AMA
AMERICAN MEDICAL ASSOCIATION

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October 5, 2020

The Honorable Seema Verma
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–1734–P. Medicare Program; CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs: Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule.

Dear Administrator Verma:

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 2021 Physician Fee Schedule (PFS) and Quality Payment Program (QPP) proposed rule, published in the *Federal Register* on August 17, 2020 (85 Fed. Reg. 50074).

While there are numerous important proposals in this proposed rule which we provide comments on below, the AMA has been particularly focused on four issues. First, the calendar year (CY) 2021 rate setting and conversion factor deliver a significant decrease overall to physician payment. The proposals related to relative value units (RVUs), office and outpatient evaluation and management (E/M) visits, and the application of budget neutrality together result in a conversion factor that poses a very real threat to the ability of many physicians to deliver health care services to their patients. Our AMA strongly supports implementation of CMS' new office visit policy and believes it will lead to significant administrative burden reduction and better describe and recognize the resources involved in office visits as they are performed today. However, we are deeply concerned that the corresponding budget neutrality cuts are deeply problematic during or immediately after the SARS-CoV-2 or COVID public health emergency (PHE), during which physician practices have experienced severe reductions in revenue. The almost 11 percent cut to physician payment is impactful in a most harmful way, especially during these unprecedented times. We urge CMS to use its authority to waive budget neutrality, and to bring physician

payment up to a level commensurate with their service. We offer several recommendations on how the impact of the conversion factor can be lessened.

Second, the AMA opposes CMS' decision not to incorporate the revised office and outpatient E/M values in the global surgical codes, as this disrupts relativity and treats the same physician work differently based on whether the service is a stand-alone or post-operative visit. The AMA asks for CMS to convene the RUC and other stakeholders to discuss the global surgical codes and the add-on codes issues before moving forward with the proposed policies scheduled to take effect on January 1, 2021. The AMA supports the RUC recommendations on how to implement the global surgical codes. The AMA recommends that the implementation of the GP1X add-on code be postponed.

Third, the AMA continues to work closely with CMS to promote improvements to the Medicare Quality Payment Program (QPP). The AMA appreciates CMS' proposals to introduce a more clinically relevant, less burdensome approach to the Merit-based Incentive Payment System (MIPS) via the new MIPS Value Pathways (MVPs) and makes recommendations that we believe are critical to the successful implementation of MVPs. The AMA supports the MIPS flexibilities that CMS implemented during the COVID-19 pandemic and urges the agency to continue these policies through 2021 as the pandemic remains an ongoing crisis and disruptive to the fair and accurate evaluation of physician performance in MIPS. We recommend CMS postpone its transition away from the Group Practice Reporting Option web-interface and associated measures until 2023. The AMA does not support the CMS proposal to transition MIPS Alternative Payment Models (APM) to the Alternative Payment Model Performance Pathway (APP), as the quality measures should match the focus of the APM.

Fourth, the AMA is grateful that CMS moved so quickly to provide critical flexibilities for telehealth policies. CMS telehealth policy changes during the PHE enabled patients to get much needed care. Patients and physicians now understand the value and importance of telehealth. Consequently, the AMA urges CMS to continue to strengthen telehealth policies: making permanent several telehealth services, removing geographic and site of service barriers, and continuing to cover services through the end of the year following the year in which the PHE ends. These services should include audio only visits.

It is important to state the obvious our physicians have stepped into harrowing situations in heroic form, providing around-the-clock care while facing workforce challenges and shortages of personal protective equipment during the SARS-CoV-2 or COVID pandemic. COVID-19 has exposed the weaknesses in our health care system as well as opportunities for improvement, but the dedication of our physicians to deliver quality care for all patients, especially in emergency and pandemic situations, remains unchanged. In response to the COVID-19 pandemic, many physician practices closed to conserve personal protective equipment and to reduce the virus' spread. The impact of COVID-19 has been devastating to physician practices. While some patient visits and surgeries were postponed during the early months of COVID-19 public health emergency (PHE), many patients have foregone those services completely. As a result, some patients did not receive the care they needed to prevent or manage their condition, and physician practices were not able to meet their expenses related to their practices even with the modest assistance from the Medicare Accelerated and Advance Payments, the Provider Relief Fund, and other small business supports.

Our AMA continues to put the concerns of our physicians, our medical students, and the patients they serve at the forefront of everything we do. We are particularly concerned that the impact of some

proposals combined with COVID-19 will continue to widen the gap for marginalized and minoritized communities. While the data remain incomplete, the data that have emerged on the racial and ethnic patterns of the COVID-19 pandemic show that the virus has clearly disproportionately affected Black and Latinx, American Indian/Alaska Native—particularly in the Navajo Nation—Asian-American, and Pacific Islander communities. As CMS prioritizes proposals and creates future plans for addressing health care needs during a pandemic, the agency must also prioritize promptly providing culturally appropriate public health information to minoritized populations through appropriate channels and ensuring access to telehealth services for underserved areas in order to assist those communities access health care services while maintaining CDC-recommended physical distancing practices. Our AMA is committed to not only reducing health disparities, but to increasing health equity, in the wake of the pandemic, the public health emergency, and beyond.

The AMA comments are guided by our AMA policies, informed by our members, and presented through a COVID-19 and health equity lens.

The following outlines our principal recommendation to the 2021 proposed rule.

Physician Fee Schedule (PFS)

- The AMA strongly supports the January 1, 2021 implementation of the improvements to the E/M office visits, including those bundled into the post-operative period of surgical procedures. However, the physician payment cuts due to budget neutrality adjustments cannot take effect. CMS should exercise the full breadth and depth of its administrative authority to avert or, at a minimum, mitigate these unconscionable payment cuts. The AMA offers several alternatives.
- The AMA recommends a new data collection process and potential changes to the underlying PE methodology should be explored related to practice expense relative values with the goal of an effective, transparent, and fair data collection effort.
- The AMA urges CMS to continue and make permanent several telehealth services, to remove barriers to access based on geography and site of service, and to continue the coverage and payment policies that it has put in place for audio-video and audio-only services during the COVID-19 public health emergency (PHE) through the end of the year following the year in which the PHE ends.
- The AMA is concerned that CMS has fundamentally misinterpreted the structure of the Remote Physiological Monitoring codes, as intended within the CPT code set, particularly with regards to CPT codes 99457 and 99458, and does not agree these codes only describe treatment management services.
- The AMA supports permanently allowing the supervision of residents in teaching settings through audio/video real-time communications technology, the virtual presence of teaching physicians during Medicare telehealth services and believes these changes should be made permanent. Other important scope of practice issues are highlighted in our comments.
- The AMA urges CMS to finalize the CPT codes, CPT guidelines, and AMA/Specialty Society RVS Update Committee (RUC) recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC.
- The AMA supports the opioid use disorder policies, including the expansion of the monthly bundled payment codes to all substance use disorders and the payment of physicians in emergency departments to stabilize patients with withdrawal symptoms.

Other Provisions of the Proposed Rule

- The AMA continues to have ongoing concerns about the potential impact of cuts to payment rates for clinical testing services paid on the Clinical Laboratory Fee Schedule.
- The AMA does not support the timing of the proposal to transition the Medicare Shared Savings Program (MSSP) quality measures from the GPRO web-interface to the MIPS Alternative Payment Model (APM) Performance Pathway. Instead, the AMA recommends CMS gather stakeholder feedback and postpone the transition until 2023.
- The AMA strongly supports the proposal to defer requiring electronic prescribing of controlled substances (EPCS) for Medicare Part D prescriptions until 2022 and deeply appreciates CMS' recognition of the hardship that implementation of such a requirement in 2021 would impose on patients and physicians.
- The AMA requests CMS provide more information about the drug products impacted by the proposed change to Section 505(b)(2) of the Food, Drug, Cosmetic Act.
- The AMA strongly urges CMS to limit any unnecessary complications or burden that could impede physicians' adopting, scheduling, planning, implementing, testing, training, and using new EHRs in clinical environments. The AMA strongly urges CMS to not require physicians to use 2015 Edition Cures EHRs before January 1, 2023.
- The AMA greatly appreciates and strongly supports the significant flexibilities that CMS has provided for Medicare Diabetes Prevention Program (MDPP) suppliers during the COVID-19 PHE, in particular allowing patients to receive MDPP services more than once during their lifetime and allowing access to sessions provided on a virtual basis. The AMA recommends that these flexibilities be made permanent.

Calendar Year 2021 Updates to the Quality Payment Program (QPP)

- The AMA urges CMS to increase the composite score complex patient bonus and to expand favorable scoring policies to small practices throughout the MIPS categories.
- The AMA supports CMS' proposal to reduce the previously-finalized 2021 MIPS performance threshold from 60 to 50 points in light of the COVID-19 pandemic. We urge CMS to consider maintaining the threshold at 45 points and to similarly reduce the additional performance threshold to incentivize ongoing participation in MIPS.
- The AMA appreciates CMS' efforts to make MIPS more clinically relevant and less burdensome with the MIPS Value Pathways approach, which adopts several AMA recommendations.
- We support postponing MVP implementation until 2022 due to the COVID-19 pandemic.
- We reiterate our strong support for collaboration between CMS and specialty societies to develop MVPs and urge the agency to finalize changes that will allow MVPs to be more innovative, flexible, less burdensome, and meaningful to patients.
- The AMA strongly urges CMS to maintain the weight of the cost category at 15 percent and the quality category at 45 percent of the final MIPS score for the 2021 performance year in light of the unknown impact of the COVID-19 PHE on the cost measures, frontline physicians' focus on continuing to care for patients during this pandemic, and to provide physicians more time to familiarize themselves about their resource use.

- The AMA urges CMS to maintain topped out measures that have a linkage to cost measures or MVPs, and to revise the existing quality measure benchmark methodology to incorporate more of a manual+data driven approach.
- The AMA strongly urges CMS to extend the extreme and uncontrollable circumstances hardship exception flexibilities due to the COVID-19 public health emergency (PHE) through at least 2021.
- The AMA supports CMS' proposal to use performance period benchmarks for the CY 2021 MIPS performance period rather than baseline period historic data, agreeing with CMS' concerns that 2019 performance data may not be a representative sample of historic data. We also urge CMS to consider the impact COVID-19 will have on 2020 and 2021 data and setting future benchmarks.
- The AMA is concerned with CMS' proposal to truncate the performance reporting period as it relates to scoring flexibility for changes that impact quality measures. We urge CMS to work with measure stewards and relevant specialties to evaluate the data to determine whether a cut-off of nine months skews performance.
- The AMA does not support CMS' proposal to include the Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) Eligible Clinicians. The AMA also has concerns with the new Hospital Wide All Cause Readmission measure for MIPS.
- The AMA asks that CMS reconsider the proposed QCDR testing timeline and allow QCDRs two nomination cycles to complete reliability and validity testing for new measures.
- The AMA strongly supports CMS' proposal to allow physicians to report on the Health Information Exchange (HIE) Bi-Directional Exchange measure by a yes/no attestation and we encourage CMS' new direction in measure design that increases flexibility while reducing physician reporting burden.
- We urge CMS to consider how EHR vendor-captured data can reduce physician reporting burden. The AMA believes CMS should create broad categories of Promoting Interoperability objectives allowing physicians to attest "yes/no" to the use of certified electronic health record technology (CEHRT) itself to achieve those categories.
- We urge CMS to adopt more Improvement Activities related to the management of COVID-19 such as practices providing COVID-19 screening, diagnosis, or treatment, whether in-person or via telemedicine.

We thank you for the opportunity to provide input on this proposed rule. Our detailed comments on the proposed rule 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

2021 Physician Fee Schedule and Quality Payment Program Proposed Rule
Detailed Comments of the American Medical Association

I. Calendar Year 2021 Physician Fee Schedule Ratesetting and Conversion Factor

A. Calendar Year 2021 Medicare Conversion Factor and Recommendations for Mitigating the Payment Cuts Due to Budget Neutrality
B. Determination of Practice Expense (PE) Relative Value Units (RVUs)
C. Determination of Potentially Misvalued Services Under the Physician Fee Schedule and Valuation of Specific Codes
D. Telehealth and Other Services Involving Communications Technology
E. Care Management Services and Remote Physiologic Monitoring Services
F. Revisions for Payment for Outpatient E/M Visits and Promoting Stability during COVID-19 Public Health Emergency
G. Scopes of Practice and Related Issues
H. Valuation of Specific Codes
I. Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Services Furnished by Opioid Treatment Programs (OTPs)

II. Other Provisions for the Proposed Rule

A. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and a Comment Solicitation on Payment for Specimen Collection for Covid-19 Tests
B. Medicare Shared Savings Program (MSSP)
C. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD plan
D. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act
E. Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule
F. Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

III. CY 2021 Updates to the Quality Payment Program

A. MIPS Value Pathway (MVP) Development
B. Merit-based Incentive Payment System Alternative Payment Model Performance Pathway (APP)
C. MIPS
    1. Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020
    2. MIPS Performance Threshold and Additional Performance Threshold
    3. Quality Category
    4. Cost Performance Category
    5. Promoting Interoperability
    6. Improvement Activities
D. Advanced Alternative Payment Models (AAPMs)

I. Calendar Year 2021 Physician Fee Schedule Ratesetting and Conversion Factor

A. Calendar Year 2021 Medicare Conversion Factor and Recommendations for Mitigating the Payment Cuts Due to Budget Neutrality

- **Recommendation**: The AMA strongly supports the January 1, 2021 implementation of the improvements to the E/M office visits, including those bundled into the post-operative period of surgical procedures. However, CMS should exercise the full breadth and depth of its administrative authority to avert or, at a minimum, mitigate the unconscionable payment cuts due to budget neutrality adjustments when implementing the office and outpatient office visit coding and payment changes that it has finalized for 2021. Recommendations include: waiving budget neutrality under the public health emergency authorities, postponing implementation of GPC1X until it is better defined, implementing GPC1X with no budget neutrality offset, using previous over-estimated spending to lessen the budget neutrality adjustment, and phasing-in the budget neutrality cuts over multiple years.

The American Medical Association (AMA) strongly supports the Centers for Medicare & Medicaid Services (CMS) adoption of the AMA Current Procedural Terminology (CPT) Editorial Panel coding framework and the AMA/Specialty Society Relative Value Scale Update Committee (RUC) recommended values for office and outpatient evaluation and management (E/M) visits to be implemented on January 1, 2021. The framework was the result of substantial collaboration by an AMA-convened workgroup which brought together more than 170 state medical and specialty societies. CMS' new office visit policy will lead to significant administrative burden reduction and will better describe and recognize the resources involved in clinical office visits as they are performed today.

We are deeply concerned, however, that the proposed rule identifies a profoundly steep budget neutrality adjustment which will be required in 2021 to offset the payment increases for certain office visits and other services. The proposed CY 2021 PFS conversion factor is $32.26, marking a significant decrease of $3.83 below the CY 2020 PFS conversion factor of $36.09. The proposed CY 2021 anesthesia conversion factor is $19.96, a decrease of $2.25 from the CY 2020 conversion factor of $22.20. The CMS proposed conversion factors include the budget neutrality adjustment.

