AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT

james.madara@ama-assn.org

September 6, 2022

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–1770–P. Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts.

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) 2023 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 July 29, 2022 (87 Fed. Reg. 45860).

Our comments are guided by AMA policy, informed by our members, and developed through the COVID-19 public health emergency (PHE) and a health equity lens. In addition, our comments addressing policy and technical modifications within the Resource-Based Relative Value Scale (RBRVS) and those addressing individual Current Procedural Terminology® (CPT®) codes were developed in collaboration with the AMA/Specialty Society RVS Update Committee (RUC). The AMA fully supports the RUC recommendations and urges CMS to consider the Relative Value Units (RVUs), direct expense inputs, and additional comments and recommendations provided by the RUC on individual codes and proposed provisions within the MFS.

The AMA continues to express our strong support for CMS' efforts to significantly expand coverage for telehealth services through the addition of about 150 services that can now be provided via telehealth, including emergency department visits, critical care, home visits, and telephone visits. These efforts have allowed and will continue to allow Medicare telehealth services to continue to be available to patients all over the country, not just in rural areas, and patients will continue to be able to receive telehealth services in their homes or wherever they are located. Through your partnership, the AMA successfully worked with Congress to keep telehealth flexibilities in place for 151 days after the PHE ends. The AMA looks forward to our continued partnership as we continue to pursue legislative changes to achieve comprehensive and permanent telehealth reforms.

Reforming the Medicare physician payment system continues to be our top advocacy priority. Late last year, physician advocates from across the country united to successfully persuade Congress to delay a "perfect storm" of Medicare payment cuts that, if enacted, would have severely impeded patient access to care. Unfortunately, if Congress does not act by the end of the year, these delayed cuts, and some new ones, will take effect in 2023 and cause serious disruption to physician practices. Before the end of the year, we are advocating that Congress:

- Extend the Congressionally enacted 3 percent temporary increase in the MFS;
- Provide relief for an additional 1.5 percent budget neutrality cut that is planned for 2023;
- End the statutory annual freeze and provide an inflation-based update for the coming year; and
- Waive the 4 percent PAYGO sequester necessitated by passage of legislation unrelated to Medicare.

As you know, the AMA is deeply alarmed about the growing financial instability of the Medicare physician payment system due to a confluence of fiscal uncertainties physician practices face related to the ongoing pandemic, statutory payment cuts, lack of inflationary updates, and significant administrative barriers. The payment system is on an unsustainable path that is jeopardizing patient access to physicians. The resulting discrepancy between what it costs to run a physician practice and actual payment, combined with the administrative and financial burden of participating in Medicare, is incentivizing market consolidation.

The AMA has engaged in a process of working with our national specialty and state medical association Federation partners to determine the best path forward to get the Medicare physician payment system on a more sustainable track. In recognition of the need for the House of Medicine to come together in pursuit of legislation to reform the Medicare physician payment system, the AMA, along with our Federation partners—including those representing primary care, surgical care, and other medical specialists—to develop and endorse the Characteristics of a Rational Medicare Physician Payment System, signed by the AMA and 120 state medical and national specialty societies. These core set of principles serve as the basis for reforming the broken physician payment system. We have also been working to increase awareness of the problems in the current system among Members of Congress to build interest and support for the needed reforms. The AMA looks forwarding to working with the Agency to strengthen the Medicare physician payment system.

The AMA is alarmed that CMS estimates that one-third of MIPS-eligible clinicians would receive a penalty based on the 2023 proposals and urges the Agency to lower the 2023 MIPS performance threshold to avoid penalizing one in three physicians and other medical professionals in a program that is costly, burdensome, and disproportionately punitive toward small practices and practices that care for low-income patients. As physician practices continue to face challenges stemming from the COVID-19 public health emergency, including severe staffing shortages, the AMA strongly urges CMS to apply the automatic Extreme and Uncontrollable Circumstances hardship exception in the 2022 performance period and conduct targeted outreach and education to assist physicians and group practices that were impacted by the pandemic to resume MIPS participation without undue burden or expense.

To help CMS rescue the MIPS program and make it more clinically relevant and patient-centered, the AMA makes several recommendations in response to the MIPS Value Pathway (MVP) Request for Information. Among other things, we urge CMS to: work closely with the national medical specialty societies to develop MVPs that are patient-centered and focused on improving patient care, rather than the individual metrics; reduce the number of metrics in an MVP and incentivize participation in MVPs; test

and implement new and existing measures that are tailored to achieving the desired outcome of the MVP; adjust MVPs to reflect the higher cost of caring for low-income patients and address social determinants of health; and provide timely, actionable claims data analysis. There are specialties who see the current MVP approach as a step in the right direction, but we are concerned that MVPs as currently designed mirror many of the flaws in MIPS which, without changes, will deflate interest and financial commitment to develop and participate in MVPs.

The following outlines our principal recommendations on the 2023 Proposed Rule.

Calendar Year 2023 Updates Physician Fee Schedule (PFS)

- The AMA strongly supports CMS' proposal to continue paying for telehealth services that were scheduled to be covered only through the end of the COVID-19 Public Health Emergency (PHE) for an additional 151 days beyond the end of the PHE.
- CMS should continue its current coverage and payment policies for telephone visits and audio-visual telehealth services until the joint CPT/RUC Telemedicine Office Visits Workgroup determines accurate coding and valuation, as needed, for office visits performed via audio-visual and audio-only modalities.
- CMS should lift the frequency limit on subsequent nursing facility visits delivered through telehealth as physicians already must provide the required regulatory patient visits in-person. At a minimum, no limitation should be applied to the frequency of subsequent nursing facility visits for at least 151 days after the PHE ends.
- CMS should update pricing data on a more frequent basis for all direct PE inputs so that adjustments will not be so dramatic. The AMA acutely understands the underlying unfairness that the real increase in clinical labor costs for physician practices is not recognized through an update to the conversion factor and calls on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2023 and all future years.
- The AMA appreciates CMS' efforts to find a commercial rent data source to replace the residential rent data used in the practice expense geographic practice cost indices (GPCI) and believes the criteria applied to evaluate alternative sources of rent data are appropriate and encourage CMS to continue this ongoing effort.
- The AMA is engaged in an extensive effort to collect practice cost data from physician practices. We ask that CMS pause consideration of other sources of cost data for use in the Medicare Economic Index (MEI) until the AMA effort is complete.
- The AMA supports CMS' call for comment on the frequency of the updates. In the future, all significant PE data updates (Physician Practice Information Survey results, supply and equipment pricing, and clinical staff wage rates) should occur simultaneously and should be transitioned to avoid abrupt impacts to individual services and specialties. We understand the need for consistent and timely updates to the practice cost data and look forward to developing a mechanism to update these data on a more frequent basis.
- For non face-to-face remote therapeutic monitoring (RTM) services, the AMA strongly encourages CMS to halt its proposal for 4 new G-codes, allow for general supervision when physicians and other QHPs use the treatment management services and continue to cover CPT codes 98980 and 98981. The AMA also recommends that CMS negate the need for a crosswalk by accepting software as a direct practice expense input.
- The AMA recommends that CMS apply the office E/M visit increases to the office visits, hospital visits and discharge day management visits included in surgical global payment, as it has done historically.

- CMS should conduct a demonstration to determine the financial and operational efficiencies for Medicare patients with underlying medical conditions who require integral dental services as a condition of their covered, primary Medicare Part A service.
- The funding source to cover the dental services should be separate from and without impact on the Medicare Physician Payment Schedule.
- Due to the increased education and training of physicians, the serious medical conditions associated with hearing loss, the ability of physicians to better treat and diagnose the whole patient, and the negative consequences of removing physicians from the care team, it is imperative that the Administration continue to require that physicians order audiology services.
- The AMA supports the proposal to allow the OTP intake add-on code to be furnished via telehealth for the initiation of treatment with buprenorphine, including use of audio-only communication technology when audio-video is not available to the patient, and urges that it be finalized. The AMA also recommends that OTPs continue to be allowed to furnish periodic assessments using audio-only communication for patients who are being treated with buprenorphine, methadone, or naltrexone following the end of the COVID-19 PHE.
- The AMA supports CMS' proposal for new bundled monthly codes for chronic pain management and treatment and urges that they be finalized.
- The AMA supports the proposals to extend the enforcement policy of sending a letter to physicians who are not in compliance with the EPCS requirement and to align the EPCS timeline with the availability of data.
- The AMA urges CMS to adopt the RUC's recommended work RVUs and direct PE inputs for vaccine administration services. The AMA supports CMS' proposal to annually update the payment amount for administration of Part B preventive vaccines to account for changes in the cost of administering those vaccines.
- The AMA supports adoption of CMS' proposals to expand Medicare coverage of and reduce beneficiary cost-sharing for colorectal cancer screening tests.

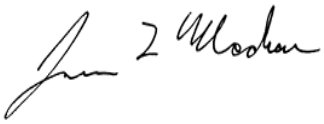
Calendar Year 2023 Updates to the Quality Payment Program (QPP)

- Due to the continued effects of the COVID-19 PHE, CMS should apply the automatic Extreme and Uncontrollable Circumstances Hardship Exception in the 2022 MIPS performance period and target technical assistance to those physician practices that have received a hardship exception due to COVID. In addition, we urge CMS to work with Congress to extend the $500 million exceptional performance bonus, which expires in payment year 2024 under current law. Finally, the AMA urges CMS to reduce the performance threshold to avert more penalties and to specifically assist small practices in reporting MIPS data.
- The AMA supports the expansion of high priority measures but recommends that CMS further define what characteristics would enable a measure to be classified as related to health equity.
- The AMA does not support CMS' proposal to increase the data completeness criteria to 75 percent beginning with the 2024 MIPS performance period.
- The AMA urges CMS to apply consistent standards for when a measure is proposed for removal. CMS should provide an opportunity for measure developers to provide supplemental data to demonstrate why a measure should continue to be included in the program, including data on disparities in care. In addition, CMS should consider performance rates across reporting options before proposing to remove a measure from the program and the impact it may have on a particular specialty or sub-specialty.

- The AMA supports scoring the administrative claims measures in the quality performance category using performance period benchmarks but urges CMS to explore other methods by which the performance can be benchmarked.
- The AMA supports applying the complex patient bonus to facility-based MIPS eligible clinicians.
- The AMA does not support CMS' Qualified Clinical Data Registry termination plan.
- The AMA supports the increased focus on integrating health equity into MIPS including the expansion of the high priority measure definition but does not support the inclusion of the Screening for Social Drivers of Health measure.

We thank you for the opportunity to provide input on this Proposed Rule. Our detailed comments are in the enclosed attachment. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD

CY 2023 Physician Fee Schedule and Quality Payment Program Proposed Rule
Detailed Comments of the American Medical Association

I. CY 2023 UPDATES TO THE MEDICARE PHYSICIAN FEE SCHEDULE (MFS)

A. Determination of Practice Expense (PE) Relative Value Units (RVUs)
B. Geographic Practice Cost Indices
C. Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation
D. Evaluation and Management (E/M) Visits
E. Rebasing and Revising the Medicare Economic Index (MEI) and Practice Expense Data Collection
F. High-Cost Medical Supplies – Payment for Skin Substitutes
G. Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services
H. Telehealth and Other Services Involving Communications Technology
I. Proposal and Request for Information on Medicare Parts A and B Payment for Dental Services
J. Audiology Services and Waiver of Physician Order
K. Opioid Treatment Program (OTP) Telecommunications Flexibilities
L. Intensive Outpatient Treatment for Substance Use Disorder (SUD) Treatment
M. Chronic Pain Management
N. Electronic Prescribing of Controlled Substances (EPCS)
O. Immunization Administration and Payment for Preventive Vaccine Administration Services
P. Expansion of Coverage for Colorectal Cancer Screening
Q. Request for Information: Medicare Potentially Underutilized Services

II. CY 2023 UPDATES TO THE QUALITY PAYMENT PROGRAM (QPP)

A. Merit-based Incentive Payment System (MIPS)
B. MIPS Value Pathway (MVP)
C. Medicare Shared Savings Program (MSSP)
D. Advanced Alternative Payment Models (AAPMs)

I. CY 2023 UPDATES FROM THE MEDICARE PHYSICIAN PAYMENT SCHEDULE (MFS)

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

1. CY 2023 Clinical Labor Pricing Update

Recommendation:

- CMS should update pricing data on a more frequent basis for all direct PE inputs, so adjustments will not be so dramatic. The AMA acutely understands the underlying unfairness that the real increase in clinical labor costs for physician practices is not recognized through an update to the conversion factor and calls on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2023 and all future years.

CY 2023 marks the second year of a four-year transition to the new clinical labor cost data that will be completed in CY 2025, much like the transition used in updating the supply and equipment price updates that were completed in CY 2022. **In the future, CMS should update pricing data on a more frequent basis for all direct PE inputs, so adjustments will not be so dramatic. The AMA acutely understands the underlying unfairness that the real increase in clinical labor costs for physician practices is not recognized through an update to the conversion factor and calls on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2023 and all future years.**

The AMA also reiterates that the total direct practice expense pool increases by 30 percent under this proposal, resulting in a significant budget neutrality adjustment. Practice expense comprises 44.8 percent of the physician payment and the pool of this payment is fixed by statute. Therefore, increasing payment for clinical labor shifts funds that were previously directed to supplies and equipment. Since the overall size of the practice expense component is static, a larger proportion of that 44.8 percent is now clinical labor, relative to before the proposed wage rate update. By increasing the clinical labor pricing, physician services with high-cost supplies and equipment are disproportionately impacted by the budget neutrality component within the practice expense relative values. The scaling of direct expenses, to 50 cents on every dollar fully recognized as direct costs, puts a huge and unfair burden on specialties that require expensive supplies and other direct costs to care for their patients. While the increase in clinical labor is appropriate, it is not appropriate that physicians and other qualified health care professionals, notably from a few small specialties, are negatively impacted by the change.

Finally, please note a correction in the NPRM *TABLE 5: CY 2023 Clinical Labor Pricing* where the Final Rate Per Minute for L041A Angio Technician should be 0.60 rather than 0.58. It is also missing an * to denote one of the three clinical labor types with a pricing increase this year. According to the preamble text, "We are also proposing the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 MFS Final Rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032)."

B. Geographic Practice Cost Indices

Recommendation:

- The AMA appreciates CMS' efforts to find a commercial rent data source to replace the residential rent data used in the practice expense GPCI and believes the criteria applied to evaluate alternative sources of rent data are appropriate and encourages CMS to continue this ongoing effort.

CMS proposes to update the physician work geographic practice cost indices (GPCIs) in 2023 to reflect 2017-2020 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data. For the 2023 practice expense GPCIs, CMS proposes to utilize the 2015 through 2019 American Community Survey (ACS). The 2023 professional liability insurance (PLI) GPCIs will reflect 2020 premium data gathered by a contractor from state insurer rate filings. CMS also proposes to reduce the number of distinct localities in California from 32 to 29. CMS also proposes several methodological changes to the computation of GPCIs, including modifications to occupations used as proxies from the BLS OES data and weighting changes to the geographic adjustment factor (GAF). Finally, CMS extensively discusses and defends the current use of county-level residential rent data as a proxy for relative cost differences in physician office expense. We appreciate CMS efforts to find a commercial rent data source to replace the residential rent data used in the practice expense GPCI. We believe the criteria applied to evaluate alternative sources of rent data are appropriate and encourage CMS to continue this ongoing effort.

C. **Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation**

Recommendation:

- The AMA urges CMS to continue to rely on the Relativity Assessment Workgroup process, utilizing objective screens to identify any potential misvaluation of services with global periods. The CMS public comment process may also be utilized to identify potential misvaluations, as it has been successfully utilized for this purpose.

In preparation for future rulemaking, CMS is seeking public comment on strategies to improve the accuracy of payment for the global surgical packages. Along with RUC, the AMA is critical of the presumptions in the RAND study methodology and has outlined those flaws in previous comment letters to CMS, which included intermittent reporting and participation, variation of specialties and states participating and the size of practices eligible to participate.

CMS continues to project broad assumptions that proceduralists are not providing the post-operative visits that are included in the global periods. However, the most common surgical procedure, cataract surgery, illustrates the flaw in conflating the valuation of the individual visits with the RAND reports on the ongoing claims reporting of 99024 *Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*. surgery. As the most frequently performed surgery to Medicare patients, this example should lead as an example for other surgical procedures. Post-operative visits are a proxy for work, but CMS is punitive with how it applies this work. For example, if a patient is staying less than 23-hours in the hospital, CMS is applying a lower intensity of work to that service even though the service provided is the same as an inpatient hospital visit.

The AMA believes that the misvalued services process is the appropriate avenue to address any services that may have incorrect post-operative visits in its global period. A blanket approach to address all 010-day and 090-day services only targets physicians performing surgery.

In the last ten years (2012-2022), the RUC has reviewed 43 codes or 17 percent of all 010-day global period services and 227 codes or 11 percent of all 090-day global period services. All the services not reviewed by the RUC are low volume services (less than 10,000 for the 010-day global services and less than 20,000 for the 090-day global services). 010-day and 090-day global period services make up approximately 9 percent of allowed charges in the Medicare Physician Payment Schedule and the RUC has reviewed the 010-day and 090-day services that account for over 8 percent of the payment schedule. Therefore, all high-volume services and the top allowed charges for 010-day and 090-day services have been RUC reviewed and finalized by CMS in the last 10 years.

The AMA urges CMS to continue to rely on the Relativity Assessment Workgroup process, utilizing objective screens to identify any potential misvaluation of services with global periods. The CMS public comment process may also be utilized to identify potential misvaluations, as it has been successfully utilized for this purpose.

D. <u>Evaluation and Management (E/M) Visits</u>

Recommendation:

- The AMA recommends that CMS finalize the recommendations for all the E/M visits.

The AMA commends the Agency for accepting the work RVU recommendations for the hospital inpatient or observation codes, nursing facility codes, home or residence visit codes, emergency department visits and prolonged services codes. This was the result of significant collaboration by an AMA-convened workgroup that brought together more than 30 specialty societies involved in surveying these services. CMS' acceptance will lead to a significant reduction of administrative burden given the streamlined descriptions that allow for better recognition of the resources involved in these visits as they are performed today. **The AMA recommends that CMS finalize the recommendations for all the E/M visits.**

The AMA also recommends that CMS apply the office E/M visit increases to the office visits, hospital visits and discharge day management visits included in the surgical global payment, as it has done historically.

1. **Nursing Facility Visits (CPT Codes 99304-99316)**

Code	Long Descriptor	CMS Proposed Work RVU	RUC Recommended Work RVU
99304	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.	1.50	1.50
99305	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.	2.50	2.50
99306	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	3.50	3.50
99307	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.	0.70	0.70
99308	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	1.30	1.30
99309	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	1.92	1.92

99310	Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	2.80	2.80
99315	Nursing facility discharge day management; 30 minutes or less	1.50	1.50
99316	Nursing facility discharge day management; more than 30 minutes	2.50	2.50

CMS is proposing to adopt the RUC recommended work RVUs for all the nursing facility codes, however, requests comments on the code descriptor times.

99306, 99308 & 99310

While CMS is proposing to accept the RUC recommendations for CPT code 99306 (work RVU = 3.50), they considered maintaining the current work RVU of 3.06, since there was no change in the overall time of 80 minutes total. Therefore, the Agency requested comment on the accuracy of the time noted in the descriptor for CPT code 99306. CMS notes that it is not clear why CPT code 99306 would have the same descriptor time and medical decision making as CPT code 99310, which is a subsequent visit, thus appearing like they are the same service. CMS seeks clarification, especially regarding the vast similarities of these two descriptors noted for these services.

The AMA would like to note that although the total time stayed the same for CPT code 99306, the intra-service and post-service times have changed. Currently the pre-service time = 15, intra-service time = 45 and post-service time = 20 minutes. The RUC recommended 15 minutes pre-service time, 50 minutes intra-service time, and 15 minutes post-service time. Each of these components represents a different intensity. This increase in intra-service time represents approximately a 14 percent increase in work per unit of time, therefore the increase in the work RVU to 3.50 is appropriate.

Both the initial nursing facility care CPT code 99306 and the subsequent nursing facility care CPT code 99310, indicate high level decision making or 45 minutes must be met to report either. The AMA notes that although reporting by time or medical decision-making appears the same in the descriptors, physicians will clearly know which code to report based on whether it is an initial or subsequent visit. The RUC and CPT Editorial Panel intentionally worded the descriptor for CPT code 99306 *initial nursing facility visit, high MDM, to 45 minutes must be met or exceeded*, although the intra-service time is 50 minutes. This was to maintain the "pattern" of time increments to make it easier for individuals to recall which code to report if they are using time-based reporting. Therefore, the initial nursing facility visits are in 10-minute increments, 25 minutes for the straightforward/low level MDM (99304), 35 minutes for the moderate level MDM (99305) and 45 minutes for the high-level MDM (99306). Likewise, the CPT Editorial Panel maintained generally a 15-minute increment for the subsequent nursing facility visits. It is not exactly 15 minutes for all since for the subsequent nursing facility visits, the straightforward MDM and low-level MDM are represented in separate codes. Therefore, the time increments in the descriptors are 10 minutes for straightforward MDM, 15 minutes for low level MDM, 30 minutes for moderate level MDM and 45 minutes for high level MDM.

Lastly, for CPT code 99308, CMS is proposing to accept the RUC recommendations; however, they considered maintaining the current work RVU of 1.16 given there was a decrease in the total time for the service and no change in the descriptor time. The intra-service time was 18 minutes. CMS is soliciting comment regarding the RUC recommendations that the total time be rounded down to 15 minutes instead of rounding up to 20 minutes, when using total time on the date of the encounter for code selection (minutes must be met or exceeded) and are seeking clarification on this difference.

As stated above, the time in the descriptor for 99308 should be 15 minutes to maintain the 15-minute increment pattern for the subsequent nursing facility visit codes.

The AMA urges CMS to accept the times listed in the code descriptors for the initial (25, 35, 45 minutes) and subsequent nursing facility visits codes (10, 15, 30, 45 minutes) to maintain an easy incremental pattern for those who are reporting these services based on time.

2. **Annual Nursing Facility Assessment (CPT Code 99318)**

Code	Long Descriptor	CMS Proposed Work RVU	RUC Recommended Work RVU
99318	Evaluation and management of a patient involving an annual nursing facility assessment, which requires these 3 key components: A detailed interval history; A comprehensive examination; and Medical decision making that is of low to moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 30 minutes are spent at the bedside and on the patient's facility floor or unit.	Accept Deletion	Deleted from CPT 2023

CMS proposes to accept the deletion of CPT code 99318, however states that they are seeking comment on whether there is a need to keep this code for Medicare purposes. **The AMA agrees with the CPT Editorial Panel decision to delete CPT code 99318 and we agree with CMS that the service is reported sufficiently with other codes.**

3. **Prolonged Services**

Recommendation:

- The CPT/RUC Workgroup on E/M will reconvene to discuss if revisions are needed to the CPT codes and guidelines. Our strong preference is that CMS would reconsider their proposed policy related to prolonged services and rely on the current CPT codes and guidelines. However, we believe that it is critical to ensure consistency and we urge CMS to work with the CPT/RUC E/M Workgroup immediately to bring CMS and CPT prolonged services policies into alignment.

CMS proposes to create new G codes (GXXX1, GXXX2 and GXXX3) to describe prolonged services for hospital, nursing facility and home visits, as they believe the CPT reporting guidelines for prolonged service 993X0 will lead to duplicative payment and confusion regarding total time spent per patient. This proposal mirrors CMS finalized policy for non-payment of 99417 in 2021 with a substitution to report G2212 *Prolonged service office or other outpatient* instead. In addition, CMS proposes to make CPT codes 99358 and 99359 invalid for Medicare purposes in 2023 as they assert it would cause confusion and invite duplicative billing.

The AMA and the CPT Editorial Panel urged CMS to be engaged throughout the E/M coding guideline development process, since 2018. This proposal reflects a failure to raise and address concerns about the definitions and valuation processes of these high-volume services while the codes were being developed. The result is two different methodologies for reporting prolonged services, which creates administrative burden, increases potential improper reporting and is counter to the principles espoused in the Proposed Rule for the 2019 Medicare Physician Payment Schedule and the guiding principles of the CPT/RUC Workgroup on E/M.

It is important to explain the intentions of the CPT Editorial Panel in developing the codes and guidelines for prolonged services. We urge CMS to consider the CPT background below when finalizing the prolonged services policies for 2023. **It is imperative that physicians have one set of clear codes and guidelines to report prolonged services. The CPT/RUC Workgroup on E/M will reconvene to discuss if revisions are needed to the CPT codes and guidelines. Our strong preference is that CMS would reconsider their proposed policy related to prolonged services and rely on the current CPT codes and guidelines. However, we believe that it is critical to ensure consistency and we urge CMS to work with the CPT/RUC E/M Workgroup immediately to bring CMS and CPT prolonged services policies into alignment.**

<u>CPT Background Related to Prolonged Services</u>

Background for Start Time

In July 2018, CMS proposed a shortened prolonged services code to be used with any office visit level that would be 30 minutes, GPRO1. The recommended value was 1.17 RVUs or half that of 99354 because it was half the time. CMS stated: "Stakeholders claim that the threshold of 60 minutes for CPT code 99354 is difficult to meet and is an impediment to billing these codes." CMS also proposed significant changes to the payments for office visit services. In response, the AMA assembled a joint CPT/RUC Workgroup that held public meetings in addition to the standard CPT public processes. As a result of this Workgroup, a new prolonged services code, 99417, for office visits was submitted to the CPT Editorial Panel.

It is noteworthy that the original application for office visit descriptors was worded (for example for 99215): *When using time for code selection, a minimum of 40 minutes of total time is spent on the date of the encounter.* It was decided to not use "typical time" because there was long-standing inconsistency between CPT general time guidelines that directed level selection based upon the closest times and CMS direction that the typical time was a threshold when time was the basis of code selection. The Workgroup deferred to CMS policy in order to promote consistency and reduce administrative burden and created a

threshold definition of time. CMS then communicated that it would be helpful to state the range of time specific to each code and list this in the CPT code set. For example, 99214 would be revised from requiring a minimum of 30 minutes to be for services that were 30-39 minutes in duration, because 99215 would begin at 40 minutes. Likewise, 99215 would be for 40-54 minutes because 99215 plus 99417 would start at 55 minutes. This useful suggestion was adopted by the CPT Panel along with a table directly in the CPT guidelines.

In the 2020 Proposed Rule, CMS proposed acceptance of the work of CPT and published the table for use of 99417, the same table as CPT created. The 2020 Final Rule later officially adopted the work of the CPT Panel. The AMA immediately began education and published the changes in detail on a public site of the AMA. As part of the change from a threshold to a range, some language related to the start time for 99417 in the CPT guidelines was perceived as ambiguous. In May 2020, the Panel corrected this by making it clear the prolonged services began at 15 minutes past the threshold time. The table that guided coding did not require any change and was part of the information used in the RUC survey. Additionally, the issue of the start time for prolonged services was not material to the times or valuation of either 99202-99205, 99211-99215 or 99417.

Despite the clarity of the table that was published in the Federal Register, CMS stated confusion regarding several terms in the Proposed Rule for the 2021 Medicare Physician Payment Schedule. Moreover, CMS appears to have used the purported confusion to draw erroneous conclusions about the intended usage. By the publication of the Final Rule, CMS surely was aware of the May CPT Panel clarifications. CMS stated:

> Having reviewed the policy we finalized last year, we believe that allowing reporting of CPT code 99417 after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. As a specific example, the time range for CPT code 99215 is 40–54 minutes. If the reporting practitioner spent 55 minutes of time, 14 of those minutes are included in the services described by CPT code 99215. Therefore, only 1 minute should be counted towards the additional 15 minutes needed to report CPT code 99417 and prolonged services should not be reportable as we finalized last year (see Table 33 of the CY 2020 MFS Final Rule). Therefore, we are proposing that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99417 could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service.

We have two primary concerns with this interpretation:

First, it is inconsistent with how nearly all other time-based codes are used in the CPT code set. There are numerous examples throughout the CPT code set which have time-based codes that have an implied time range, without expressly listing the range in the code descriptor. Typically, the CPT guidelines will list a separate table to indicate the actual time range. In this instance, and based on the suggestion from CMS officials, the CPT code descriptors included the time range. Importantly, this time range includes the exact same principles as previously accepted in sections throughout the CPT code set (e.g., Principal Care Management, etc.). It is discouraging that a principle that was agreed upon by AMA and CMS prior to publication to directly address administrative burden is now the catalyst for added burden.

Second, it is inconsistent with the mandate to maintain relativity within Statute. We remain concerned that the Agency is misguided in their thinking regarding when to give work recognition for crossing a threshold, especially given the clarity of the CPT and CMS published table in the 2020 Final Rule. The

concern that this is allowing 0.61 work RVUs for "1 minute" demonstrates a failure to recognize the conundrum of any threshold. Examples of the impact of 1 minute include 99204 becoming 99205 (0.9 RVUs) and 99214 becoming 99215 (0.88 RVUs). Most notably CPT code 99354 is not reported until 30 minutes is reached. Thus, the transition from 29 to 30 minutes is 2.33 RVUs. Had CPT continued to use the word "typical" which was defined by CMS as synonymous with "minimal" in policy, the similarity to 99354 would be obvious. The 0.61 RVUs assigned to G2212 is not allowed until 29 minutes after the typical time, virtually identical to the 30 minutes for 99354, but with a value of less than one third per minute at the threshold time. Therefore, the stated goal of a shorter time threshold in proposing GPRO1 was not met and the valuation was dramatically reduced. Further, because there is one code, not an initial and subsequent, the result is the work RVUs of G2212 are the same for 29 minutes for the first unit and 15 minutes for the second unit, if more than one unit is reported. This is counter to relativity.

Background for Survey Times

During the public E/M Workgroup process and CPT processes, there was much debate about whether to use total time on the date of the encounter or whether to add time related to the service on a date other than that of the visit. The Workgroup agreed that total time on the date of the encounter would be used as it is simpler to track and document. The issue of recognizing all of the work was explained as a topic to be addressed in the valuation process. Office visits always had pre and post work that was not limited to the date of the encounter, though some did occur on the date of the encounter, such as charting. For example, the 2006 post service time for 99215 reads: "Complete medical record documentation. With the help of clinical staff, handle any treatment failures or adverse reactions to medications that may occur after the visit. Provide necessary care coordination, telephonic or electronic communication assistance, and other necessary management related to this office visit. Receive and respond to any interval testing results or correspondence. Revise treatment plan(s) and communicate with patient as necessary." For the purpose of a consistent survey, and not to create an office visit "global period," it was decided to ask the survey respondents for the typical time over the 3 days prior to the date of the encounter, the date of the encounter and over the seven days after the date of the encounter. The add-on code 99417 was limited to time on the date of the encounter and had to be at least 15 minutes. CMS accepted the time and value and appropriately did not consider the pre-time or post-date of encounter time of the base code in finalizing policy on 99417 or G2212.

