category score, and to extend it to traditional MIPS participants as well. Further, MVP participants should receive automatic credit for the Promoting Interoperability (PI) and IA categories for reporting population health or beneficiary engagement quality measures via a OCDR.
- Take full advantage of the flexibility to demonstrate use of CEHRT (e.g., straightforward yes/no attestation) found in The Health Information Technology for Economic and Clinical Health Act, especially considering CMS's National Quality Strategy goal of transitioning to dQMs by 2030. Adoption of dQMs makes the PI category obsolete since the technology standards are inherently built into quality measure specifications and the use of health IT in an interoperable fashion will be necessary to enable dQMs.

Develop MVPs by Condition, Episode of Care and Clinical Priority Areas, Not by Specialty

# **Recommendations:**

- CMS should delay implementation of the *Focusing on Women's Health* and *Quality Care in Mental Health and Substance Use Disorder* MVPs until both MVPs are refined to reflect the care journey of patients needing obstetric versus gynecologic care and, similarly, for patients needing mental health care versus substance use disorder treatment. We also oppose inclusion of the Psychoses and Related Conditions cost measure in the *Quality Care in Mental Health and Substance Use Disorder* MVP.
- The AMA urges CMS not to finalize its proposal to combine the *Promoting Wellness* and *Optimizing Chronic Disease Management* MVPs into a single *Value in Primary Care* MVP.
- CMS should work closely with the national medical specialty societies to develop an MVP
  prioritization framework and work with the specialty societies to develop MVPs that address
  priority areas, such as substance use disorder, maternal health, care coordination and integration
  between primary care physicians and non-primary care specialists, as well as home-based care
  options for patients with chronic conditions.

The AMA strongly disagrees with CMS's concern that a proliferation of MVPs could introduce added complexity, thereby undermining their original purpose. To be successful, MVPs should hold physicians accountable for the quality and cost of a condition or episode of care, rather than merely compile specialty

measure sets. As we discussed above, a surplus of measures or MVPs, in this case, is not the root cause of the significant administrative burden created by MIPS, and we oppose limiting MVP choice and clinical relevance in the name of burden reduction. Rather, CMS should be intentional about the MVPs that it creates and should develop them around conditions, episodes of care, and clinical priority areas that have the potential to improve patient outcomes and reduce avoidable costs for a broad range of Medicare beneficiaries. Limiting MVPs to one per specialty is overly simplistic and does not account for different sub-specializations and varying practice arrangements.

Most finalized and proposed MVPs repeat many of the same problems as traditional MIPS—notably a lack of clinical relevance to physicians and the way they practice, as well as individualized patient needs. For instance, orthopaedic and neurosurgeons who specialize in spine surgery appear to fall under the Musculoskeletal Care and Rehabilitative Support MVP, but the functional status measures capture rehab/therapy/chiropractic services and not surgery. Therefore, the MVP has little to no relevancy for surgeons or patients for deciphering physician outcomes when deciding to have spine surgery. By contrast, CMS 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 orthopaedic 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, rather than developing MVPs at the broad specialty level and simply repackaging problematic measures. MVPs should move us closer towards patient-centered care, not further from it.

Regarding the proposed MVP Focusing on Women's Health, we believe the MVP as written does not appropriately distinguish between the maternity care population and the gynecologic population and that these measures are not "limited, connected, or complementary" as emphasized by the current MVP Guiding Principles. The intention of the MVP is muddied by including measures across these distinct populations without consideration of how these two populations are treated differently in practice. A refined MVP more focused on gynecology and women's health prevention and wellness with a separate MVP focused on maternity care is more in line with these guiding principles and the intent of MVPs as expressed by CMS, as well as the Administration's goals on improving maternal health. Until these changes are made, the AMA urges CMS to delay implementation of the Focusing on Women's Health MVP.

Similarly, the *Quality Care in Mental Health and Substance Use Disorders* MVP as proposed conflates two distinct patient populations and specialties. Addiction medicine physicians specialize in the prevention, evaluation, diagnosis, and treatment for patients with substance use disorders (SUDs), whereas psychiatrists may treat a broader patient population with mental and behavioral health conditions. Lumping together distinct mental health conditions into one MVP is not helpful to patients and does not map to their patient care journey. Instead, CMS should refine the MVP to focus on the prevention and treatment of mental health conditions and develop a separate MVP focused on SUD. **Until these changes are made, the AMA urges CMS to delay implementation of the** *Quality Care in Mental Health and Substance Use Disorders* **MVP.** 

Furthermore, we strongly oppose the inclusion of the Psychoses and Related Conditions cost measure in this MVP. We believe inclusion of this measure in MIPS or MVPs will have the undesired effect of creating a disincentive for psychiatrists to participate in the Medicare program, which is at odds

with CMS's proposals earlier in the rule and request for comment about how to improve participation among psychiatrists.

The AMA urges CMS not to finalize its proposal to combine the *Promoting Wellness* and *Optimizing Chronic Disease Management* MVPs into a single *Value in Primary Care* MVP. We reiterate our concern that MVPs will not be clinically relevant if developed to apply across an entire specialty, particularly one as broad as primary care. Moreover, as MVPs are still in their initial years, it is unclear how many physicians will opt to use them, and we believe CMS should be expanding the set of MVPs not shrinking it. Regardless of CMS's final decision, CMS should not include the Preventive Care and Wellness composite measure in any of these MVPs due to the concerns outlined by the AMA later in this letter.

We reiterate organized medicine's strong recommendation that CMS work closely with the national medical specialty societies to develop an MVP prioritization framework and work with the specialty societies to develop MVPs that address priority areas, such as substance use disorder, maternal health, care coordination and integration between primary care physicians and non-primary care specialists, as well as home-based care options for patients with chronic conditions. We also believe that providing more timely data in both traditional MIPS and MVPs will improve the accuracy and utility of quality and cost measurement and enable CMS and specialty societies to develop new MVPs based on valid, reliable, and clinically relevant MIPS and QCDR measures, identify promising new measure concepts, and agree on additional high-priority clinical areas and patient populations to target to reduce avoidable costs and improve quality.

Remove the Total Per Capita Cost Measure from MVPs

#### **Recommendation:**

• CMS should remove TPCC from MIPS. At a minimum, TPCC should not be included in any MVPs.

As discussed in detail later in this letter, the AMA has significant concerns with the Total Per Capita Cost (TPCC) measure, and we firmly believe that it should not be included in any MVP. At a minimum, CMS should remove the TPCC measure from every MVP that includes an alternative episode-based cost measure. While the AMA believes the problematic TPCC measure should be removed entirely from MIPS, its removal from MVPs would be a step in the right direction and would create an incentive for physicians to opt into MVPs.

In the 2020 proposed MPS rule, CMS explained that it proposed to include the revised TPCC measure because there were no other primary care measures. In 2024, we believe this rationale no longer has standing as there are 10 chronic condition episode-based cost measures in the program or in the pipeline that evaluate the costs of primary care. Furthermore, any MVPs aimed at chronic conditions should promote investing in preventive services as a critical element of the transformation to value-based care. However, including TPCC could unfairly penalize physicians for successfully improving the utilization of recommended preventive services due to the way total costs are measured in the same year as services provided. While higher utilization of preventive services likely reduces costs in the long-term, TPCC is not currently designed to capture those long-term savings and therefore does not appropriately account for the value of those services with its current methodology.

Moreover, as discussed in detail later in this letter, the AMA has concerns that TPCC is using outdated CPT coding specifications, which will significantly impact the reliability and validity of the measure and lead to inaccurate measure results and unintended consequences for physicians and physician groups. We raise a number of concerns and questions about the use of monthly benchmarking for TPCC, including a lack of meaning, as well as lack of alignment between a monthly TPCC measure and quality measures, which are scored on an annual basis. Our concerns about double counting of costs within the TPCC measure and other episode-based measures have not been alleviated, and we are urging CMS to release more detailed information about the overlap between cost measures in the annual experience report. We also wish to highlight a recent study<sup>34</sup> published in *JCO Oncology Practice*, which found that oncologists scored poorly on cost measures and raises concerns that TPCC does not fully account for the inherent variation in costs by providing standard-of-care medicine by specialty. Finally, the AMA remains concerned about the possible disproportionate effects resulting from the revised TPCC methodology and making measure exclusions at the specialty, as opposed to service, level. *Ensure MVPs and Subgroup Reporting Remain Voluntary* 

#### **Recommendation:**

• The AMA continues to strongly oppose retiring traditional MIPS and making MVP participation mandatory and we reiterate our belief that subgroup reporting should not be required to report on an MVP.

The AMA continues to strongly oppose retiring traditional MIPS and making MVP participation mandatory. CMS must recognize that there may not be a viable APM for every specialty or sub-specialty to participate in and, therefore, we believe it is important to permanently retain traditional MIPS as an option for those clinicians. If CMS designs MVPs with their intended goal to reduce burden and improve clinical accuracy, then physician practices will naturally gravitate to MVPs over time without having to be forced.

Subgroups

Facility-Based Scoring

# **Recommendation:**

• CMS should use a group's facility-based score for subgroups reporting an MVP if applicable.

CMS proposes that it will <u>not</u> apply this same policy and calculate a facility-based score for subgroups who participate in MVPs. The AMA is confused by this proposal and does not understand why CMS will calculate a facility-based score for groups who report via MVPs, but not subgroups if it is trying to incentivize MVP and subgroup reporting. CMS uses the group's score for cost measures as previously finalized and can do the same for the facility-based score. Therefore, the agency would continue calculating a facility-based score for traditional MIPS clinician or group reporters if applicable and assign the higher of the scores. We continue to support CMS's policy of applying the higher of the scores for individual clinicians based on traditional MIPS or MVPs, and we believe that CMS should similarly apply the group's facility-based score to the subgroup score, if applicable. This would be consistent with other policies for subgroups, including cost scoring.

<sup>&</sup>lt;sup>34</sup> DOI: 10.1200/OP.22.00858 JCO Oncology Practice 19, no. 7 (July 01, 2023) 473-483.

# **Complex Patient Bonus**

#### **Recommendation:**

• The AMA does not support CMS's proposal to eliminate the subgroup complex patient bonus and base the score based on the affiliated group's complex patient bonus.