Under the Medicare Access and CHIP Reauthorization Act (MACRA), the statutory physician payment update for 2021 is zero percent. Moreover, the drastic 11 percent reduction in the Medicare conversion factor is necessitated by the proposed additional spending of $10.2 billion. The RUC recommendations account for only half of this additional spending, and therefore, half of the reduction. The remaining spending increases and resulting conversion factor reduction is attributed to various CMS proposals to increase valuation for specific services. Of serious concern is the proposed $3.3 billion increase in spending attributed to the GPC1X E/M office visit primary care add-on code. The GPC1X add-on code substantially increases the magnitude of the budget neutrality adjustment factor by more than 3 percent.

The AMA is deeply concerned about the impact of the sizable budget neutrality cuts this update will impose on many physicians and health care professionals who do not report office visit codes, including radiologists, pathologists, and physical therapists, all of whom face estimated 2021 payment cuts of 9 percent to 11 percent solely due to budget neutrality, as projected in Table 90 of the proposed rule. Specialties including general surgeons, critical care physicians, and anesthesiologists face estimated cuts

ranging from 7 percent to 8 percent. The budget neutrality driven cuts will additionally reduce the positive impacts of the office visit changes for primary care physicians, oncologists, pediatricians, and other specialties for whom office visits comprise a significant proportion of their services.

Payment reductions of this magnitude would be a major problem at any time, but to impose cuts of this magnitude during or immediately after the COVID-19 pandemic, including steep cuts to many of the specialties that have been on the front lines in efforts to treat patients in places with widespread infection, is unconscionable. Survey and claims analysis suggest that physician practice revenue decreased at least 50 percent between March and May 2020,[1] which translates to approximately $70.6 billion reduction in revenue based on AMA analysis of CMS' National Health Expenditure data for 2018. Some physician practices may be able to recoup a portion of that revenue, but not all physicians will be able to do so. The nation-wide reopening due to COVID-19 is occurring in phases for physician practices, yet certain patients are unable or unwilling to leave home for an in-office service or procedure. Job losses due to COVID-19 are affecting patients' insurance coverage, and physicians will not be able to see nearly as many patients as they did prior to the pandemic due to new safety precautions and personal protective equipment supply. In addition to having reduced in-office capacity due to safety precautions, physicians also face increased expenses post-pandemic due to these same safety precautions.

According to a recent AMA COVID-19 Financial Impact Survey, 81 percent of physicians report their revenue was lower in August 2020 compared to when they completed the survey in February 2020. On average, revenue was reported to be 32 percent lower. Six months after the Secretary declared COVID-19 a public health emergency, the volume of patient visits remains reduced. Sixty-nine percent of respondents reported fewer weekly visits at the time of the August survey than prior to the pandemic. On average, weekly office visits fell from 100 to 72 between February 2020 and the time of the survey–a decline of 28 visits per week. Pediatricians, ophthalmologists, and general surgeons were most likely to have a decrease in weekly visits. CMS' sweeping expansion of Medicare telehealth policies resulted in a substantial increase in the use of audio-video tools and mobile devices to provide care during the pandemic to patients who are vulnerable to severe illness from COVID-19, who have mobility issues, and who are social distancing. These telehealth visits only partially offset the decline in weekly face-to-face visits. Combined, telehealth visits and in-person visits remain 29 percent below pre-pandemic levels. The survey shows that several of the physician specialties who will face the largest cuts due to budget neutrality were also least able to make up for the lack of in-person care through telehealth, such as anesthesiologists who reported an average of three telehealth visits per week, general surgeons who reported providing five telehealth visits per week, and ophthalmologists reported seven.

We believe it is a reasonable assumption that practice revenue would be reduced by a minimum of 25 percent from the norm over the June 2020 to August 2020 timeframe. This reduction would amount to another $35.3 billion loss in revenue based on AMA analysis of CMS' National Expenditure data for 2018. While some of that physician revenue loss has been offset by the CARES Act[2] Provider Relief

[1] AMA, COVID-19 Financial Impact Survey; Fair Health, Healthcare Professionals and the Impact of COVID-19; MGMA, COVID-19 Financial Impact on Medical Practices; AMGA, Surveys of Financial Impact of COVID-19; Primary Care Collaborative, Primary Care & COVID-19: Surveys.

[2] H.R. 748, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), was enacted on March 27, 2020, as Public Law 116-136.

Fund grants, the estimated $11 billion physicians have received thus far from the $50 billion of general distribution funding represents only 10 percent of the total estimated revenue loss of physicians.

In addition, CMS loaned a $40.4 billion as a lifeline to physicians, health care professionals, and other Part B suppliers during the initial phase of the pandemic through the Medicare Accelerated and Advance Payment Program.[3] Under current terms, these loans will be recouped by offsetting 100 percent of Medicare payments beginning soon. The AMA is seeking regulatory and statutory improvements to these loan repayment terms, including a considerably lower interest rate. Although, even in the event of improved terms, many physician practices face the possibility that they will still be in the process of repaying these loans when the budget neutrality cuts take effect, compounding its negative impact.

These challenges highlight the urgent need for CMS to ensure practices facing severe economic strain and uncertainty can continue meeting the needs of patients during and after the public health emergency. We strongly urge CMS to implement the recommendations below to mitigate the payment cuts due to budget neutrality. Now more than ever, we need physician practices on strong financial footing and open to combat COVID-19.

1. *Waive Budget Neutrality Under the Public Health Emergency Authority*

The AMA deeply appreciates the actions of the Administration to provide flexibility, regulatory relief, and financial assistance for physicians to meet the needs of patients during this unprecedented PHE. We joined 170 state medical and national physician specialty societies in a letter requesting that HHS and CMS exercise similar flexibility to not apply budget neutrality requirements for the E/M changes. Physician practices continue to see large revenue losses this year and face increased expenses. Certain patients are unable or unwilling to leave home for an in-office service or procedure, and physicians are not able to see as many patients as they did before COVID-19 due to new safety precautions and personal protective equipment supply. We are very concerned that additional revenue reductions could create significant access problems during a continuing public health emergency.

In Appendix 1, we provide a table that presents examples of flexibilities undertaken by CMS to address the COVID-19 public health emergency. The first part of the table addresses waivers that CMS has provided with explicit authorization under section 1135 of the Social Security Act. The second part of the table presents examples of policies that CMS has adopted that do not have explicit waiver authority but for which CMS has undertaken rulemaking to adopt as special policy during the COVID-19 PHE. The last part of the table lists examples of actions taken by CMS without either explicit statutory authorization (for example, specific aspects of the Accelerated and/or Advanced Payment Program) or without explicit statutory waiver authority. Our purpose in bringing these examples to your attention is not to suggest that these policies were inappropriate. **Rather, we believe CMS is exercising appropriate flexibility to address an unprecedented public health emergency and we are requesting you exercise similar flexibility to not apply physician fee schedule budget neutrality for the E/M changes in 2021.**

[3] *See* https://www.cms.gov/files/document/accelerated-and-advanced-payments-fact-sheet.pdf. Last accessed September 21, 2020.

2. Postpone Implementation of GPC1X and Allow the CPT Editorial Panel to Better Define It

The GPC1X E/M add-on code substantially increases the magnitude of the budget neutrality adjustment, thus increasing the payment cuts for clinicians who do not report office visits by more than 3 percent. In addition, the agency has received comments that the proposed code is not clearly defined, including from the AMA, specialty societies, and the Medicare Payment Advisory Commission (MedPAC). The RUC was unable to provide a relative value recommendation on GPC1X due to the lack of clarity on the purpose, use, and reporting of this code. Furthermore, due to the lack of clarity on when code GPC1X can be billed, CMS may face oversight risk from the Office of Inspector General in relation to overutilization of GPC1X without explicit criteria for when the code can be billed. **Therefore, if CMS wishes to pursue the GPC1X E/M add-on code, the AMA continues to recommend CMS postpone implementation to allow the CPT Editorial Panel to better define it.**

4. Implement GPC1X with No Budget Neutrality Offset

If CMS moves forward with the GPC1X add-on code, CMS should not apply budget neutrality since it is a new code established by regulation. We believe CMS has the authority to exclude changes in law and regulation, including the new add-on code, which affect spending from the calculation of budget neutrality, analogous to its treatment under the Medicare Sustainable Growth Rate (SGR) system of certain new benefits that increased spending but were outside the control of the physician community. Specifically, Section 4503 of the Bipartisan Budget Act of 1997 states that one of the four factors used to set the SGR is (emphasis added):

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

Several examples of expenditures that CMS has treated as pass-throughs in the SGR based on the law and regulation factor are available. After Medicare preventive benefits were expanded, for example, CMS increased the law and regulation factor of the SGR to account for the addition of new benefits and also to reflect higher payment rates that CMS established for the prostate screening test through regulation. Under the SGR system, these changes were excluded from budget neutrality and had to be explicitly accounted for in the SGR to avoid penalizing physicians for statutory or regulatory changes made by Congress or CMS which increased spending in ways that were not under the control of physicians. The budget neutrality exclusion remains relevant today. CMS no longer needs to account for statutory or regulatory changes in the SGR, but it remains necessary to exclude statutory and regulatory changes that affect spending from the calculation of budget neutrality.

In addition, the language in Section 1848(c)(2)(B)(ii)(I) and 1848(c)(2)(B)(iii) of the Social Security Act illustrates that Congress intended to provide flexibility to the Secretary in determining budget neutrality adjustments. The language provides, "… the Secretary shall, to the extent the Secretary determines to be necessary" and also states "… the Secretary, in making adjustments under clause (ii) shall consult with…organizations representing physicians." This language illustrates that in determining which changes should be subject to budget neutrality adjustments, Congress intended to provide authority and latitude to the Secretary to make these determinations.

5. Use Previous Over-Estimated Spending to Lessen the Budget Neutrality Adjustment

The previous administration based the 2013 budget neutrality offset for Transitional Care Management (TCM) on a significantly greater estimate of initial utilization of the service than what actually occurred. At that time, CMS estimated there would be 5.6 million claims for TCM when actual utilization was just under 300,000 the first year and still less than one million after 3 years of implementation. For 2013, the Obama Administration reduced Medicare physician fee schedule spending by more than $700 million based on its overestimate of TCM utilization. Given the statutory authority for budget neutrality adjustments to be made "to the extent the Secretary determines to be necessary," this statute allows CMS to account for past overestimates of spending when applying budget neutrality. **CMS could lessen the impact of the budget neutrality adjustment for the office visit increases in 2021 by restoring the over-estimated budget neutrality adjustment from the first few years of TCM.**

6. Phase-in the Budget Neutrality Cuts Over Multiple Years

Both Congress and CMS have acted in the past to mitigate negative impacts of payment cuts with large redistribution effects by phasing them in over time. While the statute has specified some of these phased transitions, CMS has provided for others using its own regulatory authority. For example, the statute specifies that GPCI changes above a certain threshold are phased in over two years and misvalued code reductions above a certain threshold are phased in over two years. Other times, CMS has phased-in policies that are expected to be significantly redistributive absent explicit statutory direction. For example, in the 2007 physician fee schedule final rule, CMS adopted a major change to the practice expense methodology and adopted a phase-in of the payment impacts over four years (71 FR 69638). In the 2010 physician fee schedule final rule, CMS began using a new survey of practice expenses that resulted in significant redistributions in payment. CMS used its regulatory authority to adopt these changes over a transitional period (74 FR 61751). **Similarly, cuts due to budget neutrality offsetting the proposed office visit increases which will significantly reduce payments for certain specialties and health professionals in 2021 should be phased in by CMS over multiple years.** To be clear, we are not asking CMS to phase in implementation of the E/M changes but rather to phase in the payment reductions for certain specialties and health professionals in 2021 due to budget neutrality.

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

- **Recommendation**: The AMA urges CMS to begin working with the AMA and the RUC immediately to initiate a new data collection process and to discuss any potential changes to the underlying PE methodology. The AMA provides initial comments on potential data collection and methodological changes related to practice expense relative values and emphasizes the goal of having an effective, transparent, and fair data collection effort.

Physician Practice Expense Data Collection

CMS provides a brief update on a January 2020 convened Technical Expert Panel (TEP) and analyses performed by the RAND Corporation. While not currently proposing changes to the practice expense methodology or data collection process, CMS states that comments on the RAND reports are welcome during the comment period, or anytime thereafter via email at PE_Price_Input_Update@cms.hhs.gov. CMS notes that they intend to convene a Town Hall with all stakeholders in the future to discuss the

practice expense methodology and data collection effort. We encourage CMS to solicit and review stakeholder feedback before proposing any changes and initiating further research.

Clinical Labor Costs

CMS specifically calls for comments on the best source of data for wage rates used in computing clinical labor costs. CMS currently utilizes data from the U.S. Bureau of Labor Statistics (BLS) to determine a cost per minute estimate for each of 50 different clinical staff professions. For example, CMS currently assumes the hourly wage for a Registered Nurse (RN) in the United States to be $30.60, or $0.51 per minute. According to 2019 data at https://www.bls.gov/oes/current/oes291141.htm the mean hourly wage for an RN is $33.45 or $0.56 per minute. **The BLS is a reliable and transparent source of data and we see no rationale to consider a different data source. However, CMS should keep the data up-to-date and should use the most recent year of available BLS data to determine clinical labor costs.**

RAND Reports and Activities

CMS continues to rely on the RAND Corporation to provide research and analysis regarding potential data collection and methodological changes related to the practice expense relative value unit (PE RVU). RAND has focused on the following three issues:

1. Updating and/or improving the data used in the indirect cost-allocation process;
2. Refining the current indirect cost-allocation process; and
3. Using hospital outpatient costs to inform or replace the current process to establish the physician practice expense relative values

We will provide initial comments on this activity and the RAND reports. **However, we urge CMS to begin working with the AMA and the RUC immediately to initiate a new data collection process and to discuss any potential changes to the underlying PE methodology.**

1. *Updating and/or Improving the Data used in the Indirect Cost-Allocation Process*

RAND conducted a thorough review of physician surveys, literature and data sources and determined that there is not an adequate source of existing data to replace the practice cost information currently utilized in the indirect cost-allocation process. RAND includes a suggested survey in an Appendix to the latest report. The survey is complex and attempts to collect information that is not essential to the existing methodology. The previous Physician Practice Information (PPI) was also too lengthy and included information desired by either CMS or individual specialty societies, but not imperative to the indirect cost methodology. The next survey must be administered to collect only the absolute required information.

RAND and CMS also imply that data collection should be less granular with fewer specialties surveyed to simplify their processes. While some condensing of the number of specialties surveyed may be possible (e.g., if specialties have similar costs), several specialties have recently objected to the lack of specific recognition or delineation in the survey process. Any changes only to "simplify" should not disadvantage practicing physicians. **We strongly urge CMS to work with the AMA and other stakeholders to plan an effective, transparent, and fair data collection effort.**

2. 2007-2008 Physician Practice Information (PPI) Survey

The PPI Survey was led by the AMA, with the participation and cooperation of CMS and 72 national medical specialty societies and other health care professional organizations. The 2007-2008 survey collected physician practice data, which was then purchased by CMS to utilize in the 2010 Medicare Physician Payment Schedule. The survey was designed to update the specialty-specific practice expense per hour data used to develop practice expense relative value units (RVUs). The PPI survey was coordinated by the AMA to collect recent, reliable practice expense data using a consistent survey instrument for all specialties and health care professionals. Prior to the PPI survey, CMS relied on data from the 1995-1999 AMA Socioeconomic Monitoring Surveys (SMS) for most specialties to determine Medicare payment. The 2007-2008 PPI survey included responses from 7,403 health care professionals across 51 physician specialties and other health care professional groups. Complete practice cost data were collected from 3,659 of these respondents and were eligible to be included in the practice cost computations provided to CMS.