Basis of Time used in CPT

CPT use of "total time" refers to the combined face to face and non-face to face times and is on the date of the encounter. CMS use of "total time" refers to the sum of face to face and non-face to face pre, intra and post-date of the encounter times. CPT publishes the time in the descriptor. CMS refers clinicians and coders to time files which adds complexity and burden for clinicians and coders.

CMS G codes for Hospital Inpatient or Observation Care, Nursing Facility and Home or Residence Services

CMS as part of their continued confusion over the starting times for these E/M services proposes three new G codes to describe the same work as the single CPT code 993X0.

*GXXX1 Prolonged **hospital inpatient or observation** care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact*

*GXXX2 Prolonged **nursing facility** evaluation and management service(s); each additional 15 minutes*

*GXXX3 Prolonged **home or residence** evaluation and management service(s); each additional 15 minutes*

The AMA notes the following concerns with the proposal of these three separate G codes to describe prolonged services.

First, and most importantly, this proposal creates administrative complexity, which is counter to all the work that has been done over the past three years. Having both a CPT code and a HCPCS II G code for the same service creates unnecessary complexity. Furthermore, having to reference a separate table imbedded in CMS rulemaking adds burden to simply having the time ranges included in the CPT codes themselves.

Second, without the table, it is unclear what "total time for the primary service" means. Most readers would interpret it as the time on the date of the encounter as we are unaware of a case wherein prolonged services start times have ever been based upon the total time in the CMS time file. It also remains unclear, even after reviewing the table whether the prolonged services time is only that time on the date of the encounter or over the whole service. The base code selection method is clear and familiar and thus why CPT chose it.

Third, it is based upon flawed arithmetic regarding total time once a prolonged service is performed, if the prolonged service is based on the total direct and non-direct time on the date of the encounter. The home/residence service 99345 best illustrates the point, even though it has no 15-minute gap before starting prolonged services. The base code is selected using a time of 75 minutes on the date of the encounter. That is clear. The prolonged services reporting threshold is reached only when 141 minutes is reached on that day according to the table. This is because the total time is 25 minutes before the date of the encounter, 74 minutes on the date of the encounter and 27 minutes after the date. This is 126 minutes, plus 15. This does add up to 141 minutes. However, it is entirely unclear why CMS believes a service that requires prolonged services on the date of the encounter would not require the typical pre and post services, if not more. Assume those times remain unchanged. Accordingly, 99345 plus GXXX3 is ((25+(25+74+27+15)+27)) or 193 total minutes, not 141 minutes.

Fourth, if the arithmetic is not flawed, then the prolonged services accrue over the service period. This would not require using the CMS time files, but it would require knowing when the service period, created only for the purposes of a RUC survey, begins and ends. That information is not even in the time file. Additionally, the total time would not be known until 7 days past the service date had passed. This has administrative complexity compounded with administrative infeasibility.

Mixing and matching total and intra times, simply does not work. What does work, is what was designed by CPT and valued by the RUC. In a formula this would be: ((pre)+(intra CPT time + prolonged 15 min) + post) = ((25+(75+15)+27)=142 total minute to report both codes and this appears to be the CMS goal.

Fifth, the CMS methodology, as shown in Table 18 of the Proposed Rule, varies across families and thus is inconsistent with relativity. What is not evident from Table 18 is that the office visits have 14 minutes of unrecognized time; the inpatient or observation services have 15 minutes of unrecognized; and the nursing facility and home or residence services have prolonged services start without a gap time. In each case the prolonged service is 15 minutes and 0.61 work RVUs, but in each use the time and method of determining the time beyond the base code minimum threshold for time-based reporting varies.

Prolonged Services (99358 and 99359)

CMS has commented on these services extensively. They were not paid until 2017. CMS has often included them in Care Management services tables and noted that there is no overlap with services such as transitional care management. In the 2020 Final Rule, CMS noted several concerns and noted they would not be payable in relation to an office visit. Now CMS variably states they will not be allowed in relation to E/M services, or they will be invalid ("I" status) for Medicare.

We recognize the concerns of CMS and agree that potential overlap should be eliminated. We believe that the other care management services have not eliminated the need to recognize a substantial amount of work on single day. The volume should drop substantially as reporting will no longer be allowed for time on the date of the encounter. Incorrect reporting should be addressed, but improper reporting by the few should not lead to these codes being eliminated. The CPT Editorial Panel may consider revisions, but request that CMS be an active participant, outside of rulemaking in the public and open CPT processes.

4. **Payment for Multiple Same-Day Visits**

Recommendation:

- The joint CPT/RUC Workgroup on E/M services will reconvene and determine if clarification in CPT is needed.

CMS manuals include many longstanding policies regarding when more than one Other E/M visit can be billed by the same practitioner for the same patient on the same date of service, particularly when a patient is being transferred among multiple care settings. CMS states that CPT reporting instructions do not place any limitations on the number of visits that can be billed. CMS is proposing their longstanding manual policies for same-day visits. **The joint CPT/RUC Workgroup on E/M services will reconvene and determine if clarification in CPT is needed.**

5. **Split (or Shared) Services**

Recommendation:

- We continue to strongly urge CMS to allow physicians and qualified health professionals to bill split or shared visits based on time or medical decision-making. We strongly urge CMS not to disrupt team-based care in the facility setting and to revise the split or shared visit policy to allow the physician or qualified health professional (QHP) who is managing and overseeing the patient's care to bill for the service.

The AMA appreciates CMS for proposing to delay, until January 1, 2024, the requirement that only the physician or QHP who spends more than half of the total time with the patient during a split or shared visit can bill for the visit. CMS cites the concerns raised by the AMA and 46 national medical specialty societies in our March 29th letter that adopting this policy change would drastically disrupt team-based care and interfere with the way care is delivered in the facility setting. **We continue to strongly urge CMS to allow physicians and QHPs to bill split or shared visits based on time or medical decision-making.**

In response to CMS' reservations with billing split or shared visits based on medical decision-making and the collective concerns of medicine with billing split or shared visits based on the majority of time, the CPT/RUC Workgroup on E/M will convene to address clarification and definitional requirements for split or shared visits. The CPT/RUC Workgroup on E/M 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 in the office and outpatient settings. These services are proposed for implementation in additional settings in this Proposed Rule.

We support 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, billing based on the physician or QHP who performs more than 50 percent of the total time of the visit will disincentivize and jeopardize the continuation of these care relationships. There is significant variability in how much time it takes to perform elements of the visit based on factors such as the level of training and expertise of the physician and QHP. Using medical decision making to direct the management of the patient's care determines the course of treatment for the patient, but it typically does 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 bill for it.

We understand that CMS believes time-based billing is auditable; however, CMS has a long history of auditing E/M services based on documentation in the medical record substantiating appropriate billing based on history, exam, and medical decision-making. We see no reason why CMS would be unable to continue to use these same program integrity levers to audit split or shared visits billed on the basis of time or medical decision-making.

We strongly urge CMS not to disrupt team-based care in the facility setting and to revise the split or shared visit policy to allow the physician or QHP who is managing and overseeing the patient's care to bill for the service. We look forward to providing additional input following the CPT/RUC Workgroup on E/M meeting.

The Joint CPT/RUC Workgroup on E/M will convene to determine if changes are required to the prolonged services, multiple same-day visits and split (or shared) visit codes and guidelines. It is anticipated that the CPT Editorial Panel could review any resulting coding application at the February 2023 meeting for potential publication in CPT 2024.

6. **Visits Included in Codes with a Surgical Global Period**

Recommendation:

- The AMA recommends that CMS apply the office E/M visit increases to the office visits, hospital visits and discharge day management visits included in surgical global payment, as it has done historically.

As stated in previous communication with the Agency, the AMA strongly believes it is appropriate to apply the increased 2021 valuation of the office E/M visits to the visits incorporated in the surgical global packages and disagrees with the CMS decision to not apply the office E/M visit increases to the visits

bundled into global surgery payment. The AMA also believes that the increases in the hospital visits and discharge day management services should be applied to the surgical global period. CMS should not hold specific specialties to a different standard than others. **The AMA recommends that CMS apply the office E/M visit increases to the office visits, hospital visits and discharge day management visits included in surgical global payment, as it has done historically.**

7. **Physician Time Reporting for Critical Care Services**

Recommendation:

- The AMA urges CMS to maintain its longstanding policy of using the CPT time reporting thresholds for critical care codes 99291-99292.

In the CY 2023 NPRM, CMS proposed a change to the time reporting rules for all Critical Care services that the Agency instead framed as a technical correction. In the CY 2022 MFS Final Rule, CMS had stated, "Similar to our proposal for split (or shared) prolonged visits, the billing practitioner would first report CPT code 99291 and, if 75 or more cumulative total minutes were spent providing critical care, the billing practitioner could report one or more units of CPT code 99292." However, in the CY 2023 MFS NPRM, CMS noted that in last year's rule it had "…intended to state that CPT code 99292 could be billed after 104, not 75, or more cumulative total minutes were spent providing critical care." CMS also noted that their proposed "technical correction" would apply to all critical care services, regardless of whether the care for a patient is being provided by a single physician, multiple physicians from the same group and specialty providing concurrent care, or physicians and QHPs who are reporting critical care as a split (or shared) visit.

However, changing the long-standing CPT and CMS rules for Critical Care time reporting is not a simple clarification and would use time reporting rules that are disparate from those in place when CMS and the RUC last reviewed CPT codes 99291 and 99292. **This proposal instead represents a broad policy change and would result in a severe cut to overall Medicare allowed charges for Critical Care services.** This proposal is inconsistent with how nearly all other time-based codes are used in the CPT code set. There are numerous examples throughout the CPT code set which have time-based codes that have an implied time range, without expressly listing the range in the code descriptor. In this instance, the discrete time reporting thresholds are instead provided in a table in the CPT guidelines.

Reporting Critical Care Time

Total Duration of Critical Care	CPT Codes
Less than 30 minutes	Appropriate E/M codes
30–74 minutes (1/2 hour–1 hour 14 minutes)	99291 X 1
75–104 minutes (1 hour 15 minutes–1 hour 44 minutes)	99291 X 1 and 99292 X 1
105–134 minutes (1 hour 45 minutes–2 hours 14 minutes)	99291 X 1 and 99292 X 2
135–164 minutes (2 hours 15 minutes–2 hours 44 minutes)	99291 X 1 and 99292 X 3
165–194 minutes (2 hours 45 minutes–3 hours 14 minutes)	99291 X 1 and 99292 X 4
195 minutes or longer (3 hours 15 minutes–etc.)	99291 and 99292 as appropriate

This proposal represents a major deviation on the long established and well understood coding rules and creates administrative complexity and risks unintentional incorrect coding. CMS' proposed change to modify the critical care time reporting rules, which were in place when CMS and the RUC last reviewed CPT codes 99291 and 99292, would inappropriately decouple the relationship between physician work and physician time for all critical care services in excess of 74 minutes. This policy change would also improperly modify the relativity between critical care and the proposed values for all other E/M services. **The AMA urges CMS to maintain its longstanding policy of using the CPT time reporting thresholds for critical care codes 99291-99292.**

E. Rebasing and Revising the Medicare Economic Index (MEI) and Practice Expense Data Collection

1. CMS Proposal on Updates to the Medicare Economic Index (MEI)

Recommendation:

- The AMA is engaged in an extensive effort to collect practice cost data from physician practices. We ask that CMS pause consideration of other sources of cost data for use in the Medicare Economic Index (MEI) until the AMA effort is complete.

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 practices costs. The MEI measures changes in the prices of resources used in medical practices including, for example, labor (both physician and non-physician), office space and medical supplies. These resources are grouped into cost categories and each cost category is assigned a weight (indicating the relative importance of that category) and a price proxy (or proxies) that CMS uses to measure changes in the price of the resources over time. The MEI also includes an adjustment to account for improvements in the productivity of practices over time.

From 1975, when payments reflected the usual, customary, and reasonable charge payment methodology, through 1993, the year after implementation of the Resource Based Relative Value Scale (RBRVS), the physician earning component was 60 percent and the practice expense component, including professional liability insurance (PLI) costs, was 40 percent. These initial weights were derived from data obtained from the AMA. In the nearly 50 years since the initial establishment of the MEI, data collected by the AMA has served as the consistent source of information about physicians' earnings and their practice costs.

In 1993, the MEI components were updated, using AMA data, and then proportioned to 54.2 percent Physician Work, 41 percent Practice Expense and 4.8 percent PLI. Currently, the allocation is 50.9 percent Physician Work, 44.8 percent Practice Expense and 4.3 percent PLI. The CMS proposal is to dramatically shift payment allocation away from physician earnings (work) to practice expense: 47.3 percent Physician Work, 51.3 percent Practice Expense and 1.4 percent PLI using non-AMA data.

MEI History

	1975-1992	1993	Current	Proposed
Physician Work	60%	54.2%	50.9%	47.3%
Practice Expense	40%	41.0%	44.8%	51.3%
Professional Liability Insurance	(incl with PE)	4.8%	4.3%	1.4%

The current MEI weights are based on data obtained from the AMA's Physician Practice Information (PPI) Survey. This survey was last conducted in 2007/2008 and collected 2006 data. As discussed below, the AMA is actively engaged in a process to collect these data again.

CMS proposes to update the MEI weights using 2017 data from the United States Census Bureau's Service Annual Survey (SAS). However, the Agency clarifies that they will not implement these new weights in 2023 as they must first seek additional comments due to significant redistribution. The proposed shift in payment weights from physician work to practice expense principally favors 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 percent), Geriatrics (-2 percent), Internal Medicine (-2 percent) and Pediatrics (-2 percent). In summary, this proposal redistributes physician payment from physician work to the business side of health care. This proposal is particularly unfortunate as physicians face uncertainty about the Medicare conversion factor and continue to suffer from burnout. The Administration should be doing more to emphasize the importance of physicians, rather than directing resources away from their individual contributions.

In addition to significant specialty redistribution, geographic redistribution would also occur, as CMS proposes to modify weights of the expense categories (employee compensation, office rent, purchased services and equipment/supplies/other) within the practice expense GPCI. A significant reduction in the weight of office rent from 10.2 percent to 5.9 percent would lead to reductions in the payment to urban localities and increases to payment in rural areas and states with a single GPCI. CMS's impact analysis should also be expanded to consider how significant decreases in PLI payment may negatively impact geographical areas with relatively high PLI premiums.

The changes in the MEI that CMS is proposing are almost entirely related to the category weights. A change in the price proxy is recommended for just one of the cost categories which accounts for only 2 percent of the index. CMS is not proposing a change to the productivity adjustment. The proposed changes in the category weights are primarily derived from the Census Bureau's 2017 SAS for the "Offices of Physicians" industry, which was not designed with the purpose of updating the MEI. As a result, there are key areas (physician work, nonphysician compensation and medical supplies) where CMS must use data from other sources to work around this important gap.

Several of the flaws in utilizing the SAS data for this purpose, include:

- Seven percent of the revenue for "Offices of Physicians" on the 2017 SAS was from non-patient care sources (e.g., grants, investment income) and any expenses associated with these sources cannot be excluded.

- The SAS for "Offices of Physicians" collects payroll and benefits for all staff combined but the MEI has separate cost categories for physician and non-physician compensation. Non-physician compensation is further broken out in the MEI by staff type. CMS is proposing to use the Bureau of Labor Statistics' (BLS) 2017 Occupational Employment and Wage Statistics (OEWS) data to estimate the share of SAS personnel costs that apply to physicians (including QHPs) and non-physicians. Based on the 2017 OEWS, CMS states that 63.2 percent of employee compensation for "Offices of Physicians" is for physicians and QHPs. CMS appears to have misclassified registered nurse salaries in this estimate. Additionally, the OEWS only covers employees, so it is missing compensation for a large segment of the physician population (practice owners). To compensate, CMS is proposing to estimate total compensation for practice owners as a share of practice net income from the 2017 SAS (the difference between total revenue and total expense which amounted to $44.9 billion out of $490.9 billion in revenue for 2017). The share of net income proposed is the estimated percent of patient care physicians that are owners (46.5 percent), averaged from the 2016 and 2018 AMA Physician Practice Benchmark Surveys, resulting in an estimated $20.9 billion in compensation for owners. **CMS' estimate of $20.9 billion in compensation for owners represents just 10 percent of total compensation for all physicians and QHPs ($203.8 billion), which is far out of line with any reasonable estimate since nearly half of physicians in the United States are owners**.

- CMS used BLS data to split out the US Census SAS data using the North American Industry Classification System (NAICS) 6211 "Offices of Physicians" category. However, only 64 percent of employed physicians are in this category in both the US Census SAS and BLS OEWS datasets. This analysis excludes 36 percent of physicians who are employed in other health care settings, such as hospitals. For example, the NAICS 6221 "General Medical and Surgical Hospitals" category was not included in CMS' analysis and this category includes 158,880 employed physicians according to the 2017 BLS OEWS data. Hospital-based physicians have a higher proportion of physician earnings and PLI cost relative to other practice costs, as many of these other costs are the responsibility of the hospital or other facility. The CMS proposal greatly underrepresents the cost share of physician work and PLI relative to practice expense due to this inappropriate exclusion.

- In the current MEI, CMS excludes expenses for separately billable supplies and drugs. The 2017 SAS for "Offices of Physicians" has a single category for Medical Supplies without any breakout for the separately billable component. To estimate separately billable supply and drug expense,

CMS proposes to age forward AMA-PPI results for these expenses and then compare the estimated total to Medical Supplies expense from the SAS (finding that 80 percent of Medical Supplies expense is for separately billable medical supplies or drugs). There are two problems with the CMS proposed approach: 1) The measures used to age expenses forward are not entirely appropriate (using growth in Medicare Part B drug spending when an all-payer measure would be better, and using measures of inflation (CPI and PPI from BLS) to age spending); and 2) totals estimated from two entirely different surveys are being compared when those surveys may have different populations and methods (for example, the wording of the questions and direction on what to include in the category could be entirely different).

- The dramatic decrease in the weight for PLI cost seems unrealistic. In 2021, the Medicare physician payment schedule allowed charges were $91 billion. If PLI payment only represented 1.4 percent of this payment, total Medicare spending on its share of these premiums and self-insured actuarial costs would be $1.274 billion. With more than one million physicians and other health care professionals billing Medicare, this would compute to Medicare paying an average of $1,275 per individual. Assuming Medicare represents approximately 25 percent of physician payment, an understated $5,100 in PLI premium cost results. This is in direct contradiction to the volume weighted PLI premium costs of $21,700 computed by CMS elsewhere in the Proposed Rule. It appears that a 4-5 percent PLI weight is more appropriate than the proposed 1.4 percent.

2. Practice Expense Data Collection

Recommendation:

- The AMA supports CMS' call for comment on the frequency of the updates. In the future, all significant data updates (PPI Survey results, supply and equipment pricing, and clinical staff wage rates) should occur simultaneously and should be transitioned to avoid abrupt impacts to individual services and specialties. We understand the need for consistent and timely updates to the practice cost data and look forward to developing a mechanism to update these data on a more frequent basis.

The AMA acknowledges that the data currently utilized for the MEI are outdated and we understand the CMS desire to update these data. In 2019, the AMA House of Delegates also discussed the need for updated data and asked the AMA Board of Trustees to consider a new practice cost data collection effort. AMA leadership supported a pilot study in 2020, which was successful and led to additional review in 2022. As we commented to CMS in September 2020, and discussed with CMS staff in several meetings, the AMA hopes to collaborate with CMS on a new physician practice cost survey. The AMA engaged multiple vendors and committed significant resources in planning a new effort. A strategy to collect data in 2021, based on 2020 cost information, was postponed until physician practices resumed to normalcy after the SARS-CoV-2 public health emergency. It is anticipated that 2022 data could be collected, beginning in mid-2023. **The AMA supports CMS' call for comment on the frequency of the updates. In the future, all significant data updates (PPI Survey results, supply and equipment pricing, and clinical staff wage rates) should occur simultaneously and should be transitioned to avoid abrupt impacts to individual services and specialties. We understand the need for consistent and timely updates to the practice cost data and look forward to developing a mechanism to update these data on a more frequent basis.**

<u>2020 AMA Practice Expense Pilot Study</u>

In March 2020, AMA staff conducted in-depth interviews of physicians and financial experts from several practices to help inform the planning of a practice expense pilot study. The practices represented varied specialties and practice characteristics. The interviews were encouraging and helpful in developing the study design. Improvements in information systems over the last decade, coupled with potential outreach to financial experts in each practice, indicate that a new data collection effort could be successful.

The AMA retained the services of WebMD professional/Medscape Market Research to conduct the pilot study in Summer 2020. The pilot was administered to 32 physician practices. These practices represented 31 specialties of various practice types and sizes. Physicians were interviewed from various geographic regions throughout the United States. Although the point of contact in each practice was the physician, because of the nature of the data collected, other practice members who are more directly involved in the management and financial aspects of the practice were also recruited. These financial experts included physician partners in the practice, practice managers, practice accountants, practice controllers, or practice chief financial officers.

The pilot included two parts. In the first, each practice completed an online "advance worksheet" which recorded answers to questions about practice characteristics, financial information, staffing, and hours of direct patient care. In the second part, a moderator reviewed the advance worksheet information, and then remotely interviewed each practice using audio visual technology. The moderator spent one to two hours with each physician/financial expert discussing the worksheet answers using a discussion guide. The moderator evaluated the ease with which the practice was able to answer the advance worksheet questions, explored reasons why the questions were or were not easy to answer, evaluated how long it took the practice to answer the questions, determined which practice staff were best able to answer the questions and how the questions might be modified to make them easier to answer.

The pilot study successfully concluded in August 2020. Two key decisions were made at the conclusion of the pilot study: 1) It would not be prudent to conduct a cost survey until physician practices returned to "post" COVID normalcy, as demonstrated by national spending data; and 2) a shift in the focus of the data collection format is necessary as fewer physicians are owners and practice consolidation has led to a need to target financial experts directly. These learnings led to a new AMA effort in 2022.

2022 AMA Practice Interviews and Methodological Design

As the AMA gained confidence via health care spending and claims data that relative physician costs returned to pre-COVID conditions; steps were taken to position medicine to re-engage in a new survey effort. In May 2022, the AMA contracted with Mathematica to develop a sampling method and a design methodology to survey financial experts at physician practices to collect practice cost data at the specialty level. Mathematica is expected to provide reports to the AMA beginning in late August through the end of 2022. The AMA has also re-engaged with WebMD professional/Medscape Market Research to potentially partner with Mathematica on the effort, with the hope to reach both small physician practices and complex practices and large health systems.

Simultaneously, the AMA led interviews with the Chief Financial Officers and other financial experts from 20 larger organizations in Summer 2022, including academic practices, large single specialty practices, private equity groups, and multi-specialty health systems. Every specialty was represented within these practices. Nearly 75,000 physicians work in these 20 practices combined. These discussions led to significant learnings for both the AMA and Mathematica. Most importantly, it is apparent that

improvements in financial data systems, and a powerful desire to participate, make a new data collection effort possible.

As the reports from Mathematica are completed, the AMA will provide frequent updates to CMS and the national medical specialty societies. CMS has relied on AMA physician cost data for 50 years in updating the MEI and 30 years in updating the RBRVS. As CMS states in this Proposed Rule, the PPI survey "is the most comprehensive source of PE survey information available." The PPI survey data collection effort was successful because CMS worked closely with the AMA, national medical specialty societies and other health care professional organizations on every aspect of the project. **We urge CMS to collaborate with the AMA on this new data collection effort to ensure consistency and reliability in physician payment. Updates to MEI weights should be postponed until new AMA survey data are available. It is anticipated that the new data collection effort would begin in 2023 and be based on 2022 data.**

F. High-Cost Medical Supplies – Payment for Skin Substitutes

1. High-Cost Disposable Supplies

Recommendation:

- The AMA recommends that CMS separately identify and pay for high-cost disposable supplies priced 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.

The AMA calls on CMS to separately identify and pay for high-cost disposable supplies (i.e., priced more than $500). In agreement with the RUC, the AMA makes this recommendation to address the outsized impact that high-cost disposable supplies have within the current practice expense RVU methodology. The 2023 Medicare Physician Payment Schedule includes 77 supply items with a purchase price of more than $500. These high-cost supplies represent $1.17 billion in direct costs for 2022 and 18 percent of all practice expense supply costs in the non-facility setting. The current system not only accounts for a large amount of direct practice expense for these supplies but also allocates a large amount of indirect practice expense into the PE RVU for the procedure codes that include these supplies. Because of specialty pools and how the PE formula derives the code-level indirect practice expense in part as a multiple of the code-level direct practice expense inputs, when CPT codes include a high-cost disposable supply, a larger portion of indirect practice expense is allocated to the subset of practices performing the service which is subsidized by the broader specialty and all other physicians and health care professionals. If high-cost supplies were paid separately with appropriate HCPCS codes, the indirect expense would no longer be associated with that service. The result would be that indirect PE RVUs would be redistributed throughout the specialty practice expense pool and the practice expense for all other services. **The AMA recommends that CMS separately identify and pay for high-cost disposable supplies priced 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.**

2. **Payment for Skin Substitutes**

Recommendation:

- The AMA agrees with CMS' proposal in the current NPRM "to treat skin substitutes (including synthetic skin substitutes) as incident to supplies as described under section 1861(s)(2)(A) of the Act

In the CY 2022 Proposed Rule, the AMA supported the creation of eight HCPCS codes (GXXAB, GXXAC, GXXAD, GXXAE, GXXAF, GXXAG, GXXAH, and GXXAI) for synthetic skin substitutes as this conforms to the RUC policy on high-cost disposable supplies. **Thus, the AMA agrees with CMS' proposal in the current NPRM "to treat skin substitutes (including synthetic skin substitutes) as incident to supplies as described under section 1861(s)(2)(A) of the Act when furnished in non-facility settings and to include the costs of these products as resource inputs in establishing practice expense RVUs for associated physician's services effective January 1, 2024."**

3. **Changing the Terminology of Skin Substitutes**

Recommendation:

- The AMA requests that CMS, and any relevant industry representatives, work directly with the CPT Editorial Panel to determine the best approach. Finally, the AMA maintains that items of this nature (i.e., high-cost disposable supplies) should remain separately reportable and not bundled within practice expense as aforementioned.

CMS proposes to replace the term "skin substitutes" with the term "wound management" or "wound management products" which CMS asserts more accurately describe the suite of products that are currently referred to as skin substitutes. CMS further states that skin substitute products are not a substitute for a skin graft as they do not actually function like human skin that is grafted onto a wound. Instead, CMS states that these products are applied to wounds to aid wound healing and through various mechanisms of action, they stimulate the host to regenerate lost tissue. Further, CMS states that the terminology change would not include bandages or standard dressings, which are not considered skin substitutes.

The AMA disagrees with this terminology change and all terminology proposals being considered (i.e., wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds). The CPT description of skin substitutes was carefully created to describe the procedures related to skin replacement surgery and further, adjacent tissue repairs. In CPT 2022, the CPT Editorial Panel was very purposeful with the creation of these codes, as they are with any code creation, to specifically describe the instances that are, and are not, appropriate to report as the application of skin substitutes. In contrast to skin substitutes, the CPT procedure codes associated with wound care management are markedly different in both their purpose, as well as products used in their delivery.

The RUC and CPT Panel processes operate in an open and transparent manner. When this family of codes was created in 2012, the Panel heard from many different stakeholders regarding variations in the technology. In the provided definition and related code descriptors from CPT 2022, it is clear that skin substitutes are very specific and separately reportable from wound dressings. Changing the terminology to "wound management" would differ from CPT nomenclature and cause confusion and inconsistent

reporting. The CMS proposed terminology incorrectly states that skin substitute products are not technically a substitute for skin, but rather, a wound covering that is used to promote healing. This is not factual, as the application of skin substitutes provide a very specific purpose of temporary or permanent coverage of open skin wounds. For example, temporary skin substitutes are used to decrease pain, augment healing, and close the clean wound until skin is available for grafting. Permanent skin substitutes are used to add or replace remaining skin components and provide a higher quality of skin than a thin skin graft. Therefore, the assumption that a skin substitute is just a wound covering is inaccurate as the application is part of the recovery process and does function similarly to skin as it is not always removed. In either the temporary or permanent circumstance, the skin substitute is allowing for the construction of natural dermis which goes above and beyond a "wound covering" or the application of an ointment, etc. Currently, the CPT coding guidelines specifically outline the application of skin substitutes grafts as non-autologous human skin (dermal or epidermal, cellular and acellular) grafts (e.g., homograft, allograft), non-human skin substitute grafts (i.e., xenograft), and biological products that form a sheet scaffolding for skin growth. Therefore, there is the possibility that as technology evolves, new categories of wound care may become available. However, the CPT guidelines and reporting for skin substitutes are clear and they do not include the application of non-graft wound dressings (e.g., gel, powder, ointment, foam, liquid) or injected skin substitutes and those items should not be lumped together in a catchall terminology such as "wound management."

If CMS has identified the need for additional granularity or terminology, we ask that they work closely with the CPT Editorial Panel and the relevant medical specialty societies to determine the optimal pathway forward. It is imperative that CMS and the CPT Panel have the same understanding and background when it comes to these important codes, as creating inappropriate and/or inconsistent terminology will create additional burden for physicians and patients who receive these services.

The AMA and CPT Editorial Panel appreciate CMS noting the potential for confusion related to the term "wound care management." **However, we request that CMS, and any relevant industry representatives, work directly with the CPT Editorial Panel to determine the best approach. Finally, the AMA maintains that items of this nature (i.e., high-cost disposable supplies) should remain separately reportable and not bundled within practice expense as aforementioned.**

G. Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services

Recommendation:

- The AMA strongly encourages CMS to halt its proposal for 4 new G-codes, allow for general supervision when physicians and other QHPs use the treatment management services and continue to cover CPT codes 98980 and 98981. The AMA also recommends that CMS negate the need for a crosswalk by accepting software as a direct practice expense input.

The AMA is disappointed by CMS' continued concerns about RTM "…treatment management codes as described by the CPT and RUC." The AMA does not share CMS' "…concern about the inclusion of clinical labor in codes that could be billed by qualified nonphysician healthcare professionals…." Separate HCPCS II (G) codes cause confusion, create administrative burden for physicians and other QHPs, and fail to adequately pay for professional activities.

As clarified in the AMA comment letter for CY 2022 MFS Proposed Rule, the primary billers of RTM codes are not nurses and physical therapists, rather they are a range of professionals including

physiatrists, nurse practitioners, and physical therapists. For all codes in the RTM family, the clinical staff type of RN/LPN/MA will be typical, because it was estimated that most of the RTM services will be reported by physicians or nurse practitioners. However, physical therapists would supervise physical therapy assistants or physical therapy aides when they provide the same RTM services. The AMA agrees with CMS that tasks performed by physical therapy assistants are billable when provided under the direct supervision of the physical therapist and under the physical therapist's NPI number, making "incident-to" policy irrelevant. Separate HCPCS II (G) RTM codes are not warranted to merely address which clinical staff type is utilized in assisting the physician or other QHPs who provide the service. Further, CMS has created two G-codes that include no direct practice expense clinical staff time, GRTM3 and GRTM4. The AMA disagrees with the creation of these G codes, not only because of the unnecessary administrative burden, but also because of confusion around clinical staff activities. Specifically, even though some QHPs do not employ clinical staff, the overall time for these activities is comparable. Generally, when QHPs do not employ clinical staff, the QHPs perform the clinical staff activities and, hence, time associated with the practice expense clinical staff component of a CPT code themselves. GRTM3 and GRTM4 will disproportionately and negatively impact QHPs that do not employ clinical staff because these QHPs will receive no payment for practice expense work that they must perform themselves to deliver appropriate patient care for RTM services.