In the 2020 MFS Final Rule, CMS finalized policy to permit subgroups to receive the complex patient bonus and apply the bonus based on the patient population of the subgroup. Now, CMS is proposing to eliminate the complex patient bonus at the subgroup level and base the bonus on the affiliated group complex patient score and retroactively apply the change. The necessity of the policy change is unclear to the AMA. We do not understand why CMS "cannot identify the necessary beneficiary data" given CMS calculates numerous administrative claims measures at the subgroup level, which is also based on claims data. It also fails to recognize unique characteristics of a subgroup from the affiliated group. Therefore, the AMA does not support the proposed change.

This potential lack of administrative capability by CMS to apply the complex patient bonus at the subgroup level once again raises our concern with the methodology for scoring the complex patient bonus. In our 2022 MFS comments, we highlighted our lack of support and concern that limiting the complex patient bonus to clinicians who have a median or higher value on either the HCC risk score or the dual eligible percentage can unfairly penalize clinicians who have many complex patients, but who fall below the median for all other clinicians. Therefore, we continue to recommend that CMS standardize the risk indicators by using the median instead of the mean, and use a more robust measure of variation than the standard deviation. As a result, we continue to urge CMS not to do anything further to limit or reduce the number of clinicians who are eligible to receive the complex patient bonus based on the medical needs of their patients, since this could reduce access to care for complex patients and worsen health equity instead of improving it.

# C. Merit-based Incentive Payment System (MIPS)

MIPS Performance Threshold

#### **Recommendation:**

 For the 2024 performance period, which will follow five years of MIPS hardship exceptions and severe disruptions due to the COVID-19 PHE, CMS should reduce the performance threshold to avoid penalizing more than one-half of MIPS eligible clinicians as currently projected. At a minimum, CMS should freeze the performance threshold at 75 points.

CMS is proposing to increase the performance threshold to 82 points in 2024, from 75 points in 2023. The agency proposes to use a prior period, or lookback, of three years to establish the performance threshold in 2024 and future years and would use the average of 2017, 2018, and 2019 mean performance data to set the 2024 MIPS performance threshold. The AMA strongly urges CMS to reduce the performance threshold to a degree that avoids penalizing more than one-half of MIPS eligible clinicians who are currently facing near-record levels of inflation coupled with a proposed 3.36 percent reduction to their payment due to Medicare budget neutrality requirements. Compounding this financial distress with an expansion of MIPS penalties threatens the viability of physician practices and patient access to care. At a minimum, to lessen the economic drain on physician practices, CMS should freeze the performance threshold at 75 points.

CMS estimates that 54 percent of MIPS eligible clinicians would receive a penalty averaging 2.4 percent if the proposed 82-point performance threshold was finalized. The AMA is extremely concerned about the ability of physician practices to take on the financial burden of these penalties while continuing to absorb the costs of participating in MIPS, having their Medicare physician payments eroded due to pay cuts, while faced with rising prices for equipment, rent, and other overhead expenses, as well as increasing staff salaries due to workforce shortages. According to a 2021 <a href="study">study</a> published in <a href="study">JAMA</a>, compliance with MIPS costs \$12,811 per physician per year. In addition, physicians spend 53 hours per year on MIPS-related tasks which is equivalent to a full week of patient visits. In total, physicians and other health professionals, along with clinical and administrative staff, spent 202 hours per physician per year on MIPS-related activities. This study is based on 2019, prior to full MIPS implementation, and is likely an underestimate of today's costs.

In 2024, physicians will be in the fifth year of a six-year statutory freeze on Medicare payment updates under MACRA. Worse, due to budget neutrality requirements in the MFS physicians face a 3.36 percent reduction to the Medicare conversion factor next year. These payment cuts would be untenable in usual times, but they are colliding with persistently high inflation as measured by CMS's MEI, which is projected to be 4.5 percent in 2024. In fact, between 2001 and 2023, the cost of running a medical practice increased 47 percent, or 1.8 percent per year. In striking contrast, physician pay has increased just nine percent over the last twenty-two years, or 0.4 percent per year, according to data from the Medicare Trustees. Adjusted for inflation, Medicare physician pay declined 26 percent from 2001 to 2023, or by 1.3 percent per year. Before factoring in MIPS penalties, physician pay does not go nearly as far as it used to. While the AMA is calling on Congress to replace the statutory freeze with inflationary updates, CMS must avoid exacerbating the financial distress facing physicians with the proposed increased performance threshold.

Furthermore, we are concerned about the disproportionate impact on small and independent practices, as well as those physicians who care for a greater number of historically minoritized and marginalized patients. Based on our <u>analysis</u> of the 2021 MIPS performance period, there were three times as many clinicians in small practices that had MIPS scores resulting in penalties – 11.9 percent versus 3.36 percent overall. In addition, more than a third of small practices received a neutral payment adjustment, likely through the Extreme and Uncontrollable Circumstances (EUC) hardship exception due to the COVID-19 PHE, which will not be available in the 2024 performance period. The analysis also found that the disparity between smaller and larger practices was larger for family physicians than other specialists. The average score for a small family practice small practices was 71.1 compared to 89.9 overall. We wish to be clear that we do not believe this reflects the quality or cost of care delivered by small practices but rather the undue administrative burden and high costs of complying with MIPS. The Government Accountability Office has <u>highlighted</u> these barriers to participation for small and rural practices.

We have also heard from specialists who have the Cost and Promoting Interoperability performance categories reweighted to zero that they were barely able to meet the 75-point performance threshold in 2022 despite achieving near perfect scores on the measures available to them. Our understanding is that the problem stems from CMS's topped out policies, which coupled with the reweighting policies, put certain specialists at a significant disadvantage over others. We are seriously concerned that increasing the performance threshold to 82 points would result in unfair penalties to certain specialists through no fault of their own but due to the flawed program design.

Moreover, we are concerned that this proposal could worsen health inequities. According to a <u>study</u> in *JAMA* that looked at the first year of MIPS, physicians with the highest proportion of patients dually

eligible for Medicare and Medicaid had significantly lower MIPS scores compared with other physicians. A 2022 JAMA study similarly found that physicians caring for more medically and socially vulnerable patients were more likely to receive low scores despite providing high-quality care. These studies suggest that MIPS may penalize physicians for social factors outside of their control and consequently, due to budget neutrality requirements, transfer resources from those caring for poorer patients to those caring for more affluent patients. This is called the reverse Robin Hood effect. CMS should not expand this flawed program to increasingly penalize physicians with as much as a nine percent reduction of Medicare payments, particularly on the heels of the COVID-19 PHE and when physicians must absorb the highest practice costs in recent history despite the lack of an inflationary update.

CMS Proposal to Use a 3-year Prior Period to Establish the MIPS Performance Threshold

Regarding CMS's proposal to use a three-year prior period to establish the MIPS performance threshold, we believe this has promise to improve stability in the program in future years. However, the AMA does not believe it is appropriate to increase the performance threshold from 75 to 82 points in 2024 based on 2017-2019 data, which is up to seven years old. The program has been operating with a failsafe under the EUC hardship exception since 2019 due to the COVID-19 PHE, and the 2017 and 2018 performance years were markedly different from the current program—the requirements to comply are more strict, 25 cost measures now account for 30 percent of the final score, and many bonus points have been retired. Furthermore, the Total Per Capita Cost and Medicare Spending Per Beneficiary measures that were in place in 2017-2019 look drastically different now, as they underwent reevaluation and were introduced in 2020. Yet, the MIPS cost category was zeroed out in 2019, 2020 and 2021 due to the COVID-19 PHE. In fact, most physician practices are only just now seeing any performance feedback in the cost category based on the 2022 performance period, and it is likely that there are many who applied for reweighting of the cost category due to the impact of the pandemic. Therefore, we believe CMS should decrease the performance threshold in 2024 or, at a minimum, maintain the 75-point threshold.

Targeted Review

## **Recommendation:**

• The AMA does not support CMS's proposal to only provide a 30-day targeted review period. The AMA recommends that CMS allow for a 60- to 90-day Targeted Review period that allows for a minimum of 60-days after payment adjustments are released. We support CMS's proposal to allow subgroups to submit a targeted review application.

Based on several years of experience working with practices on the MIPS program, in most instances physicians are not aware of their payment adjustment or any discrepancies until the MFS payment adjustments take place. The MIPS program is extremely complex and administratively burdensome, so we urge CMS to allow practices time to digest their final MIPS scores and see how the adjustments play out before closing the opportunity to request a Targeted Review. The process to appeal any irregularities with MIPS should not be another burdensome exercise that places physicians on a clock. Often the final scores produced by CMS are ripe with errors and CMS must go back to fix errors. Therefore, timing the window to request a review so close to the release of MIPS scores (30-days) is unfair, especially since this is a provision within MACRA that Congress specifically mandated as part of the program.

## **Recommendation:**

• The AMA supports CMS's proposal to remove the Health IT Vendor Category as an eligible third-party intermediary to submit data on behalf of eligible clinicians.

Due to CMS's ongoing experience and concerns with Health IT vendors submitting data that is inaccurate and unusable for MIPS, we support CMS's proposal to remove Health IT Vendors as a third-party intermediary eligible to submit data on behalf of physicians. As CMS highlights, most Health IT vendors are already qualified registries so eliminating the option should not be a hardship on physician practices. The change also provides CMS with additional oversight of Health IT vendors which will improve data integrity. However, CMS must ensure that any Health IT vendors that are acting as third-party intermediaries must inform their provider clients of this change and properly support them during the transition.

Quality Performance Category

# **Data Completeness**

#### **Recommendation:**

• The AMA does not support CMS's proposal to increase the data completeness threshold starting in 2027. We continue to urge CMS to not move forward with its finalized policy to increase the data completeness threshold to 75 percent starting in 2024 and revisit the policy.

As the AMA has stated in previous comments, the increased reporting requirement runs counter to CMS's 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 data completeness requirement within the MIPS program). Starting in 2024, CMS will increase the data completeness requirement to 75 percent of all eligible patients and is now proposing to increase the requirement to 80 percent starting with the 2027 performance period. 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 eCQMs within MIPS are 100 percent.<sup>35</sup> 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 is not yet universally available. Therefore, we request that CMS work with a few registries and practices to compare what 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.