The survey was administered by dmrkyentec (DMRK) and collected information on practice characteristics; physician time spent in direct patient care and other activities; and financial data, including practice cost data utilized not only for practice expense valuation within the Resource-Based Relative Value Scale (RBRVS), but also for the Medicare Economic Index (MEI).

AMA staff economists and the vendor retained by CMS, The Lewin Group, analyzed the data in early 2009 and submitted practice cost data to the Administration on March 31, 2009. CMS released a Notice of Proposed Rule Making (NPRM) on July 1, 2009, indicating that the PPI survey was the most comprehensive source of practice expense survey information available to date and that the Administration would fully utilize the data obtained from the PPI survey in determining 2010 Medicare payments.

The PPI survey data led to payment redistributions between specialties and other health care professionals. CMS provided an impact table in the NPRM indicating that 70 percent of the specialties and other health care professionals received payment improvements resulting from the PPI survey and other methodological changes. Primary care payments improved by as much as six percent. However, 11 specialties or professions were reduced by five percent or more, including a 10 percent decrease for cardiology and radiology.

3. *2020 AMA Practice Expense Pilot Survey*

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 survey 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 of the pilot survey, 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 complete.

The pilot study successfully concluded in August 2020. The AMA will convene meetings with CMS and with the national medical specialty societies and other health care organizations to share lessons learned from the pilot study and to discuss the potential for a large-scale survey. It will be important that the AMA, CMS and the specialties work collaboratively to ensure a successful survey effort.

Ideally, a 2021 AMA Practice Expense Survey would be planned. However, the COVID-19 pandemic has dramatically altered physician practice revenues, staffing and expenses in 2020. Querying physicians and their financial experts in 2021 on their 2019 data may also be problematic. **We recommend that a 2022 survey be planned and fielded, collecting 2021 data, using lessons learned from the AMA pilot survey. Discussions with CMS, AMA, and other stakeholders should begin in early 2021 to work toward this important goal.**

Refining the Current Indirect Cost-Allocation Process

RAND discusses an alternative framework to determine and allocate indirect practice costs to the individual service level. Conceptually, the RAND discussion focuses on a desire to achieve greater relativity within the indirect costs. For example, while the direct expense methodology assumes the same wage rate for a registered nurse (RN), regardless of specialty, the indirect costs do not have a uniform standard such as rent cost per square footage. RAND, and some TEP members, expressed concern that variance in rent costs should only be applicable via the geographic practice cost indices (GPCIs), not within specialties' indirect costs.

To achieve greater relativity and uniformity, RAND proposes that the indirect costs should be segregated into several categories (no more than 10) and allocated on independent allocation methodologies. One example is electronic health record (EHR) costs could be allocated by clinical time. This specific example warrants further discussion as some have argued that EHR costs could be attributed as a direct cost. If a cost is to be allocated to an individual service based on physician time and clinical staff time, that may be more easily accomplished via the current direct practice expense methodology.

RAND notes "We anticipate that developing such a new system as this one would require substantial input from organized medicine and other stakeholders to specify the cost categories and the forms of allocators." We agree. If CMS desires to pursue new methods of allocation, it will be necessary to discuss the expense, allocator and reason for modification prior to the initiation of a new data collection effort.

Using the Hospital OPPS to Determine Physician Cost Relativity

Despite opposition by organized medicine in previous comment letters and members of the TEP in January 2020, RAND and CMS continue to discuss and perform analysis to translate the practice cost relativity of hospitals to the practice cost relativity of physician offices. We strongly object to this pursuit. Section 4505 of the Balanced Budget Act of 1997 requires CMS to (1) utilize, to the maximum extent practicable, generally accepted cost accounting principles which recognize all staff, equipment, supplies and expenses, not just those which can be tied to specific procedures, and use actual data on equipment utilization and other key assumptions, (2) consult with organizations representing physicians regarding methodology. Any proposal to use the relativity of hospital charge data to determine the relativity of practice costs within a physician office is not consistent with these statutory provisions.

Throughout the report, RAND states, "There is no gold standard for determining which methodology results in more-accurate reflection of resource-use." Yet, the report reflects a bias that macro-level hospital charge data are somehow more accurate than micro-level physician data. The current physician data are supported by granular CPT reporting, extensively reviewed standardized direct costs, and a survey conducted by the professions who incur the actual costs. Hospital charge data are often based on existing Ambulatory Payment Classification (APC) Medicare payment amounts, reflecting a relativity of APC payment rather than actual cost relativity. As payment is based on packages of services, the granularity of coding is not consistent with the granularity of coding for physician services.

RAND notes the following challenges in using the Hospital Outpatient Prospective Payment System (OPPS) data:

- Differences in the underlying costs and services mix between office and outpatient settings;
- The use of different procedure codes for similar services;
- Packing rules defining the items and services included in the payment; and
- Grouping of services to determine the payment rates.

These "challenges" are instead obstacles to an accurate, fair, and transparent physician payment system. RAND attempts to resolve all these shortfalls and obstacles by making numerous assumptions, including using 99490 *Chronic care management* to represent the pre- and post- practice costs of services. RAND further carries forward their flawed assumptions from other work for CMS related to visits included in the surgical global calculation into this analysis. RAND proposes to only include the practice costs for follow up visits that mirror the number of 99024 claims submitted. We strongly oppose the RAND method of imputing visits for each procedure with a 010 and 090 global period with data on postoperative visits reported with a 99024.

The results of this analysis should preclude CMS and RAND from continuing with this work. Sixty percent of all services would increase or decrease by 50 percent or more with a change to this methodology. Impacts to specialties are not tolerable (Examples: Hematology/Oncology—11 percent,

Interventional Radiology–23 percent, Vascular Surgery–27 percent). It is difficult to comprehend how such an analysis could be released during a pandemic and months before some physicians are facing 11 percent payment reductions due to the implementation of the office visit and other service payment improvements.

We urge CMS to refocus all efforts on a new practice expense data collection effort. CMS should convene a Town Hall meeting as discussed and immediately begin working with the AMA and other stakeholders to launch a new physician practice expense survey in 2022.

C. Determination of Potentially Misvalued Services Under the Physician Fee Schedule and Valuation of Specific Codes

- **Recommendation**: The AMA refers to the RUC recommendations on specific services that are potentially misvalued. The RUC will place CPT code 22867 on the next Level of Interest review.

RUC Progress in Identifying and Reviewing Potentially Misvalued Codes

Since the inception of the Relativity Assessment Workgroup, the RUC and the Centers for Medicare & Medicaid Services (CMS) have identified 2,553 services through over 20 different screening criteria for further review by the RUC. The RUC has recommended reductions and deletions to 1,489 services, more than half of the services identified, redistributing $5 billion. The RUC looks forward to working with CMS on a concerted effort to address potentially misvalued services. A detailed report of the RUC's progress is appended to this letter *(Attachment 01).*

Public Nominations of Potentially Misvalued Services

CMS received public nominations for one code as potentially misvalued, CPT code 22867 *Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar: single level*. **The RUC will place CPT code 22867 on the next Level of Interest for review.**

D. Telehealth and Other Services Involving Communications Technology

- **Recommendation:** The AMA urges CMS to continue and make permanent several telehealth services, and to seek authority to remove barriers to access based on geography and site of service. The AMA recommends that CMS continue to cover services that it began covering as telehealth services during the COVID-19 public health emergency (PHE) through the end of the year following the year in which the PHE ends to allow experience with delivery of these services via telehealth after the coronavirus is no longer a threat. Payment rates for telehealth services should continue to be the same as for in-person services during this period of time. CMS should also continue its current coverage and payment policy for audio-only services for the same period of time.

During the COVID-19 PHE, pursuant to authority granted in the CARES Act, CMS waived the geographic and site of service originating site restrictions for Medicare telehealth services found at Section 1834(m) of the Social Security Act. The AMA remains deeply grateful for these flexibilities,

which have allowed Medicare patients across the country to receive care from their homes. With many physician offices closed, elective procedures postponed, and patients as well as many physicians, other health professionals, and practice staff required to stay at home for a long period of time, the ability to provide services directly to patients regardless of where they are located via telehealth has allowed many vital health care services to continue. In addition to facilitating continuity of care for patients being treated for acute and chronic conditions, telehealth has also facilitated initial assessment of patients experiencing potential COVID-19 symptoms and those who have been in close contact with people diagnosed with COVID-19 to determine if referrals for testing or treatment are indicated while minimizing risks to patients, practice staff, and others. Currently, these flexibilities remain in effect as Health and Human Services Secretary Azar has extended the PHE declaration at least through October 23, 2020. CMS does not propose to permanently waive the geographic and originating site restrictions on the provision of telehealth services because the agency believes it lacks authority to do so without action by Congress.

CMS' actions during the PHE have generated a dramatic expansion in Medicare telehealth services. CMS is proposing to permanently keep several codes that were temporarily added to the Medicare telehealth list, including the prolonged office or outpatient visit code and certain home visit services. CMS also proposes to keep additional services, including certain emergency department visits, on the Medicare telehealth list until the end of the calendar year in which the PHE ends to allow more time to study the benefit of providing these services using telecommunications technology outside the context of a pandemic. This new Category 3 would provide a basis for adding or deleting services from the Medicare telehealth list on a temporary basis where there is likely clinical benefit, but where there is not yet sufficient evidence available to permanently consider the services under Category 1 or 2 criteria. CMS requests comments on the Category 3 approach.

Additions to Medicare Telehealth Services List

The AMA supports adding CPT codes 90853 (group psychotherapy), 96121 (neurobehavioral status exam), 99XXX (prolonged E/M), 99483 (assessment and care planning for patient with cognitive impairment), 99334-99335 (domiciliary or rest home visit), and 99347-99348 (home visit) to the Medicare Telehealth Services List. The proposed rule indicates that if the originating site restrictions that preceded the PHE are reimposed, then home visits will only be covered when delivered via telehealth for patients receiving treatment for a substance use disorder or co-occurring mental health disorder.

Addition of Category 3 to the Telehealth Services List

The AMA strongly supports the proposal to create a Category 3 within the Medicare Telehealth Services List and supports using Category 3 at least through the end of the calendar year in which the COVID-19 PHE ends. The AMA recommends, however, that Category 3 become a permanent addition to Medicare telehealth policy. New technologies and new methods of using existing technology to benefit patients are being developed continuously, and patients' access to and comfort with them is also evolving continuously. It is impossible to develop evidence about the clinical benefits of these new technologies and approaches without the financial ability to implement them by having Medicare treat them as covered services. A permanent Category 3 would provide a mechanism for allowing real-world assessments of promising new approaches before they are authorized for permanent use.

While the AMA agrees with the rationale that CMS has provided for establishing Category 3, it is not likely to be possible to fully assess how the services in Category 3 will be best delivered via telehealth beyond the COVID-19 PHE until after the SARS-CoV-2 virus is no longer a threat. If the COVID-19 PHE ends during 2021, then extending coverage of the Category 3 services only until the end of 2021 may not be sufficient to fully understand the impact of these telehealth services in the "new normal" health delivery system. The AMA recommends that CMS consider extending coverage of the Category 3 services for a longer period, such as through 2022, or through the end of the year *following* the year in which the public health emergency ends.

For the same reason, the AMA also strongly recommends that CMS maintain payment rates for telehealth services at the same rate as in-person services at least through the end of the year following the year in which the PHE ends. Before the PHE, telehealth services provided by physicians in a non-facility setting, such as a physician office, were paid as if they were provided in a facility setting. This significantly reduced payment rate was likely one factor contributing to the slow adoption of telehealth modalities prior to the PHE. Just as the AMA urges CMS to maintain coverage for important telehealth services to allow sufficient time to understand how they will best be delivered after the SARS-CoV-2 virus is no longer a threat, we also urge CMS to maintain the current payment policies for that same period of time so that there is sufficient opportunity to gather data on the resources involved in delivering telehealth services.

According to a recent AMA COVID-19 Financial Impact Survey[4] of 3,500 physicians, whereas only 20 percent had provided at least one telehealth visit a week in February 2020, by the height of the pandemic 77 percent were providing telehealth visits and this summer, 68 percent were still providing telehealth services. More than half of respondents expect their delivery of telehealth services to remain at its current level through the end of this year, 29 percent expect their use of telehealth to further increase, and 14 percent say it will decrease. Predicting the way telehealth will be used once the coronavirus is no longer a threat would be even more difficult.

Services to Be Included in Category 3

1. Emergency Department Visits

The AMA supports including all of the CPT codes listed in Table 10 within Category 3, but strongly recommends including CPT codes 99284 and 99285 for Level 4 & 5 Emergency Department Visits in addition to 99281-99283. There are no bright lines separating codes 99284-99285 from 99281-99283 in terms of whether and how often an in-person physical examination by the billing emergency physician is needed. There are many types of patients with complex problems that require extended assessments but where physical examination by the emergency physician may not be necessary as long as one or more health professionals are in the room with the patient. Several studies have found that telemedicine support in emergency departments can reduce the frequency of expensive and dangerous transfers of trauma patients to trauma centers without adverse effects on patients. A number of small rural hospitals are successfully using telemedicine for patients in their emergency departments in order to enable higher-

[4] AMA, COVID-19 Financial Impact Survey; Fair Health, Healthcare Professionals and the Impact of COVID-19; MGMA, COVID-19 Financial Impact on Medical Practices; AMGA, Surveys of Financial Impact of COVID-19; Primary Care Collaborative, Primary Care & COVID-19: Surveys.

quality care than would otherwise be possible. For example, the University of Mississippi's TelEmergency program has supported rural emergency departments in the state for nearly two decades by drawing on local nurse practitioners and emergency physicians based at the University of Mississippi Medical Center.[5] In addition, a new study of telemedicine emergency services in rural communities has found significant cost savings from this approach.[6]

Below are four examples of patient scenarios in which emergency services would need to be available via telehealth:

- Young male status post lap chole suddenly became hypotensive on the floor. The patient was transferred to the intensive care unit (ICU) where a telehealth provider ordered labs, saw the patient had low hemoglobin, initiated blood transfusions and fluids, asked nurses to place additional IVs, ordered a CAT scan and discussed results of acute bleed with surgeon at home to coordinate a return trip to the operating room emergently to stop the bleeding.

- A middle age female with COVID-19 at a small hospital intubated for respiratory failure and began getting sicker. Larger hospitals were full and unable to accept transfer of patients. The telehealth provider worked with the respiratory therapist to change ventilator settings, add heavier sedation and paralytics, and teach bedside staff how to prone patients with telehealth nurse assistance. After many days of therapy, the patient's condition improved, preventing the need for a transfer.

- An elderly patient with septic shock in a small hospital due to a urinary source. During the evening, their blood pressure continues to go down and a telehealth provider is notified by bedside nurses. On the call, an anesthesiologist is requested to come place a central line and arterial line for treatment with vasopressor, antibiotics, and fluids. The telehealth physician asks a respiratory therapist to place the patient on Bipap to support breathing. After aggressive interventions, the patient's condition improves over 24 hours and the patient is able to leave the ICU.