Further, the AMA is disappointed that CMS has chosen to create two new G-codes, GRTM1 and GRTM2 which mimic CPT codes 98980 and 98981 as these G codes will include the same physician work and direct practice expense inputs. CMS asserts that the difference is that the G-codes "…will allow general supervision of the clinical labor found in the direct PE inputs." The AMA reminds CMS that supervisory restrictions are CMS rules and, as such, CMS is choosing not to allow for an exception to their own rule. Instead, CMS' G-codes create additional confusion and administrative burden to accommodate the supervision exception, and accommodate CPT codes 98980 and 98981 being non-payable by Medicare. The AMA contends that this "solution" is not necessary, and it would be more straightforward to allow for general supervision of CPT codes 98980 and 98981.

CMS is seeking comment on the "…RTM devices that are used to deliver services that meet the "reasonable and necessary" standard…." The CPT Editorial Panel specifically developed the RTM family of codes to be more granular than remote physiologic monitoring (RPM) in the types of devices used. The Panel designed the family so that additional device supply codes could be added to the family as clinically appropriate requests were received by the CPT Editorial Panel. The intention was that if an RTM device was not yet represented with a device supply code the treatment management codes could be utilized so the physician or other QHP could receive payment for the work associated with managing treatment and monitoring data originating from an RTM device, even if they were not receiving payment for the device itself. CMS' proposed requirement that to report GRTM1 and GRTM2, CPT codes 98975, 98976 or 98977 must also be billed, undermines the intent of the family of codes. By limiting use of the new G-codes, this restriction is counter to the Agency's claims to be proposing the G-codes to increase access. Rather than provide comments on RTM devices in this comment letter, the AMA encourages CMS to review RUC recommendations for new CPT codes describing devices and the associated costs as they make their way through the CPT and RUC processes. **The AMA strongly encourages CMS to halt its proposal for 4 new G-codes, allow for general supervision when physicians and other QHPs use the treatment management services and continue to cover CPT codes 98980 and 98981.**

For CY 2022, CMS decided to crosswalk the direct practice expense for 98976 to RPM device supply code 99454 rather than accept the RUC's recommendation for a new supply item, *Remote respiratory therapy system*, stating that this $25 monthly rental fee would not be paid as a direct cost under the MFS. The monthly fee per patient comprises the leasing of the Bluetooth sensors (2 provided in each rental)

placed on top of the patient's inhalers (typically 1 daily use inhaler and 1 rescue inhaler) as well as use of the app technology for tracking. For CY2022 CMS stated that the Agency has historically "considered most computer software and associated licensing fees to be indirect costs." The AMA believes that this is an inaccurate assertion. While this may have been the case with generic software like Microsoft Office, it is not true for procedure-specific software. There were 207 CPT codes for 2023, that included "software" direct inputs. CMS would not be setting a precedent of including software and associated licensing fees in codes like 98976. The 43 CMS equipment codes containing software are listed below:

CMS Code	**EQUIPMENT Description**
ED009	computer and VDT and software
ED020	computer workstation, nuclear pharmacy management (hardware and software)
ED040	genetic counseling, pedigree, software
ED051	multimodality software
ED058	CAD Software
ED060	sheer wave elastography software
ED063	Sequence data analytics (alignment/variant calling) and reporting software
EP090	IkoniLan Software
EQ008	ECG signal averaging system, w-P-waves and late potentials software
EQ013	EEG analysis software
EQ018	EEG, digital, standard testing system (computer hardware & software)
EQ027	Farnsworth-Munsell 100-Hue color vision test w-software
EQ070	barostat system, with hardware & software
EQ075	breast biopsy imaging system, stereotactic (imager, table, software)
EQ087	cognitive abilities testing software (Woodcock Johnson)
EQ135	impedance recording workstation w-software
EQ187	nutrition therapy software (Nutritionist Pro)
EQ196	pH recording workstation w-software (Bravo)
EQ197	pH recording workstation w-software (Digitrapper)
EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)
EQ212	pulse oxymetry recording software (prolonged monitoring)
EQ218	range of motion (spinal) device and software (Myo-Logic)
EQ222	rhinomanometer system (w-transducers and software)
EQ284	reader software, CASCADE (Caldwell Labs)
EQ298	Coronary CTA Post Process Software
EQ303	dermal imaging software
EQ305	Diabetes education data tracking software
EQ307	Electrophysiology, Pulmonary Vein Processing Software
EQ312	INR analysis and reporting system w-software
EQ315	Left Ventricular Function Software
EQ329	ZEPHR impedance / pH reflux monitoring system with data recorder, software, monitor, workstation and chart
EQ330	EEG, digital, testing system (computer hardware, software & camera)

EQ380	flow cytometry analytics software
ER019	densitometry unit, fan beam, DXA (w-computer hardware & software)
ER030	film dosimetry equipment-software (RIT)
ER055	radiation therapy dosimetry software (Argus QC)
ER070	portal imaging system (w-PC workstation and software)
ER077	image-acquisition software and hardware (Brainwave RealTime, PA, Hardware)
ER081	Calcium Scoring Software
ER112	Software and hardware package for tumor and other distribution Quantitation
ER123	Sanet Vision Integrator display/software
ES029	video system, capsule endoscopy (software, computer, monitor, printer)
ES049	incision programming software

To date CMS has valued the practice expense for the RTM PE-only codes using crosswalk methodology. While the AMA acknowledges that using a crosswalk could result in similar total resource costs, the AMA questions the use of a crosswalk to CPT code 99454 which would overvalue the PE for 98976 where the only input is the monthly fee of $25. This crosswalk approach is not resource-based. Monthly fees such as the one previously recommended for 98976 represent a per-patient, single-use item, and thus is appropriately included as a direct supply. **The AMA recommends that CMS negate the need for a crosswalk by accepting software as a direct practice expense input.**

H. Telehealth and Other Services Involving Communications Technology

Recommendations:

- The AMA strongly supports the CMS proposal to continue paying for telehealth services that were scheduled to be covered only through the end of the COVID-19 Public Health Emergency (PHE) for an additional 151 days beyond the end of the PHE.
- CMS should continue its current coverage and payment policies for telephone visits and audio-visual telehealth services until the joint CPT/RUC Telemedicine Office Visits Workgroup determines accurate coding and valuation, as needed, for office visits performed via audio-visual and audio-only modalities.
- CMS should lift the frequency limit on subsequent nursing facility visits delivered through telehealth as physicians already must provide the required regulatory patient visits in-person. At a minimum, no limitation should be applied to the frequency of subsequent nursing facility visits for at least 151 days after the PHE ends.

1. Extension of Telehealth Services Beyond PHE

During the COVID-19 PHE, with strong support from the AMA, CMS significantly expanded the Medicare Telehealth List through the addition of about 150 services that can now be provided via telehealth, including emergency department visits, critical care, home visits, and telephone visits. It also created two new categories of interim telehealth services. Codes in Category 3 of the Medicare Telehealth List are covered on an interim basis through the end of 2023 to allow data to be developed after the PHE has ended that could help CMS determine whether these services should be permanently added to the Medicare Telehealth List or not. An additional category of services was only slated to be available via telehealth until the end of the PHE.

In March 2022, the Consolidated Appropriations Act included several provisions extending the telehealth policies that have been in place during the PHE for an additional 151 days after the PHE ends. For example, Medicare telehealth services will continue to be available to patients all over the country, not just those in rural areas, and patients will continue to be able to receive telehealth services in their homes or wherever they are located without going to a medical facility. The law also delayed the requirement for Medicare patients to see a physician in-person 6 months prior to receiving their first telehealth service for a mental health condition and extended the availability of audio-only telehealth services. Consistent with these provisions, CMS proposes to similarly extend Medicare telehealth coverage for the codes that were only going to be on the telehealth list through the end of the PHE for 151 days after the PHE ends. The AMA strongly supports this proposal and urges that it be finalized.

2. Future Payment Policies

In response to an AMA recommendation that the three CPT codes for telephone visits be added to Category 3 and be covered on an interim basis through 2023, CMS states that it decided not to add the telephone visit codes to Category 3. CMS confirms, however, that the telephone visit codes will now be covered on the Medicare Telehealth List for 151 days after the PHE ends. CMS also raises concerns about the statutory authority to extend telehealth coverage for these services, noting that the Agency believes the statute requires telehealth services be so analogous to in-person care such that the telehealth service is a substitute for a face-to-face encounter, but that the audio-only CPT codes are inherently non-face-to-face. Section 1834(m)(2) of the Social Security Act, which CMS cites in the proposed rule as the basis for this belief, pertains only to the "Payment Amount" for telehealth services. The only reference in Section 1834(m) to which services may be covered when provided via telehealth is in 1834(m)(4)(F)(i), the definition of telehealth service, which includes "any additional service specified by the Secretary." There is no prohibition in the statute against defining telephone visits as telehealth services.

During the COVID-19 PHE, physicians have had much more experience with delivering telehealth services, including audio-only services, than was the case prior to the pandemic. The AMA has now formed a CPT/RUC Telemedicine Office Visits Workgroup to assess the available data and ascertain the appropriate next steps to determine accurate coding and valuation, as needed, for office visits performed via audio-visual and audio-only modalities. The AMA urges CMS to continue its current coverage and payment policies for telephone visits and audio-visual telehealth services until the joint CPT/RUC Telemedicine Office Visits Workgroup has an opportunity to do its work.

CMS is also proposing that, following 151 days after the PHE ends, Medicare telehealth services would revert to being paid at the "facility" rate instead of the "non-facility" rate. The rationale for this proposal is that CMS believes that the facility payment amount "best reflects the practice expenses, both direct and indirect, involved in furnishing services via telehealth." Section 1834(m)(2) of the Social Security Act, however, requires the Secretary to "pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system." If the physician is based in a non-facility setting, therefore, such as an office, the statute requires that the services provided using a telecommunications system be paid at the non-facility rate.

CMS reiterates in this proposed rule its plan to allow telehealth services for the diagnosis, evaluation, and treatment of mental health conditions to continue to be payable after the 151-day period following the end

of the PHE, including audio-only services. The rule cites as an example that the office and outpatient visit codes will be reportable when furnished via audio-only technology for mental health conditions. The AMA would appreciate having more information about how physicians and other health professionals should plan to report these codes in a way that the administrative contractor would know that the audio-only service was for a mental health condition.

3. Telehealth Visits for Nursing Facility (NF) Patients

In the 2021 final rule, CMS finalized a policy to allow subsequent visits to be furnished via Medicare telehealth once every 14 days in the NF setting. Prior to the COVID-19 PHE, Medicare telehealth visits in the NF setting could only be furnished once every 30 days. In explaining this policy, CMS expressed concern about potentially providing a disincentive for NF patients to receive in-person physician visits.

During the PHE, this frequency limit has not been applied. It is not clear in the proposed rule whether this is among the policies that will be extended for 151 days after the PHE ends. The AMA recommends that no limitation be applied to the frequency of subsequent nursing facility visits for at least 151 days after the PHE ends. The AMA further recommends that this frequency limit be permanently eliminated.

The discussion in the 2021 rule about 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 an NF "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, CMS reinstated the requirement that was in place prior to the PHE that the NF patient visits required by regulation must be provided by the physician in-person and cannot be provided via telehealth. Given that the regulatory visits are already required to be provided in-person, the AMA recommends that CMS remove the frequency limit on furnishing subsequent nursing facility visits via telehealth. When a patient in an NF 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 telehealth visit in the NF could help avoid the patient being transported to an emergency department.

I. Proposal and Request for Information on Medicare Parts A and B Payment for Dental Services

CMS has the broad authority to explore the delivery of new services, to test approaches that reduce health care spending, and to modify or terminate approaches that do not advance the Agency's goals around quality, health equity, and costs. CMS should marshal expertise in dental services and clinical care to test the effectiveness of its proposal to cover dental services that are integral to a Medicare Part A procedure or service.

Recommendation:

- CMS should conduct a demonstration to determinate the financial and operational efficiencies for Medicare patients with underlying medical conditions who require integral dental services as a condition of their covered, primary Medicare Part A service. The demonstration should be the vehicle for vetting the proposals CMS is making in the proposed rule for dental services determined to be inextricably linked to the clinical success of a covered medical service, and a funding source separate from and without impact on the Medicare Physician Payment Schedule should be used to cover these dental services. The demonstration should leverage existing

evidence linking dental services to clinical quality outcomes for the Medicare Part A procedures listed and should lead to more research on the effectiveness of the dental services for the services beyond those piloted.

The AMA has long recognized dental care is an important component to address the total health needs of a patient. Our AMA recognizes the importance of managing oral health and access to dental care as a part of optimal patient care. Over the years, the AMA has worked with the American Dental Association (ADA) and other interested national organizations to improve access to dental care for Medicare beneficiaries. Together with the ADA, the AMA has explored opportunities for collaboration on a comprehensive strategy improving oral health care and education for clinicians. The AMA is committed to working with interested national medical specialty societies and state medical associations to encourage and promote research into dental health, and to increase patient access to dental services. We have also supported several dental health initiatives: (1) expanding health services research on the effectiveness of expanded dental coverage in improving health and preventing disease in the Medicare population; (2) examining optimal dental benefit plan designs to cost-effectively improve health and prevent disease in the Medicare population; and (3) quantifying the impact of expanded dental coverage on health care costs and utilization. The AMA is committed to research on dental coverage, benefits, and options which will inform policymakers on how best to deliver effective, affordable dental services. While the AMA sees the need for dental care, we have serious concerns with the method CMS is proposing to extend this coverage in the proposed rule. The details in the proposed rule are very few, just citing that the proposed services would be paid for under Medicare Part A and Part B. We acknowledge that Medicare Part B covers services rendered from other health care providers in addition to physicians (such as physician assistants, nurse practitioners, speech language pathologists). As it relates to payment of dentists, the AMA wants to clarify we do not believe the Medicare Physician Payment Schedule is the appropriate fit for immediate inclusion of dental services or benefits for Medicare beneficiaries. Indeed, the AMA has long highlighted the problems with the Physician Payment Schedule, including budget neutrality and the lack of new funding to appropriately pay for new or revalued services. The AMA believes the Medicare system will be increasingly burdened and challenged in its effort to fit dentists into a system established for physicians, given that the current system is already facing significant fiscal and operational problems that will only be further exacerbated.

CMS has the broad authority to explore the delivery of new services, to test approaches that reduce health care spending, and to modify or terminate approaches that do not advance the Agency's goals around quality, health equity, and costs. CMS should marshal expertise in dental services and clinical care to test the effectiveness of its proposal to cover dental services that are integral to a Medicare Part A procedure or service.

1. **Proposals to Clarify the Interpretation of Section 1862(a)(12) of the Act and Codify Current Payment Policies for Certain Dental Services**

Proposed Payment for Inpatient Hospital Dental Services

CMS proposes to codify its interpretation of the relevant statute and current regulation to allow for an exception to allow Medicare Part A payment for inpatient hospital services connected with the provision of dental services[1] where the individual's underlying medical condition, clinical status, or severity of the

[1] In the proposed rule, "dental services" refers collectively to "the care, treatment, filling, removal, or replacement of teeth of structures directly supporting the teeth. The AMA accepts this definition of dental services for the purpose of responding to this proposed rule.

dental procedure requires hospitalization in connection with the provision of such services. CMS notes the previous interpretation of their existing policies was too narrow, and that through this section, they are codifying the current payment policies under Medicare Part A. The AMA supports CMS' clarification of Section 1862(a)(12) and codifying the existing payment policies for the exceptions to allow certain dental service coverage when the individual's underlying medical condition, clinical status, or severity of the dental procedure requires hospitalization in connection with the provision of such services.

CMS should emphasize that dental procedures are permissive before a Medicare Part A service but are not expected. Further, the AMA asks for CMS to share the full list of dental services rendered prior to or during inpatient Medicare Part A procedures obtained from the comment period, so that stakeholders can respond to the list of dental procedures performed. Similar to the Telehealth List,[2] the Dental List could include the appropriate code, a short descriptor, the status, or which Medicare Part A procedure(s) associated with the dental service, and any limitations. The AMA asks that the list of dental services not be finalized until after CMS compiles and shares the proposed list of dental services with the public for comment.

The descriptors that CMS lists for the 5 suggested procedures do not clarify what is involved in some of the services. The terms used, such as "restorative" in restorative dental services (to eradicate infection in a patient requiring an organ transplant) leave much to interpretation in terms of what is actually included. Restorative may mean an extraction, or it may mean performing a root canal and addressing the oral issue in a different way. Important to understand and operationalize is whether the dental services to restore are intended to address the limited oral issue in preparation for the organ transplant, or whether care would be rendered to another, longer but logical conclusion. This example is an important one to discuss in terms of payment, because the scope of services and the services performed will certainly impact payment under this policy. CMS is asked to provide much more depth on what it proposes should be considered for each Medicare Part A procedure under this new policy as "dental services."

Proposed Clarification of the Interpretation of Section 1862(a)(12) and the Codification of Current Payment Policies for Certain Dental Services

CMS proposes "to interpret the statute under section 1862(a)(12) of the Act to permit Medicare payment under Parts A and B" for dental services it considers inextricably linked to a Medicare Part A service, whether those dental services are performed in the inpatient or outpatient setting. CMS notes that in a limited number of circumstances, dental services are paid under Medicare Part B. CMS references payment policies for dental services in its policy manual (the Medicare Benefit Policy Manual, Chapter 15)[3] and the Medicare National Coverage Determinations Manual, chapter 1, Part 4.[4]

CMS lists the dental services that could be considered inextricably linked to and substantially related and integral to the clinical success of the following 5 Medicare Part A procedures that are listed in the MBP and NCD Manuals, and proposes the Medicare Part A procedures and the dental services should be covered under Medicare Part A and Part B:

1. Reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor;

[2] For the Telehealth List, access https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
[3] IOM Pub 100-02, Chapter 15, section 150.
[4] IOM Pub 100-03, Chapter 1, Part 4, section 260.6. Also referred to as "the NCD Manual."

2. The wiring or immobilization of teeth when done in connection with the reduction of a jaw fracture;
3. The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease;
4. A dental splint only when used in conjunction with covered treatment of a medical condition; and
5. An oral or dental examination performed as a part of a comprehensive workup prior to renal transplant surgery (such as services described by ICD-10 Z94.0 and codes D0150, D0180, or D0160).

Assuming CMS has determined previously that these dental procedures could be inextricably linked to and substantially related and integral to the clinical success of the above listed Medicare Part A procedures, the AMA accepts that evidence and clinical review have already been provided to substantiate the dental service coverage when provided on an inpatient basis when the patient's underlying medical condition, clinical status or severity of the dental procedure requires hospitalization. The AMA asks that going forward, CMS require the presentation and review of research as well as clinical evidence to justify the link between a dental procedure listed and the Medicare Part A procedure. The AMA supports expanding health services research on the effectiveness of expanded dental coverage in improving health and preventing disease in the Medicare population, and the approach we suggest is consistent with our policy. We believe this approach will better inform all clinicians of what they should consider in the care of their patients in advance of the above listed Medicare Part A procedures, and in advance of possible dental services.

The AMA does not want CMS to continue to cite proposed payment under Medicare Parts A and Parts B for dentists with a broad brush. We acknowledge that payment for a dental or oral examination could be made for dentists under Part A if performed by a dentist on a hospital's staff, or under Part B if performed by a physician. Furthermore, the NCD Manual is clear that a dentist is not a physician when performing a dental or oral examination. We continue to offer below further insight to why inclusion of dentists under Medicare Part B would not be practical at this time. The AMA includes this list of important questions related to the integration of dentists under Medicare Part B that are not addressed in the Proposed Rule, and should be open for public comment:

1. Would dentists be viewed as health professionals, and would the Medicare Provider Enrollment, Chain, and Ownership System be expanded to include them?
2. Would dental offices be subject to conditions of participation or conditions of coverage as hospitals and ASCs are?
3. Would dentists be required to report quality measures if performing dental services inextricably linked and substantially related and integral to the clinical success of a Medicare Part A procedure?
4. Would dentists be required to use electronic dental record systems?
5. Dentists have their own coding system and claim form—how would this be integrated into the Medicare program generally, and into the Medicare physician fee schedule specifically?

CMS should create a pathway for payment of dentists under Medicare Part B with all the necessary administrative, enrollment and compliance requirements that other providers must meet under the same section. It is important for CMS to detail how dentists would be expected to onboard into the Medicare system in order to deliver the dental services as described. The process of being a Medicare provider is a necessary pre-requisite for all other providers, and dentists performing these services should be held to the same standard. Auxiliary personnel such as dental hygienists, dental therapists, or registered nurses who

provide dental and ancillary services furnished incident to the dental procedure must also be properly enrolled in the Medicare system.

The AMA defers to the ADA to determine whether the descriptions of dental services deemed inextricably linked to and substantially related and integral to the clinical success of the 5 Medicare Part A procedures are accurate. The AMA knows there may be alternatives to any one procedure, so a range of dental services may have to be contemplated on a case-by-case basis depending on the beneficiary's unique medical and dental condition. Whereas CMS has included layman's descriptions of the dental services that could be inextricably linked to and substantially related and integral to the clinical success of the above listed Medicare Part A procedures, CMS should also routinely use the Current Dental Terminology (CDT) codes to identify the suggested procedures. The terminology CMS uses in the proposed rule may broadly describe the dental service to patients, but the AMA asks CMS to use appropriate terminology to identify the dental services intended to be used with Medicare Part A services. Descriptions of dental services should not replace the CDT.

In the final rule, the AMA asks CMS to clearly state that payment for the proposed dental services associated with the inpatient Medicare Part A procedures described will not impact the physician payment schedule. CMS has signaled that it is codifying its existing policies related to dental services in the proposed rule as well as expanding them to include dental procedures that are inextricably linked to, and substantially related and integral to the clinical success of the other covered medical service(s). CMS currently pays a contractor price for associated dental services, and CMS has indicated that those payments do not significantly impact costs. The proposed rule lacks an impact analysis on the dental proposal, indicating that the anticipated impact of the proposed policy is insignificant. The lack of an impact analysis or cost modeling does not allow us to properly consider the impact of paying dentists under Medicare Part B.

The AMA agrees CMS should include the examples of the dental services for which payment is permitted under its current policy, noting both the descriptions of the dental services along with their CDT codes, including services that are ancillary to the dental services (such as x-rays, administration of anesthesia, use of an operating room, and other hospital facility services). The AMA believes CMS should clarify what it anticipates as a part of the dental procedure, including the ancillary services, so all stakeholders involved in the patient's care have a sense of the procedures and the costs.

Proposed Update to Current Payment Policies for Dental Services

CMS lists 3 additional Medicare Part A procedures where it believes the clinical success may require the performance of certain dental services: (1) restorative dental services to eradicate infection in a patient requiring an organ transplant; (2) dental or oral examination and treatment prior to a cardiac valve replacement; and (3) dental or oral examination and treatment prior to a valvuloplasty procedure. While the AMA does not dispute the connection between the dental services and potential medical outcomes as described, the AMA urges CMS to take a more methodical approach to adding additional services to its list at this time. CMS has noted already MACs have the ability to make case-by-case determinations for dental services inextricably tied to Medicare Part A procedures, and MACs routinely authorize such services. The AMA notes that leaving dental coverage determinations to the MACs could create inconsistencies between states, which will be counter to CMS' efforts to reduce health inequities. Moving forward, the AMA asks for CMS to institute a process to allow medical and dental experts through an advisory panel to hear relevant evidence and research on which dental services should be considered and excepted from the dental exclusion. The AMA asks for CMS to move away from making these coverage

determinations in the Physician Payment Schedule proposed rule and absent a transparent process to consider the evidence. CMS suggests a future timeline and process for the consideration of additional Medicare Part A procedures; the AMA asks for CMS to implement its process and to consider the additional 3 procedures under that new, proposed system.

CMS proposes to pay contractor price for CY 2023, or until it has further data to establish prospective payment rates. It is not clear how long the contractor rates would continue beyond 2023, and for that reason, the AMA repeats the suggestion that CMS pilot its coverage and payment for dental services in a demonstration program until it can amass sufficient data to establish its policies. CMS should model expected utilization, collect data, evaluate its payment, and present the information back to stakeholders before finalizing its policies.

2. Other Clinical Scenarios for Dental Services Integral to Other Covered Medical Services

The AMA limits our comments to the 5 Medicare Part A professional services referenced in the proposed rule that are in the NCD Manual, as we are unable to comment on a broader list of procedures that would be suitable for integral dental services at this time. Important to the AMA limiting our comments to the proposed procedures and declining to offer or consider additional services at this time is the need for a process that involves a physician-led team with medical and dental experts versed in the science and evidence for procedures and services that will be covered under 411.15(i).

At the start (or codification) of the dental services policy for existing Medicare Part A services, CMS should focus on the dental services it has determined, based on clinical evidence, experience, cost, and quality outcomes, to be inextricably linked to the clinical success of the five listed Medicare Part A services. CMS acknowledged in the proposed rule that other services such as joint replacements, head and neck cancer surgery, or immunosuppressant therapy for other cancer treatments may be suitable for certain dental services. CMS also acknowledged that for some of these additional procedures, clinical evidence does not support the need for a dental exam and dental treatment. More than asking for feedback in the proposed rule, CMS needs to institute a process for reviewing evidence, research, and stakeholder involvement to inform its future decisions on coverage. CMS may also utilize an Advisory Board or Panel for this specific purpose. The Advisory Board or Panel can analyze the suggested Medicare Part A procedures and determine which inextricably linked dental services should be associated with the procedures. Again, we reiterate that any of these covered medical procedures should be only those needed to be provided on an inpatient basis consistent with section 1862(a)(12) based on the patient's condition.

The AMA strongly supports the team approach to patient care, with each member of the team playing a clearly defined role as determined by his or her education and training. While we greatly value the contribution of dentists to the physician-led care team, the majority of dentists are not trained at a level equivalent to the four years of medical school, three-to-seven-years of residency training, and 10,000-16,000 hours of clinical training that is required of physicians. In order to be recognized as a physician with an unlimited medical license, medical students' education must prepare them to enter any field of graduate medical education and include content and clinical experiences related to each phase of the human life cycle.[5] Conversely, dentists must complete four years of dental school, without having additional residency or clinical training requirements. The AMA understands that most of the procedures described in the examples in the proposed rule could be performed by general dentists. If this were the case, the expectation would be for the care to be led by and coordinated by the beneficiary's medical physician leading the Medicare Part A service or procedure. For those dentists who are specialists, such as

[5] https://medicine.vtc.vt.edu/content/dam/medicine_vtc_vt_edu/about/accreditation/2018-19_Functions-andStructure.pdf.

oral surgeons with MD degrees, it is important to consider that the primary procedure for the patient in the instances described are medical procedures under Medicare Part A and therefore, the medical physician should lead the care team. The American Dental Association (ADA) even defines a dentist as someone that evaluates, diagnoses, and treats diseases, disorders or conditions of the oral cavity, maxillofacial area and the adjacent or associated structures.[6] This definition highlights the narrow specialty that dentists have and the importance of a physician-led care team. Given the complexity of the patient population, it is essential that we retain collaborative guardrails that require dentists to consult physicians who have the education and training to effectively manage the entire treatment plan, including holistic patient needs.

As such, it is imperative that it is emphasized to the entire care team, including dentists, that the decision for renal transplant surgery is a physician-led decision, and to ensure that dentists practice within the confines of their state scope of practice laws, which does not include making decisions about the renal health of a patient. For consideration of any Medicare Part A medical procedures listed in the section of the proposed rule, physicians should lead the care team, stakeholders should have input, the deliberations be transparent, and provide data on cost, quality, and outcomes. In addition to establishing a process and an advisory committee of medical and dental experts, the AMA asks CMS to consider addressing the following questions, which will help operationalize its proposals:

1. How should a physician determine whether to proceed with the medical service before or without the dental service? Is there a threshold for this determination for each procedure?
2. How should dental services be coordinated with a patient's physician?
    - Assuming the patient has a routine source of dental care, how should a dentist initiate the outreach to a patient's physician regarding a dental or oral procedure before a Medicare Part A procedure?
    - In the event a Medicare Part A patient does not have a routine dental home, how would the dental services inextricable to the surgery be handled?
    - Does the patient's physician have a new obligation to seek out a dentist for a patient who may need to have a Medicare Part A procedure and who may or may not need dental services?
3. If a patient refuses to have the dental services performed, but consents and requests to proceed with the medical procedure, should the Medicare Part A procedure be performed?
4. How do we recognize the dental services rendered in the calculation of quality scores and for reporting?

CMS asks for comments on whether dental services furnished after the covered medical procedure or treatment might be covered under Medicare. Again, the AMA has serious concerns about how this may be determined, and the coordination between the physician and the dentist to make these decisions. The AMA believes a more thoughtful and deliberative process is necessary to make these determinations, even where clinical evidence may already exist. We reiterate our request for CMS to establish a demonstration program to better coordinate how this might be operationalized.

3. Establishment of a Process to Consider Additional Clinical Scenarios for Future Updates

CMS should further develop its process for soliciting and evaluating clinical scenarios where dental services are inextricably linked to, and substantially related to the clinical success of a Medicare Part A procedure. CMS should involve a team of medical and dental experts to review the submissions. The

[6] https://www.aadsm.org/scope_of_practice.php.

process should be transparent, noting any dental, medical, or other groups that put forth the suggested procedures. Again, CMS should implement a demonstration project to test all aspects of its proposal for dental services, including the solicitation and evaluation of Medicare Part A procedures and inextricably linked dental services. Auxiliary services for consideration associated with the Medicare Part A procedures should also be solicited and shared publicly for public comment and possible inclusion. The AMA strongly cautions against moving quickly without a thoughtful process—CMS should establish a process that is evidence-based and involves stakeholder feedback. The AMA asks CMS to develop a demonstration model, including a process to consider additional Medicare Part A and inextricably linked dental services.

4. Request for Comment on Other Potentially Impacted Policies

CMS asks for feedback on other potentially impacted policies from the proposed rule dental services. While there are a number of policies impacted by the proposed dental services expansion, the AMA highlights the following and asks CMS to consider them in its demonstration before making any policies final.

a. Coordination of Care. Recognizing that some Medicare beneficiaries may have supplemental dental coverage or a Medigap plan for dental coverage, it still remains the case that most dental services are not coordinated with a beneficiary's medical providers.

b. Financing and Delivery. As CMS proposes to include dental services that are inextricably linked to Medicare Part A procedures through a regulatory process, the AMA points out that the costs for these dental services should not impact the Medicare physician payment schedule. The physician payment schedule is already under tremendous strain with the current procedures and providers, and the potential inclusions on dentists for dental services will only push the system to the edge of an already sinking cliff.