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

<sup>&</sup>lt;sup>35</sup> 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.

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, come 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.

# Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

#### **Recommendation:**

• The AMA supports CMS's proposal to require groups, virtual groups, subgroups, and APM entities to contract with a CAHPS for MIPS survey vendor to administer the Spanish survey translation to Spanish-preferring patients.

The AMA supports the changes and believes allowing the survey to be administered in Spanish will most likely improve response rates. We also urge CMS to consider expanding the requirement to other languages in the future. We believe that the results of the survey would better reflect the true perspectives of patients if they were provided in their preferred language.

# ICD-10 Coding Changes

#### **Recommendation:**

• The AMA supports removing the 10 percent ICD-10 coding change factor since that cut-off did not seem to be based on any empirical analyses and agree with making these determinations based on the effect to the various data collection types. However, we are concerned with truncating data to only nine months.

The AMA supports CMS's proposal to modify the criteria used to assess ICD-10 coding updates, specifically removing the 10 percent change factor since the cut-off did not seem to be based on any empirical analyses. We also agree with making these determinations based on the effect to the various data collection types. However, we remain concerned that the current approach to truncate the performance period to nine months may not yield sufficient data to establish reliable measure scores and/or benchmarks. Ensuring that the scores used to evaluate physician performance and used 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.

Expand the definition of high priority measures to include health equity-related quality measures and to satisfy the outcome measure requirement

#### **Recommendation:**

• The AMA continues to support the expansion of high priority measures to also include health equity related quality measures. We also recommend that measures classified as health equity should satisfy the outcome measure requirement in MIPS.

Given the priority to address inequities in care and the resources required to address social risk factors, reporting on a measure that falls under health equity should satisfy the outcome measure requirement within MIPS. There are a limited number of outcome measures within the program and further incentivizing the reporting of health equity measures will allow practices to better focus their efforts on

addressing health equity issues. Addressing social risk factors and inequities in care is a factor that improves care outcomes.

We also continue to highlight to CMS the lack of any guidance or detail explaining how CMS determines which measures are considered health equity related. We encourage CMS to provide additional information on what characteristics or other features of a quality measure would enable it to be classified with this label. In addition, we recommend that CMS consider classifying a measure as health equity-related if a measure developer can demonstrate there are variations in performance across patient populations or other characteristics. For example, last year, the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE) submitted data from GIQuIC registry during the 2023 rulemaking cycle demonstrating that there are disparities in care when results for QPP 425, *Photodocumentation* of Cecal intubation, are analyzed by race, ethnicity, and age. If a measure developer is able to demonstrate that performance varies across race, ethnicity, insurance, or another factor, we believe that these measures should be defined as high priority and promote physician activities to address inequities in care.

# Technical Updates- Removal of High Priority Bonus Points

#### **Recommendation:**

• The AMA continues to not support CMS's finalized policy that beginning in the CY 2022 performance period/2024 MIPS payment year to remove high priority bonus points.

In the 2024 MFS Proposed Rule, CMS seeks comment on its technical updates to revise § 414.1380(b)(1)(v)(A) to state that, beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive these measure bonus points for submitting high priority measures. The AMA does not support CMS's finalized policy to no longer provide bonus points for reporting additional high priority measures. Moving to high priority measures, such as outcome or health equity measures is an important goal, and physicians should continue to be recognized and compensated for this increased effort through bonus points.

# Quality Measure Inventory

We offer the following measure specific comments:

• Pregnant/Postpartum cardiovascular disease (CVD) risk assessment

This measure recently underwent review by the Consensus-Based Entity (CBE) and did not achieve endorsement due to concerns over the inadequacy of the evidence. Because this measure was not endorsed, we do not believe that it is appropriate to consider it for inclusion in MIPS.

• Prevention and Wellness Composite

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. The AMA also strongly opposes CMS's intention to remove the seven individual measures if this composite is implemented in MIPS. The individual measures address important preventive care activities, and the proposal would eliminate 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 cannot support inclusion of this measure in MIPS.

# • Connection to Community Service provider

While the AMA supports the intent of this measure, we do not believe that the implementation of this process measure at the individual clinician or group level in MIPS is appropriate, particularly due to the absence of any resources or tools that would be widely and readily available to clinicians and practices. Measures must be evidence-based and facilitate improvements in patient care. Unfortunately, the developer does not provide any evidence to support the five social needs, nor did they sufficiently justify the requirement to connect a patient with a community services provider on at least one need within 60 days. A recent article in *JAMA* specifically points out 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 authors also point out that screening for social risk vs. social needs requires different methods and in fact there is little overlap between social risk screening and social need screening. Social risk screening relies on validated screening measurement tools and social need screening queries whether a patient desires assistance. This measure does not make a distinction and is not supported by evidence.

At a minimum, the measure should align with the work of the HL 7 Gravity Project and the USCDI. In addition, the measure itself is not yet tested to demonstrate reliability and validity since only data for two screening tools (which are not required) were provided and most of the information outlined is based on CMMI's Accountable Health Communities project, which involved community health centers/health systems and therefore does not provide sufficient information on how this 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. Because we do not believe that this measure will result in effective change, we do not support its inclusion in MIPS or MVPs.

#### • Screening social drivers of health

The AMA continues to oppose inclusion of this measure in the program. We are dismayed to see that CMS continues to ignore these concerns and plans to incorporate it into multiple specialty sets. CMS has not made any attempt to address our concerns, which we outlined at length in our letter on the CY2023 proposed changes to this program, dated September 6, 2022. 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."<sup>37</sup>

At a minimum, we urge CMS to ensure that the measure is further specified to align with data standards such as the HL7 Gravity Project and USCDI, standardize which survey tools may be used, and determine that the specifications produce scores that are reliable and valid. In addition, it is imperative that CMS reduce the complexity of the measure and evaluate whether it has any demonstrated links to directly improving patient outcome without any unintended consequence of creating patient harm. Until these

<sup>&</sup>lt;sup>36</sup> 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

<sup>&</sup>lt;sup>37</sup> 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

concerns are addressed, this measure should not be included in the program, nor should it be incorporated into specialty sets or MVPs.

# • Gain in Patient Activation Measure

While we support measures that encourage physicians and practices to focus on ensuring that patients are equipped to manage their health and health care, we question whether this measure has been tested for reliability and validity at the individual clinician level. The data provided during the Measures Application Partnership (MAP) focused on the reliability and validity of the tool. In addition, the measure has not been reviewed for endorsement maintenance by the CBE for at least seven years. New data on performance, feasibility of data collection and reporting burden should be available, as well as testing information. Therefore, the measure must be re-evaluated for continued endorsement prior to inclusion of this measure in MIPS and placed within specialty measure sets.

# • Controlling High Blood Pressure

The AMA recommends further improving the usefulness of the controlling high blood pressure measure. An ongoing challenge is the lack of Medicare coverage for home blood pressure devices which is a barrier to improving control rates of Medicare beneficiaries. The AMA submitted a <u>request</u> to CMS asking for a benefit category determination so that the AMA can pursue national coverage determination. We recommend the following additional specific updates to the measure specifications:

- Revise the measure guidance to require the use of a validated blood pressure device. The revised measure guidance states that it is the responsibility of each clinician to confirm the automated blood pressure monitor or device used to measure blood pressure is acceptable and reliable. However, it provides no guidance on how to determine if a device is accurate and reliable. Rather it puts the onus on the clinician to research and identify what device to use in order to ensure clinically accurate data. AMA suggests that the measure only include blood pressure readings from devices on the United States Validated Device List (validateBP.org). 38
- Replace "device" with "remote monitoring device." AMA agrees that the measure should include both an 'automated blood pressure monitor' and "device" but suggests the word 'device' may be confusing. AMA suggests that "device" be replaced with "remote monitoring device."
- <u>Use average blood pressure rather than most recent readings</u>. Current clinical guidelines recommend that clinical decision-making be based upon the average of multiple blood pressure measurements, not single readings. Clinical quality measures should align to clinical guidelines. While AMA recognizes the complexities of switching to an average blood pressure, the USCDI now includes Average Blood Pressure as a data element in the latest version 4.<sup>39</sup>

<sup>&</sup>lt;sup>38</sup> Muntner P, Shimbo D, Carey RM, et al. Measurement of Blood Pressure in Humans: A Scientific Statement from the American Heart Association. Hypertension. 2019;73:e35–e66. https://doi.org/10.1161/HYP.0000000000000087

<sup>&</sup>lt;sup>39</sup> The Office of the National Coordinator for Health Information Technology. United States Core Data for Interoperability, Version 4. July 2023. <a href="https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi">https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi</a>. Accessed August 7, 2023.

• Lower the blood pressure threshold for the diagnosis of hypertension to 130/80. AMA recommends that the quality measure be consistent with current guidelines and scientific statements, which defines hypertension as systolic blood pressure of ≥130 mmHg or diastolic blood pressure of ≥80 mmHg.<sup>40</sup>

Cost Performance Category

# **Episode-Based Cost Measures**

#### **Recommendations:**

• The AMA opposes inclusion of the Psychoses and Related Conditions measure in MIPS due to concerns it could have a significant negative impact on the provision of mental health services to the most vulnerable patients. We also urge CMS to increase the case minimum for the Depression, Heart Failure, Low Back Pain, and Emergency Medicine measures to ensure the measures meet a high level of reliability at the group and individual level.

CMS is proposing to add the following five new episode-based cost measures with a 20-episode case minimum: Psychoses and Related Conditions, Depression, Heart Failure, Low Back Pain, and Emergency Medicine. CMS is also proposing to remove one episode-based cost measure – Simple Pneumonia with Hospitalization.

The AMA opposes the addition of the Psychoses and Related Conditions measure to MIPS. This measure evaluates the costs for patients hospitalized for schizophrenia, delusional disorders, brief psychotic disorder, schizoaffective disorder, manic episode with psychotic symptoms, bipolar disorder with psychotic symptoms, major depressive disorder with psychotic symptoms, or unspecific psychosis. CMS notes that it has selected this measure because psychoses-related hospitalizations are one of the most common inpatient stays, and therefore, the measure has the potential to be impactful on Medicare spending. The AMA does not believe that measure selection should be based on potential savings to Medicare without an understanding of whether savings can be derived by reducing avoidable services while maintaining or improving the quality of care.