- An elderly patient is admitted to the ICU for a blood clot in lungs with metastatic cancer history. During the middle of the night, the patient's condition deteriorates and requires more oxygen. A telehealth provider notified by bedside staff to provide orders/treatment. The telehealth provider discusses options with patient and family members and the family decides what lifesaving measures should be taken.

2. Home Visits

Although CMS proposes to permanently add two codes for home visits (99347-99348) to the Medicare Telehealth Services List, it proposes to cover two other, higher-level home visit codes (99349-99350) as Category 3 services. The higher-level home visit codes are viewed as vital services to have available via

[5] *See* Galli R et al. "TelEmergency: A Novel System for Delivering Emergency Care to Rural Hospitals." *Annals of Emergency Medicine* 51(3): 275-284 (March 2008).
[6] *See* Ward M et al. "Averted Transfers in Rural Emergency Departments Using Telemedicine: Rates and Costs Across Six Networks." *Telemed J E Health*. 2020 Aug 24. doi: 10.1089/tmj.2020.0080. (Online ahead of print)

telehealth by home care physicians. It is important to note that when a telehealth visit is scheduled or started, the physician does not know how complex it is and thus does not know what code to use until the visit has been completed. If CMS decides not to cover the most commonly used higher codes of 99349 and 99350 via telehealth, this would mean that, if at the end of a telehealth visit the complexity warrants a 99349, the physician's options are to undercode and bill 99348 to get paid something (undercoding is also considered fraud) or bill a 99349 knowing that they will not be compensated for the visit at all.

The excluded higher-level codes are most commonly used because of the complexity of homebound patients with multi-morbidities and annual mortality rates of 20-25 percent. For example, many patients call their physician about "flu-like symptoms." An audio-video visit is then set up to assess them where the presumption is COVID-19, the goals of care are identified, and the patient and their family usually opt not to go to the hospital. The visit may take an hour and a half with multiple family members present in-person or by video as a plan of care is developed. Often, hospice referrals are initiated, and numerous medications are prescribed (comfort medications) to have on hand. If the physician had not been able to do these visits, the patient or family would have called 911.

The AMA understands that if the originating site restrictions that existed before the PHE are reimposed, the home visit codes will only be available for use in telehealth visits with patients who have a substance use disorder or co-occurring mental health disorder. In the hope that medically necessary telehealth coverage will be able to continue for other patients in their homes besides those with substance use disorders, we provide additional examples of patients for whom home visits via telehealth should continue to be covered permanently.

A recent study (not yet published) reviewed 96 patient profiles over a four-month period. The average age of the pilot study population was 82 years (range: 17 to 98 years), patients had 13 chronic conditions (range: 5 to 32) and were taking a median of 17 medications (range: 8-47). Two profiles of patients treated via telehealth help to illustrate the complexity of managing care for this patient population:

- Patient #1: 81-year-old patient
  20 chronic medical conditions: anemia chronic disease, HFpEF, CKD 3, anxiety, depression, leg swelling, intractable back pain, chronic opioid use, HTN, HL, IBS
  19 medications
  Multiple complaints including leg swelling, weakness, depression, chronic pain, diarrhea, SOB/DOE.
  32 minutes for provider just to do medication reconciliation with the patient, and additional 26 minutes needed to address the multiple other medical conditions, assess respiratory status, leg swelling, mood, mobility, and review goals of care.

- Patient #2: 77-year-old patient
  History of lymphoma, DM, HTN, leg swelling, hypothyroid, sz disorder, constipation, and weakness.
  Lymphoma and declining physically despite aggressive treatment (prior to pandemic)
  Patient and family decided to transition to palliative care and eventually hospice care during the pandemic where access to medical care was dramatically curtailed.
  Telehealth important in management of this complex patient in management of DM (Steroid use caused fluctuation in blood glucose levels), seizures related to underlying lymphoma, leg swelling

related to antihypertensive medication/steroid use, constipation related to opioid use, and overall goals of care/transition to hospice care.

Additional Category 3 Services

The AMA also recommends including CPT codes 99217-99220 (observation care), 99221-99226 (initial hospital care), 99234-99239 (hospital discharge management), 99468-99476 (neonatal and infant critical care), 99477-99480 (intensive care), and 99291-99292 (critical care) in Category 3. These codes can be helpful or even essential for enabling patients to receive high-quality specialty care in isolated rural communities, communities affected by natural disasters, communities affected by local disease outbreaks, and similar situations. Although it is *preferable* to have these services performed by physicians who are physically in the room with the patient, that may not be *possible* if an emergency or disease outbreak occurs in an area, a physician becomes ill, or there is a delay filling a vacant position. In these situations, the only option may be to have a physician of the appropriate specialty who is located in a distant city determine diagnoses and direct patient treatment. It is only possible to access this specialty care if the physician at the distant site can be paid adequately for their time and expertise.

Any other CPT codes in Table 11 that have been used frequently during the COVID-19 PHE should also be included in Category 3 at least through the end of the calendar year in which the COVID-19 PHE ends. The rationale stated for creating Category 3 is that "it would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for these services when furnished by telehealth as soon as the COVID-19 PHE ends without first providing an opportunity to use information developed during the COVID-19 PHE to support requests for permanent changes to the Medicare telehealth services list." We believe this same rationale supports continuation of any CPT codes that have been frequently used, unless there is evidence that use of the codes have been harmful.

Continued Use of the Patient's Location as an Originating Site

The AMA urges CMS to make every effort to obtain permanent statutory authorization for delivery of Medicare telehealth services to patients wherever they are located. Although the expansion of the services on the Medicare Telehealth Services List has been very beneficial, by far the biggest beneficial impacts of Medicare's changes in telehealth policies in 2020 have come from the ability to deliver services to patients wherever they are located. Physicians have identified many situations in which telehealth can offer advantages compared to traditional office visits. For example, a recent paper in *JAMA Neurology* described how observations in clinical settings may provide a less realistic perspective on patient functioning than observation in the home.[7]

The need to deliver telehealth services to patients wherever they are located, including in their own homes, existed before the pandemic and will continue after the pandemic ends. Many patients have health conditions or functional limitations that make travel to a physician's office, hospital, or other location difficult or risky regardless of whether there is a pandemic. The coronavirus is not the only infectious disease for which remote assessment would avoid exposing health care workers and other patients to a symptomatic patient. There are many circumstances other than infectious disease outbreaks, such as

[7] Bloem BR, Dorsey ER, Okun MS. The Coronavirus Disease 2019 Crisis as Catalyst for Telemedicine for Chronic Neurological Disorders. *JAMA Neurol.* 2020;77(8):927–928. doi:10.1001/jamaneurol.2020.1452

natural disasters and weather emergencies, in which it would be undesirable or impossible for patients to travel to an office or other site for care.

Technical Refinement of Telehealth List to Reflect Current Coding

The AMA supports the proposal to automatically adjust the codes on the Telehealth List when replacement codes are developed for existing services.

Inpatient, Nursing Facility, and Critical Care Visits and Consultation

We support the proposal to maintain flexibility regarding the ability to perform required visits via telehealth services. There are many circumstances in which it may be necessary or preferable to use telehealth instead of an in-person visit, e.g., a patient may be more accurately assessed remotely by their own physician than in-person by a non-physician practitioner or a physician who has not been treating the patient. For the same reason, the AMA recommends removing or reducing the limitation on frequency of telehealth visits in hospitals. Physicians should be allowed to use their professional judgment to determine what frequency of telehealth services versus in-person visits will best meet a patient's needs. Moreover, there are many circumstances other than the coronavirus pandemic in which remote visits and consultations may be the only safe or feasible option, such as natural disasters, weather emergencies, and local infectious disease outbreaks. The AMA supports the proposal to reduce the limitation on the frequency of telehealth visits in nursing facilities.

Removal of References to Specific Technology

We support the proposal to remove references to telephones and other technologies from the Telehealth List. The goal of Medicare payment should be to enable patients to receive the care they need, not to specify the specific technology used to deliver that care.

Continuation of Payment for Audio-Only Visits

The AMA strongly urges CMS to continue payment for audio-only services at least through the end of the calendar year in which the COVID-19 PHE ends and preferably at least through 2022. Expanded use of audio-video telehealth services during the pandemic has made it clear that requiring the use of video limits the number of patients who can benefit from telecommunications-supported services, particularly lower-income patients and those in rural and other areas with limited internet access. It would be inappropriate to prevent these patients from accessing such services. In addition, we have heard from many physicians about the need to have access to audio-only services because a number of their patients, even those who own the technology needed for two-way real-time audio-video communication, do not know how to employ it or for other reasons are not comfortable communicating with their physician in this manner.

In addition, physicians need the ability, on an ongoing basis, to provide assistance by telephone to patients who need the types of information or advice that can be appropriately provided by phone without requiring face-to-face contact either by video or in an office. CMS had authorized brief audio-only services prior to the pandemic, but these are a small subset of the situations in which patients could benefit from telephone contacts with the physician, many of which could avoid the need for face-to-face

office visits. The AMA developed telephone-only service codes specifically to define the types of services that can and should be delivered via telephone.

Similar to the AMA's concerns about ending coverage of Category 3 too soon, we also believe it is important to maintain the current coding, coverage and payment rates for audio-only services until after the novel coronavirus is no longer a threat, preferably for another two years, or through the end of the year following the year in which the PHE ends. During this time, the CPT Editorial Panel and the RUC can work to review and develop new telephone/audio-only services.

Coding and Payment for Virtual Services

The AMA supports finding ways to pay for a broader array of virtual services than what is permitted under the narrow definition of telehealth that CMS currently uses. The experience that physicians have had in using virtual services during the PHE will provide important insights as to how this should be done. In order to get the most out of this experience, CMS should consider expanding the purpose of Category 3 to include development of new codes for Communication-Based Technology Services (CBTS) and appropriate payment amounts. The AMA does not support limiting CBTS to "inherently non-face-to-face services." There is a continuum of ways to deliver services to patients, and some patients may need or want a virtual approach to a service that other patients need or want to have delivered in-person. For example, there is evidence that patients with low health literacy benefit from technology-based services that allow them more time to receive and understand information needed to successfully manage their health problems than they would be able to have in a typical face-to-face encounter with a physician or other clinician.[8] Section 1834(m) of the Social Security Act does not prohibit paying for services delivered through communications-based technologies that are similar to face-to-face services.

Clarification of Policies for Telehealth Services

The AMA supports the proposed clarification that incident-to services can be delivered in conjunction with a telehealth visit. The AMA also supports treating telehealth services delivered within the same building as in-person services, such as an attending physician in one room of a hospital using telehealth technology to deliver care to a patient in another room. The AMA also recommends that similar treatment be given to services that are delivered in separate buildings when the physicians need to be in a separate building. Permitting only services "within the same building" to be treated this way will limit access to care for patients when physicians have to be located in separate buildings due to building configuration issues, financial constraints, or other reasons. From the patient's perspective, there is no difference between seeing a physician by video if the physician is on a different floor of the same building or if the physician is in a different building adjacent to the building in which the patient is located.

Direct Supervision by Interactive Telecommunications Technology

The AMA supports continuation of the current policy through the end of the calendar year in which the PHE ends but recommends that this policy be made permanent. The fact that remote supervision is

[8] *See* Bickmore TW, Pfeifer LM, Jack BW. "Taking the Time to Care: Empowering Low Health Literacy Hospital Patients with Virtual Nurse Agents." *CHI '09: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems,* April 2009

inappropriate in some cases does not justify refusing to pay for it under any circumstance. In many rural and underserved areas patients may be unable to access important services if the only physician available has to supervise or deliver services at multiple locations and may not be available to supervise services when all patients need them. Failure to allow remote supervision can mean that a patient would be unable to receive the service at all, rather than forcing in-person supervision to occur. Both patients and CMS rely on physicians' professional judgment to determine the most appropriate services to deliver, and the same principle should apply to how supervision is provided.

E. Care Management Services and Remote Physiologic Monitoring

- **Recommendation:** The AMA applauds the significant steps forward to advance digital medicine in the Medicare program. The AMA is concerned that CMS has fundamentally misinterpreted the structure of the RPM codes, as intended within the CPT code set, particularly with regards to CPT codes 99457 and 99458, and does not agree these codes only describe treatment management services. The AMA agrees with CMS' clarification that practitioners may furnish RPM services to remotely collect and analyze physiologic data from patients with acute conditions as well as patients with chronic conditions. The AMA recommends extending flexibilities relating to RPM codes until after the novel coronavirus is no longer a threat, preferably for another two years, or through the end of the year following the year in which the PHE ends.

The AMA applauds the significant steps forward to advance digital medicine in the Medicare program. There remains a compelling need to modernize the Medicare program to enable practice transformations to ensure that Medicare is able to meet the needs of beneficiaries while improving patient health outcomes, increasing cost effectiveness, improving population health, enhancing care team experience, and promoting equity. The rapid advances in technology should be leveraged and deployed to achieve these essential goals. The AMA has detailed in the past four years the substantial commitment the organization has made to support practice transformations to address these challenges. The AMA's Digital Medicine Payment Advisory Group (DMPAG) continues to provide clinical expertise at the intersection of technology and medicine to identify additional technology-enabled services and provided helpful feedback incorporated below.

The AMA is pleased to see CMS propose payment for 9925X for automated point-of-care retinal imaging. Digital health technologies, including augmented intelligence (AI)-based systems, hold much promise to help advance the quadruple aim of enhancing the patient experience of care and outcomes, improving population health, reducing overall costs for the health care system while increasing value, and supporting the professional satisfaction of physicians and the health care team. However, in order to ensure continued investment and innovation in these important technologies, it is critical that high-quality, clinically validated, FDA-cleared or approved systems are adequately reimbursed. A lack of adequate reimbursement for these emerging technologies is one of the key factors that could limit clinical integration of high-quality AI-based systems. As such, the AMA encourages CMS to adopt the RUC recommendations for 9925X.

Remote Physiologic Monitoring and Management (RPM)

The AMA strongly supports CMS' continued use and payment of CPT codes 99453, 99454, 99457, and 99458 which were developed to describe the professional and technical components of remote

physiologic monitoring. CMS support of these service has had a tremendous impact on expanding access for patients in need of remote monitoring services.

The RPM codes were developed through concerted and thoughtful deliberations with input from nationally recognized clinical experts in digital medicine services as well as coding, valuation, and coverage. The DMPAG requested creation of these new codes by submitting an application to the CPT Editorial Panel. The Panel, with input of the national medical specialties, worked through the thoughtful CPT process and ultimately approved these new codes. The DMPAG aggregated and conducted in-depth interviews with national flagship health systems and providers deploying these services and evaluated significant supporting meta-analysis of clinical trials establishing clinical benefit. An existing body of evidence exists, which was relied upon in making such recommendations, demonstrating that these services will increase value and improve patient health outcomes, particularly for patients with multiple co-morbidities, chronic conditions, those facing access barriers due to geography, limited mobility, and those who are medically fragile.

1. *Remote Physiologic Monitoring Treatment Management Services*

The AMA appreciates CMS' responsiveness to the stakeholder community in providing guidance on the use of RPM services. However, the AMA is concerned that CMS has fundamentally misinterpreted the structure of the RPM codes, as intended within the CPT code set, particularly with regards to CPT codes 99457 and 99458. Much of the guidance and interpretation provided in the proposed rule is inconsistent with stakeholders' understanding and the CPT Editorial Panel's intent for proper use of the codes. If implemented without correction, these misinterpretations will have a disruptive effect on the operations of physician practices that are providing these essential services and the patients who depend on this care.