A CMS demonstration project is critically important to see how to best involve dental services proposed. With the rise of health care delivery models, accountable care organizations (ACOs), and other care management services, it is important to consider how dental services would be delivered and financed.

c. Budget Neutrality. The AMA has urged CMS to work with Congress to address the budget neutrality issue in the physician payment schedule, and the AMA continues to emphasize that CMS should exercise the full breadth and depth of its administrative authority to avert or, at a minimum, mitigate physician payment cuts brought about because of budget neutrality. With the proposal to include dental services through a regulatory addition, the AMA strongly opposes the use of the physician payment schedule to expand dental services. Payment for dental services should be fully funded like the other parts under Medicare Part B and should not exacerbate the current reductions physicians face under budget neutrality. The current physician payment schedule system often pits physician specialties against each other, and it should not be CMS' intention to put dentist at odds with physicians over the same, limited, unfunded pool of money. New provider services should not be subject to budget neutrality, especially those that are implemented through regulation. In 2023, the payment of any dental services as proposed in the rule should be outside of the physician payment services pool. Furthermore, the calculation of future payments should remain outside of the Medicare physician payment service calculation, and should be the subject of future comment, study, and analysis.

d. Care Coordination and Physician-Led Teams. By the very nature of believing a dental service is inextricably linked to the quality and clinical circumstances of a Medicare Part A procedure, it is fair to assume that a potential patient's situation contains a degree of risk and warrants care coordination among providers. The AMA believes a patient's physician leading the Medicare Part A procedure should lead the team coordinating the care, which includes leading the dentist involved in the dental services. It is not possible to say whether the existing care management codes currently used adequately describe and account for time spent coordinating for dental services; this should also be explored as a part of the CMS demonstration project.

It is imperative to put the health and safety of the patient first. This means not creating silos in the delivery of appropriate health care. Accordingly, it is imperative that if the interpretation of physician is changed, the importance of the physician-led care team is reinforced. The medical-dental collaboration is an important one, and the way it is operationalized is crucial to its success.

e. Quality Reporting. The integration of dental services into Medicare Part A procedures will undoubtedly impact quality. The CMS demonstration project should explore how to best account for procedures performed with and without recommended dental services to better account for and understand the impact of the dental services on clinical outcomes.

5. Request for Comment on Potential Future Payment Models for Dental and Oral Health Care Services

CMS notes its broad waiver authority under section 1115A(d)(1) of the Act, which allows it to waive requirements of title XVIII of the Art. CMS points to 2014 Health Care Innovation Awards Round 2[7] (HCIA R2) to highlight that several participants tested models of clinical care that included payment for dental and oral services. The reference to the HCIA holds little to no relevance for the purpose of financing dental services inextricably linked to Medicare Part A services.

HCIA R2 focused on several goals including reducing costs in outpatient or post-acute care settings and fostering new payment models to support service delivery innovation. The HCIA R2 models focused on populations, sites of service, and medical conditions unlike those proposed in this rule.

- Altarum Institute created the Michigan Caries Prevention Program[8] for early childhood dental care to establish dental homes early in childhood. Enhanced fee-for-service payments were provided to dentists for delivering preventive dental services to children under the age of three.

- The Children's Home Society of Florida (CHS) expanded access to preventive, primary, dental, and behavioral health care services. Most dental services were for dental caries. The proposed per beneficiary per month payment model was unsuccessful in negotiating a payment contract with any Medicaid managed care organizations by the conclusion of the award.[9]

[7] https://innovation.cms.gov/data-and-reports/2020/hcia2-fg-finalevalrpt.

[8] According to the HCIA R2 Report, "The impact of the program on Medicaid expenditures could not be examined … . [Altarum] was unable to engage payers after finding insufficient evidence of cost savings."

[9] As noted in the HCIA R2 Report, "IT was not possible to conduct a rigorous impact evaluation of the CHS program and measure the impact of the intervention on service use and cost…."

- The Trustees of Columbia University in New York City created the MySmileBuddy program and engaged hospital-based pediatric dental delivery clinics to identify and refer eligible families, but "directly engaging providers was not a core component of the service delivery model." A per beneficiary per month Medicaid payment to dentists was proposed, but the awardee did not implement the model during the study period.

The HCIA R2 that CMS references in discussing future payment models does not include any examples of Medicare patients, individuals needed inpatient hospital services, or the kinds of dental services that are included in the proposed rule. The HCIA R2 models provide no insight on how to successfully structure payment to dentists for dental services to a Medicare beneficiary in an inpatient hospital setting prior to or in conjunction with a serious Medicare Part A procedure.

The AMA recommends CMS undertake a demonstration project to explore how to pay dentists for the services envisioned associated with a limited set of Medicare Part A procedures, ensuring that the dentists bill their services to the hospital facility or alternatively, submit a claim to Medicare by becoming a Medicare provider. The AMA reiterates that the dental services proposed in the rule should be paid under Medicare Part A or Part B but should not impact the physician payment schedule. The physician payment schedule is not configured or stable enough to make payments to dentists for the services highlighted in the proposed rule. Though it is possible that the suggested services will not have a large financial impact, the full extent of the cost of these services is currently unknown since they have not been paid out or tracked before this point in time. The AMA does not believe dentists should draw down from the limited physician payment services bucket, which will only exacerbate a problem that is already at a critical point for physicians.

J. Audiology Services and Waiver of Physician Order

Recommendation:

- Due to the increased education and training of physicians, the serious medical conditions associated with hearing loss, the ability of physicians to better treat and diagnose the whole patient, and the negative consequences of removing physicians from the care team it is imperative that the Administration continue to require that physicians order audiology services.

The AMA opposes removing the physician order requirement for certain audiology services. Currently all diagnostic tests, including audiology tests, must be ordered by the treating physician who uses the results to manage the beneficiary's care. This order requirement helps ensure that the physician has a relationship with the beneficiary, and that the tests are reasonable and medically necessary. However, the proposed rule would remove the order requirement under certain circumstances for certain audiology services furnished personally by an audiologist for non-acute hearing conditions.

The AMA understands the need to ensure that audiology services are provided in a timely and accurate manner. Though the AMA applauds the Department for considering the importance of audiology services, the AMA does not believe that audiologists should be allowed to provide these services without an order from a physician.

The AMA remains steadfast in its commitment to patients who have said repeatedly that they want and expect physicians to lead their health care team and participate in their health care determinations. 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.[10] However, by removing the requirement that physicians issue orders for audiology services, this rule could effectively remove physicians from the care team and result in suboptimal health outcomes with increased costs, without improving access to care.

While all health care professionals play a critical role in providing care to patients, and audiologists are important members of the care team, their skillsets are not interchangeable with that 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.[11] By contrast, audiologists, complete only four years of education, and one year of an externship.[12] Even Medicare Part B does not recognize audiologists as being able to treat or manage patients. Patients expect the most qualified person—physician experts with unmatched training, education, and experience—to diagnose and treat injured or sick individuals and make often complex clinical determinations on the nature of a potential hearing issue.

Additionally, it is more than just the vast difference in hours of education and training; it is also the difference in rigor and standardization between medical school/residency and audiology programs that matter and must be assessed. During medical school, medical students receive a comprehensive education in the classroom and in laboratories, where they study the biological, chemical, pharmacological, and behavioral aspects of the human condition. This period of intense study is supplemented by two years of patient care rotations through different specialties, during which medical students assist licensed physicians in the care of patients.[13] During clinical rotations, medical students continue to develop their clinical judgment and medical decision-making skills through direct experience managing patients in all aspects of medicine. During medical school and following graduation, students must then pass a series of examinations to assess their readiness for licensure. At this point, medical students "match" into a three to seven year residency program during which they provide care in a select surgical or medical specialty under the supervision of experienced physician faculty. As resident physicians gain experience and demonstrate growth in their ability to care for patients, they are given greater responsibility and independence.

In order to increase positive health outcomes, CMS should be moving towards a care system where hearing tests are a routine part of primary care visits, instead of placing audiology services into a silo where the physician may not even know that the patient was complaining of auditory problems. Hearing has a large impact on the holistic health of an individual, and as such, audiology tests should always be ordered by a physician so that the test results can be thoroughly reviewed and incorporated into care plans immediately, as well as ensure that "providers are aware of communication limitations with their patients to whom they must convey critically important health information."[14]

Furthermore, many audiological problems, not just balance impairments, have or could have serious medical implications. For example, higher systolic blood pressure was found to be associated with hearing loss and hypertension was also associated with a faster decline in hearing acuity.[15] Moreover,

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[10] https://www.ama-assn.org/system/files/scope-of-practice-protect-access-physician-led-care.pdf.
[11] https://www.ama-assn.org/system/files/scope-of-practice-physician-training.pdf.
[12] https://www.audiology.org/careers/become-an-audiologist/.
[13] https://medicine.vtc.vt.edu/content/dam/medicine_vtc_vt_edu/about/accreditation/2018-19_Functions-andStructure.pdf.
[14] National Academies of Sciences, Engineering, and Medicine. 2016. Hearing Health Care for Adults: Priorities for Improving Access and Affordability. Washington, DC: The National Academies Press. https://doi.org/10.17226/23446.
[15] *Id*.

"many medications have potential ototoxic effects; the best known are certain antibiotics and chemotherapy agents." Additional complications associated with hearing loss include communication difficulties, limitations in activities of daily living and instrumental activities of daily living, and cognitive function and dementia.[16] In fact, people with hearing impairment were found to be significantly more likely to experience dementia with moderate hearing loss increasing the risk of dementia three-fold, and severe hearing loss increasing the chance of dementia by five-fold.[17] Beyond the increased risk of dementia recent "literature suggests a relationship between pure-tone hearing and cognitive function as well as between some measures of auditory processing and cognitive function. Emerging data suggests other measures that fall within the audiology scope of practice may serve as useful early indicators of cognitive impairment as well."[18] As such, all aspects of hearing and hearing loss have implications on the general health of patients and should be assessed by a physician to either prevent more serious illnesses such as dementia or to consider what hearing loss might mean for the patient holistically including increased blood pressure, hypertension, a need to change medication regimes, and more. Bypassing a physician evaluation and referral can lead to delayed or incorrect diagnoses resulting in failure to treat reversible causes of hearing loss or inappropriate treatment that could cause lasting harm and increased costs to patients. Therefore, it is in the clinical best interest of the patient to be assessed by a treating physician for potentially serious medical implications associated with auditory issues and the best way to ensure that happens is to continue to require that physicians order audiological services.

Likewise, the fact that only certain audiology services will not require a physician order, resulting in a bifurcation of the code, highlights the fact that medical management is needed for audiology services. The Administration acknowledges that for certain audiology services such as vestibular function tests, it is important to have a physician treat the patient due to the potentially serious medical implications of disequilibrium symptoms. As noted above, there are many potentially serious medical implications associated with various hearing problems. Allowing audiologists to individually provide services without a physician order because of the perception that there are not serious medical implications associated with some hearing issues is a false medical assumption which should not be perpetuated within our health care system. Especially when Medicare is treating an overall older population which is much more likely to have comorbidities with serious implications if warning signs, such as hearing loss, are not acknowledged, and properly treated as early as possible. As such, as recognized by the bifurcation of code, it is important to have physicians perform medical management for hearing issues since mismanagement could result in serious negative health consequences for patients and since audiologists are not trained to perform this type of patient care. Therefore, the requirement that physicians should order audiology services for all audiology issues should not be removed.

Moreover, we share the Administration's concern about closing the loop in terms of communicating test results and treatment received by audiologists to physicians, increased and unnecessary costs due to improperly order audiology services, and changes in behavior and practice patterns leading to overutilization of audiology services.

Expanding the scope of practice for non-physician practitioners (NPPs) has resulted in an increased cost of care due to inappropriate prescribing, unnecessary referrals to specialists, and unnecessary orders for diagnostic imaging studies such as x-rays. For example, a study published in *JAMA Internal Medicine* found nurse practitioners (NPs) ordered more diagnostic imaging than primary care physicians following

[16] *Id*.
[17] https://www.nia.nih.gov/news/whats-connection-between-hearing-and-cognitive-health.
[18] https://www.mdpi.com/journal/audiolres/special_issues/cognitive_decline_audiology_scope_practice.

an outpatient visit. The study controlled for imaging claims that occurred after a referral to a specialist.[19] The authors opined this increased utilization may have important negative ramifications on costs, safety, and quality of care. They further found greater coordination in health care teams may produce better outcomes than merely expanding NPPs scope of practice alone. In addition, a recent study from the Hattiesburg Clinic in Mississippi found that allowing NPs and physician assistants (PAs) to function with independent patient panels under physician supervision 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.[20] Specifically, the study found that non-nursing home Medicare ACO patient spend was $43 higher per member, per month for patients on a NP/PA panel compared to those with a primary care physician. Similarly, patients with an NP/PA as their primary care provider were 1.8 percent more likely to visit the ER and had an 8 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 9 of the 10 measures compared to the non-physicians.[21]

Additionally, a Mayo Clinic study compared the quality of physician referrals for patients with complex medical problems against referrals from NPPs for patients with the same problems. Blinded to the source of the referrals, a panel of five experienced physicians used a seven-instrument assessment to determine the quality of each referral. Physician referrals received "significantly higher" scores in six of the seven assessment areas: (1) referral question clearly articulated; (2) clinical information provided; (3) documented understanding of the patient's pathophysiology; (4) appropriate evaluation performed locally; (5) appropriate management performed locally; and (6) confidence returning patient to referring health care professional. Physician referrals were also more likely to be evaluated as necessary than NPPs' referrals, which were more likely to be evaluated as having little clinical value.[22]

This sampling of studies clearly shows that NPPs are significantly less accurate in their diagnoses and treatment when they are not part of a physician lead care team. Since audiologists are also NPPs and since changing the ordering requirements would remove audiologists from physician-led care teams, it is very likely that these same patterns of patient care concerns and increased spending would follow if the proposed removal of physician ordering is finalized. While audiologists are valued health professionals who work for and with physicians, they do not possess the medical training necessary to perform the same duties as physicians, nor are they able to provide patients with the medical diagnosis and full spectrum of treatment options they require. Audiologists are not physicians, a physician-led hearing health care team, with coordination of services, is the best approach for providing the highest quality care to patients.

Therefore, due to the increased education and training of physicians, the serious medical conditions associated with hearing loss, the ability of physicians to better treat and diagnose the whole patient, and the negative consequences of removing physicians from the care team it is imperative that the Administration continue to require that physicians order audiology services more accurately.

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[19] D.R. Hughes, et al., A Comparison of Diagnostic Imaging Ordering Patterns Between Advanced Practice Clinicians and Primary Care Physicians Following Office-Based Evaluation and Management Visits. JAMA Internal Med. 2014;175(1):101-07.

[20] https://ejournal.msmaonline.com/publication/?m=63060&i=735364&view=contentsBrowser.

[21] *Id*.

[22] 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.

K. Opioid Treatment Program (OTP) Telecommunications Flexibilities

Recommendation:

- The AMA supports the proposal to allow the OTP intake add-on code to be furnished via telehealth for the initiation of treatment with buprenorphine, including use of audio-only communication technology when audio-video is not available to the patient, and urges that it be finalized. The AMA also recommends that OTPs continue to be allowed to furnish periodic assessments using audio-only communication for patients who are being treated with buprenorphine, methadone, or naltrexone following the end of the COVID-19 PHE.

As discussed elsewhere in this comment letter, the AMA strongly supports continuing the greatly increased Medicare coverage for telehealth services, including audio-only services, that was implemented during the COVID-19 PHE. One of the conditions for which these telehealth flexibilities has been exceptionally important for patient care is treatment of opioid use disorder (OUD). There are many barriers to patients with OUD initiating and continuing in a treatment plan, including pervasive stigma, prior authorization requirements and other insurance plan barriers, shortages of physicians and other health professionals to provide the needed treatment services, and lack of access to transportation, childcare and other support services to make regular OTP and office visits feasible.

There is no question that availability of OUD treatment services via telecommunications, including audio-video and audio-only, has had a major impact in reducing these barriers to care, including for OTPs. Patients who experience stigma and fear going to an OTP in-person can avoid that problem with telehealth. Patients who are not located near an OTP or who cannot readily get to it due to lack of transportation or other responsibilities such as caregiving or work can much more easily access care via telehealth or telephone. CMS should allow OTPs to use telehealth or audio-only to initiate treatment with buprenorphine. In addition, the expiration of the COVID-19 PHE will do nothing to change this situation with barriers to accessing periodic assessments and it would be a grave mistake to eliminate the existing flexibilities when the PHE ends.

To learn more about physicians' use of the telehealth flexibilities during the PHE and to consider the optimal policies after the COVID-19 PHE ends, the AMA assisted addiction specialty organizations in a 2020 survey directed specifically at physicians and other health professionals who treat patients with OUD. A key finding of this survey was that more than 80 percent of X-waivered survey respondents who treat patients with OUD wanted virtual visits and other telehealth options to continue after the COVID-19 PHE. Especially in light of the escalation in drug overdose deaths during the COVID-19 PHE and the contribution of illicitly manufactured and highly lethal fentanyl to this death rate, it is extremely important to make evidence-based treatment for OUD as accessible to patients as possible. The AMA strongly supports the telecommunications proposals for OTPs and urges that they be finalized.

L. 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.

M. Chronic Pain Management

Recommendation:

- The AMA supports the CMS proposal for new bundled monthly codes for chronic pain management and treatment and urges that they be finalized. As described in the proposed rule, the AMA understands that claims for the monthly care management services may be submitted in addition to claims for other services that patients need which may continue to be separately billed. The AMA recommends broadening the types of pain care for which the new monthly codes may be used so that they do not exclusively apply to pain that has persisted for at least three months. GYYY1 and GYYY2 should also be able to be used for treatment of acute pain and palliative care services.

The 2022 Medicare payment rule included a discussion of potential new policies for physicians treating patients with chronic pain, with CMS indicating that it would consider the comments it received in future rulemaking. For 2023, CMS proposes new monthly bundled payments for management of patients with chronic pain, identified as codes GYYY1 and GYYY2. The first of these codes is defined as:

> *Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community-based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month.*

The second code would apply to up to three units of an additional 15 minutes of chronic pain management per month. CMS proposes to define chronic pain as pain lasting more than three months.

In the 2022 rule, CMS solicited comments on whether it should create separate coding and payment for chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether these services are already appropriately recognized in the payment system. It noted the intersection between the problems with pain care and the worsening epidemic of drug overdose deaths, primarily due to illicitly manufactured fentanyl, other synthetic opioids, and methamphetamine. In

its comments, the AMA agreed with CMS that untreated and inappropriately treated pain may translate to increased Medicare costs as more patients experience functional decline, incapacitation, and frailty.

Although the AMA appreciated the discussion in the 2022 rule regarding the need for Medicare payment policies to better support management of patients' pain, the AMA stated that any new payment policies developed by CMS should not be limited to management of chronic pain but should also focus on improving support for acute pain, as well as pain related to the treatment of cancer, sickle cell disease, and for those in need of palliative care. The AMA believes that increased support for the comprehensive management of acute pain can improve patient outcomes in terms of function as well as mental health and lead to greater emphasis on individualized patient-physician shared decision making. Importantly, better treatment of acute pain could also reduce the number of patients whose pain progresses from an acute to a chronic condition. Patients with pain make frequent visits to multiple physicians and to emergency departments, experience a great deal of stigma, and are more likely to require expensive treatments. Patient outcomes will be better and Medicare spending will be lower if Medicare payment policies enable physicians to help prevent patients from developing chronic pain, rather than only paying for treatment after patients' medical diagnoses and treatments become more complicated.

As the 2019 HHS Inter-agency Pain Management Best Practices Task Force Report and other studies indicate, there are many different causes of pain, and patients differ in their responses to treatment, so patients who have pain require individualized treatment. Failure to customize treatment appropriately can and does result in significant disparities in outcomes, particularly for low-income and historically marginalized and minoritized patients. Medicare payments must allow physicians and their practice staff to spend sufficient time with patients who have acute pain, intermittent pain, pain associated with serious illness requiring palliative care, or chronic pain to determine the best ways of treating them and to proactively monitor the patients' progress in pain control and function so that changes in treatment can be made before problems worsen.

As CMS notes in this proposed rule, it has recognized the need to provide additional, flexible monthly payments to physicians for patients who have chronic diseases and behavioral health conditions through its payment policies for the Chronic Care Management, Principal Care Management, and Collaborative Care Management codes. The types of activities these codes support—care management, development of treatment plans, time spent by the physician outside of face-to-face visits with the patient, and consultations with other members of the patient's care team—are equally important for managing patients with pain. When a patient seeks help from a physician for pain, the physician should be able to follow up with the patient to determine if the prescribed therapy is working, have time to make appropriate adjustments to therapy as needed, and be able to consult with other physicians and health professionals who may be involved in the patient's care, such as a pain specialist, physiatrist, and physical and occupational therapists.

In comments on the 2022 proposed rule, the AMA also suggested providing the option to manage patients' pain care through a monthly bundled payment, such as the payment CMS previously developed for managing office-based treatment of substance use disorder. This letter stated that a comprehensive approach that gives physicians the flexibility to focus on providing care that patients with painful conditions require in a comprehensive way could significantly improve patient health outcomes while preventing increased Medicare costs associated with the complications that can arise due to untreated or undertreated pain.

The AMA appreciates that CMS has included a bundled payment for pain management in the current proposed rule and urges that it be finalized. The proposed monthly care management bundle

will better recognize the comprehensive treatment planning and oversight that patients with pain need while also allowing other services that patients need that are not included in the bundle to be separately coded. Consistent with our comments on last year's rule, however, the AMA recommends that the new care management payment be more broadly defined to apply to patients with other types of pain besides chronic pain. Although CMS has solicited comments on separate approaches for addressing acute pain, it is not clear to us why the current proposal could not simply be broadened for this purpose. Patients with acute pain will also benefit from diagnosis, assessment and monitoring, administration of a validated pain rating scale, a person-centered treatment plan, and the other elements included in the proposed chronic pain management bundle.

N. Electronic Prescribing of Controlled Substances (EPCS)

Recommendation:

- The AMA supports the proposals to extend the enforcement policy of sending a letter to physicians who are not in compliance with the EPCS requirement and to align the EPCS timeline with the availability of data. The AMA recommends that CMS provide technical and financial support resources to physicians to help them adopt EPCS and encourage Part D plan sponsors to provide positive incentives for EPCS such as waiving prior authorization.

In the 2022 Medicare payment final rule, CMS established a number of EPCS policies. With several exceptions, for example, for physicians who prescribe fewer than 100 Part D prescriptions annually, physicians were required to electronically prescribe Medicare Part D controlled substances in 2022 with compliance enforcement starting in 2023. For the first year of enforcement, compliance consists of a letter being sent to the physician and urging them to adopt EPCS. CMS proposes to extend the enforcement policy of sending a letter to the physician through the second year of enforcement, 2024. The AMA supports this proposal and urges that it be finalized. CMS also proposes to adjust timelines for the EPCS requirement to align its actions with the availability of data as, for example, the Agency cannot ascertain if a physician has prescribed fewer than 100 Part D controlled substance prescriptions until after the year has ended. The AMA supports this alignment of the timelines.

Practices that have not yet adopted EPCS continue to face uncertainty as they still do not know when or how the Drug Enforcement Administration (DEA) requirements for multifactor authentication will be modified. The AMA remains hopeful that, once issued, these modifications will streamline implementation of EPCS for practices, make it easier for EPCS to be integrated into physicians' regular workflows, and lower its cost and administrative burden. There may also be time needed for EPCS vendors to adjust their products to comply with the revised DEA regulations.

CMS seeks comments on additional actions that it could take in the future to enforce compliance with the EPCS requirement, but without having an "unintended consequence of incentivizing prescribers to stop prescribing controlled substances to Part D beneficiaries, where appropriate, should they not have EPCS set-up." The AMA recommends that CMS offer to assist practices that have not yet adopted EPCS. For example, along with the correspondence informing them of the EPCS requirement, CMS could supply information about where physicians can obtain technical support and financial assistance for adopting EPCS. In addition, CMS should urge Medicare Advantage Part D and standalone Part D plan sponsors to provide positive incentives to physician practices for EPCS adoption, such as waiving prior authorization requirements for controlled substance prescriptions if they are submitted electronically.

O. Immunization Administration and Payment for Preventive Vaccine Administration Services

Recommendation:

- The AMA urges CMS to adopt the RUC's recommended work RVUs and direct PE inputs for vaccine administration services. The AMA supports CMS' proposal to annually update the payment amount for administration of Part B preventive vaccines to account for changes in the cost of administering those vaccines. We also urge CMS to consider a number of factors that could impact administration of COVID-19 vaccines prior to decreasing their payment rate in the year following the end of the Emergency Use Authorization (EUA) declaration.

The COVID-19 PHE has shone a bright spotlight on the vital role of vaccinations in public health and the critical role of physicians in vaccine education, counseling, and administration. Adequate reimbursement for vaccines and their administration is necessary to recognize the costs associated with the procurement, storage, and administration of vaccines that extends beyond the average wholesale price of any particular vaccine. The AMA urges CMS to adopt the RUC's recommended work RVUs and direct PE inputs for vaccine administration services (CPT codes 90460, 90461, 90471, 90472, 90473, and 90474).

The AMA supports CMS' proposal to update the flat $30 payment amount for administration of Part B preventive vaccines (i.e., influenza, pneumococcal, and HBV vaccines) to account for the changes in costs of administering these vaccines. CMS proposes to base these updates on the annual increase to the MEI. However, as outlined in detail above, the AMA has significant concerns with CMS' consideration of other sources of cost data for use in the MEI. Instead, we urge CMS to collaborate with the AMA on a new practice expense data collection effort.

The AMA appreciates CMS' clarification that it would maintain the current payment rate of $40 per dose for the administration of the COVID-19 vaccines through the end of the calendar year in which the March 27, 2020, EUA declaration under section 564 of the FD&C Act for drugs and biological products ends. Regarding CMS' proposal to reduce the payment rate from $40 to $30 in the following year, we urge CMS to carefully consider the numerous factors that may affect the ongoing campaign to continually vaccinate Medicare beneficiaries against serious disease and death resulting from COVID-19. Physicians currently engage in extensive counseling regarding the COVID-19 vaccines and boosters, including their safety, effectiveness, and patient eligibility. Additionally, these vaccines require uniquely cold storage and are packaged in multi-dose vials. These factors lead to higher administration costs for physician practices and must be considered prior to lowering the payment amount for administration of the COVID-19 vaccine. Finally, the AMA supports CMS' proposal to continue the additional payment of $35.50 when a COVID–19 vaccine is administered in a beneficiary's home through 2023.

P. Expansion of Coverage for Colorectal Cancer Screening

Recommendation:

- The AMA supports adoption of CMS' proposals to expand Medicare coverage of and reduce beneficiary cost-sharing for colorectal cancer screening tests.

The AMA greatly appreciates CMS' proposal to expand Medicare coverage of certain colorectal cancer screening tests by reducing the minimum age payment limitation from 50 to 45 years, consistent with a

recently revised recommendation by the United States Preventive Services Task Force (USPSTF). We also support expansion of the definition of colorectal cancer screening tests to include a follow-up screening colonoscopy after a Medicare covered non-invasive stool-based screening test returns a positive result. Therefore, beneficiary cost sharing for the initial stool-based test and the follow-up screening colonoscopy test would not apply and both tests would be paid at 100 percent of the Physician Payment Schedule as screening services. The AMA recognizes colon cancer as a leading cause of cancer deaths in the United States and supports CMS' efforts to reduce barriers to screening, prevention, and early detection of colorectal cancer. Moreover, we appreciate that these policies would advance health equity by promoting access to much-needed cancer prevention and early detection within rural and minoritized and marginalized communities that are especially impacted by the incidence of colorectal cancer.

Q. Request for Information: Medicare Potentially Underutilized Services

Recommendation:

- CMS should significantly improve access to Medicare diabetes prevention services and cover validated self-measured blood pressure monitoring devices to improve hypertension control.

CMS invites feedback regarding ways to identify and improve access to high-value, potentially underutilized services by Medicare beneficiaries and seeks comments on how to mitigate some of the obstacles to care. Improving health outcomes has long been a major AMA strategic focus area, especially with respect to preventing two of the nation's most common chronic diseases: type 2 diabetes and heart disease. There are significant opportunities for the Medicare program to improve and strengthen its policies in both areas.

1. Diabetes Prevention

Medicare diabetes prevention services are woefully underutilized. Numerous recommendations were included in the recent Congressionally-mandated report of the National Clinical Care Commission (NCCC) that would rectify this problem if adopted by CMS. For example, a key step that CMS could take to improve the effectiveness of its efforts to prevent patients with prediabetes from progressing to type 2 diabetes is to adopt the NCCC recommendation to cover hemoglobin A1c testing to screen for prediabetes. In addition to the NCCC, the US Preventive Services Task Force (USPSTF) recommends preventive screening for diabetes and prediabetes, with a grade of B, which under the Affordable Care Act authorizes the Secretary to provide coverage for this screening test for patients with Medicare.

The HbA1c does not require fasting and has less day-to-day variations due to stress or other illness, and therefore, HbA1c is both more convenient for patients and more reliable than a fasting plasma level or an oral glucose tolerance test. Although HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for over 10 years, CMS does not pay for the HbA1c test for screening for prediabetes, even though HbA1c test results can be used to qualify for the Medicare Diabetes Prevention Program (MDPP). The lack of Medicare coverage for the screening HbA1c test disadvantages Medicare beneficiaries compared to those with commercial insurance, which typically does cover the HbA1c test for screening, and precludes patient referrals to the MDPP. The AMA reiterates its previous requests that CMS expand Medicare Part B coverage of HbA1c testing to include the indication of screening for prediabetes or abnormal glucose. This coverage policy would allow physicians to better adhere to the clinical recommendations issued by the USPSTF and American Diabetes Association

Standards of Care, both of which recommend use of any of three testing methods to screen for abnormal blood glucose: fasting plasma glucose, HbA1c, and two-hour plasma glucose tolerance test.

The NCCC further recommends that: MDPP be approved as a permanent covered benefit (not only a model expansion service); coverage of MDPP be expanded to include virtual delivery; the "once in a lifetime" limit on participation in the MDPP be removed; and CMS streamline its MDPP payment process. Differences in program eligibility, delivery modality, and duration between the National DPP (led by CDC) and the MDPP (led by CMS) should be eliminated, and funding should be provided for new payment models that allow for greater up-front payments and more equitable risk-sharing between CMS and MDPP program delivery organizations. In addition, there should be an increase in payment levels to MDPP program delivery organizations to make MDPP programs financially sustainable.

MDPP suppliers are not paid for their efforts to introduce individuals to the benefits of the diabetes prevention program, to recruit potential beneficiaries to join, and to provide additional program supports to participants. Continuing to base payments to the suppliers contingent on the beneficiary achieving a weight loss goal, attending a specific number of sessions or any other performance goal is not consistent with the MDPP pilot program, which paid suppliers for delivering the service. Additionally, other preventive health programs, namely smoking cessation and obesity interventions, do not pay based on the beneficiary achieving a particular outcome. CMS should not base MDPP payments to suppliers on outcomes either.