To hold inpatient psychiatrists responsible for access to and timely follow-up for outpatient care for persons with psychotic disorders is not appropriate. Inpatient psychiatrists cannot be held accountable for addressing acute and chronic clinical needs of their patient in an environment where support for patients leaving the hospital is often inadequate. The acceptable scope of responsibility for the hospital physician is the development of an appropriate discharge plan with recommendations that are communicated in a timely way to the designated outpatient provider.

While inpatient psychiatrists do their best to treat patients in a way that will prevent rehospitalization, there is no recognition in the proposed measure that the inpatient psychiatrist rarely serves as the provider for follow up outpatient care. Traditional case management services often do not adequately meet the needs of individuals with severe mental illnesses who are transitioning from inpatient to outpatient care. Additional work, including consideration as to how accountability for this interaction can best be

attributed and measured, needs to be done to build on what we know now and identify best practices that can be effectively implemented. More research needs to be done to identify the components necessary to increase successful transitions and begin to make a meaningful impact on the cost of care.

We also believe the measure is at odds with CMS's proposals in this rule designed to expand patient access to behavioral health services, given the measure will negatively impact Medicare physician payment for psychiatrists. Notably, CMS is seeking comment on "how to increase psychiatrist participation in Medicare given their low rate of participation relative to other physician specialties." We believe the addition of this measure in MIPS will have the undesired effect of creating a disincentive for psychiatrists to participate in Medicare. For these reasons, we oppose inclusion of the Psychoses and Related Conditions cost measure in MIPS.

The AMA also urges CMS to increase the case minimum for the Depression, Heart Failure, Low Back Pain, and Emergency Medicine measures to ensure the measures meet a high level of reliability at the group and individual level. We continue to believe that physician performance on any administrative claims measure should not be used for payment or be publicly reported unless a minimum reliability of 0.80 can be demonstrated AND the risk adjustment model is developed, tested, and released for comment prior to implementation with social risk factors adequately addressed in the model. Testing must involve the individual and group level, including various sizes of groups. Statisticians and researchers generally believe coefficients at or above 0.80 are considered sufficiently reliable to make decisions about individuals based on their observed scores, although a higher value, perhaps 0.90, is preferred if the decisions have significant consequences.<sup>41</sup>

Based on Table 44 in the rule, the mean reliability for the Emergency Medicine measure at the individual level, as well as the Heart Failure and Low Back Pain measures at the group and individual level do not meet this reliability standard, on average. Worse, for the Depression, Heart Failure, and Low Back Pain measure, less than 100 percent of groups and individuals meet CMS's low reliability threshold of 0.4. In the case of the Heart Failure measure, as few as 87 percent of individuals meet this bare minimum threshold. This limited information calls into serious question the reliability of these four measures. We strongly urge the agency to increase the case minimums for these cost measures and to release more detailed reliability testing data.

# Total Per Capita Cost Measure

#### **Recommendation:**

• The AMA strongly urges CMS to remove the Total Per Capital Cost (TPCC) measure from MIPS as part of its comprehensive reevaluation of the measure. At a minimum, TPCC should be removed from all MIPS Value Pathways (MVPs).

As the AMA provided in our comments regarding reevaluation of the TPCC measure, we strongly urge CMS to remove this measure from MIPS. Measures should only cover costs that physicians can reasonably control. TPCC cannot meet that criterion because it holds physicians accountable for patients'

<sup>&</sup>lt;sup>41</sup> See e.g., Webb, Noreen, et al. *Reliability Coefficients and Generalizability Theory*. Handbook of Statistics, Vol. 26. 2006 Elsevier B.V. DOI: 10.1016/S0169-7161(06)26004-8. http://web.stanford.edu/dept/SUSE/SEAL/Reports\_Papers/ReliabCoefsGTheoryHdbk.pdf and Del, Siegle. Instrument Reliability. Educational Research Basics. University of Connecticut. Accessed 06/13/2016. http://researchbasics.education.uconn.edu/instrument\_reliability/.

medical conditions that are managed outside of their organization and for costs they cannot influence, such as drug prices. If CMS does not remove TPCC, CMS must address the attribution, exclusions, and double counting concerns raised in the following sections. Furthermore, we strongly believe that TPCC should not be included in any MVPs, but especially not in those MVPs with episode-based cost measures (e.g., Optimal Care for Kidney Health MVP, Advancing Care for Heart Disease MVP, Value in Primary Care MVP).

# Relevance

In the 2020 MFS proposed and final rules, CMS considered removing the TPCC measure from the program and not replacing it with the revised version. However, CMS decided against removal and explained its decision as follows: "we developed and implemented only a handful of episode-based measures at this time, [so] a substantial proportion of clinicians would be left with only the Medicare Spending Per Beneficiary (MSPB) clinician measure for the cost performance category. Because fewer than half of all clinicians in MIPS meet the case minimum for the MSPB clinician measure, and no other measure addresses the costs of primary care, we stated that we believe it is appropriate to use the best version of the total per capita cost measure available to us."

The AMA strongly urges CMS to revisit whether TPCC is necessary, and we strongly believe that it is not based on CMS's own rationale from 2020 rulemaking. Unlike in 2020, there are now 23 episode-based MIPS cost measures currently in use and many more in the development pipeline. Many of these measures address the costs of primary care. In fact, in the Chronic Condition Episode-Based Cost Measures Attribution Methodology FAQ document, CMS provides the top five specialties for each of the 10 chronic condition episode-based cost measures developed to date. Of the 10 measures, internal medicine is in the top five for all. In addition, family practice is in the top five for seven of the 10 measures. Further, including the Wave 4 episode-based cost measures, which CMS is proposing to include in MIPS in this rule, episode-based cost measures now account for 36.8 percent of all Medicare Parts A and B spending.

Furthermore, we believe it is inappropriate to put measuring the largest number of physicians in the Cost Performance Category above getting the measures and methodology right. We are pursuing legislative refinements to MACRA that would give CMS more flexibility to develop and use cost measures without an arbitrary target of Medicare Part A and Part B expenditures and to score cross-category measures. We hope the agency will work with the AMA and Congress to seek this authority so CMS can prioritize actionable measures with a demonstrated need for improvement and that measure cost within the context of quality.

# Use of Current Procedural Terminology® (CPT®)

CPT, Fourth Edition, is a listing of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians and other qualified health care professionals. It is the most widely accepted nomenclature for the reporting of physician and other qualified health care professional procedures and services under government and private health insurance programs and is actively updated numerous times per year to keep pace with evolutions in medicine. Category I code updates become effective on January 1 of each year. Many of the measures included in the MIPS cost measures incorporate CPT codes in their definitions. It is essential that CMS's measure specifications use the applicable CPT code set to ensure that the appropriate base and measurement data are selected for the specific timeframes.

The AMA reviewed the coding specifications currently posted to the QPP website for 2023 and found that the coding specifications for the TPCC have not been updated since 2020. The Evaluation & Management (E/M) section of the CPT code set underwent a major update in 2021, resulting in changes to the Office & Other Outpatient visit codes. In 2023, other code ranges were updated as well, including the Inpatient & Observation codes, Nursing Facility codes, and Emergency Medicine codes to name a few. These changes are on top of the usual yearly addition/revision/deletion of codes throughout the set.

The CPT coding specifications for TPCC have not been updated since 2020 and do not align with the CPT codes for the current year (2023). The AMA is concerned that the outdated measure specifications will significantly impact the reliability and validity of the measures, and lead to inaccurate measure results and unintended consequences for physicians and physician groups. The AMA strongly recommends that the TPCC measure not be utilized to evaluate physicians on cost performance in the MIPS program at least until these issues are resolved. The AMA recommends that CMS implement processes to review and update all coding specifications for these measures annually to ensure that the specifications align with the most current coding conventions available.

# Monthly Benchmarking

It is only with the release of the 2022 cost measure benchmarks that it became apparent to the AMA that the revised TPCC measure is using a monthly, or four-week, benchmark period evaluating cost performance. We have questions and concerns about this approach that we feel were not properly vetted during the reevaluation and review period because this change was not readily apparent to interested parties, including the members of the technical expert panel, as well as measure endorsers. We believe that this change to a monthly reporting period compromises the validity of this measure. For example, we do not believe CMS has adequately tested a monthly risk adjustment methodology, nor do we believe that a monthly cost assessment meets face validity. Therefore, we request CMS examine the impact of this shift on the overall variation of the costs and consider to what extent are those differences due to scenarios such as a new vs. established patient in the practice or seasonality of patient visits (e.g., snowbirds)? In addition, services and related spending for certain chronic conditions are likely distributed over several months, or longer, while service utilization and spending for acute conditions will be concentrated in one month. Are physicians who see patients with multiple chronic conditions fairly and accurately measured against physicians who see patients for acute conditions and vice versa? Further, we are concerned that a physician who is attributed six months of care could be disadvantaged compared to a physician who is able to spread the cost of care across all twelve months.

We are also alarmed about the lack of any meaning between a monthly TPCC measure and current quality measures. There are no quality measures reported by monthly rates since they would not be clinically meaningful, so while there might have been some use to an annual TPCC measure, we believe that this revised monthly TPCC measure has lost any relevance or ability to be aligned to quality. For a diabetes patient, what does one month of total per capita cost tell us? Does CMS plan to develop and require reporting monthly quality measures? How does CMS currently represent and explain the difference in reporting periods for quality vs cost to physicians?

# Revised TPCC Attribution Methodology

In 2020, the TPCC attribution methodology was significantly revised. The revised TPCC eliminates the problem of attributing costs that occurred before the physician ever saw the patient; the AMA agrees that physicians should not be held responsible for such services. However, we have concerns about other aspects of the revised attribution approach. The revised attribution methodology assumes that a primary

care relationship exists if two things happen within three days or three months, and not otherwise. This will lead to new problems as identified in the following examples:

- If a patient is getting cataract surgery or knee surgery, the surgery center will generally require the patient to be cleared for surgery by a primary care physician. The patient will find a primary care physician to examine them, the physician will likely order an electrocardiogram (EKG), and under the new TPCC measure, it appears that the physician will be accountable for everything that happens to the patient over the next 12 months, including the cataract surgery or knee surgery that was the only reason they came to see the physician in the first place. The revised measure could cause primary care physicians to refuse to do pre-surgical clearance visits on new patients in order to avoiding having the surgery patients appear on his or her attribution list.
- If a new patient comes to see a primary care physician, and the patient has multiple chronic conditions or health problems, the revised measure will give the physician an undesirable disincentive to schedule follow up visits within three months, so the patient and their costs are not attributed to the physician.
- On the other hand, new patients who are healthy or whose health problems are appropriately managed and who do not need to come back to see the primary care physician for six months or one year would not be attributed to that physician. The low costs would not be reflected in the primary care physician's TPCC average, making it appear higher than reality. In that case, the primary care physician would need to order an EKG or other test simply to trigger attribution.