In this proposed rule, CMS lays out a process of RPM that is not aligned with the intended use of the RPM codes as described by CPT coding guidelines. CMS outlines a potential patient scenario that describes CMS' proposed intended use of the current array of RPM CPT codes. First, the RPM service is initiated, and the patient is provided with a device and instructed on how to use it (99453 and 99454). Second, the physician or other qualified health care professional (QHP) spends 30 minutes of intra-service time reviewing, analyzing, and interpreting the data collected over a 30-day period (99091). Last, the clinician develops a treatment plan informed by the data and spends at least 20 minutes in communication with the patient (99457 and 99458). The proposed rule makes it clear that CMS interprets the entire service of 99457 and 99458 as treatment management.

The AMA does not agree with CMS' interpretation that codes 99457 and 99458 only describe treatment management services. In addition to developing and managing the treatment plan, CPT codes 99457 and 99458 are intended to describe the physician or other QHP work of reviewing, analyzing and interpreting the data collected by an RPM device. Additionally, CMS indicates that the 20 minutes of time described by 99457 must be spent in "…direct, real-time interactive communication with the patient." However, interactive communication with the patient is only one element of the service. Codes 99457 and 99458 are meant to capture the amount of time a physician spends in the 30 day period performing all of the activities needed for remote physiologic monitoring inclusive of at least one "interactive communication," but not exclusively "interactive communication." CMS goes on to provide clarification that "interactive communication" for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of

data transmission." The CPT code set defines real time synchronous communication in Appendix P as electronic communication using interactive telecommunications equipment that includes, at a minimum, audio and video. This language was purposely not included in the guidelines or descriptor for CPT code 99457 because real time synchronous communication is simply not practical as a minimum requirement to report these services. CMS interpretation of interactive communication is a challenge for many of the patients that depend on remote physiologic monitoring services. For example, many patients, especially seniors, may not have a cellphone and can only receive landline calls when they are awake and at home. If they do have a cellphone, it may not be a smartphone with video capabilities. Moreover, if they have a computer, it may not have camera and/or speakers needed for synchronous communication such as video conferencing. Many seniors also lack access to high speed broadband internet. In addition, it is not clinically necessary, and is impractical to communicate with every patient for 20 minutes. A significant value of RPM is that patients can receive ongoing care with minimal interruption. Patients with stable conditions will require less direct communication time.

In summary, the time in the descriptor for codes 99457 and 99458 is for all elements of the work related to remote physiologic monitoring (e.g., review, analysis, interpretation, development of treatment plan and treatment management including patient communication) and is not meant to be limited to only synchronous time spent communicating with the patient regarding their treatment plan.

In addition, CMS misinterprets the relationship between CPT codes 99091 and 99457:

- 99091 *Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days*;
- 99457 *Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes*.

CMS seems to indicate that 99091 is followed by 99457, or that these CPT codes could possibly be used together, however the CPT code set is clear in the parentheticals associated with both codes that it is not appropriate to report CPT codes 99091 and 99457 together. In addition, there is a parenthetical following 99091 stating "(Do not report 99091 if it occurs within 30 days of 99339, 99340, 99374, 99375, 99377, 99378, 99379, 99380, **99457**)" (emphasis added). This clear guidance is included because the two codes include substantial work overlap. CPT code set guidelines regarding 99091 state that "[c]ode 99091 should be reported no more than once in a 30-day period to include the physician or other qualified health care professional time involved with data accession, review and interpretation, modification of care plan as necessary (including communication to patient and/or caregiver), and associated documentation." It is clear from this statement that both codes include review and interpretation, work related to the treatment/care plan and communication with the patient.

The AMA encourages CMS to consider these points of misunderstanding before finalizing the proposed guidance on RPM codes. Specifically, the AMA calls on CMS to remove restrictions stating that interactive communication must be real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission. Further, we ask that CMS clarify that although patient communication is required to report 99457, it is only one element of the code and

thereby does not have to total 20 minutes. Rather, interactive communication should be for the amount of time that is clinically necessary and appropriate. Finally, we urge the agency to align with CPT code set guidelines that state CPT codes 99457 and 99091 should not be used in conjunction with one another.

2. RPM Services not Limited to Patients with Chronic Conditions

The AMA agrees with CMS' clarification that practitioners may furnish RPM services to remotely collect and analyze physiologic data from patients with acute conditions as well as patients with chronic conditions.

3. Flexibility during the Public Health Emergency (PHE)

The AMA thanks CMS for the significant efforts it has made to address the COVID-19 pandemic, including flexibility for reporting RPM services. We agree that these flexibilities should remain in place at least until the PHE ends and revert back to the requirements established in the CPT codes that CMS previously adopted at the close of the PHE. However, consistent with our recommendations on flexibilities provided for telehealth services, we recommend extending flexibilities relating to RPM codes until after the novel coronavirus is no longer a threat, **preferably for another two years, or through the end of the year following the year in which the PHE ends.** This will ensure patients have appropriate access to care as care plans transition after the PHE and physicians have appropriate time to adjust their practices.

4. Monitoring Periods

The AMA is supportive of efforts to ensure that physicians can use codes as appropriate and necessary to reflect practice and patient needs. The AMA supports the use of CPT to describe all physician services and the CPT Editorial Panel remains open to receiving any applications from stakeholders to implement changes in coding to describe monitoring periods for RPM treatment and management services.

F. Revisions for Payment for Outpatient E/M Visits and Promoting Stability during COVID-19 Public Health Emergency

- **Recommendation:** The AMA strongly urges CMS and HHS to utilize their authority under the COVID-19 PHE to mitigate the financial distress sure to result from the proposed implementation of the new Medicare office visit payment policy. We reiterate and amplify the recommendation of the RUC for CMS to apply the office visit increases uniformly across all services and specialties and to apply the office visit increases to the office visits included in surgical global payment, as it has done historically. The AMA and the RUC raise significant concerns and oppose the integration of the code GPC1X, as it is a confusing descriptor and results in unexplained, significant increases in the utilization assumptions.

Evaluation and Management–Office Visits

The AMA supports and amplifies the comments of the AMA RUC on the E/M visits. The RUC commends the CMS decision to align the E/M office visit coding changes with the framework developed by the CPT Editorial Panel and to implement the significant increases to the payment for office visits,

based on the RUC recommendations on the resources required to perform these services. This was the result of significant collaboration by an AMA-convened workgroup that brought together more than 170 state medical and specialty societies. CMS' new office visit policy will lead to significant administrative burden reduction and better describe and recognize the resources involved in office visits as they are performed today. Unfortunately, these office visit payment increases are required by statute to be offset by payment reductions to other services, through an unsustainable reduction of nearly 11 percent to the Medicare conversion factor, of which 3 percent would be directly related to the creation of GPC1X.

We appreciate the actions that CMS is taking to provide flexibility to physicians and health care professionals to meet the needs of patients during the COVID-19 pandemic. As a result of confronting the novel coronavirus in hard-hit communities and mitigating its spread throughout the country, many practices face a myriad of economic hardships. We are concerned that the financial instability created by this public health crisis will be exacerbated by budget neutrality adjustments required when CMS implements a widely supported Medicare office visit payment policy finalized for 2021. **Therefore, we strongly urge CMS/HHS to utilize its authority under the public health emergency declaration to preserve patient access to care and mitigate financial distress due to the pandemic by implementing the office visit increases as planned while waiving budget neutrality requirements for the new Medicare office visit payment policy.**

Total Time Definition for Evaluation and Management Office Visit Codes

Beginning in 2021, physicians may select the level of office visit (99201-99215) based on either medical decision making or total physician time on the date of encounter. In the CY 2020 PFS Final Rule, CMS finalized adoption of the RUC recommended survey median total times utilized in the valuation of office visits. However, CMS stated that they would continue to review the proposed times. When CMS establishes pre-, intra-, and post-service times for a service, these times always sum to the total time. In the Notice of Proposed Rulemaking (NPRM) for 2021, CMS stated it would be illogical for component times not to sum to the total time. CMS notes that commenters on the NPRM for CY 2020 stated that CMS should adopt the survey total median time as recommended by the RUC. However, CMS indicated that it did not believe commenters sufficiently addressed why the sum of minutes in the components would differ from the total minutes and differ from CMS' view and systems requirement that total time must equal the mathematical total of component times. Beginning for CY 2021, CMS is changing their

CPT Code	***Pre-Time***	***Intra-Time***	***Post-Time***	***RUC Recommended Total Time (survey median total)***	***CMS Proposed Total Time (sum of components)***
99202	2	15	3	22	20
99203	5	25	5	40	35
99204	10	40	10	60	60
99205	14	59	15	85	88
99211	0	5	2	7	7
99212	2	11	3	18	16
99213	5	20	5	30	30
99214	7	30	10	49	47
99215	10	45	15	70	70

initial proposal on total time and are proposing to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.

The RUC recommends that CMS accept the median survey times instead of the component time totals. The RUC did attempt to explain to CMS that the median survey total time for the office visits should be utilized to retain relativity. The RUC understands that the total time is usually a sum of the pre-, intra- and immediate post-service time. However, the way physician time was captured for the recent office visits was different than the typical survey. For purposes of the office visit survey, the pre-service time was described as three calendar days prior to the office visit, the intra-service time was described as the calendar day of the office visit and the post-service time was described as within seven days following the office visit. Each respondent reported three different times for each office visit code. The respondents were asked to indicate zero for the three day before/seven days following the encounter, if not typical. These three times were summed, and a total time determined for each respondent. The median total time will not necessarily equal the sum of the median times for each of the three-time periods. For example, one physician might spend 5 minutes preparing to see a patient on the day prior to a visit based on their own workflow pattern, while another physician may perform all the pre-service work on the morning of the office visit. Therefore, both physicians would have responded differently on the survey for the times spent three days prior and on the date of service, but the total time would remain the same. For the office visits, the work is the same level of intensity regardless of whether performed on the date of encounter or other dates surrounding the office visit.

Using the median total time effects five codes (99202, 99203, 99205, 99212 and 99214). The median total time from the survey is within 10 percent of the sum of the survey medians of the individual time components. Since the method of capturing the time data was different, the total time displayed should be different, not the sum of the components of pre-, intra- and immediate post service time.

The inconsistency here results from applying the corrective median function three times to granular data components, rather than once to their sum. The total time from individual surveys as adjusted by the median function is mathematically correct. The difference between this result and the sum of the medians is due differing variability in the components, and not an inaccuracy that requires remedy.

Total time is the appropriate measurement of time and each individual survey respondent's total time response should be used in determining the median total time. CMS will not be appropriately capturing the physician time for the office visits, which were based on a robust survey, if they use the sum of the component times instead of the RUC recommended median total time.

Revaluing Services that are Analogous to Office/Outpatient E/M Visits

The AMA applauds CMS for maintaining the relativity of the RBRVS by applying the office visit increases to the maternity care services. However, we noticed that CMS is also proposing to apply the office visit increases to other sets of services where office visits may not be specifically bundled. CMS employs a variety of reasons and methodologies to apply the office visit increases to specific services. CMS proposes to apply increases to services simply because an office visit was referenced as supporting rationale, but not a direct crosswalk in developing a work RVU. In addition, there are prospective adjustments using a variety of methodologies such as applying general percentage increases. These

methodologies are not resource-based and do not accurately account for the physician or qualified health care professional's work, time and intensity required to perform these services. The most egregious methodology is a blanket increase percentage based on a broad-based estimate of the overall change in the work associated with assessment and management with the overall increase in the work of the office visits. Applying increases via these various methodologies is causing anomalies in relativity among services. For example, the increases to some of the psychotherapy services will now skew the relativity not only to the psychotherapy services provided along with an E/M service but to other services within the psychiatry section.

CMS states "the post-operative visits in the 010 or 090-day global surgical code periods are often valued with reference to RVUs for separately-billed E/M visits, but the bundled post-operative visit RVUs do not directly contribute a certain number of RVUs to the valuation of the procedures." This statement is both false and misleading. Survey respondents directly provide the number and level of post-operative visits included in a service while concurrently providing their work RVU estimates for the surgical global period for the 010 and 090-day services under review. This is validated by using magnitude estimation to other 010 and 090-day global services, augmented in part by comparing services with the RUC/CMS IWPUT metric (which directly includes the post-operative visit work RVUs in its formula). When survey respondents provide their input on the physician work required to perform a service, the post-operative visits are part of that RVU valuation recommendation. Although the specific RVUs of each post-operative visit are not added to the total work RVU of a service via a systematic formula, CMS should not imply that the post-operative visits are not included in the valuation. Additionally, the number and level of office visits in a global period does directly increase the practice expense RVUs for the valuation of the procedures.

CMS also questions the number and level of post-operative visits and implies that the physician work for office visits are not the same when performed in a surgical global period. The data from the survey of office visits demonstrate that the physician work is the same regardless whether the office visits are performed stand alone or as part of a surgical global period. Specifically, the survey results for 99213 and 99214, illustrate that the values and times provided by surgical physicians are similar, if not the same as primary care and other medicine physicians.

CPT	Source	Response	Work RVU	Total Time	Pre 3 Days	Intra-time Same Day	Post 7 Days
99213	**RUC REC**	**1650**	**1.30**	**30**	**5**	**20**	**5**
99213	PCP	694	1.20	30	5	20	5
99213	Surgery	468	1.39	30	5	20	5
99213	Medicine	488	1.35	32	5	20	5
99214	**RUC REC**	**1691**	**1.92**	**49**	**7**	**30**	**10**
99214	PCP	703	1.92	49	7	30	10
99214	Surgery	469	2.00	47	7	30	10
99214	Medicine	519	2.00	50	8	30	10

The AMA recommends that CMS apply the office visit increases uniformly across all services and specialties. CMS should not hold specific specialties to a different standard. The AMA urges CMS to apply the office visit increases to the office visits included in surgical global payment, as it has done historically.

The AMA and the RUC have submitted substantial comments to CMS in the past regarding why it is appropriate to apply the increased valuation of the office visits to the visits incorporated in the surgical global packages. CMS has historically applied increases to office visits to the surgical global periods (1997, 2007 and 2011). CMS has not adequately addressed these comments previously.

Comment Solicitation on the Definition of HCPCS Code GPC1X

CMS is soliciting from the public comments providing additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how CMS might address those concerns and how CMS might refine the utilization assumptions for the code. The RUC attempted to review GPCIX in January 2020 and submitted the results of its discussion in February 2020. The RUC's recommendations are included below. We do add two additional concerns regarding GPCIX, 1) confusion regarding the correct descriptor and 2) unexplained increases in the utilization assumptions.