The AMA urges CMS to restructure its payment in a manner that treats the MDPP as a comprehensive program encompassing activities that go beyond the sessions themselves, rather than just a series of patient encounters. This would mean paying suppliers for the many activities carried out to keep patients engaged, and for outreach to recruit, retain, and support patients. It is well established that increased session attendance is correlated closely to weight loss, but CMS should delve deeper into what elements increase session attendance and be sure the payments recognize those efforts. It is possible for CMS to have an additional incentive payment for achieving established outcomes, but the current payment structure fails to meet MDPP supplier costs and is largely contingent on the MDPP patient's performance. Taken together, this threatens the viability of the limited number of MDPP suppliers. The AMA would like to see MDPP suppliers receive payments for their efforts put into the long journey to preventing diabetes, not just for the attainment of the goal.

The MDPP has the potential to be transformative to the Medicare program but limiting coverage to in-person programs does not realistically consider the changing landscape of health education and behavior modification programs, especially in the wake of COVID-19. Individuals have learned to successfully navigate virtual group and individual sessions for education, for worship, for mental health appointments, and for other group gatherings. The permanent inclusion of virtual MDPP would be an effective and innovative change by CMS welcomed by many.

Previous AMA comments on MDPP services provide additional details regarding the once-per-lifetime limit, the need for virtual suppliers to be included, and the need to stop viewing community-based organizations providing MDPP services as high-risk. The AMA recommends that CMS make numerous changes to improve the effectiveness of diabetes prevention for patients with Medicare.

2. Hypertension Control

Another AMA priority is improving hypertension control. After a steady increase of US adults with controlled blood pressure, the numbers are now heading in the wrong direction, with an estimated 60

percent of those with hypertension not in control. An analysis of National Health and Nutrition Examination Survey data found that adults with controlled blood pressure increased from 31.8 percent in 1999-2000 to 48.5 percent in 2007-2008. This rate remained stable and then declined to 43.7 percent from 2017-2018. In addition, ethnic and racial differences in blood pressure control continue among US adults, with a lower proportion of non-Hispanic Black adults having controlled blood pressure compared with non-Hispanic White adults, for example.

To help improve hypertension control, the AMA and American Heart Association have jointly submitted a formal request to CMS for the Medicare program to cover validated self-measured blood pressure (SMBP) monitoring devices. SMBP monitoring is a well-validated approach of measuring blood pressure outside of the office, and it is a more accurate predictor of cardiovascular events and mortality than office-measured blood pressure. Current US guidelines, scientific statements, and the 2020 US Surgeon General's Call to Action recommend the use of out-of-office blood pressure measurements for confirming a diagnosis of hypertension, titrating treatment, and following up to assess blood pressure control.

SMBP monitoring is also useful for improving blood pressure control among patients who have been diagnosed with hypertension. Patients who use SMBP are more likely to be engaged in self-managing their blood pressure. With regular SMBP monitoring using a validated device, patients can better understand the effects of diet, exercise, smoking, medication adherence and other factors on their blood pressure levels and be more motivated to start or sustain healthy behaviors. SMBP is an important part of a team-based approach to hypertension control. The AMA strongly recommends that CMS establish national Medicare coverage for validated SMBP devices to help improve self-management of hypertension.

II. CY 2022 UPDATES TO THE QUALITY PAYMENT PROGRAM (QPP)

A. Merit-based Incentive Payment System (MIPS)

Recommendation:

- Due to the continued effects of the COVID-19 PHE, CMS should apply the automatic Extreme and Uncontrollable Circumstances Hardship Exception in the 2022 MIPS performance period and target technical assistance to those physician practices that have received a hardship exception due to COVID. In addition, we urge CMS to work with Congress to extend the $500 million exceptional performance bonus, which expires in payment year 2024 under current law. Finally, the AMA urges CMS to reduce the performance threshold to avert more penalties and to specifically assist small practices in reporting MIPS data.

The AMA continues to hear concerns about the negative consequences of the COVID-19 public health emergency on physician practices in 2022. The Omicron surge in late 2021 and early 2022 caused substantial infections, hospitalizations, and deaths. Physicians once again put their patients first and launched into action to care for the flood of COVID-19 patients. They temporarily halted non-urgent procedures and took on greater expenses due to supply chain issues. MIPS participation could not carry on as usual during the Omicron tidal wave. In addition, we continue to hear grave concerns about staffing challenges. Medical practices report difficulty hiring and retaining administrative and clinical staff, particularly as they are competing against local hospitals for the same talent. The AMA is very concerned that this will jeopardize MIPS participation, particularly for small and independent physician practices that do not have the resources to compete on salary for staff. **We strongly urge CMS to apply the**

automatic Extreme and Uncontrollable Circumstances Hardship Exception in the 2022 MIPS performance period to hold physicians harmless from unfair penalties due to the ongoing COVID-19 PHE.

As the Agency looks ahead to 2023 and to potentially transition out of the COVID-19 phase of MIPS, we urge CMS to offer targeted outreach and assistance to the individual physicians and group practices that have applied for or received an automatic Extreme and Uncontrollable Circumstances hardship exception in 2019, 2020, or 2021. CMS should release information about those practices, including their size, specialties, and location, to inform a sufficient policy response to allow them to transition back into MIPS participation without having to flip a switch as the program policies have changed dramatically since 2018, when, for example, there were not any episode-based cost measures. We are especially concerned that any practice that relied on the hardship exception due to the significant disruptions of COVID-19 for multiple years will be at a tremendous disadvantage going into the 2023 performance period. CMS must conduct this targeted outreach as soon as possible during the performance period to ensure that these physicians and practices have ample time and opportunity to come into compliance with MIPS in a manner that keeps the reporting burden and costs as low as possible.

The AMA opposes the application of budget neutrality in Medicare physician payment, including MIPS payment adjustments. Budget neutrality in MIPS means penalizing small and independent practices, as well as practices that care for a high proportion of dually eligible Medicare and Medicaid patients, [23] to fund incentives for large health systems that have the staff and technological resources to manage and report metrics to CMS.[24] There is no evidence that this reverse Robin Hood effect improves outcomes for patients and common-sense dictates otherwise. In fact, these findings position MIPS directly counter to the Administration's goal to improve health equity.

However, there must be incentives to participate in MIPS. As mentioned in our MVP comments above, the costs and time spent by physicians each year to participate in this complex and ever-changing MIPS program are not sustainable.[25] To help ensure a return on investment in MIPS and to avert the Reverse Robin Hood effect of budget neutrality, the AMA urges Congress to extend the $500 million exception performance bonus. **We strongly encourage CMS to support the extension of this bonus payment to continue to incentivize MIPS high performers without exacerbating the negative financial impacts on small and independent physician practices.**

Finally, CMS should lower the MIPS performance threshold to a degree that avoids penalizing one-third of MIPS eligible clinicians. We understand that the statute requires CMS to set the performance threshold at the mean or median, and CMS proposes to maintain it at 75 points for the 2023 performance period. However, we are seriously alarmed that CMS proposes a

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[23] Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP. Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA.* 2020;324(10):975–983. doi:10.1001/jama.2020.13129

[24] "Clinician affiliation with a health system was associated with significantly better 2019 MIPS performance scores. Whether this represents differences in quality of care or other factors requires additional research." Johnston KJ, Wiemken TL, Hockenberry JM, Figueroa JF, Joynt Maddox KE. Association of Clinician Health System Affiliation With Outpatient Performance Ratings in the Medicare Merit-based Incentive Payment System. *JAMA.* 2020;324(10):984–992. doi:10.1001/jama.2020.13136

[25] Khullar D, Bond AM, O'Donnell EM, Qian Y, Gans DN, Casalino LP. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. *JAMA Health Forum.* 2021;2(5):e210527. doi:10.1001/jamahealthforum.2021.0527

performance threshold that would result in one-third of all MIPS eligible clinicians receiving a penalty. Due to the COVID-19 PHE, MIPS has held physicians harmless from penalties and reduced participation requirements since 2019. The program only went live in 2017, so for three of its first five years of implementation, MIPS was dramatically scaled back as a result of COVID-19. We are continuing to hear of the ongoing impacts of COVID-19 on physician practices in 2022 and have grave concerns about the ability of physician practices to hit a target higher than 75 points in 2023. As physician practices emerge from a once-in-a-century pandemic, CMS must use every lever in its statutory authority to avoid a situation that applies a MIPS penalty of up to 9 percent on the physicians who put their patients' lives ahead of their own lives and livelihoods for two and a half years.

Furthermore, CMS admits that 80 percent of eligible clinicians who do not submit any MIPS data and, therefore, would be subject to a 9 percent penalty, are small practices. **CMS must proactively contact and assist these small practices to understand the challenges preventing them from participating in MIPS and resolving those problems so that they can have a fair chance at avoiding a Medicare penalty**.

1. **Cost Performance Category**

Recommendation:

- The AMA seeks insight into CMS' decision to change the designation of the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure.

The AMA urges CMS to clarify the rationale behind its decision to change the designation of the MSPB Clinician cost measure to a care episode group. We are concerned that this technical change could reduce urgency to develop new episode-based cost measures as classifying MSPB as a care episode group would help CMS achieve its statutory mandate to capture half of expenditures under Medicare Parts A and B via episode-based cost measures. The AMA continues to support the development of episode-based cost measures as they have the potential to be more valid, reliable, and actionable, as well as the potential to hold physicians accountable only for the costs within their control.

2. **Quality Performance Category**

<u>Expand the definition of high priority measures to include health equity-related quality measures</u>

Recommendation:

- The AMA supports the expansion of high priority measures but recommends that CMS further define what characteristics would enable a measure to be classified as health equity-related.

While the AMA supports broadening the definition of high priority measures to also include health equity-related quality measures, we note the lack of any guidance or further detail explaining how CMS will determine which measures would be considered to be 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 is able to demonstrate that there are variations in performance across patient populations or other characteristics. For example, the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society

for Gastrointestinal Endoscopy (ASGE) submitted data from the GIQuIC registry during this rule-making 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.

CAHPS for MIPS Survey Measure Case-Mix Adjustment Model

Recommendation:

- CMS must ensure that this modification improves the reliability and validity of the scores and demonstrates that the revised scoring better reflects the quality of care provided.

While the AMA does not necessarily disagree with CMS' premise that collecting information on the language spoken by the participant at home is potentially more accurate than the language used by the respondent to complete the survey, we request that CMS share more detail on how this revision would improve the reliability and validity of the scores. We find it difficult to provide substantive feedback with just the general statement that the analysis of 2019 performance period data showed that there were minimal impacts on scoring. The AMA supports this modification as long as CMS shares sufficient data demonstrating that the revised scoring better reflects the quality of care provided.

Adding Items Related to Health Disparity and Price Transparency to the CAHPS for MIPS Survey Measure

Recommendation:

- Please refer to MSSP comments on page 86 for recommendations related to this provision.

Data Completeness Criteria

Recommendation:

- The AMA does not support CMS' proposal to increase the data completeness criteria to 75 percent beginning with the 2024 MIPS performance period.

The AMA appreciates the proposal to continue the data completeness criteria at 70 percent for the upcoming 2023 performance period and urges CMS to reconsider increasing it to 75 percent beginning in the 2024 MIPS performance period. As we have stated in previous comments, the increased reporting requirement is counter to CMS' goals of reducing administrative burden within the MIPS program and CMS has not yet adequately addressed our concerns. Physicians do not stop complying with quality protocol once they hit minimum threshold requirements. However, they may just stop submitting data to CMS due to the administrative burden of data collection and reporting, especially if reporting on patient reported outcome measures.

We also believe that physicians and practices are being held to a higher bar than any other CMS quality program other than potentially MSSP since it has been aligned with many of the MIPS requirements. 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 and 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.

Furthermore, some specialties provide services across multiple sites using the same NPI/TIN 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. Specialties such as anesthesiology, radiology, gastroenterology, geriatricians, emergency medicine, and primary care physicians have these challenges with site of service differing; yet, the NPI/TIN remains the same. Therefore, until physicians and other eligible physicians can work within an environment where data and care are integrated seamlessly across settings, and providers, it is premature to continue to increase data completeness and encourage reporting through a registry or EHR.

While it remains unclear why there is such a significant disparity across CMS quality programs, we believe that CMS must factor in the additional changes that physicians and practices will encounter over the next few years. Specifically, they will be asked to take on reporting of MVPs and shifting to digital quality measures. These initiatives along with the additional work to ensure that a certain percentage of eligible cases or patients are reported increases the complexity of the program. We continue to ask that CMS recognize the ongoing changes to which MIPS participants have been asked to be responsive and not create more reporting burden at this time. Practices must have stability in the reporting requirements to focus on improvement and reduced burden to transition to MVPs and digital quality measures.

Measures Proposed for Removal

Recommendation:

- The AMA urges CMS to apply consistent standards for when a measure is proposed for removal. CMS should provide an opportunity for measure developers to provide supplemental data to demonstrate why a measure should continue to be included in the program, including data on disparities in care. In addition, CMS should look at performance rates across reporting options before proposing to remove a measure from the program and the impact it may have on a particular specialty or sub-specialty.

CMS continues to omit information on the potential negative impact a measure proposed for removal may have on a specialty, particularly with the move to MVPs. Physicians need to be able to report measures that are clinically appropriate and for many practices, especially those in small practices without an EHR, the removal of quality measures can inhibit their ability to reach the minimum measure requirement. Therefore, CMS must consider the availability of measures that a specialty can report. Many of the measures proposed for removal are also vital metrics that if not implemented in practices could potentially do harm to patients. Without measures that span specialties and can be collected without an EHR, CMS is disadvantaging physicians in small and rural practices that are providing necessary care for patients.

The AMA also remains concerned with CMS' continued efforts to remove quality measures from MIPS regardless of whether the measure is truly topped out and not just representative of top performers or one data source. Furthermore, these determinations are being made in the absence of additional analyses that may demonstrate that inequities in care may still exist even when performance may appear to be generally high. For example, the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) submitted data from the GIQuIC registry during this rule-making cycle demonstrating that there are disparities in care when results for QPP 425, Photo documentation of Cecal Intubation, are analyzed by race, ethnicity, and age. These results should lead CMS to reconsider remove of a measure and we urge CMS to enable opportunities for measure developers to provide supplemental data prior to proposing the removal of a measure.

In addition, there is a lack of transparency with CMS' process for removing measures. We believe the process is not consistently applied across measures. Specifically, a high-performance rate on one reporting option for a specific measure should not be considered an automatic trigger for removal as we do not believe that performance from one data source can be considered representative of actual clinical care and rather the benchmarks across all reporting options should be topped out before a reporting option or a measure is no longer included in the program.

We urge CMS to maintain topped out measures that have a linkage to cost measures or MVPs so that the program begins to measure value. CMS continues to remove topped out process measures that can aid in determining whether a break in process leads to increased or decreased cost and/or better outcomes and/or may not reflect true performance across all physicians but do identify top performers. We remain concerned that CMS' approach to topped out measures may discourage physicians from reporting on important aspects of care that they may not be currently providing to all their patients, especially as we begin to measure the cost of care.

The AMA reiterates our concern that CMS is biased towards its own measures and ignores the policies it has finalized when measures are developed by CMS or under CMS contract. For example, Measure 130: Documentation of Current Medications in the Medical Record measure, which was developed by CMS, has been consistently listed as topped out since 2017 but remains in the program. We recognize that it is a widely reported measure, but CMS must be uniform in its policies. Otherwise, it is providing the perception that CMS is biased towards its own measures and not transparent with its evaluation. Furthermore, because of the COVID-19 PHE, measure developers, qualified clinical data registries, medical societies, and others have delayed measure development and testing. With CMS removing measures from the program and organizations unable to test and offer new measures to alleviate the strain for practices, at a minimum, CMS should delay the removal of MIPS quality measures. This will allow QCDRs time to provide their users with better options. This will also allow a grace period for practices still feeling the effects of the PHE such as lowered patient volumes, staff shortages, and administrative help who will have to navigate the deletions of longstanding quality measures to the MIPS program.

<u>Screening for Social Drivers of Health (SDOH) Proposed Measure</u>

Recommendation:

- The AMA does not support inclusion of the *Screening for Social Drivers of Health (SDOH)* measure in the program until it is adequately specified and tested. Its implementation must also be a part of a larger initiative to ensure that best practices and education are widely available.

The AMA supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes. While we appreciate the urgency, we are concerned that doing something prematurely will impede progress on the issue. We are concerned that people are placing too much emphasis on asking patients about their social needs/SDOH and not enough emphasis on addressing those needs. Too many organizations are leaving patients to "navigate to nowhere," which will just make things worse. We need a coordinated effort across the health care ecosystem including how to best address patients' needs and provide interventions.

The AMA continues to have significant issues on how the measure is designed and the lack of adequate specification and testing as we believe that this measure will produce results that are not reliable and valid. We are also extremely concerned with the lack of alignment of the measure specifications for MIPS when compared to what was proposed for the Hospital Inpatient Quality Reporting Program. For example, in the IPPS final rule, the Screening for Social Drivers of Health measure's numerator definition allows a hospital to screen a patient on "one or all" of the five factors. While there is significant risk that comparisons will be made where one hospital only focuses on screening on one health-related social need while others focus on all five factors, the measure as proposed for MIPS does not provide this level of detail and is not consistent with previous statements regarding the need to ensure consistency in specifications of related measures across CMS quality programs.

Based on feedback we received from Gravity Project subject matter experts, for applicable domains quality measures should only include tools that have been psychometrically tested, including sensitivity and specificity, against gold standard tools. Therefore, the drivers/domains included in the measure should align with data standards such as the HL7 Gravity Project and USCDI.

- At this time, only food insecurity has been finalized and uses a gold standard tool. This is food insecurity with the USDA Food Security Module.
- Housing instability and transportation remain in a draft phrase.
    - HUD has a gold standard tool for Housing Instability in development.
- There are tools currently in the food security domain that have not been fully tested. They may meet content and face validity (the Gravity Project base standard), but they have not been tested for sensitivity and specificity against the USDA module and thus may create concerning levels of false positives, and more importantly false negatives.

The lack of standardization of the tool or factors assessed or testing for reliability and validity goes against fundamental measure development principles outlined by NQF and the CMS Blueprint. CMS would be better served to focus on the typical measure development process for these measures rather than the trial-and-error data submission and reporting approach currently proposed. Ideally, a gold standard screening instrument across all domains should be developed that implements the standards that Gravity has recommended. This could be a compilation of multiple standardized and validated tools. Efforts related to SDOH, must also begin to consider and address broadband access so we are not creating a digital divide when it comes to access to telehealth and digital tools. In addition, prior to holding providers accountable for screening patients and the associated data collection, there needs to be an education effort explaining the importance of the information, best practices for collecting the data and intentions for use, as well as education related to privacy and security. As a result, the AMA does not support the inclusion of this measure in MIPS at this time. In addition, this measure should not be considered for use in MVPs until best practices and education are widely available, the measure is adequately specified and tested, and there has been multiple years of reporting experience in MIPS.

Risk-standardized Acute Cardiovascular-related Hospital Admission Rates

Recommendation:

- The AMA does not support inclusion of the *Risk-standardized Acute Cardiovascular-related Hospital Admission Rates* measure in the program.

While we appreciate the proposal to initially limit attribution of this measure to MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities with at least 1 cardiologist, the AMA does not believe that this change fully addresses all of our concerns. The AMA continues to strongly believe that while it is useful to understand the rate of admissions for patients with heart failure particularly for quality improvement, measures used in accountability programs must be based on strong evidence, actionable to ensure that improvements can be driven by those held accountable and proven to be reliable and valid at the levels to which the measure is attributed.

The AMA is concerned with the lack of evidence to support attribution of the measure at the individual physician level. Attribution must be determined based on evidence that the accountable unit is able to meaningfully influence the outcome, which aligns with the National Quality Forum (NQF) report, Improving Attribution Models.[26] We believe that there are several concerns that are not adequately addressed including:

- Heart failure patients are often cared for by more than one cardiologist.
- More clarity around the definition of inpatient vs. outpatient providers (e.g., cardiologists) would be helpful.
- Many practices in large organizations comprise both primary and specialty practices and therefore it is not entirely clear how attribution might be determined.
- This may be of concern, for example, with Advanced Practice Practitioners (APP) who are often considered primary care but may also be in a cardiology practice. In this scenario, if a cardiology-specific APP has the most patient touchpoints, attribution could fall within primary care while in fact the cardiology practice is driving costs.
- Another example is an electrophysiologist who sees an appropriately referred patient for a device—and sees that patient twice in one year (e.g., the initial consultation, a follow-up visit)—she will now "own" the heart failure care for the year over the primary care provider, based on attribution logic.

The AMA is also disappointed to see the minimum measure score reliability results of 0.401 using a minimum case number of 21 patients. We believe that measures must meet minimum acceptable thresholds of 0.7 for reliability. We acknowledge that this change would require a higher minimum sample size, which would reduce the number of NPIs or TINs to which the measure would apply. Even with this change, we believe that a sufficient number of patients would still be included in the measure, and it would further ensure that the results yield more reliable and accurate representations of the quality of care provided.

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[26] National Quality Forum. Improving Attribution Models. Final Report. August 31, 2018. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88154. Last accessed July 24, 2022.

The AMA also notes that CMS only submitted face validity testing during the NQF review, and we encourage CMS to conduct further testing to demonstrate the validity of the measure as it relates to its application to each of the accountable units to which the measure is attributed. We recommend that CMS consider testing that demonstrates whether this measure attributed to physicians and practices is correlated to other outcome measures such as the hospital wide readmission measure (HWR) or total per capita cost (TPCC) measure. Face validity alone should not be considered sufficient.

The AMA supports and is encouraged to see that social risk factors were tested and will be included in the risk adjustment approach. We strongly recommend that dual eligibility be included in the adjustment since the results demonstrate that it is strongly predictive of an admission. We remain concerned that CMS continues to test social risk factors after assessment of clinical and demographic risk factors, and it is unclear why this multi-step approach is preferable. On review of the Evaluation of the NQF Trial period for Risk Adjustment for Social Risk Factors report,[27] the approaches to testing these data should be revised to strategies such as multi-level models or testing of social factors prior to clinical factors and that as access to new data becomes available, it may elucidate more differences that are unrelated to factors within a physician's or practice's control. Additional testing that evaluates clinical and social risk factors at the same time or social prior to clinical variables rather than the current approach with clinical factors prioritized should be completed. This additional testing may provide support for inclusion of additional variables such as PCP density and further emphasize the need to include dual eligibility.

CMS must also balance the desire to apply this measure to the broadest number of physicians possible with the unintended consequences of inappropriately attributing measures to physicians for which they cannot meaningfully influence patient outcomes. The AMA asks that CMS carefully consider the potential misinformation that could be provided to patients and caregivers if the measures do not have a clear evidence base to support attribution of the outcome to a specific physician and could potentially produce scores that are invalid and unreliable. CMS must continue to ensure that the measures within the MIPS program remain parsimonious and are not duplicative. To address the duplicative issue, **we recommend that CMS continue to use either the All-cause Unplanned Admission for MCC for MIPS measure or pursue the individual condition-based measures rather than include both measures in MIPS.**

MIPS Quality Performance Category Health Equity Request for Information

The AMA supports the current list of self-reported patient characteristics on which CMS should focus data collection efforts. Each will provide useful information that is important for measuring disparate care and further enable physicians and others to improve the quality of life and outcomes of patients. While all of these items are important, we encourage CMS to be selective and use a staged approach on which factors should first be prioritized for data collection and reporting. The current lack of data availability and standardization on the social determinants of health and other disparities, limited implementation of the surveys needed to collect this information, and piecemeal implementation of sources and tools to address these needs must first be addressed. No efforts to develop and implement measures or stratify results around these factors should move forward until the underlying data and data collection tools are standardized and widely collected at the point of care. For example, the HL7 Gravity Project's efforts to

[27] National Quality Forum. Evaluation of the NQF Trial period for Risk Adjustment for Social Risk Factors. Final report. July 18, 2017. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85635. Last accessed July 24, 2022.

standardize these data elements will serve to ensure consistent collection and transmission of these data but as of right now, only data standards for food insecurity have been finalized. The sharing of these data points across providers and settings is integral to ensuring that physicians, practices, health plans, and other stakeholders are coordinating efforts and we believe that data standards that enable interoperability are imperative to the success of these measurement efforts.

Moving forward with any characteristic for which the data are not yet standardized and education on best practices for data collection are not available would just add burden at the point of care and creates the potential to exacerbate any inequities or harm the individual patient's and community's trust with individual physicians, hospitals, and other providers. It is also imperative that we answer the questions "why are we collecting this data" and "what else will it be used for." Community trust in data collection and data use must first be established. Both technical and data governance issues must be included as program goals. As more and more information is collected, it necessitates further considerations around how to protect and secure data. Parallel efforts of data collection and privacy-preserving practices can and happen at the same time. How the collection and use of data could further disparities must always be considered. Prior to initiating a data collection effort or expanding the type of data collected, CMS must first evaluate if the necessary technical, governance, and legal protections are in place to bolster an individual's privacy.

We encourage CMS to ensure that there are the resources and tools to assess and address a patient's social needs and these other characteristics with accompanying financial and other incentives widely available at the point of care to accompany the collection of these data. While programs, toolkits, and other efforts to address these social needs are increasingly prevalent, their availability remains fragmented across markets, regions, and states. The burden of identifying, selecting, and implementing the most effective programs for a specific social determinant of health and within a community or region should not be left to the individual physician or practice and there must be financial or other incentives to assist in covering the initial and ongoing implementation costs. We also encourage pilot testing of innovative strategies to improve health equity and reduce disparities to demonstrate their effectiveness as well as to continue to expand the library of available resources and tools.

Developing Quality Measures that Address Amputation Avoidance in Diabetic Patients Request for Information

The AMA supports the general concept of developing process and outcome measures that address the upstream risk factors to prevent lower extremity amputations in patients with a diagnosis of diabetes. We encourage CMS to expand their focus beyond just those measures that might reduce a patient's risk after a diagnosis of diabetes to include measures that seek to screen and provide interventions to those individuals at risk for developing diabetes (prediabetes).

Regarding the current processes and outcomes listed for potential inclusion in the composite measure, we encourage CMS to consider how such a measure would account for how advanced an individual's diabetes diagnosis is. For example, hemoglobin A1c (HbA1c) goals should be individualized for patients, and controlling HbA1c is most relevant for preventing peripheral neuropathy, but once neuropathy occurs, the evidence does not demonstrate that it will improve with tighter HbA1c control. Similarly, "screening" for peripheral neuropathy no longer makes sense once a patient is diagnosed with it. We also recommend that the technical expert panel consider the emerging evidence that glucose variability, and not an individual's HbA1c level, is potentially a better predictor of ulcer risk. We also question whether

an ulcer risk level is consistently documented by physicians and if not, whether education around this risk assessment would be needed prior to widespread implementation.

We also recommend that CMS and its technical expert panel consider to whom the process or composite measure would be attributed, particularly since if it is a primary physician reporting either measure, evaluations of footwear and offloading of ulcers are better addressed by a podiatrist and would frequently capture referral rates rather than actual evaluations and interventions to address foot ulcers.

Regardless of whether the process and/or composite measure is pursued for specification and testing, we encourage CMS to evaluate the extent to which either measure can provide data that would be useful for quality improvement at the point of care. For example, why composite measures can provide an overall snapshot of the quality provided, performance on the individual metrics may not always be immediately available and this information is critical to identifying opportunities to close care gaps. We also recommend that data around race and ethnicity and other patient characteristics are collected during measure testing to identify potential disparities and consider stratifying results in the future to address these discrepancies.

3. MIPS Final Score Methodology

Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

Scoring administrative claims measures in the quality performance category using performance period benchmarks

Recommendation:

- The AMA supports the scoring of the administrative claims measures in the quality performance category using performance period benchmarks but also urges CMS to explore other methods by which performance can be benchmarked.

While we support this change to timeframes that will likely better represent current clinical care, it does not address our ongoing concerns of using a representative sample of historic data. Many of the baseline periods will include data from 2019, 2020, and 2021 data—all of which are impacted by the COVID-19 pandemic. We encourage CMS to avoid the use of these data for benchmarking purposes.

CMS must continue to evolve the program to enable the development of measures that can truly identify quality problems while still ensuring that they are reliable and valid. The AMA has repeatedly highlighted to CMS the need to evolve its benchmark methodology to better distinguish care and ensure that it meets scientific evidence. In addition, physicians should be provided with information reports based on historical data and be able to opt-in to having any of the administrative claims measures attributed to them. This choice is imperative until CMS is able to demonstrate that these measures use a reliable attribution model that is not reliant on retrospective data.

4. Calculating the Final Score

Eligibility for the Complex Patient Bonus

Recommendation:

- The AMA supports applying the complex patient bonus to facility-based MIPS eligible clinicians.

CMS should recognize and provide additional complex patient bonus points to clinicians regardless of the proportion of such patients within a practice. We encourage CMS to continue to identify additional opportunities to reward care that is provided to these individuals.

Request for Information on Risk Indicators for the Complex Patient Bonus Formula

CMS should select the indicators that are best representative of social risk and medical complexity and continue to work with other federal agencies and external stakeholders to improve the data on which these concepts are determined. The AMA supports CMS including additional indicators in this formula such as the Area Deprivation Index (ADI) to ensure that the characteristics of the patients seen by an individual physician or practice are adequately and correctly captured. We encourage CMS to move beyond the current set of proxies on which both social risk and medical complexity are determined. While these data are useful, they are not sufficient in identifying the full spectrum of patients with risk factors that can also positively or negatively impact a patient's access to medications, treatments, and other services and a physician's ability to deliver the needed services and treatments.

The formula for the complex patient bonus currently assesses the extent to which clinicians treat patients who have multiple chronic conditions, not just whether they treat low-income patients. This is important, because many of the quality measures currently used in MIPS can penalize physicians who treat Medicare beneficiaries with multiple health problems, regardless of the patients' income. In addition, it is important to recognize that providers who qualify as "safety net providers" because they predominantly serve low-income, medically underserved individuals may not have the ability to adequately address the health care needs of some patients who have complex problems or specific types of diseases. CMS policies should support and encourage access for these patients to the physicians who have the specialized expertise necessary to treat them effectively, regardless of the overall characteristics of the patients that those physicians treat. The complex patient bonus can serve as a tool for doing this, but not if it is limited to physicians or providers that only serve large numbers of low-income patients.

We were disappointed that in the CY 2022 MFS Final Rule, CMS limited the complex patient bonus to clinicians who have a median or higher value on either the HCC risk score or the dual eligible percentage, since this can unfairly penalize clinicians who have many complex patients, but who fall below the median for all other clinicians. We 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.