Another significant problem with the revised methodology is that it does not identify the end of a clinician's primary care responsibility for a patient. TPCC assigns responsibility for all Medicare Part A and B costs for 12 months after attribution. However, because CMS is aware that Medicare beneficiaries switch physicians or move to new states, the revised measure adopted a workaround that attributes the same patients and overlapping costs to multiple clinicians in different practices if they meet the attribution criteria. To illustrate the problems with this change, under the previous measure, when a patient switches to a new primary care physician, the patient's new doctor may be held responsible for things that happened before he or she took over, but once the patient starts seeing a different doctor, the patient will be attributed to the new doctor. Under the revised measure, both physicians will be held responsible for services and procedures that happen after the patient switches to another physician. In another example, a beneficiary travels to a different city, experiences a health problem and visits a new primary care physician, who runs a laboratory test and determines the beneficiary is fine. The beneficiary returns home, but the new physician is now responsible for all spending for this beneficiary for the next year, even though the beneficiary does not even live in the community.

The AMA does not believe physicians should be held responsible for costs that occurred long after they saw the patient and potentially after the patient has moved to another city or state. Also, we do not support attribution of the same costs to multiple physicians in different practices when there is no evidence that they are practicing as a team. We have concerns about the impact of spreading accountability so widely, which CMS believes will improve care coordination. Yet this assumes data regarding services provided by other physicians is readily available and therefore actionable by the attributed physician. CMS does not provide this information, and it would be next to impossible to track patients and make value-enhancing changes in their care because the revised attribution methodology relies on a lengthy list of services, including services provided by a separate physician practice. If CMS

continues using a TPCC measure, the attribution methodology should be changed to eliminate the problems created by adding 12 months of prospective accountability for multiple physicians.

# Measure Exclusions

In addition, we have concerns about the equity of the revised TPCC measure. We question the decision to make exclusions at the specialty level and not at the service level. While certain specialties would be excluded from this measure, the services they provide would not be excluded. Therefore, a practice comprised of excluded specialists might still be subject to the measure if it also uses a physician assistant or nurse practitioner who provides an E/M visit and another primary care service. This will make it hard to determine which practices are likely to be subject to the TPCC measure. It also creates a fairness issue by excluding certain specialties regarded as not providing primary care, but it then holds primary care physicians responsible for the costs of these non-primary-care services that they do not provide and cannot control.

## Apples-to-Oranges Comparison

A recent study<sup>42</sup> published in *JCO Oncology Practice* found that oncologists scored poorly on cost measures compared with other specialties in 2018 when the Cost Performance Category made up a relatively small portion of the overall MIPS score. Now that the Cost Performance Category comprises 30 percent of the final score, oncologists may face up to a four-fold increase in magnitude of penalties. We are concerned that neither the TPCC nor the MSPB Clinician measures fully account for the variation in costs in the standard-of-care medicine by specialty and urge CMS and Acumen, LLC, to consider whether specialty-specific recalibration is needed to prevent disparate payment penalties by specialty. Currently, we believe CMS is conducting an apples-to-oranges comparison.

# **Double Counting of the Same Costs**

We are also concerned that TPCC and MSPB clinician double count costs when physicians are measured on episode-based cost measures. The use of total cost of care measures incorporates many of the same costs used to construct the MSPB clinician measure and the episode cost measures. A patient's total cost could be attributed to one physician, a subset of those same costs could be included in the MSPB clinician and attributed to another physician(s), and another subset of the total costs could be attributed to multiple physicians for the episode cost measures.

One concern is that the various attribution methods could provide mixed signals to physicians as to who is actually in charge of delivering efficient care. This problem is exacerbated by the fact that many of these clinicians may be unaffiliated and thus there is no real way for physicians to actually coordinate. The delay in providing physicians with lists of attributed patients also stifles real-time coordination. We believe the extent of the problem is likely to vary with the number of measures in a physician's MIPS cost score. We urge CMS to include information about the extent of this overlap such as the distribution of the number of cost measures attributed to each TIN and TIN/NPI in its annual experience report.

CMS does not believe costs are double counted because each measure is compared to expected costs for its own beneficiaries or episodes. However, the observed costs are still being counted multiple times within different frameworks and with different benchmarks and comparison groups. Therefore, we

<sup>&</sup>lt;sup>42</sup> DOI: 10.1200/OP.22.00858 JCO Oncology Practice 19, no. 7 (July 01, 2023) 473-483.

request that CMS elaborate on how different comparison groups and benchmarks under different measures address the issue of double counting costs and demonstrate that CMS can analyze the overlap between the revised TPCC and MSPB clinician measures and the episode measures.

# Lack of Alignment with Attribution Models

CMS must address the lack of alignment of the attribution models utilized for the various administrative claims measures used for the MIPS population health quality measures and costs measures, such as Hospital-wide Readmissions (HWR), Multiple Chronic Conditions and TPCC. Based on the proposed changes to attribution in many of these measures to hold more than one physician accountable and/or leverage different approaches (e.g., plurality of charges vs. plurality of visits), physicians and practices will have different patients assigned to them for different measures. This lack of consistency across measures will further decrease a physician's ability to drive improvements in care. The lack of a cohesive approach on attribution across one program is not sustainable and must be addressed to create a system that promotes and facilitates improvements to patients in a way that is also meaningful and actionable by physicians.

CMS must address the lack of alignment of the attribution models utilized for the various administrative claims measures used for the MIPS population health quality measures and costs measures, such as HWR and TPCC. Based on the proposed changes to attribution in many of these measures, they now hold more than one physician accountable and/or leverage different approaches (e.g., plurality of charges vs. plurality of visits).

# **Cost Improvement Scoring**

### **Recommendation:**

• The AMA recommends that CMS phase-in improvement scoring and modify the methodology, so it is more intuitive for MIPS eligible clinicians.

CMS is proposing to calculate the improvement score for the cost performance category at the category level, as opposed to the individual measure level, and without statistical significance. CMS is also proposing a maximum improvement score of zero points for the 2022 performance period and one point beginning with the 2023 performance period. The AMA appreciates that CMS is taking a thoughtful approach to implementing improvement scoring in the cost performance category, and we urge the agency to gradually increase the maximum improvement score beyond the proposed one point.

We recognize that the cost measures were reweighted to zero from 2019-2021 due to the COVID-19 PHE, and MIPS eligible clinicians had the option to apply to reweight the cost performance category to zero in 2022 and 2023, as well. This category has faced the most significant disruptions due to the pandemic and physicians have little information about how they are performing on cost measures, which unlike most other MIPS measures and activities, are calculated by CMS on the backend using claims data. It may therefore not be feasible for many physicians to see any year-to-year comparisons in their cost performance data for several more years. However, we do believe that the improvement scoring should increase as the maturity of this category continues. Improvement scoring is an important component of many APMs, and we believe that MIPS should also reward improvement, as well as annual performance. However, there are many advantages to participation in APMs that do not exist in MIPS, such as incentive payments and waivers, so we believe that improvement scoring should only ever be added to performance scoring and not a separate benchmark.

Furthermore, CMS is proposing the cost improvement score is determined as follows: ((change between current and previous year performance score) / 100. We have heard that the final step of this equation, dividing by 100, has caused confusion. We believe a more straightforward approach would be to multiply the ((change between current and previous year performance scores / previous year performance score)) by the maximum percentage available for cost improvement scoring (e.g., one percent as proposed). We believe this would be consistent with the formula used for quality improvement scoring, which will further reduce confusion. This is also consistent with CMS's "description of previously finalized cost improvement scoring methodology," which provides: "we established that we would quantify the cost improvement score by subtracting the number of cost measures with a significant decline from the number of cost measures with a significant improvement, and then dividing the result by the number of cost measures for which the MIPS eligible clinician or group was scored for two consecutive performance periods, and then multiply the resulting fraction by the maximum improvement score" (emphasis added).

Improvement Activities (IA) Category

### Changes to IA Inventory

### **Recommendation:**

• CMS should finalize its proposed addition of five proposed new improvement activities and expand the quality improvement plan activity to traditional MIPS reporters in addition to MVP reporters and make it worth full credit towards the IA category. Retain and broaden IA #29 Consulting Appropriate Use Criteria (AUC) Using Clinical Decision Support (CDS) when Ordering Advanced Diagnostic Imaging.

The AMA supports CMS's proposed five new improvement activities, which we agree generally help to fill existing gaps in clinical practice areas for vulnerable patient communities, including Human Immunodeficiency Virus prevention, clinical decision support for cervical cancer screening, and behavioral/mental health and substance use screening and referrals for pregnant and post-partum women and older adults.

We also strongly support adding an activity for developing a quality improvement plan, which creates synergy between the quality and improvement activity categories, something the AMA has called for in the past, and serves as a bridge to participation in APMs. Given its significance, we believe that this activity should be worth full credit towards the IA category, similar to participating in an APM.

Additionally, while we appreciate wanting to incentivize practices to move to MVPs, we believe clinicians reporting traditional MIPS should also be eligible for this improvement activity because incentivizing quality improvement is important for all practices. Particularly as MVPs are still new and not yet available for all specialties or patient populations, we believe it is important that these practices and patient populations are not systematically excluded.