1. *Descriptors*

The code descriptor for GPC1X is different throughout different sections of the NPRM. It is difficult to respond to a call for comment when the descriptor is unclear. The RUC questions if CMS will receive appropriate feedback because of the multiple descriptors evident in the Proposed Rule. The two descriptors listed are:

- *NPRM for 2021Table 8: CY 2021 Proposed Additions to the Medicare Telehealth Services List on a Category 1 Basis*

  GPC1X Visit complexity inherent to evaluation and management associated with **primary** medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)

- *Final Rule for 2020, Text of NPRM for 2021 page 50138, Table 24 of NPRM for 2021*

  GPC1X Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services **and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition.** (Add-on code, list separately in addition to office/ outpatient evaluation and management visit, new or established)

2. *Utilization Assumptions*

In the Proposed Rule for 2020, CMS originally assumed that GPC1X would be reported with over 50 percent of all office visit claims, resulting in $2.6 billion increase in Medicare allowed charges and a 3 percent decrease to the 2021 Medicare conversion factor. The RUC responded it was concerned about the significant impact that this would have on all physicians and other health care professionals. The RUC requested CMS re-examine the utilization assumptions. CMS received comments that their 50 percent assumption overstated utilization.

In CMS' most recent utilization projections for add-on code GPC1X, CMS assumes the code would be applied to 75 percent of all office visit claims, costing the Medicare program $3.3 billion annually. This add-on code alone will account for a 3.5 percent reduction in the conversion factor. CMS does not explain why the utilization assumptions were increased from 50 percent to 75 percent. Instead, the 186,549,518-utilization assumption for GPC1X is found within utilization projection tables on the CMS website. CMS states that stakeholders have not submitted specific comments or alternative recommendations on the utilization of this "service", however, CMS' assumptions are not explained and the service itself is not clearly described.

The RUC notes that the utilization for GPC1X of 187 million claims is completely unrealistic if the intent is to append the code to office visits related to ongoing care. One metric of ongoing care are the Transitional Care Management codes (99495 & 99496) and Chronic Care Management codes (99387, 99489 and 99490), where the combined 2019e Medicare utilization totals just over 6 million for these services. This is a mere fraction of the claims CMS has projected and is utilizing to compute unsustainable budget neutrality impacts. Although the RUC cannot recommend specific utilization assumptions for a service that is not adequately described. When compared to similar services, CMS is significantly overestimating the utilization of GPC1X. **If CMS persists in implementation of GPC1X, the AMA joins the RUC in imploring CMS to re-examine and lower its 2021 utilization assumption.**

Time reporting for Prolonged Service code (99417)

As part of the 2021 office visit revisions to the CPT code descriptors and associated guidelines, the AMA CPT Editorial Panel also approved a new prolonged services code of 15 minutes duration. CMS finalized these changes and accepted the RUC recommended values in the 2020 MPFS Final Rule in November 2019. The AMA immediately embarked upon an educational program for changes effective January 1, 2021 because of the magnitude of these services. In the NPRM for the 2021 MPFS CMS raises two issues related to the prolonged services code, 99417. The first is a coding concern regarding the clarity of language. The second is a valuation concern regarding duplication of time.

Prior to the approved changes (and current in 2020) these E/M codes state a typical time. We appreciated the wide stakeholder input with respect to the presentation and guidelines for time-based coding. CMS was a participant and suggested that time ranges, rather than a single time, would add clarity. For example, when coding by time, 99215 would be reported for total times on the date of the encounter of 40-54 minutes duration. At 55 minutes there is direction to see Prolonged Services 99417. This is clearly stated in tables embedded directly in the guidelines.

During the educational process it became clear that the new concept of time ranges, and especially their effect on the concept of prolonged service time, created cognitive dissonance for those more familiar with the concept of a typical single time, with a minimum time beyond that to report a prolonged services code. Accordingly, in May 2020 the CPT Editorial Panel approved a clarification to convey the original intent that time related to prolonged services began at the starting point of the code range. The AMA is currently producing additional educational materials that reflect this change. As this was an editorial clarification only, it did not require RUC action.

The RUC recommended values for 99205, 99215 and 99417 with an understanding of the guidelines. The tables on proper use of 99417 were in the survey for that service. The medians and RUC recommended times to CMS for the purposes of valuation (and not coding) were 59 and 45 minutes respectively for 99205 and 99215. In other words, 99205 was slightly outside the descriptor range and 99215 was within the range at the lower end. This is not surprising and the typical intra-service CMS times and CPT descriptor typical face-to-face times do not match for 99205 and 99215. CMS proposes to adopt the starting point for the counting of an additional 15 minutes to begin at the upper bound of the descriptor range. Therefore with 99205 it would be reported at 89 minutes, a full 30 minutes beyond the survey time. The time for 99215 would be 24 minutes beyond the survey time. Additional units of 99417 would be reported at 15 minutes, the survey time of this service. This would create an anomaly when more than one unit of 99417 was reported.

Current prolonged services coding requires two codes to address this issue of initial and subsequent units. The goal of CPT Panel and the hundreds of stakeholders involved in the writing process was to remove the current situation where 29 minutes of prolonged service is not recognized at all, but 30 minutes is recognized the same as 60 minutes. The CMS proposal results in 29 minutes not being recognized, but 30 minutes being recognized. However, in this instance the 30 minutes is recognized as the same value as 15 minutes. The potential impact negatively affects physicians who are rendering services for new Medicare patients. We do not believe there is double counting in the case of the use of 99215 and 99417, even if the survey median total time on the date of the encounter was 45 minutes.

The AMA urges CMS to implement all the CPT revisions to the office or other outpatient services as accepted by the CPT Panel. Finalizing the proposal to reject the listed time range for the new prolonged services code will not only cause confusion because of the extensive, ongoing AMA education on this matter, but also render this vital element of the revisions ineffective. The net effect of this decision will undoubtedly increase administrative burden. If the agency believes that additional clarification is needed, the CPT Panel stands ready to review additional editorial revisions as suggested by CMS or other stakeholders.

Split/Shared E/M Office Visits–Reporting Time

There have been numerous stakeholder questions to the AMA regarding the proper reporting of split/shared visits in the office or other outpatient setting for 2021. Specifically, the questions have centered around whether a qualified health care professional's time can be counted along with the physician's time. The E/M office visit guidelines in the CPT code set clearly lay out the intended time accumulation rules for split/shared visits:

> A shared or split visit is defined as a visit in which a physician and other qualified health care professional(s) jointly provide the face-to-face and non-face-to-face work related to the visit. When time is being used to select the appropriate level of services for which time-based reporting of shared or split visits is allowed, the time personally spent by the physician and other qualified health care professional(s) assessing and managing the patient on the date of the encounter is summed to define total time. Only distinct time should be summed for shared or split visits (i.e., when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).

Furthermore, for this discussion, it is important to note the CPT definition of physician or other qualified health care professional:

> A "physician or other qualified health care professional" is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.

These professionals are distinct from "clinical staff." A clinical staff member is a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service, but who does not individually report that professional service.

Therefore, if during an E/M office visit a clinician is performing services under the definition of a qualified health care professional, that time should clearly be counted towards the total time accumulation, as long as the time is distinct.

G. Scope of Practice and Related Issues

- **Recommendation**: The AMA supports permanently allowing the supervision of residents in teaching settings through audio/video real-time communications technology. The AMA supports allowing for the virtual presence of teaching physicians during Medicare telehealth services and believes this change should be made permanent. The AMA supports permanently allowing residents to moonlight in the inpatient setting. The AMA supports permanently expanding the services that may be offered under the primary care exception. The AMA strongly opposes allowing for the supervision of diagnostic tests by non-physician practitioners. The AMA supports the proposed changes to the medical record documentation requirements as long as this provision falls in line with existing scope of practice laws and only reduces the burden of redocumentation.

Teaching Physician and Resident Moonlighting Policies

In the March 31st COVID-19 IFC, CMS amended its policy to state that, during the COVID-19 public health emergency, services of residents that are not related to their approved GME programs and are separately billable for payment under the Physician Fee Schedule will be compensated. Such changes are limited to internal moonlighting services recognized as voluntary, compensated, medically related work performed within the site where the resident or fellow is in training or at any related participating sites.

The resident must be fully licensed, and the services provided need to be separately identified from those services that are required as part of the approved GME program.

The AMA believes that residents should be afforded the opportunity to participate in either internal or external moonlighting while in good standing with their individual programs as long as such activities comply with ACGME standards.[9] ACGME standards include an 80-hour per week duty hour maximum, not allowing first-year residents to moonlight, and ensuring that moonlighting does not interfere with the ability of the resident to achieve the goals and objectives of the educational program or with the resident's fitness for work. Most importantly, moonlighting must not compromise patient safety. These restrictions on moonlighting ensure the protection of residents and patients. As long as internal moonlighting opportunities comply with ACGME standards, adoption of the new moonlighting flexibilities proposed by CMS will maintain the integrity of graduate medical education programs as well as the health and safety of the patients whom the residents serve.

During COVID-19, the ability to have residents work additional hours internally has been beneficial to the entire health care community and the patients that desperately need the residents' services. Therefore, as long as internal moonlighting standards comply with ACGME policy, the AMA supports permanently allowing internal moonlighting.

1. *Supervision of Residents in Teaching Setting through the Audio/Video Real-Time Communications Technology*

The AMA applauds the decision to allow teaching physicians to use audio/video real-time communications technology to supervise residents during the pandemic and we support the proposal to make these changes permanent. In both of the COVID-19 interim final rules with comment periods (IFCs), CMS allowed teaching physicians to supervise residents, either in-person or virtually through audio/video real-time communications technology, during the key portion of services including psychiatric services. This change in supervision is consistent with the current primary care exception, which allows teaching physicians to direct the care furnished by residents, and review the services physically provided by residents during or immediately after the visit, remotely utilizing audio/video real-time communications technology. CMS also allowed physician fee schedule payments to be made for interpretation of diagnostic radiology and other diagnostic tests if the interpretation was performed by a resident when the teaching physician was present through audio/video real-time communications technology. The AMA believes that these expansions of supervision have been successful during the COVID-19 public health emergency and sees the benefit of maintaining the ability for all teaching physicians to supervise residents via audio/video real-time communications technology permanently.

The AMA believes that if these supervision expansions are implemented in accordance with Accreditation Council for Graduate Medical Education (ACGME) policy and take into account the program, specialty, patient complexity, and competency of the resident, then this expansion will enable residents to provide additional services while still garnering the support needed from their teaching physicians.[10] Since a teaching physician will still be required to review the resident physician's interpretations and services, and ACGME has strict limit exist concerning the direct supervision by

[9] https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRResidency2020.pdf.
[10] https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRResidency2020.pdf.

interactive telecommunications technology that exclude high-risk, surgical, interventional, and other complex procedures including endoscopies and anesthesia, the AMA believes that the appropriate level of patient care and teaching physician direction will be maintained. Moreover, adding another mechanism with which to supervise residents will increase the ability to properly provide residents with timely feedback while taking into account patient, resident, and teaching physician safety by decreasing the risk of unnecessary exposure during COVID-19 and future public health emergencies.

Decisions regarding how residents will be supervised via audio/visual real-time communication technology should be implemented, reviewed, and overseen at the program level, in accordance with ACGME policy.[11] The decisions surrounding appropriate supervision and the type of technology utilized, must be appropriate for the clinical setting and the needs of the individual patient, as well as the health and safety of the residents, fellows, and teaching physicians involved. As such, the AMA acknowledges that in some situations it will be appropriate for a resident/fellow to conduct a patient encounter remotely and then discuss the case with the supervising teaching physician utilizing audio/visual communications. In other situations, the resident/fellow and supervising teaching physician should both physically participate in the patient encounter as determined by the individual program and ACGME.

This addition of audio/visual supervision does not change the responsibility of the institutions' GME Committees which must still monitor programs' supervision of residents and ensure that supervision is consistent with the provision of safe and effective patient care, the educational needs of residents, the progressive responsibility appropriate to residents' level of education, competence, and experience, and any other applicable common and specialty/subspecialty specific program requirements.

ACGME recently amended its rules to allow for audio/visual supervision of residents that are providing patient services. The AMA believes that CMS should adhere to ACGME guidelines. The AMA, in accordance with ACGME guidance, acknowledges and supports individually tailoring the supervision of each resident according to their level of competency, training, and specialty. It is important to ensure that first-year residents are directly supervised in-person and that training programs lay out audio/visual supervision requirements in advance to promote consistent understanding between the resident and the teaching physician. Each program must define when the physical presence of a supervising physician is required and each resident must know the limits of their scope of authority, and the circumstances under which they are permitted to act with conditional independence.

The AMA believes that if ACGME rules are adhered to, and the use of audio/visual real time communication equipment is individualized to support the needs of residents, teaching physicians, and their patients that this tool will be effective and will provide appropriate supervision, frequent evaluation, and open discussion. The AMA supports permanently allowing teaching physicians to supervise residents via audio/visual real time communication equipment per ACGME guidelines.

2. Virtual Teaching Physician Presence during Medicare Telehealth Services

The AMA supports allowing for the virtual presence of teaching physicians during Medicare telehealth services and believes this change should be made permanent. The AMA believes that teaching physicians

[11] https://www.acgme.org/Newsroom/Blog/Details/ArticleID/10125/ACGME-Response-to-COVID-19-Clarification-regarding-Telemedicine-and-ACGME-Surveys.

should be compensated for services performed by residents, if the resident is under the physician's personal observation, direction, and supervision to include Medicare telehealth services. With the ever-increasing use of telecommunications technology, the AMA applauds CMS' proposal to allow Medicare to make payments for teaching physician services when a resident preforms Medicare-covered telehealth services for beneficiaries while a teaching physician is present via real-time audio-visual communications technology.

Throughout COVID-19, the necessity for improved access to telehealth services has been highlighted and heightened. In an effort to provide timely access to care, adoption of this policy will promote continued innovations to advance telehealth services and improve patient care. As the medical community continues to evaluate best practices to improve provider accessibility, especially in rural and underserved areas, these modifications to CMS policy will expand patient access and improve teaching capabilities. Allowing for virtual teaching physician presence permanently, especially throughout the duration of the current public health emergency, will help to decrease the risk of unnecessary infectious disease exposure for both the patient and physician. This will improve morbidity and mortality rates among high-risk populations during COVID-19 and any other future public health crises.

Expanding the virtual teaching presence will improve the ability of attending physicians to efficiently monitor resident physicians and quickly respond to any questions or concerns. As noted above, ACGME recognizes and endorses the expansion of telemedicine and the use of audio/visual communications devices by residents and their teaching physicians. As long as the virtual presence of teaching physicians during Medicare telehealth services continues to adhere to ACGME standards, the AMA believes that an optimal learning environment, with appropriate education and supervision will be maintained.

Since this provision has been successful during COVID-19, and will provide additional access to teaching physicians, additional training for residents, and more options for patients, the AMA supports permanently allowing for the virtual presence of teaching physicians during Medicare telehealth services.

3. Primary Care Exception Policies

Under the "primary care exception," Medicare designates physician fee schedule payments to teaching hospital primary care centers for certain services of lower- and mid-level complexity furnished by residents without the physical presence of teaching physicians. In the March 31st COVID-19 IFC, CMS temporarily allowed all levels of office or outpatient E/M visits furnished by residents to be billed by the teaching physician under the primary care exception. In the May 1st COVID-19 IFC, CMS further expanded the list of services included in the primary care exception during the COVID-19 public health emergency. CMS also allowed physician fee schedule payments to be made to teaching physicians for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services.