Regarding the request for input as to whether the definition of "Essential Community Providers" in 45 CFR 156.235 ("providers that serve predominantly low-income, medically underserved individuals") adequately functions as a potential definition for "safety net providers" and whether it "could include all MIPS eligible clinicians who may receive the complex patient bonus," in its report *America's Health*

Care Safety Net: Intact But Endangered,[28] the Institute of Medicine (IOM) defined "safety net providers" as "those providers that organize and deliver a significant level of health care and other health-related services to uninsured, Medicaid, and other vulnerable patients." The IOM report stated that only a subset of the safety net consisted of what it referred to as "core safety net providers," i.e., those which offer services to patients regardless of their ability to pay and which have uninsured, Medicaid, and other vulnerable patients as a substantial share of their patient mix. This report explicitly said that in many communities, "a substantial proportion of care for uninsured and vulnerable populations is provided by private physicians and institutions…not included in the committee's definition of the core safety net," and that "In aggregate, these providers may deliver the majority of care for vulnerable populations in a community." In fact, in 2016, just over 75 percent of physicians reported that they provide care to uninsured patients, which we believe confirms these conclusions.[29]

The IOM report pointed out that if financial pressures make private physicians and other community providers less able to care for uninsured and low-income populations, it could increase pressure on other safety net providers. Consequently, if CMS wants to improve outcomes for patients who face barriers to receiving care, it should establish payment policies that encourage and assist all physicians to provide services to these patients, not just a subset of physicians. Although we agree with policies designed to provide adequate assistance to those providers which serve predominantly low-income populations, it should not come at the expense of adequate support for physicians who serve both low-income and higher-income patients.

5. Third-Party Intermediaries

Termination of Approved QCDRs and Qualified Registries That Have Not Submitted Performance Data

Recommendation:

- The AMA does not support CMS' Qualified Clinical Data Registry (QCDR) termination plan. We believe it is premature to institute such a policy given the impact COVID-19 has had on MIPS participation and QCDR stewards.

Considering the COVID-19 PHE and the flexibilities CMS has set up through the Extreme and Uncontrollable Circumstances Hardship Exemption due to the PHE, we believe it is premature for CMS to institute such a policy at this time. Many QCDRs halted reporting at various times over the last few years due to the stop in elective surgeries and surge in COVID cases, which has greatly impacted reporting. We urge CMS to revisit this policy.

Request for Information on Third-Party Intermediary Support of MVPs

The AMA asks CMS to consider the following issue when considering whether a QCDR must support all measures within an MVP. As we stated in previous letters, licensing/sharing a measure with another QCDR or Third-Party Intermediary (qualified registry or EHR) should be at the discretion of the QCDR. The licensing entity must adhere to certain standards and terms set out by the QCDR measure owner on

[28] Institute of Medicine (US) Committee on the Changing Market, Managed Care, and the Future Viability of Safety Net Providers. Americas's Health Care Safety Net: Intact but Endangered. Ein Lewin M, Altman S, editors. Washington (DC): National Academies Press (US); 2000. PMID: 25077222.

[29] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/health-policy/PRP-2017-physician-benchmark-survey-patient-mix.pdf.

measure implementation and data capture, including data validity and reliability, plus fair remuneration for measure development and ongoing measure stewardship. In addition, the entity must have demonstrated clinical expertise in medicine, quality measure development and improvement by providing methods to ensure data quality, routine metric reporting, and quality improvement consultation.

6. Public Reporting on the Compare Tools hosted by HHS

Telehealth Indicator

Recommendation:

- The AMA supports the proposed addition of a telehealth indicator to clinician and group profile pages.

The widespread implementation of telehealth due to the COVID-19 public health emergency continues to have significant potential to increase the access to health care and improve the overall health of patients. The AMA is encouraged that information on the various types of telehealth that a physician may provide will be readily available on clinician and group profile pages.

Publicly Reporting Utilization Data on Profile Pages

Recommendation:

- The AMA does not support the inclusion of utilization data until CMS is able to include data beyond just Medicare claims. In addition, sufficient testing with physicians, practices, and patients must be completed to ensure that these data accurately reflect the procedures performed by a physician and/or practice.

The AMA supports CMS' ongoing efforts to provide useful information to patients. However, we remain concerned that the utilization data would provide an incomplete and potentially inaccurate picture of the services each physician performs since it is limited to solely procedures and only includes Medicare data. As a result, we believe that this information would often be misleading to patients.

The dataset would not include any utilization for Medicare Advantage, Medicaid, Veteran Affairs, or private payor beneficiaries, and therefore, would often erroneously represent providers as having no experience with procedures that they regularly perform. Furthermore, there is no standard or systematic way to group procedures by CPT/HCPCS code beyond very broad categories from the outdated Berenson-Eggers Type of Service (BETOS) codes classification system. Handling this grouping and categorization process on an ad hoc basis will provide extensive opportunities for error, further increasing the likelihood that this summary data would be misleading to patients.

We are skeptical whether any type of disclaimer could avert the extensive confusion that this unrepresentative information may produce. For all these reasons, the AMA urges CMS to exercise extensive caution if the Agency moves forward with this proposal. We strongly support robust user testing and urge CMS to broaden the testing to include review for its accuracy and potential correction of the data by physicians and practices prior to any public release of this information.

Incorporating Health Equity into Public Reporting Request for Information

The AMA is encouraged to see that CMS is exploring what health equity-related information could be publicly displayed. We recommend that CMS focus on providing details on what language services are available, particularly the languages spoken by the physician and staff, as details on whether interpreter services are available would be less useful for patients and caregivers. It is also important to include the types of insurance the physician or group accepts beyond traditional Medicare FFS.

Regardless of what information is included in future years of Physician Compare, CMS must first pilot this data collection and share the initial results with physicians and practices prior to any public release to minimize the potential for discrimination against physicians with a variety of demographic characteristics. Physicians and practices should be able to review and request corrections to the information and CMS should refine the data based on that feedback.

7. Promoting Interoperability Program

Proposal To Require the Query of PDMP Measure

CMS is proposing to require the reporting of the Query of prescription drug monitoring program (PDMP) measure for physicians participating in the Promoting Interoperability (PI) component of MIPS. CMS further proposes to expand the Query of PDMP measure to include Schedule III and IV drugs.

The AMA continues to support PDMP Query as an optional measure in PI. As CMS points out, AMA research has shown that physician registration and use of PDMPs has increased in every state whether there is a mandate or not.[30] We agree with CMS' historical perspective that using positive incentives to advance the integration and use of PDMPs is warranted. Using positive incentives, such as PDMP reporting as an optional measure in PIP, should be retained. However, **the AMA does not support CMS' proposal to require the reporting of the Query of PDMP measure for physicians participating in PI.** Requiring more PDMP use will unnecessarily increase administrative burdens and may harm and detract from CMS' policy goals to reduce drug overdose and death.

While PDMPs can provide helpful information, they are not diagnostic tools. Physicians have reduced opioid prescribing in every state for 10 consecutive years while increasing the use of state PDMPs in every state for the past five years. Despite these efforts, drug-related mortality continues to rise.[31] The data show that there is no correlation between increased PDMP use and decreased mortality, increased access to evidence-based care for pain or opioid use disorder (OUD), or any other positive outcomes. Moreover, an AMA survey of every state PDMP's data shows that PDMPs were queried more than 910 million times in 2021, and yet, the overdose epidemic became worse—primarily due to the use of illicit fentanyl, methamphetamine, and cocaine—substances that are not contained in state PDMPs.[32] **Simply using policy levers to require that physicians and other health care professionals check PDMPs with increased frequency will not translate to a reduction in drug overdoses or deaths.**

Ending the drug overdose epidemic requires removing barriers to evidence-based care. This includes removing prior authorization for medications to treat OUD, ending the federal "x-waiver" to treat patients

[30] https://end-overdose-epidemic.org/wp-content/uploads/2021/09/AMA-fact-sheet-PDMP-2014-2020-blue-FINAL.pdf.
[31] https://www.ama-assn.org/delivering-care/overdose-epidemic/physicians-progress-toward-ending-nation-s-drug-overdose-epidemic.
[32] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

with buprenorphine for OUD, increasing access to evidence-based care for patients with pain (including opioid therapy), and increasing access to harm reduction services (e.g., naloxone, fentanyl test strips, syringe services programs). These are the policy interventions that are proven to reduce mortality and improve outcomes. CMS payment systems should reduce payment barriers like prior authorization for buprenorphine and provide more support and positive incentives for physicians to provide comprehensive, multimodal, team-based care for patients with substance use disorders and/or pain. A federal mandate to use PDMPs will not reduce mortality or improve outcomes, but it might further increase stigma for patients with pain, reduce access to evidence-based care, and take away important resources from initiatives that will have a positive effect.

There is considerable concern and emerging data showing that PDMPs have a direct effect on stigmatizing patients with pain, causing physicians to discharge patients receiving opioid therapy, and leading to increased fear of treating patients with opioid therapy. The main platform for PDMPs—Bamboo Health (formerly Appriss)—uses a proprietary and opaque algorithm that is likely contributing to the negative uses of PDMP. NarxCare, Bamboo Health's flagship product, is an overdose risk algorithm that generates a "risk score" which claims to predict a patients' risk of prescription drug overdose. Yet, there is mounting evidence that patients with complex medical histories and chronic pain are seeing their pain suddenly go undertreated. This can be attributed to a high-risk NarxCare score.

A 2021 *WIRED* Magazine investigation found that patients with high-risk scores tended to have chronic illnesses and disabilities and happened to be overwhelmingly women. Rather than having substance use disorder, they were more often high health care utilizers due to their underlying complex chronic conditions. **Their risk scores were identified as a reason to deny pain relief.** According to *WIRED*, many researchers believe that NarxCare scores and other similar screening tools are "profoundly flawed."[33] Researchers stated that "patients who are most likely to be flagged as doctor-shoppers actually have cancer, which often requires seeing multiple specialists." Moreover, An October 2021 study published in *Drug and Alcohol Dependence* found that the NarxCare scores had a false-positive rate of 17.2 percent and a false-negative rate of 13.4 percent—**with nearly one-third of patients being misclassified.**[34]

In an *Annals of Emergency Medicine* article, experts in substance use disorders reported that "the single best predictor of a future overdose is an overdose in the past. However, that risk factor does not appear in the PDMP databases and, therefore, does not figure into the algorithm's overdose risk score." Experts also stated that "the vast majority of overdose deaths today involve illicitly manufactured fentanyl or other drugs purchased in the illegal market, such as methamphetamine. This means that those with the most risk of overdose could have a risk score of 0 because the drugs they use are not prescribed by doctors."[35]

Concerns continue to emerge that the algorithm may exacerbate longstanding inequities in pain care facing Black and Brown Americans. Patients with painful conditions need to be treated as individuals. They need access to multimodal therapies including restorative therapies, interventional procedures, and medications. These include non-opioid pain relievers, other agents, and opioid analgesics when appropriate. **Patients with sickle cell disease, cancer, terminal conditions, and those on long-term**

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[33] https://www.wired.com/story/opioid-drug-addiction-algorithm-chronic-pain/.

[34] Cochran G., Brown J., Yu Z., et al. Validation and threshold identification of a prescription drug monitoring program clinical opioid risk metric with the WHO alcohol, smoking, and substance involvement screening test. Drug Alcohol Depend. 2021; 228: 109067.

[35] https://www.annemergmed.com/article/S0196-0644(22)00243-8/fulltext#relatedArticles.

opioid therapy are often stigmatized, mistreated, and undertreated because of the narrow focus on checking PDMPs.

We agree that there may be value in encouraging clinicians to check state PDMPs; however, CMS is improperly conflating this intervention with the idea that it will reduce the number of deaths from opioid prescriptions. **Increasing the number of times a clinician checks a state PDMP does not reduce drug-related mortality and there is no meaningful data suggesting PDMPs improve the quality of pain care.** Additionally, physicians have reduced opioid prescribing by more than 44 percent since 2012, but the drug overdose epidemic has gotten worse. This is because the overdose epidemic is not being driven by prescription opioid analgesics; rather, it is now mostly fueled by illicitly manufactured fentanyl, fentanyl analogs, heroin, methamphetamine, and cocaine. One study found that "although the PDMPs' intermediary purpose to reduce prescribing has been achieved by reducing opioid distribution by 7.7 percent, they have had inconsistent effects on prescription opioid overdoses, while increasing total opioid overdoses by 17.5 percent due to increasing mortality from the black market varieties by 19.8 percent" and concludes that "[s]ince PDMPs fail to achieve their ultimate goal of reducing opioid overdoses, [resources] should be re-appropriated to more effective mechanisms to reduce addiction and overdose rates, such as providing access to prescription quality opioids for medication-assisted treatment (MAT)."[36]

The AMA reiterates its support for positive incentives to assist in better integrating PDMPs into physicians EHRs. However, the evidence is clear. Requiring physicians to check a PDMP ignores the inadequacies of PDMPs and will likely increase the level of stigma and exacerbate longstanding health inequities. **Checking a PDMP will not address illicit drug use, can result in the denial of care for chronic individuals, and can lead to patient mistreatment.** More must be done to support physicians treating drug overdoses, but additional PI check-the-box measures are not the answer.

Proposed Revisions and Reporting Requirements for Level of Engagement

CMS currently allows three options for physicians to demonstrate active engagement with a public health agency (PHA) or clinical data registry (CDR). Those include (1) complete registration to submit data, (2) test and validate electronic submission of data, and (3) complete testing and validation of the electronic submission and electronically submit production data. CMS proposes to consolidate options (1) and (2) into a new option, i.e., "Option 1 Pre-production and Validation". Current option (3) would be renamed "Option 2 Validated Data Production". In addition, CMS proposes to require physicians submit their level of active engagement. Lastly, CMS proposes that physicians may spend only one EHR reporting period at the Pre-production and Validation level of active engagement, and that they must progress to the Validated Data Production level for the next EHR reporting period.

While the AMA supports CMS' proposal for physicians to submit their level of active engagement and recognizes CMS desire for physicians to progress from testing to validation and to production stages of PHA and CDR engagement, **we are concerned CMS' proposal to limit physicians' Pre-production and Validation level of active engagement to only one EHR reporting period is shortsighted.**

[36] Reason Foundation, Prescription Drug Monitoring Programs: PDMP Effects on Opioid Prescribing and Drug Overdose Mortality, by Jacob James Rich and Robert Capodilupo (July 2021), available at https://reason.org/wpcontent/uploads/prescription-drug-monitoring-programs-effects-on-opioid-prescribing-and-drug-overdosemortality.pdf.

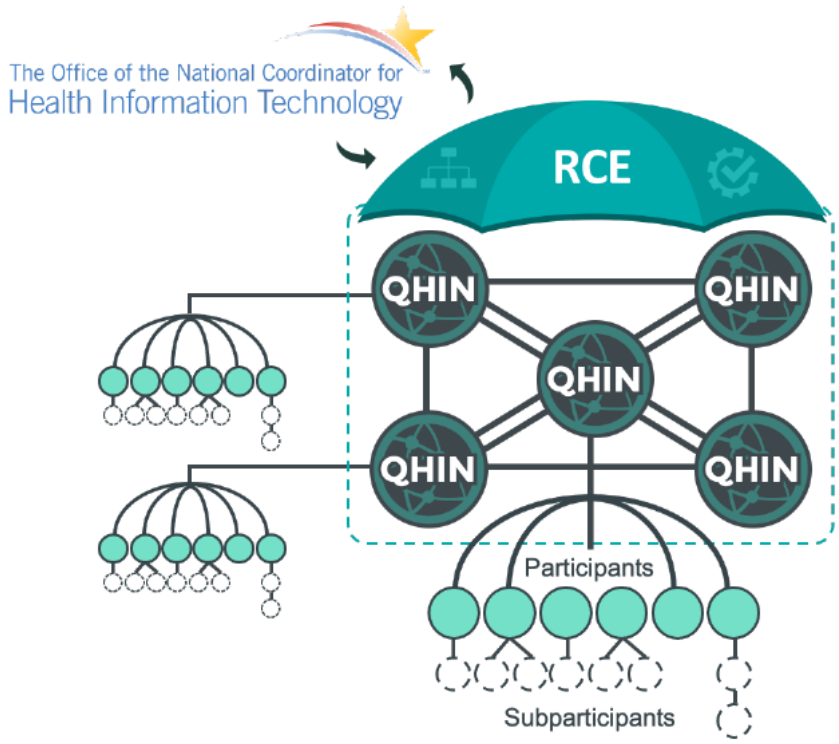
As CMS noted within its FY 2023 IPPS proposed rule (CMS-1771-P), CMS lacks information and is unaware of the current readiness or active engagement level of eligible hospitals, PHAs, and CDRs. CMS states that "eligible hospitals and CAHs currently are not required to report their level of active engagement," and that "knowing the level of active engagement that an eligible hospital or CAH selects would provide information on the types of registries and geographic areas with health care providers in the Pre-production and Validation stage." Furthermore, CMS believes that "information regarding the level of active engagement would be helpful as it would enable HHS to identify registries and PHAs which may be having difficulty onboarding eligible hospitals and CAHs." CMS believes if it collects the necessary information it "will be able to identify the barriers that prevent [hospitals] from moving to the Validated Data Production stage and work to develop solutions to overcome the barriers." It likely then holds true that CMS is also unaware of the current readiness or active engagement level of physicians. **CMS currently lacks insight on hospital and physician PHA and CDR reporting readiness and CMS states it is seeking information to help "develop solutions" to support active engagement progression.**

It is counterintuitive for CMS to discuss a lack of hospital and physician engagement awareness and to propose new information collection requirements, and yet, propose progression requirements on physicians without the necessary information to justify its own proposal. Said any other way, CMS seems to be putting the cart before the horse. **The AMA recognizes CMS need to capture engagement information and supports CMS' proposal to require physician reporting. However, the AMA does not support CMS' proposal to require that physicians progress to the Validated Data Production level after only one EHR reporting period.** Again, it is unclear how CMS can justify physician progression requirements without an informed baseline understanding of the PHA and CDR landscape. Once CMS collects active engagement information from physicians in 2023 and beyond, CMS would likely then have sufficient information to inform future policy decisions, including solutions to help physicians "overcome the barriers" and identify registries and PHAs that are "having difficulty onboarding" eligible participants. **CMS should refrain from imposing progression requirements on physicians until CMS has a clear and informed understanding of the PHA and CDR landscape, physician needs, and barriers that must be overcome.**

Proposed New Enabling Exchange Under TEFCA Measure

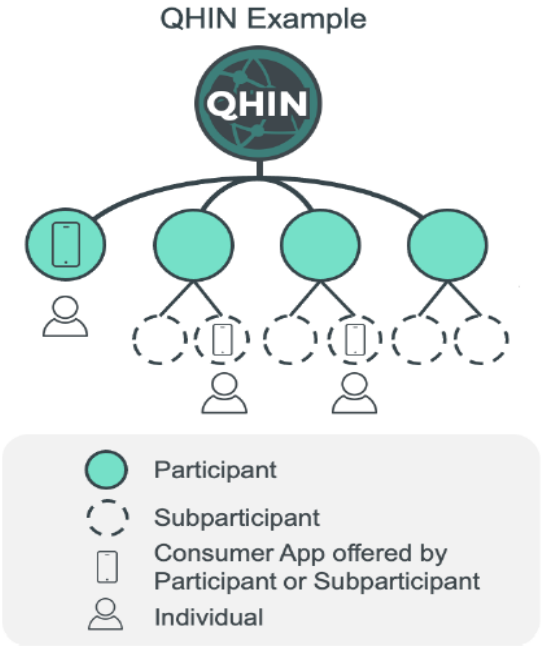
The AMA supports CMS' proposal to add an alternative measure to the Health Information Exchange (HIE) Objective under the PI component of MIPS for enabling exchange through the Trusted Exchange Framework and Common Agreement (TEFCA). The AMA agrees with CMS that including TEFCA as an optional measure will likely play an important role in physicians enabling bi-directional health information exchange. Further, the AMA supports CMS in using an attestation-based approach rather than requiring numerator/denominator measurement for PI reporting. However, as CMS explores ways to provide additional guidance or update this measure to promote future HIE and TEFCA participation, **CMS should consider the unintended consequences if TEFCA participation itself becomes unstable.**

The AMA agrees with CMS that stakeholders across the care continuum will have increasing opportunities in 2023 to enable exchange under TEFCA. Early in 2022, The Office of the National Coordinator for Health Information Technology (ONC) published information outlining the hierarchical structure of the TEFCA where:



- ONC defines overall policy and certain governance requirements.
- Recognized Coordinating Entity (RCE) provides oversight and governing approach for QHINs.
- Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.
- Each QHIN connects Participants, which connect Subparticipants.

While this structure allows for a "trickledown" of policies and technical requirements originating from ONC to subparticipants, it also creates a situation where the termination or removal of one entity can create a domino effect and impact the operations of several entities down the line. For example, a QHIN can support a broad range of participants, including health care organizations, HIEs, EHR systems, pharmacy health information technology (IT) systems, and a consumer applications (app). Each participant may support dozens or hundreds of subparticipants who, in turn, may also support hundreds or thousands of individuals. If, for instance, an EHR system ceases to participate in the TEFCA, subparticipants would likely be impacted. As a result, there could be delays in accessing, exchanging, or using needed electronic health information (EHI) or direct harm to patients and other individuals relying on EHI.



As entities incorporate TEFCA within their environments, they will likely become dependent on EHI data feeds provided by TEFCA participation. Moreover, the AMA expects several entities and health IT systems to utilize TEFCA participation to further automate administrative and clinical exchanges, e.g., prior authorization, transitions in care, or public health reporting. As a result, and like a Jenga tower, if one entity is removed the entire TEFCA stack could be in jeopardy.

ONC contemplates the "Stability of the QHIN Network" within its Principles for Trusted Exchange.[37] For instance, ONC's terms allow a QHIN to terminate its participation in the TEFCA within 90 days of notice to the Recognized Coordinating Entity (RCE)—a critical component of the TEFCA. Termination would result in the prompt removal of the QHIN, its participants, subparticipants, and individuals from the HIE network. Termination may also result in a lack of funding. ONC's terms state that "there are no guarantees that the RCE will continue unless a financial sustainability model has been put in place." The RCE may also terminate a QHIN immediately and suspend each entity's right to engage in any QHIN-to-QHIN exchange activities. Likewise, a participant or subparticipant is granted the same authority as the RCE to suspend any party's right to engage in the TEFCA.

While terms and conditions like these are important factors in a data governance framework, and the AMA does not expect a high occurrence of entity termination, we do encourage CMS to consider the following:

- Physicians who choose to use TEFCA participation to meet the HIE Objective under PI should be provided a hardship exception in instances when:
    - A physician's participation in TEFCA is limited or terminated due to a termination or suspension of an entity that precedes them in their local TEFCA hierarchy; or
    - A physician's participation in TEFCA is limited or impacted due to a termination or suspension of an entity elsewhere in the larger TEFCA network and relied on by that physician or hospital, e.g., a physician's practice under one QHIN relying on admit, discharge, or transfer messaging from a hospital under a separate QHIN.

Local or TEFCA-wide disruptions to EHI exchanges could compromise PI participants' attestations, TEFCA measure reporting, and HIE Objective success. **PI participants should not be held accountable for disruptions that are out of their control and that could impact the bi-directional exchange of information necessary for their PI measure success.**

[37] https://www.federalregister.gov/documents/2022/01/19/2022-00948/notice-of-publication-of-the-trusted-exchange-framework-and-common-agreement.

Additionally, the impact of TEFCA instability should be strongly considered as CMS explores future TEFCA polices. For instance, the AMA would not support CMS requiring TEFCA participation under the HIE Objective. As previously stated, the AMA supports optional and voluntary measures coupled with attestation-based reporting. We also expect TEFCA to undergo modifications and improvements as participation increases. The success of TEFCA will lie in its ability to conform to the needs of the end user, e.g., patients and physicians. This will likely take time and several technical and legal iterations. CMS should refrain from "locking down" the TEFCA by attaching prescriptive federal PI requirements to TEFCA participation. More work is also needed to understand the utility of TEFCA participation. Data are needed to monitor privacy and security considerations, functional interoperability, network resilience, costs, and fees, evolving technical requirements, and end-user satisfaction. **The AMA strongly urges CMS to take a wait-and-see approach prior to considering any TEFCA requirements within PI. Positive incentives, such as optional PI measures, should be utilized for several years. CMS should make informed decisions based on data prior to any TEFCA PI measure or objective requirement proposals.**

8. Advancing the Trusted Exchange Framework and Common Agreement RFI

CMS is seeking information on opportunities to encourage information exchange under the Trusted Exchange Framework and Common Agreement (TEFCA). CMS is interested in key ways that TEFCA can help advance the goals of its programs, including policy mechanisms to encourage exchange between different interested parties. CMS is also seeking comments on financial, technical, or other barriers entities could face participating in the TEFCA.

The AMA appreciates CMS' desire to promote the access, exchange, and use of data to inform population health management and care coordination. Physicians need access to the right information about the right patient at the right time. This "triple need" is fundamental to ensure physicians have access to patients' longitudinal health record. The AMA views TEFCA as an opportunity to better enable all interested parties in having access to patients' longitudinal health record. However, while TEFCA may expand the availability of medical information, more can be done to improve the usefulness of and trust in exchanged information.

Many of our members report that they can connect to local health information exchange (HIE) networks, yet they often cannot access their patients' complete health history. This results in a lack of trust and a belief that important medical information is missing. Physicians will forgo using an HIE if they do not feel they can find and receive a complete patient record. Furthermore, physicians often experience a unidirectional flow of information. While patient information is often requested from physicians' electronic health record (EHR) systems, physicians regularly do not receive information when they make similar requests. **This asymmetry often occurs when exchanging with payers. CMS must consider how its policies can rebalance this disparity.** While TEFCA includes mechanisms to require data exchange parity under its Data Use and Reciprocal Support Agreement, full end-to-end TEFCA exchange will likely not occur until late 2023. Over the next 24 months, CMS should closely monitor (e.g., through physician surveys and listening sessions) how TEFCA participation resolves data asymmetry as well as monitoring physicians' satisfaction in finding and using complete patient records.

Additionally, CMS' efforts to increase HIE among health care stakeholders must ensure patient data are protected, safe, and secure. Patients are most comfortable with physicians and hospitals having their data and are least comfortable with their data leaking outside the provider space.[38] Trust is a fundamental

[38] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.

aspect of the patient-physician relationship. Even well-informed and knowledgeable patients rely on their physicians to provide them with appropriate information, keep personal information confidential, and act in their best interests.[39] In a recent survey of 1000 patients, nearly 75 percent said they are concerned about protecting the privacy of their health data. Six in 10 patients are worried about health data being used by companies to discriminate against them or their loved ones or to exclude them from opportunities to find housing, gain employment and receive benefits. The survey also identified that over 50 percent of patients are "very" or "extremely" concerned that unnecessary access to their data could result in negative repercussions related to insurance coverage, employment, or opportunities for health care.[40] The evidence is clear, patients recognize the value of information exchanged among their providers but worry about the consequences of their information being misused by businesses or other entities, including payers. **Data privacy and data liquidity are not mutually exclusive; CMS has a responsibility to encourage both with equal emphasis.**

To promote trust, strengthen data privacy, and create a more equitable information exchange paradigm between physicians and payers, CMS should consider building its HIE policies on top of the following principles:

- Develop and implement data exchange policies, processes, and programs to better address inequities and disparities among exchange parties. Advancing information exchange equity requires filling gaps in data completeness and quality and developing an information sharing infrastructure capable of consolidating and curating individuals' demographic and health information. CMS should work with its federal partners to monitor TEFCA information exchange parity and correct for imbalances.

- Create policies that positively incentivize the collection, exchange, and use of actionable and timely information while ensuring information symmetry between physicians and payers. CMS should assess where its Medicare Advantage (MA) and HIE efforts intersect such that its policies can help physicians better understand and manage health needs and conditions at the level of the individual, within communities, and across MA populations. CMS should consider the impact of its programs, operations, and MA plan arrangements to promote a strategy that improves quality, experience, and care outcomes. MA models should advance and support population health improvement and the delivery of value-based care—centered on the patient and care team.

- Policies should elevate the collection, exchange, and use of electronic health information in a secure manner while promoting trust, ensuring data integrity, individuals' safety, and adhering to federal and state privacy laws. For example, the Health Insurance Portability and Accountability Act (HIPAA) minimum necessary standard requires covered entities to evaluate their practices and safeguards to limit unnecessary or inappropriate access and disclosure of protected health information. **Our members are concerned that by participating in HIEs with payers, MA plans could overreach into their EHRs and access unnecessary medical information.** The Office for Civil Rights emphasizes that "appropriate limits should be placed on the type and amount of information collected, used, and disclosed, and that authorized persons and entities should only collect, use, and disclose information necessary to accomplish a specified purpose."[41] CMS should reinforce this safeguard through its MA policies and HIE efforts. CMS should require that MA plans meet the needs of their beneficiaries, perform their roles within trading

[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500897/pdf/jgi_204.pdf.
[40] https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.
[41] https://www.hhs.gov/hipaa/for-professionals/faq/collection,-use,-and-disclosure-limitation/index.html.

partner agreements, and CMS should explicitly limit MA plans' HIE data requests to the minimum necessary information needed to meet their business practices.

- Use of consistent and uniform data exchange standards is critical for interoperability. Physicians are required to utilize certified health information technology (health IT) which goes through federal testing and accreditation. This creates a common information exchange framework between health IT products since they are tested and shown to conform to the same standards. CMS should explore how MA policies can be developed to require that MA plans demonstrate a similar level of conformity. This is particularly important as CMS explores new technologies to address the burden and patient harm caused by MA prior authorization practices. As an example, CMS could require that MA plans adopt, implement, and use health IT that conforms to equivalent industry standards, policies, best practices, and technical guides used in the Office of the National Coordinator for Health IT's (ONC) Certification Program. **As an initial step, MA plans should be required to document and provide evidence demonstrating how their health IT systems comply with and conform to the same technical guides EHR vendors must meet in ONC's programs.** This should be a prerequisite before CMS requires MA plans join the TEFCA.

As CMS explores polices to promote HIE use, we urge CMS to also consider the technical and resource limitations many physicians face. The vast majority of physicians believe it is important to share electronic health information to provide quality care, yet the lack of a convincing value proposition for physicians has been a major barrier to HIE use.[42] Although there is likely a net societal benefit of participating in HIEs, the return on investment for individual medical practices may not materialize. Apart from capital expenses and fees, medical practices must also adapt their workflow to benefit from HIEs. HIE adoption can be risky for small medical practices. Implementation costs, including the loss of productivity, can undermine practices' financial stability. Many medical practices lack staff with the skills and experience necessary for HIE implementation. **The AMA urges CMS to review its HIE policies through the lens of burden, costs, and other resource limitations affecting small, rural, and solo practices.** To ensure all medical practices can benefit from CMS' HIE efforts, policies should be crafted to avoid large-scale disruption and huge up-front capital investments by physicians. CMS should ensure that any HIE incentives are conditioned to support medical practices of all sizes and geographic locations, and that any requirements leverage existing certified hardware and software, i.e., EHRs, already used by physicians.