The AMA urges CMS to reverse its proposal to remove IA #29 Consulting AUC Using CDS when Ordering Advanced Diagnostic Imaging and instead broaden it to include consulting with AUC through CDS mechanisms (CDSMs) or other mechanisms as appropriate. While we appreciate that the mandatory AUC CDS program is proposed to be indefinitely delayed, consultation of AUC outside of that flawed program can be valuable and several CDSMs are already in use by physicians and other health care professionals. It is also important to recognize that clinicians can consult AUC using mechanisms other than a CDSM. Accordingly, the AMA recommends that this IA provide flexibility for the consultation of

physician-developed, evidence-based, and transparent AUC or advanced diagnostic imaging guidelines using a mechanism best suited for their practice, specialty, and workflow. In addition to modifying the activity to allow eligible clinicians to consult AUC using a mechanism of their choosing, both ordering and furnishing clinicians should be eligible to report the activity.

Awarding IA Credit for those Reporting through the APM Performance Pathway (APP)

### **Recommendation:**

• CMS should replace its current proposal to require data from at least two MIPS performance categories other than IA or attest to having completed one improvement activity in order to receive baseline credit towards the IA category for MIPS eligible clinicians reporting through the APP with the following: in cases where MIPS eligible clinicians reporting through the APP request a hardship exception and data is received for at least one MIPS performance category other than IA (not two), CMS should apply the IA baseline score and calculate a final MIPS performance score and apply it only if it would exceed the neutral score that would otherwise be achieved through the hardship exception.

The AMA appreciates CMS's desire not to cause unintended or unexpected scoring outcomes in cases where a hardship exception is approved. However, we believe this can be easily accomplished without increasing reporting burden for MIPS eligible clinicians in APMs, which is what would directly result from CMS's proposal to require data from at least two MIPS performance categories other than IA or attest to having completed one improvement activity in order to receive baseline credit towards the IA category for MIPS eligible clinicians reporting through the APP.

CMS states in the rule that prior rulemaking has "led to an interpretation by some... that the baseline score represents credit that is automatically applied in all circumstances." The agency states this was "not how [they] intended this provision to function," and they wish to "ensure that [their] rules do not automatically grant such 'credit." However, CMS's <u>APP webpage</u> overtly states that MIPS eligible clinicians reporting through the APP "automatically (emphasis added) receive 100 percent for the improvement activities performance category score" and that "no additional reporting is required," so it appears that this proposal does indeed represent a clear departure from current CMS guidance.

Participating in an APM requires substantial investment in resources and clinician and staff time and MIPS APMs represent an important bridge to participation in risk-bearing models. CMS has made it clear it wants more physicians to participate in APMs so it should be strengthening and expanding this bridge by broadening the incentives for MSSP participants to participate in MIPS through the APP, not restricting the few advantages that remain, including maintaining its current policy of automatically receiving baseline credit towards the IA category without requiring additional reporting. The clinicians participating in MIPS APMs are already doing the heavy lifting by participating in the APM, attesting to this in order to receive credit that is already awarded to them is an unnecessary burden in the name of resolving a technical issue that could easily be addressed by simply awarding the IA credit and applying the higher of the MIPS score calculated from data received, or the neutral score applied under the hardship exception.

Moreover, we have serious concerns that this policy change would be confusing to MSSP participating physicians, particularly as many resume MIPS reporting for the first time following the pandemic. We

fear physician practices may not all be aware of this change, resulting in unnecessarily low scores that they earned by participating in an APM.

Lastly, CMS established under prior rulemaking that in order to receive a MIPS composite score, it must have MIPS data from at least two categories, not three, so it is unclear why CMS would now require data from two MIPS categories in addition to IA under this proposal, rather than one.

Accordingly, we strongly recommend CMS abandon this proposal and replace it with our above recommendation which addresses CMS's concern about unintended or unexpected scores when APP reporters are approved for a hardship exception in a way that does not impose unnecessary burden and maintains current incentives for physicians participating in MIPS APMs.

Promoting Interoperability Category

### **Recommendation:**

• The AMA strongly disagrees with CMS's proposal to require a 180-day Promoting Interoperability performance period and urges CMS to retain the current 90-day period.

CMS is proposing to double the performance period for the Promoting Interoperability performance category (PI) to a minimum 180 days within CY 2024. CMS states that reporting on additional data during a longer performance period would provide physicians the opportunity to continuously monitor their performance, identify gaps in their reporting, and recognize areas that may require their investigation and corrective action. CMS believes that requiring physicians to report additional data during a longer performance period will encourage physicians to produce more data demonstrating that they are meaningful users of CEHRT. CMS also believes that physicians may not be focusing on using CEHRT throughout the year which could threaten patient safety. Lastly, CMS states its long-term goal for PI is to ensure the meaningful use of CEHRT and information exchange throughout the year, for all data, all clinicians, and all patients.

The AMA does not support CMS's proposal to double the PI performance period for CY 2024. CMS claims that physicians are not meaningfully using electronic health record (EHR) technology, that physicians are incapable of improving without government oversight, and that more administrative tasks will keep patients safe from harm. While doubling the EHR reporting requirements on physicians may seem superficial, CMS's reasoning to do so, and the seeming distrust of physicians, is concerning. CMS's accusations not only come without proof, but also run contrary to other strongly held policies by the Biden Administration—namely, the Administration's vocal opposition to government interference in medicine.

Physicians, above all else, strive to do what is best for their patients. The AMA, its members, along with physicians and medical professionals across the country, hold strong convictions to always put their patient first. After nearly three years of battling the twin pandemics of COVID-19 and medical misinformation, physicians are facing unprecedented attacks and interference by policymakers, inflaming the physician burnout crisis. While the AMA has clearly stated that all options should be on the table to address this crisis, CMS's PI proposals seemingly turn a blind eye to our appeal. Without justification or reason, CMS is proposing that physicians 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 EHR use.

The U.S. Agency for Healthcare Research and Quality (AHRQ) states 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. In a survey of 400 physician practices, 76 percent of respondents felt that MIPS is very or extremely burdensome, and 87 percent reported that MIPS payment adjustments do not cover the cost of time and resources needed for program participation. HERR burden also continues to increase. Half of physician time is spent in the EHR, 37 percent of physician/patient time is spent on nonclinical tasks, and physicians spend two hours of extra work outside the clinic.

Yet, CMS's PI proposals ignore these findings and will double the administrative and EHR requirements on physicians. The AMA reiterates that CMS's 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. As of 2021, nearly 9 in 10 U.S. office-based physicians use EHRs. 46 In terms of hourly use, throughout the course of a full year, physicians spend an average of six hours in their EHR during a 12-hour workday. 47 On average, primary care physicians spend almost an hour in their inbox alone. 48 While we should be shocked to learn so much clinical time is spent clicking boxes and searching for information, the AMA is unaware of any data that shows physicians' EHR use fluctuates during the course of a 365-day year. CMS' belief that physicians lack "focus," and that physicians need the government to tell them how to use their EHR, is condescending.

The fact is, EHR overuse is a major factor in skyrocketing physician burnout.<sup>49</sup> Physicians are struggling to meet productivity demands, rushing in and out of exam rooms, and working late into the evening to finish EHR documentation. This epidemic affects both physicians and patients and is a condition that impacts all specialties and all practice settings.

Burnout is often associated with increasing administrative responsibility due to regulatory pressures. This can lead to a reduction in the amount of time physicians spend delivering direct patient care. When a physician is burned out, it can have a significant impact on organizational productivity, morale, costs, and the quality of care. To be sure, physician burnout can itself impact patient safety. Increasing EHR use may increase patient harm, rather than reduce it. It is a falsehood to believe that expanding physicians' EHR demonstration requirements will reduce patient harm—CMS's belief is neither backed by data nor evidence.

AHRQ states that "burned-out doctors are more likely to leave practice, which reduces patients' access to and continuity of care." Research also shows that MIPS can have a disproportionately negative association with certain practices, including those that are small, rural, independent, or serve a

<sup>43</sup> https://www.ahrq.gov/prevention/clinician/ahrq-works/burnout/index.html

<sup>44</sup> https://www.mgma.com/getkaiasset/38def981-0286-4fe1-979b-731e1e308ca7/10.29.2019 MGMA-Annual-Regulatory-Burden-Report-Final.pdf

<sup>45</sup> https://www.ama-assn.org/system/files/steps-forward-taming-ehr-playbook.pdf

<sup>46</sup> https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption

<sup>47</sup> https://www.annfammed.org/content/15/5/419.full

<sup>48</sup> https://academic.oup.com/jamia/article/28/5/923/5924604?login=true#237820738

<sup>49</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9685483/

<sup>&</sup>lt;sup>50</sup> https://www.ahrq.gov/prevention/clinician/ahrq-works/burnout/index.html

high proportion of patients with low-income.<sup>51</sup> 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, means the changes become overwhelming. As a result, clinicians will experience cognitive overload and burnout. Again, the AMA expresses significant concern with CMS's PI proposals that would double the administrative and EHR reporting requirements on physicians. The AMA strongly urges CMS to continue with a 90-day PI performance period.

#### **Recommendation:**

• The AMA recommends CMS work with the Office of the National Coordinator for Health Information Technology (ONC) to update the Safety Assurance Factors for EHR Resilience Guides prior to making their use a requirement of PI participation.

The AMA agrees that implementing safety practices for EHR use is important. However, prior to requiring the use of the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides), the SAFER Guides should be updated to meet the needs of today's physicians. The SAFER Guides have not gone through a comprehensive review and update process since 2016—calling into question whether their content remains relevant. In fact, many of the citations and data points referenced in the SAFER Guides point to research conducted in 2012 and 2014. EHR technology has increased in complexity and functionality in the past 10 years.

The SAFER Guides also fail to contemplate a myriad of new technologies used across medical specialties and practices of all sizes. For example, the High Priority Practices SAFER Guide does not mention telehealth technology which, in 2023, is often embedded within the physician's EHR environment. The use of telehealth broadly expanded throughout the COVID-19 PHE to ensure uninterrupted care for patients, including those with chronic conditions. The SAFER Guides also lack details about patient data privacy. Physicians would benefit from information on the safe and effective use of their EHRs to share sensitive health information with appropriate protections. Likewise, there is a significant increase in capturing social determinants of health, sexual orientation and gender identity, and race and ethnicity data in EHRs. The AMA views the safe and effective capture and use of these data as a high priority. At the very least, the High Priority Practices SAFER Guide should be updated to reflect EHR safety practices when using these data.