The AMA supports this expansion of primary care exception services and believes that this expansion should be made permanent. Since residents will still need to demonstrate competency in the services offered before they can utilize the primary care exception, the AMA believes that the quality of services for patients will not decrease. Moreover, by allowing residents to perform more services without the presence of the teaching physician, but still within the confines of a learning environment, the education

of residents will be preserved, and likely enhanced. This expansion will increase the number of physicians who can concurrently offer services to patients in need.

The AMA believes that ACGME has put in place the necessary guidelines and restraints to ensure that residents are properly trained and supervised to safeguard the maintenance of quality of care. Since the primary care exception has been utilized to the benefit of the patient, resident, and teaching physician for many years, and the expanded set of services have been performed competently during the public health emergency, the AMA believes that the expanded list of services should be maintained permanently.

Supervision of Diagnostic Tests by Certain Non-Physician Practitioners

The AMA strongly opposes the supervision of diagnostic tests by non-physician practitioners. The AMA strongly opposes removing the requirement that physicians supervise all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests.[12] Presently, CMS acknowledges three levels of supervision: general, direct, and personal. Each level of supervision has a corresponding indicator value assigned for each diagnostic procedure.[13] General supervision requires the procedure to be furnished under the physician's overall direction and control. Direct supervision varies depending on location and the service being provided but, generally requires that a physician is present in the location the service is being performed and is available for immediate assistance and direction. Finally, personal supervision entails the physician being in the room during the procedure. These supervision requirements apply to the technical component of a diagnostic test and coincide with the provision that a physician must provide the professional component of a diagnostic service.[14]

The broad language in the proposed rule is problematic as non-physician practitioners are often not permitted to perform some of the diagnostic procedures covered under the proposed rule. The scope of practice for non-physicians is regulated usually by the states, so the inclusion of certain services in the federal proposed rule presents new challenges. For example, some states stop short of allowing non-physician practitioners to order select diagnostic procedures. As such, non-physician practitioners should not be allowed to supervise these diagnostic procedures. Prior to the COVID-19 public health emergency, physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical psychologists, and clinical social workers who were treating a beneficiary for a specific medical problem could order diagnostic tests when they used the results of the tests in the management of the beneficiary's specific medical problem. However, only "a doctor of medicine or osteopathy legally authorized to practice medicine in his or her state of practice,"[15] could act as a supervisory physician for diagnostic services. However, CMS is proposing a change that runs counter to current policy which states that, "physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives may not function as supervisory physicians for the purposes of diagnostic tests."[16]

In the May 1st COVID-19 IFC, CMS permitted physician assistants, nurse practitioners, and certain other non-physician practitioners to supervise diagnostic tests due to the extreme circumstances of the COVID-

[12] https://www.law.cornell.edu/cfr/text/42/410.32.
[13] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11043.pdf.
[14] https://www.law.cornell.edu/cfr/text/42/410.32.
[15] https://www.ssa.gov/OP_Home/ssact/title18/1861.htm.
[16] Federal Register, Nov. 20, 2009 pg 275; https://www.govinfo.gov/content/pkg/FR-2009-11-20/pdf/E9-26499.pdf.

19 PHE. CMS is now proposing to allow physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives to supervise diagnostic tests on a permanent basis, while still adhering to state laws and scope of practice limitations. Moreover, CMS is proposing to expand the scope of practice of physician assistants, which currently does not include performing diagnostic tests, by allowing individual tests to be performed by physician assistants without supervision and removing the parenthetical that requires a general level of physician supervision for diagnostic tests performed by physician assistants.

The AMA is adamantly opposed to these proposed changes and believes that diagnostic testing should only be performed by those individuals who possess appropriate clinical education and training, under the supervision of licensed physicians (MD/DO). If the proposed changes are enacted, patients will no longer be receiving the best possible care. The execution of diagnostic tests forms the foundation for diagnostic interpretation. As such, properly executing these tests is the difference between properly diagnosing a life-threatening disease in time to treat the illness, and the death of a patient.

CMS is proposing to allow non-physician practitioners to supervise diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests while still adhering to state laws and scope of practice limitations. This change is amorphous and not well defined. Based on the breadth and depth of this proposed change, it is reasonable to believe that the proposed change will encompass numerous procedures and could potentially even include things like the technical component of ambulatory electroencephalography (EEG), mammograms, monitoring for identification and lateralization of cerebral seizure focus, and electroencephalographic (channel EEG) recording and interpretation, all which currently require a general level of supervision. It could also span to the technical component of several X-ray studies and could potentially include things like the radiologic examination of the pharynx or larynx, fluoroscopies, and magnification techniques, which currently require personal supervision.[17] These are all highly technical procedures that require extensive schooling to properly perform and oversee. The training one receives could make the difference between identifying a brain tumor in time to operate and missing the warning signs until it is too late.

All health care professionals play a critical role in providing care to patients; however, their skillsets are not interchangeable with that of fully trained physicians. For example, while nurse practitioners are valuable members of the health care team, with only two to three years of education, no residency requirement and approximately 500-720 hours of clinical training, they are not trained to practice independently. Furthermore, physician assistant programs are two years in length and require 2,000 hours of clinical care. By sharp contrast, physicians complete four years of medical school plus three to seven years of residency, including 10,000-16,000 hours of clinical training. Nurse practitioners and physician assistants are integral members of the care team, but the skills and acumen obtained by physicians throughout their extensive education and training make them uniquely qualified to oversee and supervise patients' care and diagnostic exams. Physician-led, team-based care has a proven track record of success in improving the quality of patient care, reducing costs, and allowing all health care professionals to spend more time with their patients.

Without proper supervision, non-physician practitioners' level of training can strain the health care system and endanger patients. Multiple studies have shown that nurse practitioners order more diagnostic

[17] https://www.aapc.com/blog/26162-understand-medicare-physician-supervision-requirements/.

imaging than physicians, which increases health care costs and threatens patient safety by exposing patients to unnecessary radiation. For example, a study in the *Journal of the American College of Radiology* which analyzed skeletal x-ray utilization for Medicare beneficiaries from 2003 to 2015 found ordering increased substantially – more than 400 percent by non-physicians, primarily nurse practitioners and physician assistants – during this time frame.[18] A separate study published in *JAMA Internal Medicine* found that nurse practitioners ordered more diagnostic imaging than primary care physicians following an outpatient visit. The study controlled for imaging claims that occurred after a referral to a specialist.[19] The authors opined that this increased utilization may have important ramifications on costs, safety and quality of care. They further found greater coordination in health care teams may produce better outcomes than merely expanding nurse practitioners' scope of practice alone.

Moreover, while a common argument to expand the scope of practice of nurse practitioners is to increase access to care, in reviewing the actual practice locations of nurse practitioners and primary care physicians across the country, it is clear they tend to work in the same large urban areas as physicians. This occurs regardless of the level of autonomy granted to the nurse practitioners at the state level. As such, changing scope of practice regulations does not actually provide additional coverage to some of the most underserved areas.

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

Medical Record Documentation Requirements

CMS is proposing to allow any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, and to review and verify notes in the medical record made by physicians, residents, nurses, students, or other members of the medical team. The AMA supports policies and reform efforts that work to reduce the administrative inefficiencies, burdens, and expenses involved in paying for health care services. Since expanding the flexibility surrounding documentation and review of medical records for billed services will allow physicians to have more time to spend engaging in direct patient care rather than redocumenting their efforts, the AMA supports the enactment of this proposed policy.

Administrative burden and charting requirements are major reasons for physician burnout. By alleviating this burden and allowing others to share in the administration process, physicians will be able to decrease the time they spend documenting, and hopefully decrease overall physician burnout. The AMA

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[18] D.J. Mizrahi, et.al. "National Trends in the Utilization of Skeletal Radiography," *Journal of the American College of Radiology* 2018; 1408-1414.

[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.

recognizes that the electronic medical record serves important patient interests for present and future health care needs, insurance, employment, and other purposes. In keeping with the professional responsibility to safeguard the confidentiality of patients' personal information, physicians have an ethical obligation to manage medical records appropriately. Since the requirements for confidentiality and appropriate handling of records will not be put in jeopardy with the changes made by this proposed policy, the AMA believes that documentation efforts will remain accurate and in compliance with all applicable standards.

As such, the AMA supports this proposed change by CMS to allow physicians to review and sign notes made in the medical record by other members of the medical team so long as this provision stays within existing scope of practice laws and is only utilized to decrease the documentation burden that is placed on physicians. Further, the AMA supports the proposed changes to the medical record documentation requirements as long as this provision falls in line with existing scope of practice laws and only reduces the burden of redocumentation.

H. Valuation of Specific Codes

- **Recommendation:** The AMA urges CMS to finalize the CPT codes, CPT guidelines, and AMA/Specialty Society RVS Update Committee (RUC) recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC.

While there are numerous important proposals in this proposed rule which we provide comments on below, the AMA has been particularly focused on two issues. First, the AMA greatly appreciates CMS' proposal to align the previously finalized Evaluation and Management (E/M) office visit coding change with the framework adopted by the Current Procedural Terminology® (CPT®) Editorial Panel. We urge CMS to finalize the CPT codes, CPT guidelines, and AMA/Specialty Society RVS Update Committee (RUC) recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC.

I. Opioid Use Disorder (OUD) Services by Opioid Treatment Programs (OTPs)

- **Recommendation:** The AMA supports the expansion of the monthly bundled payment codes to all substance use disorders instead of solely for opioid use disorders. The AMA also supports the CMS proposal to pay physicians in emergency departments to stabilize patients with withdrawal symptoms, initiate treatment for OUD with buprenorphine, and to refer patients to community physicians and other services to help them transition to longer term treatment. The AMA is also in support of the expanded definition of OUD treatment services to include medications for opioid overdose, including naloxone.

Bundled Payments for Substance Use Disorders

Effective in 2020, CMS established three codes to report monthly treatment of patients with opioid use disorder (OUD). The codes include development of a treatment plan, care coordination, and individual and group therapy and counseling. Medications to treat OUD are paid separately.

For 2021, CMS proposes to modify the three codes so that they could be used to report monthly treatment of patients with any substance use disorder (SUD) instead of being limited to monthly management of

OUD. **The AMA strongly supports the expansion of the monthly bundled payment codes to all SUDs instead of solely OUD.** In its recent 2020 report on the national epidemic of drug overdose and death, the AMA observed that the epidemic has evolved from being driven primarily by opioid-related morbidity and mortality to a more complicated and dangerous epidemic fueled by illegally manufactured fentanyl, fentanyl analogs and stimulants like methamphetamine and cocaine. **The AMA commends CMS for recognizing this transformation and appropriately modifying the monthly treatment services to capture other SUDs.**

Initiation of Medication Assisted Treatment (MAT) in Emergency Departments

The AMA strongly supports the CMS proposal to begin paying physicians in emergency departments to stabilize patients with withdrawal symptoms, initiate treatment for OUD with buprenorphine, and refer patients to community physicians and other services to help them transition to longer term treatment. CMS cites persuasive evidence from the medical literature on the proven effectiveness of programs to initiate MAT in emergency departments. The AMA also agrees with CMS' conclusion that the work involved in initiating MAT in emergency departments is not currently accounted for in the Medicare physician payment schedule.

Naloxone Provision

In 2020, CMS began providing weekly payments to opioid treatment programs (OTPs). For 2021, CMS proposes to add naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and allow OTPs to be paid for dispensing naloxone to patients receiving OUD treatment services. **Naloxone is a critical tool for reducing opioid-related overdose deaths and the AMA strongly supports the CMS proposal to expand the definition of OUD treatment services to include medications indicated for opioid overdose, and to increase bundled payments to OTPs to cover the cost of providing take-home supplies of nasal or auto-injector naloxone.**

II. Other Provisions of the Proposed Rule

A. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and a Comment Solicitation on Payment for Specimen Collection for COVID-19 Tests

- **Recommendation**: The AMA continues to have ongoing concerns about the potential impact of cuts to payment rates for clinical testing services paid on the Clinical Laboratory Fee Schedule.

The AMA continues to have ongoing concerns about the potential impact of cuts to payment rates for clinical testing services paid on the Clinical Laboratory Fee Schedule. Many physician practices provide patients with point-of-care testing services performed by physician office-based laboratories (POLs). Physicians typically provide these services, such as rapid, point-of-care influenza testing, strep testing, and many others on thin financial margins, and at a higher cost than those performed by larger hospital, community, and reference laboratories. This makes reductions in payment rates for these important testing services especially impactful in physician office settings. Should payment rates for these services continue to decrease, it is likely that there will be a time in which POLs are no longer able to offer these rapid, point of care testing services. Should these tests no longer be available from POLs, patients will no

longer be able to receive testing, results, and treatment counseling in the same visit and will be forced to pursue multiple visits for testing and follow-up. A negative impact on patient compliance and health outcomes would likely follow.

As the nation continues to struggle with the ongoing COVID-19 pandemic, physician practices have faced significant burdens, both administrative and financial, and continue to face a myriad of issues when working to provide care to patients. Due to the significant hardships faced by practice shutdowns, persistent decreases in patient volumes, difficulties in accessing personal protective equipment, and other challenges brought on by COVID-19, we appreciate the delay in reporting clinical laboratory payment data. However, continuing potential reductions to payment rates for testing services while the cap on these reductions is moved up to 15 percent represents the potential for continued financial burden on physician practices and other hospitals and laboratories providing clinical testing services during a time when all providers are facing a severe global public health emergency. We continue to urge CMS to consider how best to limit financial strain on physician practices while preserving access to critical point-of-care testing services provided by POLs.

B. Medicare Shared Savings Program (MSSP)

- **Recommendation**: The AMA does not support the timing of the proposal to transition the Medicare Shared Savings Program (MSSP) quality measures from the GPRO web-interface to the APM Performance Pathway. Instead, the AMA recommends CMS gather stakeholder feedback and postpone the transition until 2023. The uncertainty of the measures coupled with the timing– during the COVID-19 pandemic – are reasons CMS should delay the implementation of the proposed quality measure changes.

Medicare Shared Savings Program (Shared Savings Program) was created to facilitate the coordination and cooperation among health care providers to improve the quality of care for Medicare fee-for service (FFS) beneficiaries, and to reduce the rate of growth in expenditures under Medicare Parts A and B. Through the formation of Accountable Care Organizations (ACOs), enrolled physicians and other providers may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs

CMS proposes to transition the Medicare Shared Savings Program (MSSP) quality measures from the Group Practice Reporting Option (GPRO) Web-Interface to the APM Performance Pathway (APP) starting in 2021, as well as align the MSSP quality scoring methodology with the Merit-based Incentive Payment System (MIPS) methodology. While the AMA supports eliminating unnecessary and inappropriate measures and instead would rather focus on appropriate measures for ACO accountability, which includes moving away from the GPRO Web-Interface, we do not support the timing of these sweeping changes and the uncertainty it introduces into the MSSP program during a global pandemic. When the final rule is released in December 2020, ACOs essentially will only have one month to transition to a new reporting method, upgrade their IT systems and begin reporting on all-payer data. We are very concerned that patients could be at increased risk of receiving poor quality care from this rushed transition and focus away from providing preventative care.