9. Advancing digital and electronic clinical quality measurement RFI

CMS is seeking information on its approach to fast health care interoperability resources (FHIR)-based electronic clinical quality measurement (eCQM) reporting. CMS considers the transition to FHIR-based eCQM reporting as the first step in digital quality measure (dQM) reporting and a potential model for how future digital reporting can occur. CMS is also seeking information on standards and guides needed to advance data standardization for a learning health system.

The AMA supports CMS' effort to advance quality measurement such that it is less burdensome, easier to implement, provides more timely feedback to physicians, and aligns with new models of care. We appreciate CMS' proposed plan to transition to FHIR-based eCQMs and on to dQMs. **Most notably, the AMA strongly supports CMS' intent to take a phased approach to FHIR-based eCQM reporting.**

[42] https://www.ama-assn.org/system/files/2018-10/cybersecurity-health-care-infographic.pdf.

Prior to the implementation of any mandatory FHIR-based eCQM reporting requirements within CMS' quality programs, it will be necessary to undertake voluntary reporting of FHIR-based eCQMs to allow time to learn and enhance systems and processes, both internally and among physicians and vendors.

Data standardization

The AMA agrees that utilizing standardized data for EHR-based measurement (based on the FHIR standard), and aligning with other interoperability requirements, can reduce the physicians' data collection burden for the purpose of reporting quality measures. Transitioning to FHIR-based eCQMs can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. FHIR-based eCQMs may also enable more timely feedback—leveraging the same data for multiple use cases—while also contributing to a learning health system.

A key component in CMS' FHIR-based eCQM and dQM approach will require that all entities utilize a single source for code and terminology mappings to ensure greater consistency with measure calculations and comparisons of performance. Currently, vendors, practices, health systems, and consultants perform their own mapping, which leads to data inconsistencies and is a reason why no two EHRs can reliably calculate comparable results.

Data mapping issues can be improved by building upon the strengths of existing terminologies. Terminologies should be linked based on a comprehensive ontological model (e.g., SNOMED-CT) and foundational code sets (e.g., CPT). This reduces the friction of data collection by linking structured data from different sources using equivalence statements. By optimizing the representation of data in this way, health care entities can use the same or less effort to capture and automate coding for fees and billing, extend the capabilities of clinical decision support systems (CDS), and save countless hours of manual coding, reduce errors in the process. Linked terminologies provide unique advantages to end users and optimize data for clinical care, research, quality measurement, and administrative uses. Data maps, both new and existing, should be leveraged to resolve issues around efficiency and consistency of measures across EHRs and providers. The AMA has already initiated a close collaboration between SNOMED-CT and CPT terminologies.[43]

Importantly, not only should a complete record be accessible, but also the data contained therein must be consistent, understandable, and usable to ensure data consistency. For this to occur, data must be in a recognizable electronic package (i.e., data structure or syntax) and maintain a consistent meaning (i.e., data semantics). Just as the English language is built from words and grammar, the translation from raw data to medical knowledge can only occur if the meaning of data is consistent. **Advancements in quality measurement, particularly as CMS transitions from eCQMs to dQMs, will require consistent data.** However, levels of semantic interoperability vary greatly in the health care system. Most providers agree that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care. As a practical matter, data exchanged that lacks both semantic and syntactic interoperability has little use for physicians and patients.

To improve electronic capture, calculation and reporting of quality measures, CMS should incent the use of standardized semantic content from recognized developers. In the development and specification of a quality measure intended for use in CMS programs, the clinical concepts used in the measure could be derived from recognized clinical content models. For example, if a measure is looking

[43] https://www.snomed.org/news-and-events/articles/AMA-SNOMED-announce-validation-cross-maps#:~:text=The%20collaboration%20between%20AMA%20and,and%20utilize%20healthcare%20data%20better.

at blood pressure, and using the concepts as defined in one of these models, CMS-recognized data aggregators and registries could be given incentives to use those concepts and avoid variation in data management. Incorporation of data requires the development, maintenance, and refinement of administrative codes such as ICD, foundational code sets such as CPT, and clinical vocabulary standards such as SNOMED CT, LOINC, and RxNorm. CMS should promote collaborative efforts across these different coding systems and ensure consistency when data are exchanged.

Data validation

CMS is seeking information on the potential considerations or challenges related to non-EHR data used in quality measurement. The increased volume and variety of data from outside the EHR (e.g., remote patient monitoring devices, digital health solutions, HIEs, etc.) may enhance quality measurement and quality improvement. Research has shown that most of a person's overall health is driven by social, economic, and environmental factors.[44] Much of this data resides outside the EHR. The AMA and others are actively working to develop interoperable social determinants of health (SDoH) data standards.[45] However, this data must also be reliable and validated. Low-quality data can cause patient harm and pollute quality improvement efforts. Effective quality measurement is dependent on the underlying data quality. Accuracy, integrity, usability, consistency, and standardization are characteristics of high-quality data.[46] Therefore to achieve its goals, CMS must determine how it will ensure non-EHR data used in FHIR-based eCQMs and dQMs are valid and high-quality. We recommend that CMS develop a strategy to examine the accuracy and validity of each non-EHR data element, starting with SDoH data. **The demand for high-quality data will be indispensable with the prevalence FHIR-based eCQMs and dQMs.** CMS should, in consultation with clinicians and professional organizations, determine what a minimum or "floor" for data quality should be. If data from a specific source does not meet that requirement, it should not be used in a measure until it meets the minimum expectations.

Interim steps in the near term

CMS is seeking feedback on near term approaches to migrate eCQMs to FHIR. CMS states it considers the transition to FHIR-based eCQM reporting the first step to dQM reporting and a potential model for how future digital reporting can occur.

The AMA appreciates that CMS is seeking feedback early in its approach. Migrating eCQMs to FHIR and on to dQMs will require practical approaches and adequate time to ensure measures perform as expected while limiting burden on physicians and clinical staff. As such, CMS should avoid recreating what happened during the transition to eCQMs at the start of Meaningful Use Program. At that time, CMS chose to retrofit chart-based measures and leverage nonstandard electronic data in EHRs. This process drew criticism and required significant workarounds for medical practices and registries to pull data from EHRs. **We urge CMS to see this as an opportunity to be thoughtful about which measures should transition to the FHIR-based specifications**. CMS should enable widespread implementation, testing, and feedback on how these proposed measures can be captured using existing EHR data. Furthermore, CMS must develop a strategy for measure testing to ensure that data are valid and results are reliable across practices and EHR vendors. During the Meaningful Use Program, EHR products would use the same eCQM but would produce significantly different reports for the same data types used.

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[44] https://edhub.ama-assn.org/health-systems-science/interactive/17498806#resource.

[45] https://thegravityproject.net/.

[46] Zhang, R, Wang, Y, Liu, B. Clinical data quality problems and countermeasure for real world study. Front Med 2014; 8: 352–357 (PMID: 25129380).

Measures cannot simply be re-specified in a new standard with an assumption that they will work. CMS should allow early implementers or testers of respecified measures to participate in pay for reporting to promote measure testing, refinement, and validation.

B. MIPS Value Pathway (MVP)

1. MVPs and APM Participant Reporting Request for Information

The AMA urges CMS to view MVPs as an opportunity to salvage the mightily criticized **MIPS** program by offering incentives to physicians to opt into a novel value-based track that holds them accountable based on aligned quality and cost measures within their control. MIPS is seriously flawed, and MVPs cannot merely repackage current reporting requirements and hope for better outcomes.

It costs $12,800 per physician per year to comply with the complex and ever-changing MIPS requirements, and on average, physicians spent more than 53 hours per year on MIPS-related tasks.[47] These 53 hours are equivalent to a full week of patient visits. It is not surprising then **MIPS siphons money away from small and independent practices, as well as practices that care for a high proportion of dually eligible Medicare and Medicaid patients,[48] and reroutes it to large health systems that have the staff and technological resources to manage and report metrics to CMS.[49] There is no evidence that this reverse Robin Hood effect improves outcomes for patients and common-sense dictates otherwise. In fact, these findings position MIPS directly counter to the Administration's goals to improve health equity.**

CMS should immediately remedy these problems by redesigning MIPS through MVPs to give physicians who care for underserved communities and who practice in all specialties and practice sizes the opportunity to be accountable for fewer, more meaningful measures of quality and cost. Everything outside of that paradigm, particularly the MVP foundation layer, is demonstrably doing harm to physicians and their patients, especially those with more complex medical needs and health-related social risks.

There are specialties who see the current MVP approach as a step in the right direction, but we are very concerned that MVPs as currently designed mirror many of the flaws in MIPS described above. If CMS moves ahead without any additional changes to MVPs, we are afraid that it will be impossible to convince physicians that MVPs are anything more than a rebranding of MIPS with little to no benefit to physician practices or their patients. This would reduce interest and financial commitment among specialty societies to develop novel MVPs and have a chilling effect on physician participation. As we have said in the past, physicians will be the ones making the clinical and business case to their partners in a group practice or their leadership in a health system about why it makes sense to deviate from their current participation in

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[47] Khullar D, Bond AM, O'Donnell EM, Qian Y, Gans DN, Casalino LP. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. *JAMA Health Forum.* 2021;2(5):e210527. doi:10.1001/jamahealthforum.2021.0527.

[48] Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP. Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA.* 2020;324(10):975–983. doi:10.1001/jama.2020.13129.

[49] "Clinician affiliation with a health system was associated with significantly better 2019 MIPS performance scores. Whether this represents differences in quality of care or other factors requires additional research." Johnston KJ, Wiemken TL, Hockenberry JM, Figueroa JF, Joynt Maddox KE. Association of Clinician Health System Affiliation With Outpatient Performance Ratings in the Medicare Merit-based Incentive Payment System. *JAMA.* 2020;324(10):984–992. doi:10.1001/jama.2020.13136.

MIPS and spend more money and staff time to participate in an unknown MVP track when the potential downside is significant—9 percent reduction in reimbursement on all Medicare covered professional services. A repackaging of MIPS would likely not clear either the clinical or business hurdles.

In addition, the AMA believes that CMS must abandon the notions that the MVPs, as currently constructed, are aligned with APMs and that their implementation will lead to performance data that are more meaningful. While we support CMS' ongoing efforts to reduce burden and focus reporting on an episode of care and patient outcomes, assumptions that these MVPs will achieve those goals remain out of touch due to the current MVP design and scoring. Specifically, we continue to believe that CMS must enable MVPs to be sufficiently flexible to allow specialty societies to co-develop with CMS a pathway that is similar to an APM in that it centers quality improvement, efficient resource use, patient reported outcomes and satisfaction, and enhanced technology to care for patients with specific medical conditions or episodes of care. CMS should work with the specialty societies to develop quality and cost measures based on clinical pathways as this process will ensure that any MVP finalized for use will better reflect value and provide information that is useful and actionable by the physician and the patient. In addition, while the goal may be to have MVPs serve as a bridge to APM participation, with neither a nationwide, comprehensive primary care model nor specialist models widely available in Medicare, it is difficult to envision what is on the other side of the bridge.

To be clear, we are not calling for the end of MVPs. Rather, we are calling for a new beginning. National medical specialty societies stand ready to work with CMS to develop MVPs that are geared toward improving patient outcomes around an episode, condition, or other public health priority. We also recommend seven steps to successfully implement MVPs and turn the tide on MIPS' negative impact on small, independent practices and underserved communities.

Recommendation:

- Promote innovative, patient-centered MVPs by focusing on the outcome of the MVP, rather than the metrics.

For an MVP to achieve its stated goals of improving outcomes for patients and giving patients information about where to go for high-quality, efficient care, the program needs to pivot away from the status quo and siloed categories within MIPS in order to be successful. MVPs should not merely be an extension of the MIPS specialty measure sets. Rather than taking a metric perspective, we recommend MVPs be developed and implemented as a cohesive quality program that is thoughtfully designed by physician specialty societies and other stakeholders to improve patient outcomes, including MVPs that are multi-specialty and sub-specialty focused.

Central to MVP development should be an answer to the question: what is the larger goal that the MVP will address? Does the MVP inform patients about high-quality and equitable care that is relevant to them, incentivize care coordination, and/or improve quality of life? Does the MVP address avoidable costs by helping patients prevent costly exacerbations, disease progression, complications, or duplicative services?

For example, unscheduled acute care services provided by specialists in emergency medicine would be a good candidate for an MVP that could help emergency physicians transition to an APM. CMS-supported pilot programs have already demonstrated that, with appropriate support, emergency physicians can help patients be safely discharged home and receive follow-up primary care services, avoiding both hospital

admissions and repeat emergency visits. An APM proposal based on these pilots was recommended to CMS by the Physician-focused Payment Model Technical Advisory Committee.

CMS should work closely with ACEP to ensure that the Emergency Medicine MVP is aligned with this model. Reducing ED visits and hospital admissions following an ED visit should be the priority for an MVP, rather than requiring data collection and scoring on ill-fitting measures.

Recommendation

- Incentivize MVP participation by reducing burden and the risk of penalties by creating an MVP bonus, reducing the overall number of metrics in an MVP, and aligning scoring across multiple performance categories for innovations that are applicable to multiple domains.

Reporting of an MVP should remain voluntary, and CMS should actively identify incentives to encourage MVP participation. We are concerned that few physicians will choose MVPs as the possibility of failure and a potential 9 percent Medicare penalty may be a serious barrier to overcome. Although we welcome and have long sought a requirement for fewer quality measures to be reported, CMS has also been vague on how it plans to operationalize scoring physicians on four quality measures, particularly the methodology and calculations it plans to use and incentivize participation in an MVP. MVP scoring must address these concerns. This is especially critical in light of the COVID-19 public health emergency, which already has disrupted participation in MIPS in 2019, 2020, and 2021. We continue to believe it is essential to establish a bonus payment to hold physicians harmless from steep penalties as they transition to MVPs, similar to the transition policy for MIPS.

Specifically, physicians who participate in MVPs should be held harmless from any downside risk for at least the first two years of participation while they gain familiarity with a model that is more consistent with an APM and while CMS collects and shares data about whether MVPs are meeting their goal to improve quality and reduce unnecessary costs for the Medicare program and beneficiaries. **In this same proposed rule, CMS would make it easier for physicians to form an MSSP ACO by providing up-front investments to qualifying physicians and by allowing for up to seven years of upside-only financial risk. As a starting place for making MVPs a glide path to APMs, CMS should take a similar approach to financial risk for MVP participants.**

CMS should consider the expenses to adopt and administer an MVP for physicians in small practices who have been reporting via claims, as well as physicians in health systems and group practices that have been reporting at the group practice level and may need to transition to reporting at the sub-group level. We urge CMS to consider incentives to participating in MVPs, such as aligning scoring of MVPs with MIPS alternative payment models (APMs) and across payment systems similar to the facility-based scoring methodology.

To further reduce complexity and allow physicians to better predict how they will perform on MVPs, we strongly recommend adoption of a multi-category scoring approach. Improvement Activities support quality and cost goals and are inherently captured in the data for those categories; there is no need to separately attest to check a box. Ideally, the entire Improvement Activities category should be automatically satisfied by participation in an MVP, which requires physicians to forego the option of selecting whichever measures they desire in MIPS to focus on an episode of care or clinical priority area.

Recommendation:

- Test and implement new and existing measures that are tailored to achieving the desired outcome of the MVP.

One problematic component of the MVP framework as outlined by CMS is the mandatory inclusion of the existing population health and Promoting Interoperability measures in the foundation layer. The existing administrative claims-based population health measures do not have the rigor in evidence base, reliability, or validity to be attributed at the physician level, are based on retrospective analysis of claims, and do not provide near real-time or granular enough information for physicians to make improvements in practice. The measures lead to inaccurate assessments about care and result in confusion due to the inability to accurately assign responsibility of care. The measures also move the program away from incorporating the patient's voice. Physicians treat patients at the individual level, not the population health level, so measuring them on population health measures often holds them accountable for things outside of their control.

Measures that should be included in MVPs are those that have been developed by physician-led organizations, such as specialty societies, to ensure they are meaningful to a physician's practice and patients and measure processes or outcomes a physician can control. Therefore, if population health measures must be included, we strongly recommend broadening what is considered and how population health measures are defined, as well as allowing medical specialty societies to develop and propose population health measures as part of their MVP proposal.

Further, the population health measures are disconnected from CMS' and patients' ability to evaluate high-value and low-value physicians. For instance, an MVP focused on ambulatory-based screening and intervention in patients with pre-diabetes should not include costs based on unrelated inpatient-based dialysis spending, which are captured by the current default cost measure—Total Per Capita Cost.

Moreover, the Promoting Interoperability (PI) category measures are too limiting to benefit MVP participants. Tying check-the-box performance measures to an MVP misses the intent of moving away from the MIPS status quo. Certified EHR Technology (CEHRT) is already widely in use, and we expect that EHRs will play a key role in supporting the care coordination necessary for MVP success. Anchoring an MVP to PI requirements may also unintentionally prevent physicians from adopting non-CEHRT like remote patient monitoring or telemedicine tools for fear they will not "count" in PI. Furthermore, engaging patients and interoperability are already critical to value-based care and there are far greater and more meaningful incentives found in recent Information Blocking regulations. CMS should only require physicians to provide an affirmative attestation that they adopt, implement, and use CEHRT to exchange electronic health information to receive full PI credit in an MVP. CMS has recently taken the positive step toward such an approach by allowing eligible clinicians to attest to two measures in the PI program. Finally, we urge CMS to take full advantage of the flexibility to demonstrate use of CEHRT (e.g., straightforward attestation) found in The Health Information Technology for Economic and Clinical Health Act.

These reduced reporting concepts foster a hybrid approach between MIPS and APMs and greatly reduce the reporting burden, and better help physicians prepare to participate in APM models. Of note, CMS permits Advanced APMs to use CEHRT in whatever way they choose; physicians preparing to become Advanced APMs should be given the same consideration. They will still need to attest that they are not information blocking to receive MIPS credit and will additionally be subject to ONC's information blocking regulation and HIPAA's patient access requirements.

Recommendation:

- Implement MVPs that have clinical relevance to physicians and patients regardless of CMS' ability to compare physicians across the same specialty and regardless of a corresponding APM.

CMS has expressed concerns about a proliferation of MVPs, and this fear is guiding the Agency to limit MVPs to overly broad measure sets that, in some cases, would compare physicians in the same specialty that have differing sub-specialization against one another. We have significant concerns with limiting MVPs as it repeats many of the problems with traditional MIPS—notably a lack of clinical relevance to physicians and patients. This approach also fails to account for sub-specialization and varying practice arrangements. For instance, cancer refers to many different diseases so an MVP must account for these considerations to be meaningful to disease site specialists in oncology and patients with specific cancers. This includes not only the quality measures, but also the cost and population health measures. Therefore, the American Society of Clinical Oncology (ASCO) proposed an MVP that is specific to lung cancer; however, CMS has chosen to pursue a generic Advancing Cancer Care MVP instead. We support an approach to MVP development that holds physicians accountable for costs and quality under their control during an episode of care.

Similarly, many of the quality measures included in the draft eye care MVP are not relevant to all ophthalmologists—which consists of eight distinct subspecialties with little overlap—and would not accurately show comparisons among subspecialists. Additionally, the draft MVP only included one cost measure focused on cataract surgery. Outside of cataract surgeons and comprehensive ophthalmologists, many ophthalmologists, such as retina specialists, do not typically perform cataract surgeries except in rare circumstances and thus would not be eligible for the cataract cost measure.

Alternatively, we strongly urge policymakers to work closely with the national medical specialty societies to develop an MVP prioritization framework. We stand ready to identify opportunities to develop an MVP based on valid, reliable MIPS and Qualified Clinical Data Registry (QCDR) measures; inform CMS about specialty societies' initiatives to drive quality improvement that would require new measure concepts, such as prevention of diabetes; and agree on additional high-target areas to reduce avoidable costs and improve quality.

In addition, the AMA urges CMS not to limit MVPs to clinical areas that have a corresponding APM. Most specialists are unable to participate in the APM track of the Quality Payment Program because there is no applicable APM or if there is an applicable APM, it is limited geographically. Although the Agency touts that 43 percent of eligible clinicians participate in MIPS via APMs, we note that this leaves the majority—57 percent—to remain in MIPS.

Recommendation:

- Adjust MVP payment adjustments to reflect the higher costs of caring for low-income patients and address social determinants of health.

As mentioned above, researchers have found that physicians with the highest proportion of patients dually eligible for Medicare and Medicaid had significantly lower MIPS scores compared with other

physicians.[50] CMS should utilize the new MVP approach to correct for this disproportionate impact on physicians who care for these patients and the existing complex patient bonus in MIPS does not go far enough. Instead, CMS should ensure the MVP payment adjustments reflect the differential cost of care for patients whose health and social determinants are intertwined.

Recommendation:

- Adapt MVP payment adjustments to better align with APM and other value-based payment methods.

In addition, physician specialty societies who propose MVPs should be able to recommend alternative MVP payment adjustment mechanisms, such as those that would be used in well-designed APMs. For instance, with primary care focused MVPs, the MVP developer should be able to explore monthly bonus payments analogous to per-patient-per-month payment models. For MVPs that are akin to bundled payment models, CMS should work with the MVP developer to consider episode-based payments. Many of the specialty societies who have proposed MVPs have also invested in developing physician-focused payment models that have been evaluated by the Physician-Focused Payment Model Technical Advisory Commission (PTAC) and recommended for implementation. Those specialty societies should have the flexibility to incorporate unique aspects of those payment models into their MVPs without being limited to up or down payment adjustments two years after the performance period. This would help to prepare physicians for the transition from MIPS to APMs.

Recommendation:

- Provide timely, actionable claims data analysis so physicians can identify and reduce avoidable costs.

Physicians should be held accountable for the costs that are within their control and should have access to their claims data analysis to be able to identify and reduce avoidable costs. Though Congress has taken action to give physicians access to their claims data, to this day, physicians do not receive timely, actionable feedback on their resource use and attributed costs in Medicare. What is a lower-cost physician doing differently from a high-cost physician? For example, is it that they are better at care coordination? If we do not know the answer, we cannot achieve the goal of reducing avoidable costs and overuse. Physicians and specialty societies need access to their claims data analysis to identify variations in spending that are not accounted for by differences in patient needs and to eliminate unnecessary costs. CMS should provide getting timely, actionable feedback about physicians' costs to them in the first place. In previous comments, the AMA provided a framework for providing actionable data to physicians. Technical assistance could also assist physician practices in understanding their resource utilization and how it varies from their peers. Then, specialty societies can target opportunities to reduce spending while improving quality through improving patient outcomes and other targeted measures.

[50] Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP. Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA.* 2020;324(10):975–983. doi:10.1001/jama.2020.13129.

2. MVP Development and Maintenance Processes

Recommendation:

- The AMA encourages CMS to further ensure that the MVP development and maintenance processes are transparent and there are a sufficient number of opportunities for input and collaboration as we do not believe that the current refinements to the processes are adequate or well defined. Specifically, CMS should adopt a process for MVP development and maintenance that is similar to the electronic Clinical Quality Measure (eCQM) annual timeline.

While the proposed addition of a 30-day comment period for new MVPs would allow for broader stakeholder input, it would not solve the current issue that any changes made to an MVP prior to its inclusion in a proposed rule remain a "black box" to specialty societies and implementers (e.g., registries) and we are extremely troubled by CMS stating that interested parties would not be notified in advance of rulemaking. CMS also does not define what criteria would be used to determine when an MVP is "ready" for feedback. The addition of a public facing webinar to review potential changes to existing MVPs and receive feedback is also inadequate as it does not provide sufficient opportunities for relevant specialty societies to have a meaningful and productive dialogue on the impact that MVP modifications may have.

CMS' proposals also do not solve the AMA's ongoing concern that the development and maintenance processes do not sufficiently include input from all relevant specialty societies. While we appreciate that CMS is seeking to address some of the issues voiced by the AMA and others previously, we reiterate that MVP development and maintenance must be clinician-led, and CMS should create an informal process to ensure transparency and coordination among the relevant specialty societies during the early development of an MVP.

While CMS' proposals attempt to increase transparency, we believe that CMS must also consider the potential impact that new or modified MVPs will have on those groups responsible with implementation. The MVP development and maintenance processes must provide sufficient time for registries, electronic health record system vendors, and others to integrate the new MVPs or changes to existing MVPs well before the start of the performance year. We believe that there is an example currently implemented by CMS that could serve as a model for MVP development and maintenance. Specifically, we encourage CMS to explore a development and maintenance process similar to the eCQM annual timeline (https://ecqi.healthit.gov/ecqm-annual-timeline). This annual timeline provides advance notice to vendors on proposed changes, enables them to complete any analyses or testing to ensure that the changes are feasible, and includes collaboration with measure developers. A similar process by which new MVPs or potential changes to existing ones would be posted for public comment in the first quarter of the calendar year followed by collaboration and input by relevant specialty societies in the second quarter, and posting of the new/updated MVP prior to rulemaking would ensure that broad input is received, while also providing the advance noticed needed by vendors and others. This process could be clinician-led with specialty societies playing a role similar to measure developers in assisting with creating and maintaining an MVP.

3. Subgroup Reporting

Recommendation:

- CMS should not finalize its proposal to require multispecialty groups to form single specialty subgroups to participate in MVPs beginning in 2026. MVPs should be designed to improve patient outcomes regardless of whether those outcomes are influenced by a single specialty or a cross-specialty team. In addition, there are unresolved issues, such as the availability of clinically relevant MVPs and how CMS will accurately identify multispecialty groups.

The AMA opposes CMS' plan to require multispecialty groups to form single specialty subgroups in order to participate in MVPs starting in 2026. As the QPP Experience Reports from the last three years (2018-2020) show, at least 50 percent of eligible clinicians receive their final score based on participation in a group and it will present challenges for them to determine how to best participate in subgroups. Because MVPs should focus on clinical conditions, episodes of care, and public health priorities, CMS should encourage subgroup compositions of multiple specialties, across multiple locations, and in various sizes to achieve the MVP's goals of improving care and reducing avoidable costs.

CMS must also give physicians as much time as possible to plan and make the business case for participating in MVPs as a subgroup. Most of the proposals around subgroup reporting demonstrate that additional time and consideration must be taken to ensure that clinicians and practices can successfully report through this option. We also urge CMS to identify avenues by which existing performance data could be used to model the potential results of MVP reporting, in general, and specifically through potential subgroups. We believe that by examining the end result of an MVP it will better inform CMS on the limitations of the current approach, which we view as just minimal changes to traditional MIPS, and assist in the identification of potential revisions to improve on the current flaws. It will also allow group practices to understand what information and scoring is produced by an MVP and enable them to identify how to best form subgroups and successfully engage in this process.

<u>Definitions of a Single Specialty Group and a Multispecialty Group</u>

Recommendation:

- CMS should not finalize its proposal to use Medicare Part B claims data to determine specialty information. Rather, we urge the Agency to allow subgroups to attest to their specialties during the registration process. CMS should create a drop-down for specialty designation as part of the subgroup description.

We are concerned that using Medicare Part B claims as the data source on which determinations of specialty type will not produce information that is accurate and representative of the actual specialties that may be providing care through a multi-specialty group. In fact, there is the potential for these data to identify a practice as multi-specialty when it may be just a group that includes nurse practitioners and/or physician assistants. Alternatively, it remains unclear how a larger group with multiple specialties such as primary care, cardiology, and others would be represented in this approach.

The recently released 2020 QPP Experience Report provides a useful example on why we believe that the use of Medicare Part B claims data will not produce accurate and meaningful determinations of single specialty vs. multi-specialty groups as intended. On review of Table 3 in the report, which identifies

clinician engagement by type, over 15 percent of MIPS eligible clinicians were classified as having more than one specialty during the MIPS eligibility determination period. If CMS was unable to reliably identify a single specialty for these clinicians, we believe that there is significant risk that this proposed process will misclassify groups and only increase ongoing concerns over the lack of meaningfulness and usefulness of MVPs.

Limitation of one subgroup per TIN-NPI combination

Recommendation:

- We urge CMS not to limit participation in subgroups, particularly at the outset of the MVP track.

The AMA does not support the plan to only allow one subgroup to be reported for each TIN-NPI combination since it is contrary to what we believe the intent of MVPs should be—to enable physicians from a group practice to partner with their colleagues in the same or similar specialty or who manage patient's care during an episode, such as surgeons and anesthesiologists, to report on clinically relevant measures. As a result, CMS should not limit subgroup composition for each TIN-NPI combination. We strongly urge CMS to encourage multispecialty groups to form subgroups of the requisite specialists and locations to achieve the desired patient outcomes of the MVP. Otherwise, these proposed changes will disincentivize participation in MVPs.

Subgroup description requirement

Recommendation:

- The AMA supports a broad collection of subgroup descriptions. As mentioned above, we believe that the subgroup description provides an opportunity for CMS to collect information about the specialty composition of subgroups and urge the Agency to add a drop-down box to identify whether qualified health professionals (QHPs) are participating in the subgroup.

CMS must first focus on gathering information through the proposed subgroup description to see how practices choose to form a subgroup. Any of the other proposed changes will limit our ability to understand how groups could meaningfully engage within an MVP. We encourage CMS to allow this broad data collection effort and capture whether nurse practitioners and/or physician assistants are a part of a group. This approach will provide critical information on how a group approaches team-based care around a condition or episode.

The AMA opposes the moves toward being prescriptive with only allowing a single subgroup for each TIN-NPI and attempting to define specialty type based on Medicare Part B claims. These proposals are inherently flawed and will actively disincentivize MVP participation.

Subgroup scores for administrative claims measures and cost measures

Recommendation:

- We urge CMS to adopt a scoring hierarchy that gives subgroups the higher of their subgroup or group score on administrative claims quality measures and cost measures. CMS should also

remove the Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost (TPCC) measures from MVPs unless the MVP developer specifically recommends their inclusion.

CMS must ensure that the scores produced by an MVP are actionable and meaningful to the subgroup reporting and to inform patients during their decision-making processes. Since it is too soon to know the composition of subgroups, CMS should not automatically conclude that physicians and group practices will use subgroup reporting as an opportunity to avoid attribution of administrative claims and cost measures. Rather, CMS should continue to create opportunities to encourage participation in MVPs and subgroup reporting. We recommend the implementation of a scoring hierarchy such that CMS would give the subgroup the higher of their subgroup or group score for these measures. We believe that this approach would serve as an incentive to form subgroups.

In addition, the AMA continues to oppose the inclusion of broadly applicable cost measures, the TPCC and MSPB measures, as they hold physicians accountable for costs outside of their control, do not align with quality measures, and face reliability and validity problems. Attribution also remains a challenge for many specialties and MVPs should not include these problematic measures. We urge CMS to actively partner with specialty societies to develop and pilot test new measures that are not currently on the list of MIPS episode-based cost measures.

C. Medicare Shared Savings Program (MSSP)

1. Quality Performance Standard and Reporting

Extension of eCQM/MIPS CQM Incentive

Recommendation:

- The AMA supports extending the incentive for reporting eCQMs/MIPS CQMs though performance year 2024.