Given these considerations, the AMA does not support CMS's proposal to require physicians to use the High Priority Practices SAFER Guide until they are updated to reflect changes in EHR technology and data capture that has occurred over the past 10 years. CMS should work with ONC to engage in an update of the guides, informed by stakeholder input, and undertake an education and awareness campaign to disseminate information to the field, including information tailored to small and medium-sized physician practices.

<sup>&</sup>lt;sup>51</sup> https://jamanetwork.com/journals/jama-health-forum/fullarticle/2779947

### **D.** Public Reporting- Compare Tools

Utilization Data

#### **Recommendation:**

• The AMA supports CMS's proposal to add Medicare Advantage procedure data to procedure counts.

In the AMA's 2023 MFS Proposed Rule comments, the AMA highlighted our concern with posting utilization data that was only limited to traditional Medicare given it would provide an incomplete and potentially inaccurate picture of the services each physician performs. We are glad to see CMS recognize our concerns in the 2024 MFS Proposed Rule and propose to expand the available data to include Medicare Advantage. We urge CMS to continue exploring expanding the available data sets to include Medicaid, Veteran Affairs, and private payors to provide a more accurate representation of the procedures physicians perform.

Request for Information: Publicly Reporting Cost Measures

CMS is seeking comments regarding ways to publicly report cost performance information on clinician and group profile pages beginning with data from the 2024 performance period, which would be publicly reported in 2026. Twenty-five cost measures could be available for public reporting – 23 episode-based cost measures (EBCMs), Total Per Capita Cost (TPCC), and Medicare Spending Per Beneficiary (MSPB) clinician measure. Among other things, CMS is interested in feedback about potential approaches to reporting MIPS cost measures, including whether it is more meaningful to only report aggregated episodes or include component-level cost information for the EBCMs and benchmarking and possible comparators, as well as how to best present this information to provide frames of reference for the cost performance information. For example, while higher than expected costs may be driven by adverse outcomes, overall cost is comprised of care components that consumers could perceive as higher quality (e.g., follow-up visits) as well as lower quality (e.g., re-hospitalizations).

Before we address CMS's specific questions, we wish to note the difficulty of providing CMS with detailed feedback about how best to publicly report cost measures as CMS itself has provided very little information about the current cost measures. The cost performance category is unique in that all the data is calculated on the back end by CMS using claims; nothing is reported by eligible clinicians. This means that physicians are reliant on CMS to share timely, actionable information about their performance. Yet, no cost measure information has been made available since the 2019 performance period due to reweighting the cost performance category to zero percent of the final score in 2020 and 2021 due to the COVID-19 PHE. Since then, 15 new EBCMs and the revised TPCC and MSPB measures have entered the program. Yet we do not have a sense of the drivers of high and poor performance on those measures.

Worse, despite the fact that the cost performance category accounted for 15 percent of the final score in 2019 and there were 10 cost measures, there is almost no information about this category in the 2019 QPP Experience Report. The only information that CMS made available is about how the cost measures were calculated, but this is superfluous as all cost measures are calculated using claims data. We do not know how many eligible clinicians or groups were scored on the cost measures, how many patients were attributed to each clinician or group, how far the scores deviated from the mean or median, whether performance largely hovered around the mean or was spread across the 10 deciles, and so on.

Therefore, the AMA urges CMS to include detailed cost measure information in the 2022 QPP Experience Report and to host a Town Hall or solicit feedback in another informal format following the release of the 2022 QPP Experience Report. This would allow interested parties, including MIPS eligible clinicians, to provide informed input about the ways in which CMS should publicly report cost measures for patients and their caregivers.

• How can CMS present MIPS cost measures information in a way that reflects meaningful outcomes to patients and their caregivers and the value of care, rather than cost alone?

**First, the AMA strongly opposes publicly reporting the TPCC measure.** As detailed earlier in this letter, the AMA has significant concerns with this measure and does not believe it should be used in the program. Notably, the TPCC measure is now using a monthly benchmark, which we believe removes any ability to align with quality measures, which use an annual or longer benchmark. In addition, a recent study<sup>52</sup> published in *JCO Oncology Practice* found that oncologists scored poorly on cost measures compared with other specialties in 2018. We are concerned that TPCC does not fully account for the variation in costs in the standard-of-care medicine by specialty.

Second, we firmly believe CMS should only publicly report cost measures that have at least one companion quality measure to contextualize the information for patients and their caregivers. The agency believes it cannot support a display of cost alongside quality measures because physicians may report quality measures that are clinically unrelated to the clinician's cost measures and because group-reported quality measures cannot be disaggregated to the clinician level. Rather than use these limitations as an excuse for not publicly reporting cost information alongside quality information for patients, we urge CMS to amend its approach so that only cost measures with a companion quality measure are reported. We believe it is preferable to see fewer individual clinicians with publicly reported cost measures at the outset than risk the confusion it would cause patients to see cost measure information outside of the context of accompanying quality information. CMS itself states that patients often misinterpret higher cost information as meaning higher overall quality of care. The agency should not perpetuate this misconception by providing cost information absent quality measures.

• What are the considerations for publicly reporting the total episodic cost, component level costs, or both? Do the component costs provide adequate context for patients and their caregivers to make informed health care decisions? What other specific information about MIPS cost measures, including the context of quality measures and MVPs, should we consider including on the Compare tool?

As discussed in response to CMS's RFI on Promoting Continuous Improvement in MIPS, we believe CMS should revise the quality and cost measure benchmarking scoring approach and methodology prior to publicly reporting cost measure information. There has been a lack of consideration of MIPS program policies and methodologies and the intersection with Care Compare (formerly Physician Compare), as well as a lack of solicitation for feedback and comment on the issue. The AMA first highlighted the policy disconnect in our 2017 MFS Interim Final Rule comments and have since repeatedly highlighted our concerns with the MIPS benchmarking methodology during the yearly MPS comment period.

Our primary concerns related to the MIPS benchmark methodology are as follows:

 $<sup>^{52}</sup>$  DOI: 10.1200/OP.22.00858 {\it JCO Oncology Practice}\ 19, no. 7 (July 01, 2023) 473-483.

- For topped-out or highly skewed data, thresholds are clustered close together (meaning that similar performance may not result in similar points awarded) and even relatively high performance can place a physician in one of the lower deciles. For example, a physician could score 88 percent and be in the 4th decile while another physician scores 92 percent and is in the 8th percentile. Therefore, on the same measure two physicians can perform very similarly on the measure but be awarded very different points. There is a lack of consideration of the role played by random fluctuation, especially for small denominators.
- Strictly data-driven thresholds may conflict with clinical knowledge and evidence of ideal performance or with practical considerations of quality.

These concerns are further exacerbated when applied to the measures in the Cost Category as the distribution across the deciles assumes that lower costs in the absence of any evaluation of the quality of care is better. We fundamentally disagree with this premise and also question the usefulness of this decile approach when cost differentials are less than \$100.

Therefore, we urge CMS to revise the benchmark methodologies to allow measure thresholds to incorporate clinical knowledge, consider the impact of random fluctuation, and be adjusted for practical considerations of comparison and relative performance. To address the shortcomings of the existing benchmark methodologies, we suggest that CMS implement a methodology that allows for manual manipulation of thresholds. We acknowledge that this would add process to an already complex method, but we believe that what is most important is ensuring the fairness and clinical relevance of the measure benchmarks. We further acknowledge that there may be modifications to the methodology other than what we suggest which may also address our concerns and welcome the opportunity to discuss further with CMS.

• What are the considerations for publicly reporting the national average cost, ratio of cost to the national average cost, and/or the dollar cost per episode as possible benchmarks for comparison discussed above in this section? What other benchmarks or comparator approaches should we consider?

CMS has operated Care Compare in a silo and often proposes and finalizes methodological changes through sub-regulatory comments and webinars. Currently, there are now multiple programs by which CMS attempts to rank and compare the quality-of-care physicians provide. Specifically, MIPS involves awarding points to physicians based on where they fall in decile-based categories calculated from historical quality measure data (when available). Notably, this methodology differs from CMS's Care Compare star rating public reporting program. Care Compare uses the Achievable Benchmarks of Care (ABC) methodology to place physicians into one of five categories (each with a corresponding "star rating") for purposes of helping patients compare physicians to make more informed decisions about where they seek care. In contrast, the MIPS methodology uses nine categories (and point system) to score physicians on quality measure reporting to determine whether a physician will be subject to a MIPS penalty or eligible for an incentive. As a result, through our examination, the two methodologies (MIPS and 5-star) result in inconsistent ratings and comparisons.

We urge CMS to avoid this problem by using a single methodology to publicly report cost information. As discussed above, we urge CMS to amend the cost measure benchmark methodology prior to reporting these measures on Care Compare. Any additional information, such as the national

average cost, ratio of cost to the national average cost, or the dollar cost per episode, should be considered supplemental and explanatory.

 We request comment on additional information that we may not have considered or discussed above about publicly reporting MIPS cost measures, as well as any unintended impacts and/or positive outcomes that could result from making this information publicly available on the Compare tool.

CMS does not address how the agency will publicly report facility-based scores for the cost performance category. Many physicians, particularly hospital-based specialists such as hospitalists, anesthesiologists, and emergency medicine physicians, may be measured on their attributed facility's Hospital Value-Based Purchasing (VBP) Program score for the MIPS cost performance category, unless that clinician or group receives a higher MIPS final score through another MIPS submission. Like the traditional MIPS cost measures, the facility-based scoring methodology was severely disrupted by the COVID-19 PHE and CMS did not use facility-based scoring for 2021 or 2022. Therefore, there is very limited information about this information to inform comments about how to publicly report it. Therefore, we reiterate our earlier recommendation that CMS provide additional opportunities for public feedback about publicly reporting this cost information in the future as the disruption from the COVID-19 PHE eases.

### E. Advanced Alternative Payment Models (AAPMs)

Expiring MACRA-Related Provisions

### **Recommendation:**

• CMS should support Congressional passage of the Value in Health Care Act, which would extend Advanced APM incentive payments an additional two years and give the Secretary authority to set more reasonable Qualifying APM Participant (QP) thresholds based on the pace of APM development and adoption and the design of individual models.