Health Equity Adjustment for ACOs that Report All-payer eCQMs/MIPS CQMs, and are High Performing on Quality, and Serve a High Proportion of Underserved Beneficiaries

Recommendation:

- The AMA offers the following recommendations for CMS to consider:
    - Increase the maximum sharing rate for ACOs that receive the Health Equity Adjustment.
    - Make the Health Equity Adjustment available to all ACOs, not just those reporting eCQMs/MIPS CQMs.
    - Use the ACO's MIPS Quality performance score to measure its relative quality performance, rather than creating a new "Measure Performance Scaler."
    - Increase the Health Equity Adjustment for ACOs that have both a high proportion of low-income beneficiaries and a high proportion of beneficiaries from deprived neighborhoods, rather than only considering the higher of the two proportions.
    - Drop the 85th percentile floor for the Area Deprivation Index (ADI) component of the Underserved Multiplier, and base the ADI component both on the percentage of patients

in neighborhoods with above-average ADI values and the magnitude of the ADI in those neighborhoods.
- For purposes of the Underserved Multiplier, a Medicare beneficiary should be considered as low income if they are either dual eligible or if they receive the Low-Income Subsidy.
- Eliminate the 20 percent floor on the Underserved Multiplier.
- Calibrate the "Measure Performance Scaler" so that the full 10 points will be awarded to those ACOs with a Health Equity Adjustment that is in the 90th percentile among all ACOs.
- Include the Health Equity Adjustment in the ACO Quality Performance score when it is used by physicians for reporting quality as a MIPS APM participant.

The AMA supports modifying the Medicare SSP to recognize the greater challenges that ACOs face in delivering high quality care to patients with low incomes or who live in disadvantaged communities. However, we believe that the proposed Health Equity Adjustment for ACOs will do a poor job of achieving this goal because of problems with the proposed methodology. Several aspects have the potential to worsen disparities in care, rather than to improve health equity.

Limited Benefit of the Health Equity Adjustment for ACOs

Under the current structure of the SSP, any ACO with a quality score that is above the minimum quality standard will receive the maximum amount of shared savings. Consequently, the Health Equity Adjustment will not affect the amounts that these ACOs receive. The only ACOs that could benefit from the Health Equity Adjustment would be those ACOs whose quality scores are below the minimum quality standard.

This approach is not consistent with the stated goal of rewarding ACOs that "serve a high proportion of underserved individuals and achieve high quality performance" or "encouraging all ACOs to treat underserved populations." An ACO with a high proportion of disadvantaged patients will likely have to provide additional services to those patients in order to achieve the same quality performance as an ACO that has fewer such patients. If those additional services are eligible for Medicare payments, this could reduce the amount of savings the ACO achieves and thereby reduce the shared savings payment received. If the services are not eligible for Medicare payments, the ACO will have to incur higher unreimbursed costs to deliver these services. Either way, the ACO would be financially penalized. If an ACO has received higher amounts of the proposed Advanced Investment Payments (AIPs) because it serves more disadvantaged patients, it will have to repay the AIPs from its shared savings payments before receiving any additional income from the shared savings payments. The smaller the shared savings payments for which the ACO qualifies, the longer it will take the ACO to repay those AIPs. Since the AIPs would only be provided for two years, an ACO could be in a position of having no AIPs and also receiving no shared savings payments for several years, which could jeopardize its ability to continue serving disadvantaged patients after the AIPs end.

In order to address these problems, CMS should increase the maximum sharing rate for ACOs that receive the Health Equity Adjustment. For example, the sharing rate could be increased by up to 10 percent in proportion to the size of the Health Equity Adjustment.

Restriction of Health Equity Adjustment to ACOs Reporting eCQMs/MIPS CQMs

Restricting the use of the Health Equity Adjustment only to ACOs that report all-payer eCQMs/MIPS CQMs further limits the ability of the Health Equity Adjustment to achieve its goals. The implicit financial penalty for serving disadvantaged patients affects ACOs regardless of the types of quality measures they report or the method they use to report them. If the Health Equity Adjustment is intended to support and encourage ACOs to serve disadvantaged patients, it should be available to all ACOs, and it should not be used to pressure ACOs into changing the method of quality reporting.
We urge that any Health Equity Adjustment created by CMS be available to all ACOs, not just those reporting eCQMs/MIPS CQMs.

Problems With the "Measure Performance Scaler"

We agree that a Health Equity Adjustment should recognize those ACOs that deliver higher quality care when they have similar (or higher) numbers of disadvantaged patients as other ACOs. Unfortunately, the proposed "Measure Performance Scaler" fails to do this effectively. Under the proposed methodology, ACOs would be arbitrarily divided into thirds based on their performance on each individual quality measure and CMS would assign an ACO 0, 2, or 4 points for each measure based on which percentile they fall into for that measure. This approach is completely different from the methodology used to score the same measures in calculating the ACO's quality performance score, where higher points are assigned to each decile of performance. The proposed approach would result in (1) large changes in an ACO's score based on small changes in its relative performance or (2) no change in an ACO's score based on large changes in its performance. For example, if an ACO's score on a particular quality measure is in the 67th percentile (i.e., the lowest level of the top third), the ACO would receive 4 points for that quality measure, but if it decreases to the 65th percentile (the highest level of the middle third), it would only receive 2 points, a 50 percent reduction. This could inappropriately penalize an ACO that has increased the percentage of disadvantaged patients it serves. On the other hand, no distinction is made between an ACO with a quality score in the 67th percentile and an ACO with a quality score in the 99th percentile; both would receive 4 points. This does not identify or reward "top quality performance."

No rationale is provided in the proposed rule for creating a completely different method of assessing quality for the purposes of the Health Equity Adjustment. The simplest solution would be for CMS to use the ACO's MIPS Quality performance score to measure its relative quality performance as part of any formula for calculating a Health Equity Adjustment, rather than creating a new "Measure Performance Scaler."

Problems With the "Underserved Multiplier"

a. Interactions Between Low-Income and Neighborhood Deprivation

Patients face many different types of barriers to maintaining their health and utilizing health care services, including, but not limited to, low income, inadequate housing, lack of transportation, or poor access to fresh foods. There is no single or simple way to measure the magnitude or impact of these barriers, so we support using multiple measures to assess the extent to which an ACO is serving disadvantaged patients, such as the proposal to use a measure of whether the patients are low income and a measure of the characteristics of the neighborhoods in which the patients live.

We do not agree that assigning a higher value to the Underserved Multiplier to an ACO, which has both a high proportion of dual eligible patients and a high proportion of patients living in neighborhoods that have a high Area Deprivation Index is "double-counting." As the physician leading the Neighborhood Atlas project at the University of Wisconsin wrote, "poor people who live in wealthier neighborhoods

may have better health outcomes than poor people who live in extremely disadvantaged neighborhoods."[51] Using the higher of the two measures as CMS has proposed would penalize ACOs that serve the most disadvantaged patients.

We recommend that the highest Health Equity Adjustments be awarded to ACOs that have both a high proportion of low-income beneficiaries and a high proportion of beneficiaries from deprived neighborhoods, rather than only considering the higher of the two. For example, the measures of low-income and neighborhood deprivation could be weighted and combined in calculating the Underserved Multiplier in order to measure the interaction of the two different types of barriers that patients face.

b. Arbitrary Cutoffs in Use of Area Deprivation Index

We strongly oppose the proposal to only consider beneficiaries living in neighborhoods with an ADI in the 85th or higher percentile when assessing that component of the Underserved Multiplier. This cutoff appears to be based on a single study of the relationship between the ADI and a single outcome —hospital readmission rates—that was conducted over a decade ago. A more recent study conducted found that hospital readmission rates were significantly higher for patients living in neighborhoods above the 50th percentile of ADI, and that those living in neighborhoods in the 85th—95th percentile had lower readmission rates than those from neighborhoods with lower ADI levels.[52]

In addition, the ADI are estimates using sample survey information collected as part of the American Community Survey (ACS) over multiple years. The current ADI is based on ACS data from 2015-2019, and it is impossible to know how accurately it reflects the current conditions in the neighborhoods served by an ACO, particularly given the dramatic changes that occurred during the pandemic. As the Neighborhood Atlas project at the University of Wisconsin states: "The ADI is limited as far as it uses American Community Survey (ACS) Five Year Estimates in its construction. All limitations of the source data will persist throughout the ADI - results are subject to the accuracy and errors contained within the American Community Survey data release.[53]" Consequently, it is highly problematic for CMS to create any arbitrary cutoff point in using the ADI. For example, two otherwise similar neighborhoods might be assigned an ADI score in the 84th percentile or the 86th percentile based solely on sampling and estimation errors in the data, not based on real differences in the characteristics of the neighborhoods, and an 85th percentile cutoff could include one but exclude the other.

We recommend dropping the 85th percentile floor for the ADI component of the Underserved Multiplier, and basing the ADI component on both the percentage of patients in neighborhoods with above-average ADI values and on the magnitude of the ADI in those neighborhoods, such as by summing the ADI percentiles for the neighborhoods of each patient assigned to the ACO, similar to what is being proposed for calculating the proposed AIPs.

c. Narrow Measure of Low-Income Status

Although dual eligible patients have low incomes, not every low-income Medicare beneficiary is dual eligible. As CMS notes in the proposed regulation, different states have different eligibility requirements

[51] Kind AJH, Buckingham WR. "Making Neighborhood Disadvantage Metrics Accessible – The Neighborhood Atlas," *New England Journal of Medicine* 2018;378(26):2456-2458.
[52] Hu J, Kind AJH, Nerenz D. "Area Deprivation Index (ADI) Predicts Readmission Risk at an Urban Teaching Hospital," *American Journal of Medical Quality. 2018;*33(5):493-501.
[53] https://www.neighborhoodatlas.medicine.wisc.edu/.

for Medicaid, so a low-income Medicare beneficiary could be dual eligible if they live in one state but not others. In order to have as comprehensive a measure as possible, we recommend that a Medicare beneficiary be considered low income if he or she is dual eligible or receives the Low-Income Subsidy.

d. Arbitrary Floor on the Underserved Multiplier

CMS proposes to treat an Underserved Multiplier that is below 20 percent as though it were zero. This means that an ACO with 19 percent of its beneficiaries living below the poverty line or living in high-deprivation neighborhoods would be ineligible for a Health Equity Adjustment, whereas an ACO with 20 percent of its beneficiaries meeting those characteristics could receive a Health Equity Adjustment. If the two ACOs both had sufficiently high performance on all quality measures to receive the maximum score of 26 on the Measure Performance Scaler, the first ACO would receive a Health Equity Adjustment of zero, whereas the second ACO would receive a Health Equity Adjustment of 5 (50 percent of the maximum amount), which is inappropriate.

CMS indicates that 70 percent of ACOs would have fallen below the 20 percent threshold in 2020, so this arbitrary floor would preclude most ACOs from receiving any Health Equity Adjustment, regardless of how high their quality performance is. CMS suggests that creating this floor could encourage ACOs below the floor to "expand their reach into underserved communities." However, it could also discourage ACOs that are below the floor from continuing to serve as many disadvantaged patients as they currently do, particularly if the cost of providing high quality care to those patients reduces the ability of the ACO to obtain the shared savings payments needed to cover its costs. We recommend eliminating the floor on the Underserved Multiplier altogether.

Calibration of the Health Equity Adjustment

CMS proposes to calculate the Health Equity Adjustment by multiplying the "Measure Performance Scaler" by the "Underserved Multiplier" and then capping it at 10 points. However, CMS has not provided any information to enable determination of how many ACOs would receive anywhere close to the full 10 points based on the proposed methodology.

We recommend that the points used in the "Measure Performance Scaler" be set at levels, which will result in the full 10 points for those ACOs with a Health Equity Adjustment that is in the 90th percentile among all ACOs. For example, if the top 10 percent of Health Equity Adjustment scores are no higher than 8.0, the points used in the Measure Performance scaler should be increased by at least 25 percent.

Use of the Health Equity Adjustment for MIPS APM Payment Adjustments

An ACO cannot provide high quality care to disadvantaged patients unless the physicians that make up the ACO have the resources and flexibility to do so. If a Health Equity Adjustment to the ACO quality performance score is needed to prevent an ACO from being penalized for serving disadvantaged patients, then a similar adjustment is needed to the ACO quality performance score to avoid the physicians in the ACO from being penalized under the APP option in MIPS. We recommend that the Health Equity Adjustment be included in the ACO Quality Performance score when it is used by physicians for reporting quality as a MIPS APM participant.

Proposed Benchmarking Policies for CMS Web Interface Measures for Performance Years 2022, 2023, and 2024

Recommendation:

- CMS must reconsider the proposal to score Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) and continue with the previous decision for it to be pay for reporting only for the 2022 performance year.

While the AMA supports continuing the previously established benchmark policies for the Web Interface measures, we disagree with the proposal to retroactively reverse the decision to have Quality ID #226 be pay for reporting in 2022. It would not be finalized until well into the performance year and changing course this late would only create more confusion and unnecessary work.

Clarifying the Use of Unweighted MIPS Quality performance category scores for Quality Performance Standard Determinations under the Shared Savings Program

Recommendation:

- The AMA asks CMS to clarify the difference between the "weighted" vs. "unweighted" MIPS quality performance category score.

The AMA appreciates the correction that CMS intends to make to this calculation but was unable to identify what the factors or points contribute to the differences between the "weighted" vs. "unweighted" MIPS quality performance category score. It is important for this information on what points are used to create these scores to be explained and transparent.

Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development - Request for Information (RFI)

Recommendation:

- The AMA agrees that measures that promote the screening of social drivers of health by ACOs should be considered for inclusion in SSP in the future. However, we are concerned that if this measure is implemented prematurely, progress on the issue will be impeded since the emphasis should not solely focus on asking patients about their social needs/SDOH, rather it is critical that we also evaluate the efforts to address those needs. The AMA's specific concerns with the proposed Screening for Social Drivers of Health are outlined further in this letter and these issues must be first addressed before the measure is proposed for any quality program.

In addition, much work is needed to ensure that measures on this important topic:

- Are based on tools that have been psychometrically tested, including sensitivity and specificity;
- Only include drivers/domains that are aligned with data standards such as the HL7 Gravity Project and USCDI; and
- Are fully tested for reliability and validity at the level for which the measure is attributed.

There must also be a widespread education effort explaining the importance of the information, best practices for collecting the data and intentions for use, as well as education related to privacy and security.

Addition of New Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) Survey Questions - Request for Information (RFI)

The AMA agrees that evaluating a patient's experience with discrimination due to his or her characteristics and the degree to which health care costs were discussed between the patient and physician are important questions to consider adding to the CAHPS for MIPS Survey Measure. However, before any of these questions are added, CMS should pilot their inclusion and examine whether the results can be used to provide reliable and valid comparisons. We also encourage CMS to consider whether there are alternative methods by which these questions could be collected rather than continuing to expand the CAHPS for MIPS Survey, including measure that provide near real-time feedback to physicians and via methods beyond mailed paper surveys such as the use of apps on smartphones. These additional survey collection modes could provide more timely results to practices.

Regarding the potential question on health care disparities, the AMA cautions CMS on moving too quickly on its inclusion for several reasons. The question as currently drafted is not clear on which provider the respondent is being assessed. For example, is it the physician providing care or the clerks and receptionists in the office? There is the potential for the question to gather information on multiple unrelated people and not the physician or staff. The responses to the question currently omit race, ethnicity, and language, which are also important items to include. CMS should further refine the response options using resources such as the items included in a national survey seeking to understand the types of discrimination individuals encountered and the frequency of these experiences.[54] In addition, there are multiple question options evaluating discrimination that could be adapted and piloted including, but not limited to, the Everyday Discrimination Scale,[55] Urban Institute's Coronavirus Tracking Survey,[56] and the New York City Community Health Survey.[57] While the implementation of this question likely supports broader awareness and better characterization of these issues, it will be crucial for CMS to evaluate whether the question could result in biases based on the characteristics of the physician providing the care (e.g., women, providers of color). Understanding whether these biases could occur and what impact they may have on physician performance must be understood and addressed prior to implementing this question in the measure. As a result, CMS should also collect and examine the results based on the demographics of the provider in addition to the patient.

The AMA supports efforts to increase patients' awareness on health care costs. We would note that physicians and their staff may not necessarily have all of the information regarding prices easily accessible at this time. While there are tools in development that will hopefully help improve access to this information, we encourage CMS to keep this potential lack of available information in mind as they move forward with a question around price transparency.

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[54] Nong P, Raj M, Creary M, Kardia SLR, Platt JE. Patient-Reported Experiences of Discrimination in the US Health Care System. JAMA Netw Open. 2020 Dec 1;3(12):e2029650. doi: 10.1001/jamanetworkopen.2020.29650. PMID: 33320264; PMCID: PMC7739133.

[55] https://scholar.harvard.edu/davidrwilliams/node/32397.

[56] https://www.urban.org/sites/default/files/publication/103953/perceptions-of-discrimination-and-unfair-judgment-while-seeking-health-care.pdf.

[57] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239482.

CMS must provide additional information on whether the responses for either question would be used in any of the survey summary measures and included in the scoring of the results. In addition, explicit information on how the information will be used and the purpose of collecting and publicly posting the information must be provided. We encourage CMS to provide this information for public comment prior to proposing these revisions in rulemaking.

Regarding revising this measure to make it more broadly applicable to specialty groups, we encourage CMS to pilot these potential changes and seek input from relevant specialty societies on whether these changes increasing the meaningfulness of the results. As always, robust testing to ensure that this modified survey produces results that enable reliable and valid comparisons across the various specialties and groups.

2. Additional Medicare Shared Savings Program (MSSP) Proposals

Recommendations:

- Work with Congressional leaders to support an extension of the 5 percent Advanced APM incentive payments, along with the flexibility to adjust the thresholds to qualify for the incentive payments;
- Finalize the proposal to create a more appropriate glidepath to risk, by allowing ACOs up to seven years in upside-only tracks before advancing to risk;
- Expand eligibility for advance investment payments (AIPs) to all ACOs who care for underserved beneficiaries to combat health inequities;
- Allow existing ACOs to opt into the proposed financial methodology approaches;
- Engage with physicians and other stakeholders throughout development of an administrative benchmark concept; and
- Test new concepts that would incentivize ACOs and specialists to collaborate to provide high quality, lower cost care for Medicare patients.

The AMA appreciates CMS is proposing to strengthen ACOs in response to recommendations from the AMA and additional stakeholders to improve MSSP. We believe many of these proposals will help grow participation in ACOs and realize CMS stated goal to move all Medicare beneficiaries into a value-based care model by 2030. Additionally, these proposals would build on the current financial success of the program, saving Medicare more than $15 billion and yielding more than $650 million in shared savings to ACOs.

<u>Advanced Alternative Payment Model (APM) Incentive Payments</u>

Additional comments on Advanced APM proposals included in the MFS are in Section "D" below

We share CMS concerns that the Quality Payment Program's incentive structure beginning in performance year 2023 does not create adequate incentives for physicians to move to APMs. This is compounded by the proposed cuts to the conversion factor and the expiration of MACRA's 5 percent Advanced APM incentive payments. The AMA and other stakeholders have been calling on Congress to extend these payments as ending them now would sharply discourage and disincentivize physicians' efforts to engage in APMs. The incentive payments not only help encourage physicians to enter risk-based ACO and Innovation Center models but also provide additional resources that can be used to expand services beyond traditional fee-for-service. We encourage CMS leadership to work with

Congressional leaders to support an extension of the 5 percent Advanced APM incentive payments, along with giving CMS the authority to adjust the thresholds to qualify for the incentive payments.

Glidepath to Risk

We appreciate and strongly support CMS' proposal to create a more appropriate glidepath to risk, by allowing ACOs up to seven years in upside-only tracks before advancing to risk. Additionally, we strongly support the proposal to make the Enhanced Track optional for all ACOs. Since the implementation of Pathways to Success, which required ACOs to advance to risk more quickly, we have seen a decline in new entrants to the program. A more reasonable glide path to risk will attract new participants.

Advance Investment Payments

We applaud CMS for recognizing the significant upfront resources needed to form an ACO and transition to value-based care. We have long advocated for CMS to make up front payments available to ACOs and applaud CMS' proposal to provide advance investment payments (AIPs) in MSSP. To better address health equity and expand access to accountable care for underserved beneficiaries, we urge CMS to expand eligibility for AIPs to all ACOs working to combat health inequities. Historically, beneficiaries in underserved communities have not had adequate access to health care and this significant unmet need has led to financial benchmarks that do not accurately reflect the cost of addressing the complex medical and psycho-social needs of these beneficiaries. We share CMS' commitment to advancing health equity and ensuring access to high-quality, high-value care. By providing adequate funding for all ACOs to address health related social needs and reduce disparities, we can advance our shared goal of achieving equitable health outcomes for all.

Existing ACOs and New Payment Approaches

We appreciate efforts to update MSSP's financial rules to encourage greater ACO participation, attract new participants, and incentivize serving medically complex and low-income populations. Stakeholders have long advocated for fair, accurate, and predictable benchmarking and risk adjustment policies. CMS addresses these concerns by proposing changes to risk adjustment policies, improving regional adjustments, and making it easier for some ACOs to earn shared savings. However, these policies apply only to ACOs with new agreements beginning in 2024. The vast majority of existing ACOs will not have access to these improved policies for several years unless going through the onerous process of early renewing. CMS should allow existing ACOs to opt-in to the new financial methodology approaches.

Benchmarking

We applaud CMS for recognizing the program needs a long-term solution to the benchmarking "ratchet effect" and appreciate efforts to solicit feedback on administrative benchmarks. We recognize that administrative benchmarks are a necessary step to ensure the long-term viability of the program. However, there are inherent challenges in designing administrative benchmarking; for example, accounting for regional variations in spending so that ACOs are not penalized due to their geography. We support the concept of administrative benchmarks and ask that CMS engage stakeholders throughout development.

Leverage MSSP to Increase Value-Based Specialty Care Models

Since the MSSP launched in 2012, ACOs have been instrumental in transforming our health care system through reduced costs and improved quality. As the only permanent APM, CMS should consider ways to adapt the MSSP to continue to advance value-based care and provide more opportunities for models focused on episodes of care, conditions, or specialty care to be integrated into larger APMs. To date, most specialists have not had the chance to move into an APM, despite significant interest. We urge CMS and the Innovation Center to test new concepts that would incentivize ACOs, primary care physicians and specialists to collaborate to provide high quality, lower cost care for Medicare patients.

D. Advanced Alternative Payment Models (APMs)

Recommendation:

- While the AMA appreciates that CMS would not increase the nominal amount standard of financial risk above 8 percent, this risk standard remains too high, particularly for small and rural practices that are largely left out of the APM discussion. The AMA supports CMS' proposal to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model. We support CMS' consideration of making Qualifying APM Participant (QP) determinations at the individual level and encourage the Agency to release additional information.

1. Generally applicable nominal amount standard

The AMA understands CMS' intent to create stability by permanently establishing the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers participating in APM Entities, and we appreciate that CMS is not proposing to increase the amount. However, as outlined in detail in previous comment letters, we believe that this risk standard is too high, particularly for small and rural practices that have largely been excluded from Advanced APM opportunities in the seven years since MACRA passed.

A November 2021 report from the Government Accountability Office confirmed that small and rural practices face substantial barriers to participate in Advanced APMs. Rural communities generally have lower average incomes and higher unemployment, which leads to a greater percentage of uninsured and Medicaid patients. Specialists are more likely to locate in urban areas, so it is more difficult for rural physicians to refer complex patients to specialist practices. Longer travel times can lead to lower utilization per patient and difficulty keeping appointments, which may lower margins, make it difficult to cover fixed practice costs, and make it more difficult for patients to be adherent to treatment plans, thus affecting performance on quality and cost metrics. Barriers for small practices to participate in Advanced APMs are well known, with serious concerns in recent years about regulatory burdens and physician burnout, which has been exacerbated by the COVID-19 PHE. Therefore, at a minimum, the AMA urges CMS to set the revenue-based nominal amount standard for small and rural practices participating in APMs at either the same or a lower amount as medical home models.

2. Medical Home Model 50 Eligible Clinician Limit

The AMA supports CMS' proposal to apply the 50 eligible clinician limit directly to the APM Entity participating in the Medical Home Model, rather than looking to the parent organization for the APM Entity. We appreciate CMS' acknowledgement that the Agency does not have a method in place to gather

accurate data about the site and composition of parent organizations, which may be organized in various ways and have numerous contractual relationships with other entities. Applying the size limit at the APM Entity will help to ensure that similarly situated organizations are being treated equally.

3. Request for Information: Potential Transition to Individual Qualifying APM Participant (QP) Determinations Only

The AMA supports CMS making QP determinations at the individual eligible clinician level, rather than at the APM Entity level. The AMA continues to advocate for expanded opportunities for physicians of all specialties, practice sizes, and geographic locations to have an opportunity to move into Advanced APMs. We often hear concerns that specialists are excluded or dropped from larger APMs, including ACOs, because their participation may jeopardize the APM Entity's ability to reach the QP thresholds. These exclusions do not square with the goals of ACOs and other APMs to encourage care collaboration for Medicare beneficiaries.

In addition, the policy of making QP determinations at the APM Entity level has been a source of confusion. For example, CMS resources developed for physicians generally refer to the determinations being based on that physician's proportion of revenues or patients, such as the following: "Advanced Alternative Payment Models (APMs) is a track of the Quality Payment Program that offers incentives for meeting participation thresholds based on your levels of payments or patients through Advanced APMs. If you achieve these thresholds, you become a qualifying APM participant (QP)." Changing the policy seems like it would allow physicians to have a greater degree of influence over whether or not they meet the QP thresholds.

We encourage CMS to release detailed information regarding the specialty and APM of individual eligible clinicians who would qualify as QPs at the individual level but not at the APM Entity level. CMS indicates that there is a group of eligible clinicians who participate in multiple APM Entities and who could reach the threshold through this combined participation but not in a single APM Entity. It would be very helpful to see more specifics about the impact of this policy change on physicians in all specialties and APMs.

4. Request for Information on QPP Incentives Beginning in 2023

Recommendation:

- CMS should strongly urge Congress to extend the Advanced APM incentive payments for six years and give the Secretary authority to set the revenue threshold to be a Qualified Participant (QP) in an Advanced APM. CMS should increase opportunities for physicians in all specialties and types of practice to voluntarily participate in well-designed, patient centered APMs.

<u>Physician Considerations in Choosing APM Participation</u>

One of the most important criteria for physicians in deciding whether to participate in an APM is whether the APM will give them the ability to deliver higher-quality care to their patients than is possible under current payment systems. The current payment system creates many barriers that prevent physicians from improving care for their patients. One barrier is that there is often no payment available to support the kinds of services that would improve outcomes and reduce spending.

For example, many patients who come to an emergency department with symptoms such as chest pain or syncope could return home instead of being admitted to the hospital if the emergency physician could be sure the patient would receive the necessary assistance to return home safely, and that the patient would receive prompt follow-up care from a primary care physician. Medicare does not pay emergency physicians for the time needed to: locate the patient's primary care physician and develop a coordinated discharge plan; help identify community-based health and social services for the patient; or hire a nurse or community health worker to help the patient return home safely. As a result, the only safe option may be for the emergency physician to admit the patient to the hospital.

The American College of Emergency Physicians developed an APM that would fix this problem by paying for these discharge planning and transitional care services. Although the APM was unanimously endorsed by PTAC (the Physician-Focused Payment Model Technical Advisory Committee), the model has not been implemented. As a result, patients continue to be admitted to the hospital who might otherwise have gone home. This likely disproportionately affects patients with health-related social needs and contributes to health inequities.

Many of the APMs that have been implemented do not really address the barriers in the current payment system, so the 5 percent incentive payments for participants in Advanced APMs has been a key factor in physicians' interest and even in their ability to participate in APMs. Without these incentive payments, many physicians could not otherwise cover the costs of participating, handle the downside risk, or deal with the revenue reductions that can occur from reducing avoidable services.

Ending the APM Incentive Payments

The AMA is alarmed that the APM incentive payments created under MACRA are coming to an end and strongly urges the Biden Administration to support legislation to extend them. 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. Legislation has been introduced that would extend the incentives for an additional six years and authorize CMS to set the QP thresholds so that they would not increase be unattainable for many Advanced APM participants. The Value in Healthcare Act (HR 4587) has 28 bipartisan cosponsors, most of which have joined as cosponsors in the last six months.

For physicians participating in many of the current Medicare APMs, the 5 percent APM incentive payments have been the only way they can be paid for delivering high-value services that are not supported by the payment schedule. In addition, reductions in the number of services provided when physicians are able to prevent diseases and avoid complications and exacerbations can lead to revenue losses under the payment schedule which the incentive payment can help to offset. For these reasons, the incentive payments can be more important for reducing the amount of money physicians would lose by participating in the APM than paying them more to do so.

Physicians also face significant transition costs in participating in APMs. For example, even if an APM pays for delivery of enhanced services to patients that the payment schedule alone does not adequately support, the physician practice will still have to recruit, hire, and train staff to perform those functions, and that will require incurring significant costs before services and payments can begin. APM participants also make investments in data analytics, technology, and other improvements that allow them to effectively participate in the APM that the incentive payments help to offset.

The expiration of the 5 percent payments means that it will be even more difficult than it is today for physicians to participate in APMs that rely primarily or exclusively on shared savings payments.

Consequently, it is essential for CMS to modify its APM programs to include payments for new services and funding for transitional costs so that physicians have the ability to implement better approaches to care delivery. Moreover, these APM payments must be designed in a way that enables physicians in each specialty to deliver specialty-specific services for the kinds of patients those physicians treat.

The AMA has developed a method for doing this in the Shared Savings Program and other CMS ACO programs called Payments for Accountable Specialty Care, or PASC. Under PASC, a specialist could 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 be improved by providing higher ECS payments for care of patients who have complex conditions or who are at higher risk for poor outcomes due to health-related social needs or other factors.

Choosing Participation in MIPS or an APM

The AMA believes that most physicians would prefer to be in a well-designed APM than to be in the MIPS program. MIPS payment incentives are budget neutral, with any positive payment adjustments being funded by penalties. The only exception to budget neutrality has been a $500 million allocation under MACRA for participants who exceed the exception performance threshold. Under the MACRA statute, however, this funding for those who exceed the exceptional performance threshold will expire the same year that the APM incentive payments for QPs expire.

Even while this significant additional funding was available, the annual MIPS maximum payment adjustments have been very low relative to the maximum percentages that were allowed under MACRA. Physicians who achieve the MIPS performance threshold have had positive adjustments close to zero, and even those who have achieved the exceptional performance threshold have had positive adjustments below 2 percent. Because MIPS is mostly budget neutral, and next year will be totally budget neutral with the exceptional performance funds expiring, the positive adjustments in MIPS have been much smaller than the 5 percent incentive payment for QPs. In addition, as described elsewhere in this letter, there are very significant costs involved in MIPS participation which far outweigh the potential positive payment adjustments.

The best approach is to create good APMs so that all physicians who want to participate in them can have the opportunity to do so. Until more physicians have opportunities for APM participation, most will continue to report through the MIPS program because they do not have a meaningful choice, not because they perceive the payment incentives in MIPS to be better than APMs.