Once again, the AMA is alarmed that the APM incentive payments created under MACRA are scheduled to come to an end. The AMA recognizes that CMS does not have the authority to extend the incentive payments as they were established by Congress when it passed MACRA in 2015. The AMA supports the bipartisan Value in Health Care Act (HR 5013), which has been reintroduced in the 118th Congress and would reinstate the full five-percent Advanced APM incentive payment and extend it for an additional two years. This is critical to continuing to incentivize APM adoption with still fewer than 20 percent of traditional Medicare payments flowing through APMs that qualify as Advanced APMs as of 2022. APM incentive payments often represent the only way for practices to be compensated for high-value services not supported by the traditional MFS, including working with community-based organizations to overcome barriers to care for underserved patient populations, and are an important way to offset up-front investments in new technologies or staffing, as well as revenue losses resulting from new service delivery efficiencies that can be difficult for practices to weather, particularly in the initial years of model implementation when retrospective performance payments have yet to be paid.

The bill would also freeze the QP threshold for two years and provide the Secretary with more discretion to set QP payment thresholds based on the pace of growth in APM development and adoption, as well as move away from a single one-size-fits-all QP threshold to establish separate, more reasonable thresholds based on the type and design of each APM. When this bill does pass Congress, we implore HHS to take full advantage of these newfound flexibilities.

These policies could go a long way towards closing current gaps in APM participation and more fully engaging the types of practices and patient populations that have thus far been shut out of APM participation. Importantly, these changes would also facilitate substantial progress towards CMS's goal of tying 100 percent of traditional Medicare beneficiaries to an accountable care relationship by 2030.

Qualifying APM Participant (QP) Thresholds

#### **Recommendation:**

• CMS should calculate QP determinations at both the individual and APM Entity levels and apply the more favorable score.

The AMA strongly supports CMS's intended goal behind making QP calculations at the individual clinician level, rather than APM entity level, in that it would mitigate possible incentives for APM Entities to exclude specialists from participation lists, and thereby increase specialty participation in APMs, and we appreciate the agency being responsive to the feedback previously received on this issue. At the same time, the effects of this proposal have not been included in the rule and we have some concern that there could be unforeseen and disparate impacts across certain types of practices and patient sub-populations, including rural settings, and historically minoritized and other underserved populations. It also is not clear that the policy change would lead to more specialist engagement or participation in APMs. There is no breakdown in the impact analysis, for example, of how many physicians in various specialties would be expected to achieve QP status under each methodology. While the proposed new methodology may address perverse incentives from the APM Entity perspective to keep specialists off participation lists as CMS asserts, calculating QP determinations at an individual level could have the same effect if individual specialists are dissuaded from seeking to participate in APMs because the QP threshold appears beyond reasonable reach. This is another reason why CMS should apply a separate QP threshold for specialists in APMs if afforded additional flexibilities by Congress, as noted above.

Furthermore, as CMS notes in the rule, it is natural to expect a larger relative proportion of primary care-based services to flow through APMs, particularly for models with assignment methodologies based on primary care codes. This in no way means that the non-primary care specialists who participate in those models are any less engaged or committed to the central value-based mission of the APM. In fact, patients whose care is effectively managed by a primary care physician-led team may require fewer specialty referrals if their conditions are well controlled. The fact that patients are being effectively managed and seeing specialists only when necessary is an indicator that the APM is functioning exactly as it should, not the opposite. Non-primary care specialists should not be punished for this due to a one-size-fits all calculation that fails to recognize that patients attributed to a high-functioning APM may be receiving the right mix of primary care and other specialist services. Furthermore, because specialists often tend to receive patients from a broad range of referral sources, current rules that limit certain non-primary care specialists to participation in one ACO or APM Entity can make it even more difficult for individual specialty physicians to reach QP thresholds. In addition to the other proposals in this section, we would encourage CMS to revisit this existing policy and consider allowing specialists to participate in multiple ACOs/APM Entities.

Accordingly, we urge CMS to calculate QP determinations at both the individual clinician and APM Entity levels, which is consistent with the policy for calculating MIPS final scores in which CMS uses the highest score from participation as an individual, group, and/or APM Entity. It would also help to incentivize participation in APMs, which will be even more crucial if QP thresholds increase as required

under current law. We encourage CMS to adopt this policy on a permanent basis, but at a minimum it should be adopted until more data can be collected and the downstream consequences of the proposed new approach better understood, particularly on specialist participation and certain patient subpopulations, including historically marginalized and minoritized communities.

Additionally, if CMS is looking to engage specialists in ACOs and APMs, we encourage the agency to do so through more direct policy interventions. The AMA has offered a number of suggestions to better engage specialists in APMs, including our <a href="Payments for Accountable Specialty Care">Payments for Accountable Specialty Care</a> (PASC) framework. Under PASC, a specialist would receive an enhanced payment for delivering specific types of services to patients who are referred by primary care physicians participating in the ACO. Agreements between specialists and ACOs would describe how the specialist would use these enhanced payments to improve outcomes and/or reduce avoidable spending. Health equity would also be improved by providing higher payments to help support care for patients who have complex conditions or who are at higher risk for poor outcomes due to health-related social needs or other factors. In our <a href="May 2023 letter">May 2023 letter</a> to the Physician-Focused Payment Model Technical Advisory Committee (PTAC), we outline specifically how the PASC can be used to more effectively integrate specialty care into population-based models.

We have also repeatedly urged CMS to implement more dedicated specialty models, starting with those that have been developed by the physician community and have been recommended for testing or implementation by the PTAC, none of which have been taken up by CMS to date. We were encouraged by the agency's separate request for information on episode payment models, which the AMA responded to. In our comments, we highlight the importance of designing voluntary models that have prospective payment models that allow physician participants to make needed investments in practice transformation and to deliver the services their patients need, so that physicians would know how much they would be paid before they deliver care to a patient, and they would receive that payment promptly following the delivery of services. We also discuss the importance of soliciting input from physicians earlier in the development process, providing models with a sufficient runway to generate results, designing metrics at the appropriate level so that physicians are held accountable for what they can truly control, providing regular performance feedback (more than annually), and rewarding improved patient outcomes and quality of care, not only financial performance. We look forward to continuing to collaborate with the agency to expedite the development of additional APM opportunities for non-primary care specialists.

Advanced APM CEHRT Requirement

### **Recommendation:**

• Allow the definition of CEHRT to vary based on unique model characteristics but reverse the proposal to increase the threshold to all participating eligible clinicians.

The AMA strongly supports allowing for a more flexible interpretation of CEHRT requirements to allow them to be more reflective of the unique nature of specific models, clinical conditions, and patient populations. For many years, the AMA has advocated for a more flexible approach to measuring health IT adoption and use because it enhances the clinical relevance of CEHRT, allows for faster recognition of new and evolving technological capabilities and innovations, better suits the needs of the unique practices participating in these models and the patients they serve, and ultimately leads to superior, more patient-centered care.

On the other hand, the AMA is wary about CMS's proposal to simultaneously remove the 75 percent threshold requirement and increase it to "all participants," which reflects a significant increase in burden

and reduction in flexibility. If the threshold is changed to "all participants," an entire APM Entity could fail to meet this requirement if a single clinician in one of its participating practices fails to use CEHRT for any number of reasons, including travel, sickness, or injury. Setting a 100 percent compliance threshold also risks increasing burden for CMS and APM Entities alike because it would require hardship exceptions, even if an APM entity has 95 percent, or even 99 percent compliance.

Furthermore, CMS reasons in the rule that the vast majority of <u>current</u> APM participants already report at or near 100 percent. However, this proposed threshold represents not the average but the floor for <u>all</u> APMs, including new models that may not yet exist. Expecting 100 percent compliance with no margin for error is unrealistic for any model, but particularly for new models or new participants in existing models as they are ramping up and adding new participants.

In MACRA, Congress dictated that models must meet certain criteria to qualify as an APM, including that "certified EHR technology is used." We believe this definition was intentional in recognition of the varying and quickly evolving nature of EHR technology. If Congress had wanted this CEHRT criterion to apply to each individual APM participant or a specific percentage of them, it would have expressly defined this as it did with other thresholds in the rule, including the Qualifying APM Participant threshold. Congress did not impose a threshold of 100 percent and we believe CMS is exceeding its statutory authority.

We understand that CMS wants to expand the adoption and use of and improve the interoperability of CEHRT. However, increasing a non-statutory APM CEHRT threshold is not an effective approach, it will only disincentivize and prevent physicians from participating in APMs, undercutting CMS's own goal to move more physicians into APMs.

Instead, CMS should take steps to collaborate with other federal agency partners and leverage the information they collect to highlight certified EHR adoption levels, as well as reduce reporting burden on physicians. As discussed in detail in the MSSP section of our comments, the AMA recommends CMS look to data ONC already collects to demonstrate levels of certified EHR adoption, rather than change the CEHRT use threshold to "all participants." According to this existing ONC data, as of 2021, nearly 4 in 5 office-based physicians (78 percent) and nearly all non-federal acute care hospitals (96 percent) adopted a certified EHR. ONC data can serve as a means to determine CEHRT adoption and use without burdening Advanced APM Participants with unnecessary and an unforgiving reporting requirement to meet a certain threshold of adoption.

Moreover, ONC has additional data sources that support the case for the ubiquity of certified EHRs across providers, as well as reduce the reporting burden on Advanced APMs. As discussed in more depth in the MSSP section of our public comments, ONC's HTI-1 Regulation includes a new "Insights Condition" in the EHR Reporting Program that would use data derived from the certified health IT system itself and reported by health IT developers. ONC intends for these metrics to help EHR users, federal entities, and the health IT industry better evaluate certified EHR functionality without overburdening providers to report duplicate information. The currently proposed Insights Conditions should play a major role in helping CMS identify CEHRT adoption trends and gaps, and demonstrate where providers, including Advanced APMs, are utilizing CEHRT in place of an expanded use threshold.

ONC data can help Advanced APMs fulfill their responsibility to require participants to use CEHRT. We encourage CMS to leverage ONC data from the Insights Conditions and other sources to validate CEHRT adoption and use among Advanced APMs rather than requiring an increased use threshold. For all these reasons, we urge CMS not to finalize this aspect of the proposal.

# IV. CONCLUSION

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 <a href="margaret.garikes@ama-assn.org">margaret.garikes@ama-assn.org</a> or 202-789-7409.

Sincerely,

James L. Madara, MD