While the proposed revisions may reduce administrative burden, they narrow the lens through which quality is assessed. The AMA questions whether these proposed changes will appropriately protect patients when ACOs are being financially penalized for their failure to reduce spending, or rewarded for quality improvements that are feasible to achieve through a program that does not change the underlying payment system. It is unclear how CMS landed on the proposed measure set. One of the strengths of the current set of quality measures is the inclusion of several measures related to preventive care, which incentivize providers to deliver preventive care services to their patients. Reducing preventive care may achieve short-term savings yet cause higher spending in the long-term. On the other hand, the shared savings methodology gives ACOs a direct financial incentive to reduce avoidable admissions and readmissions, therefore it is inappropriate to have one-third of the quality measures focused on these narrowly defined utilization measures. We do not believe that CMS has struck an appropriate balance between ensuring quality of care and minimizing administrative burden in a program that has a primary goal of reducing spending. Therefore, **we recommend CMS postpone transitioning away from the GPRO web-interface and associated measures until 2023 and utilize the interim period to consult with the ACO community and patient representatives to determine the best-balanced measure set.**

The AMA also has concerns with the administrative claims-based measures used for MIPS. We do not feel the proposed measures would be a better alternative to the current administrative claims-based measures. We offer the following specific comments:

- *Multiple Chronic Condition Measure vs. MIPS Multiple Chronic Condition Measure*

While complete specifications and testing have not yet been widely distributed, the limited information available on the *MIPS Multiple Chronic Condition* measure raises several concerns. The AMA encourages CMS to ensure that measures have high reliability (the reliability standard should be higher than 0.7) and demonstrate the results are valid when attributed to an ACO. Specifically, the proposed rule states that measure score reliability ranged from 0.12 to 1.00 using data from the 2018 performance year; therefore, the measure does not meet the 0.7 reliability threshold. We encourage CMS to consider increasing any case minimums required for inclusion in the denominator to ensure that a higher minimum level of reliability can be achieved across all ACOs. In addition, testing to demonstrate the validity of the measures when attributed to an ACO must be completed and face validity assessments, otherwise these measures should not be considered adequate to determine whether a measure is valid and appropriate for inclusion in MSSP. This testing should also ensure that social risk factors are tested and included in the risk adjustment approach. Based on the preliminary information provided at the 2018-2019 Measures Application Partnership (MAP) review, the AMA was encouraged to see that the Agency for Healthcare Research & Quality (AHRQ) Socioeconomic Status (SES) index and density of physician specialists were included in the risk adjustment. We urge CMS to consider additional variables such as dual eligibility, frailty, and age for inclusion. These revisions must be made prior to implementation of the measure.

Additionally, CMS provides no discussion on whether the agency would maintain pay-for-reporting when scoring ACOs on new measures and/or when measures undergo significant changes. Providing ACOs in their first contract year with only 12 months to assess performance, study measure specifications, implement workflow and IT changes necessary to capture data to document quality performance as specified by the measure steward is a huge undertaking. In addition, this time is crucial to educate clinicians and support staff on how to incorporate processes to implement the quality measures in practice. Each quality measure has its own measure specifications, exemptions, and requirements. New

ACOs need time to educate physicians and staff on measure specifications and begin tracking performance, which makes a pay-for-reporting year critical. When measures undergo significant changes, ACOs, their clinicians and the support staff need at least one year of preparation prior to being held accountable for performance on the new or revised measure.

- *Healthy "Days at Home" Measure*

Understanding the degree to which individuals spend their time at home is a useful indicator to determine if the health care system is achieving one of its primary goals–to have an individual healthy at home. While this indicator provides a broader viewpoint on the health of an individual, rather than measures such as admissions or readmissions, the many different factors that can affect a patient's "healthy days at home" raises serious concerns about whether differences in performance on this measure can be reliably attributed to the services delivered by ACOs and whether this measure could be used to truly distinguish the quality of care ACO participants receive.

The recent work by the Harvard School of Public Health and the Medicare Payment Advisory Commission (MedPAC) also highlights statistical issues that will likely be encountered when developing and ultimately implementing a measure on healthy days at home. Specifically, the analysis found that the difference between the minimum and maximum days at home was less than 11 days for Medicare beneficiaries over the age of 65, and for beneficiaries with 3 or more chronic conditions, the differences were only between 12 and 14 days across 306 markets. When the range of geographic markets were compared to the national mean, it was a difference of 5.8 days in the worst performing markets, and 5.0 days in the best performing markets across all Medicare beneficiaries aged 65 and older. Those with three or more chronic conditions showed more variation; the range of days was only 9.1 below the national mean and 7.9 above. Based on the sample used, good reliability of at least 0.7 required at least 2,000 beneficiaries and an analysis of market socioeconomic status (SES) characteristics identified several factors that were significantly associated with this measure including income, poverty, and physician and primary care physician density.

While the MedPAC concluded that the study yielded results that could provide meaningful information to compare performance across populations and guide care planning, this does not mean that it would be appropriate to use the measure to *penalize* ACOs. We caution CMS that any measure that addresses Healthy Days At Home must be attributed at a level where the outcome can be meaningfully influenced, is closely linked to structures and processes that are actionable by ACOs, feasible to implement without unnecessary burden, and demonstrably reliable and valid with appropriate risk adjustment, including social risk factors. In addition, simply adding this measure to the existing set would duplicate what is already measured through admissions and readmissions, and what is already encouraged by the overall financial incentives in MSSP.

MSSP Scoring Methodology

Making a change to MSSP quality scoring methodology introduces too much uncertainty into the MSSP program. The MIPS methodology is flawed, does not incorporate pay-for-reporting and is undergoing extensive revisions as CMS proposes to transition the program toward MIPS Value Pathways (MVPs). Therefore, making such a drastic change to the MSSP quality performance standard and measures while

CMS is in the middle of revising the QPP program and a pandemic introduces too much instability and complexity into the program.

Removing the Pay-for-Reporting Year

The proposed rule would remove the pay-for-reporting year currently provided to those ACOs beginning an initial MSSP contract as well as for individual measures that are newly introduced to the measure set. It also would remove the ability of CMS to provide pay-for-reporting when measures undergo significant changes, such as guideline changes or impacted by a public health emergency, such as COVID-19. We oppose CMS' proposal to remove pay-for-reporting. Providing the pay-for-reporting year is critical to an ACO's success. This year allows an ACO to evaluate their current workflows, data capture processes and other operational strategies to see where changes are needed and what areas to focus on. Further, providing a newly introduced measure or a measure undergoing significant changes with a pay-for-reporting year ensures there are no unintended consequences or flaws in the measure specifications before holding an ACO accountable for performance on the measure. Allowing this time to assess workflows and operations before ACOs are held accountable for performance on measures allows ACOs to be successful in getting credit for the good quality improvement work they are already engaged in, as often times a measure is not only assessing true quality but also how the quality data are captured.

We are disappointed the rule did not provide any consideration on the impact COVID-19 may have on the shared savings program in 2021. In other programs, such as MIPS, CMS is lowering the performance thresholds in light of COVID-19 and similar considerations must be given for MSSP in 2021.

C. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD plan

- **Recommendation**: The AMA strongly supports the proposal to defer requiring EPCS for Medicare Part D prescriptions until 2022 and deeply appreciates CMS' recognition of the hardship that implementation of such a requirement in 2021 would impose on patients and physicians.

The Support for Patients and Communities Act (SUPPORT Act) included a requirement that Medicare Part D prescriptions for controlled substances be electronically prescribed starting in 2021 and that the U.S. Drug Enforcement Administration (DEA) update its EPCS regulations pertaining to the biometric component of two-factor authentication. As the CMS proposed rule acknowledges, the current DEA requirements for multifactor authentication have been a significant hurdle to the greater adoption of EPCS. In particular, the rigid and burdensome requirements for biometrics included in the 2010 regulations preclude physicians from deploying user-friendly devices already found in their practices to satisfy these DEA requirements. Instead of using laptop computers and smartphones with fingerprint scanners, facial recognition, or other biometric technology, they must utilize separate biometric technology that has been reviewed by the DEA or a DEA-approved certifying organization for specific compliance with EPCS requirements. The biometric scanners found on consumer devices commonly employed in medical practices are used for secure access to other sensitive information, like banking and electronic health records, but typically do not comport with the EPCS rules.

The regulations further require that the biometric device either be co-located with or built into the computer that is being used for EPCS. This rule has led to the development of a niche market for EPCS products that are certified to comply with DEA regulations. The fingerprint reader or facial scanner on a smartphone could not be used by a physician for EPCS because, even if it had been reviewed by the DEA, the smartphone would be separate from and work independently of the EPCS software and hardware being used in the practice. The existence of this niche market allows health information technology vendors to charge high prices to physician practices to add the technology needed for EPCS and, even after assuming these costs, EPCS technology is still likely to disrupt workflows because it is not integrated with physicians' other systems.

The CMS proposed rule also describes how the COVID-19 PHE has further exacerbated problems that physicians were facing in attempting to adopt EPCS for their practices. Quarantine and social distancing guidance led many physicians to work from their homes or in alternative locations away from the technology in their regular medical offices. Whereas many physicians could have successfully used widely available consumer devices in their homes or other sites to provide telehealth services, access their electronic health records, and prescribe non-controlled medications, this DEA rule would have prevented them from using these devices for EPCS. It is ironic that the accelerated adoption of telehealth technology that has resulted from the COVID-19 pandemic could instead, lead to further setbacks in EPCS adoption.

Several months ago, to facilitate the needed update to the EPCS regulations, the DEA reopened the comment period on its 2010 EPCS interim final rule. This was a critical step forward that was very encouraging to the physician community. Going forward, we believe it is important for the DEA and CMS to work together in order to ensure that the final implementation timeline adopted by CMS for Medicare prescriptions takes into account the DEA's timeframe for implementing new regulations. Sufficient time will need to be allotted between the DEA issuance of revised regulations and the imposition of new Medicare requirements for vendors to update their products to comply with the new DEA requirements and for medical practices to acquire and transition to the new technology. For this purpose, 2022 is certainly much better than 2021, but one additional year may not turn out to be sufficient for all practices. **The AMA strongly supports the proposal to defer requiring EPCS for Medicare Part D prescriptions until 2022 and deeply appreciates CMS' recognition of the hardship that implementation of such a requirement in 2021 would impose on patients and physicians.**

D. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

- **Recommendation**: The AMA asks CMS to provide more information about the drug products that would be impacted by the proposed change before this policy is finalized.

The AMA appreciates CMS' continued focus on the high prices of prescription drugs and the negative impact that continually escalating prices has on our patients and our health care system. Ensuring prescription drugs are affordable and accessible to all patients has long been a priority of the AMA and we are encouraged by the agency's efforts and attention in this area. However, in order to properly evaluate the current proposal for Medicare Part B drug payment for drugs that are approved under the 505(b)(2) pathway, more transparency about the impacted products is needed.

The AMA agrees with CMS that, in some instances, prescription drug manufacturers exploit certain pathways to market extended exclusivities that can lead to prolonged periods of high prices for their drug products. We appreciate the agency's recognition of this "gaming" of the system and efforts to limit this anticompetitive and anti-consumer behavior. However, we are also aware that efforts to rein in manufacturer behavior and exorbitant pricing practices can ultimately result in limited access to critical therapies for patients. Absent large-scale drug pricing and payment reform, targeted efforts at reducing drug prices need to carefully consider the ultimate financial and availability impacts on patients, carefully weighing the risks and benefits of the proposed change.

While the proposal by CMS may ultimately be an appropriate step to help curb drug prices of certain products, in order to ensure there are no detrimental impacts on patients, more transparency about the products that would be impacted by the proposal is needed. Payment for drugs under Medicare Part B considers not only the cost of drug, but also the costs to physician practices for acquisition and administration of that drug product to the patient. Changes to reimbursement for these products have the potential to create situations in which the payment amount to the physician does not adequately cover these costs. This is especially important for smaller practices, who frequently pay more for products covered under Part B due to their relative lack of bargaining power and their inability to source drugs with volume discounts. Should reimbursement for drug products paid under Part B not be adequate to cover the physician costs of providing the therapy, those therapies may become unavailable to patients as the financial implications for physicians would be prohibitive. In order to ensure that patients have continued access to essential Part B therapies, CMS must provide more information about the drug products that would be impacted by the proposed change before this policy is finalized.

E. Updates to Certified Electronic Health Record Technology Due to the 21st Century Cures Act Final Rule

- **Recommendation**: The AMA has serious reservations with CMS' proposed August 2, 2022, adoption deadline for physicians to use 2015 Edition Cures Electronic Health Record (EHR). The AMA strongly urges CMS to limit any unnecessary complications or burden that could impede physicians' adopting, scheduling, planning, implementing, testing, training, and using these new EHRs in clinical environments. Instead, the AMA strongly urges CMS to not require physicians to use 2015 Edition Cures EHRs before January 1, 2023.

CMS proposes that physicians participating in the Promoting Interoperability (PI) Programs, including the PI category of the QPP, must use technology certified under the Office of the National Coordinator for Health Information Technology (ONC) Certification Program according to the timelines finalized in the 21st Century Cures Act (Cures Act) Final Rule. CMS also proposes that after August 2, 2022, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

The AMA appreciates the potential value for physicians who adopt new 2015 Edition Cures electronic health records (EHRs) and recognizes CMS' goal to promote that adoption as soon as possible. The AMA supports many of the new EHR design, development, testing, and usability changes made in ONC's Cures Act Final Rule. Particularly, we are optimistic that changes will improve physicians' experience with using EHRs, reduce the friction of exchanging medical information, and allow patients to be more engaged with their care. Therefore, ensuring a smooth rollout of new 2015 Edition Cures EHRs is critical

for physicians, hospitals, and patients to realize the full benefit of these EHR improvements. **We strongly urge CMS to limit any unnecessary complications or burden that could impede physicians' adopting, scheduling, planning, implementing, testing, training, and using these new EHRs in clinical environments. Complications associated with rollout of the 2015 Edition Cures EHRs may directly impact patient care and lead to patient harm.**

To that end, the AMA has serious reservations with CMS' proposed August 2, 2022, adoption deadline for physicians to use 2015 Edition Cures EHR. CMS has not sufficiently considered the need for separate timelines for EHR development by vendors and EHR adoption by physicians. While EHR vendors have until 23 months as of this letter to make 2015 Edition Cures EHRs available to physicians, physicians are also expected to be using those very same EHRs on the same date. Clearly, both availability and use cannot possibly happen on the same day. The American Health Information Management Association (AHIMA) states that medical practices require a significant amount of time to implement EHR systems:

> *The average implementation for a sole practitioner can take anywhere from 12 to 18 months, including planning, design, implementation, and training. For practices with two to five physicians, the implementation time can be longer. Larger group practices with multiple specialties will require even more time due in part to the greater number and variety of templates to be designed, the additional staff requiring training, and the greater number of system interfaces to be developed.*[20]

This timeline from AHIMA aligns with our members' experiences, and we expect the same to be true for newly installed or upgraded 2015 Edition Cures EHRs. Further, as previously discussed, CMS has chosen to adopt an ONC-set timeline for EHR development and deployment as the same timeline for physician EHR use. Yet, the EHR Association states that data from a survey of its members "shows that [ONC's] timeline severely underestimates the development time required for development of the new 2015 EHR Cures Update.[21]

Considering that physicians need at least 12 months to plan for new EHRs and that ONC—and by extension, CMS—has underestimated the time it will take to develop 2015 Edition Cures EHRs, **the start date for EHR adoption for all physicians is in reality closer to summer 2021—requiring vendors to hastily develop, test, certify, and release EHR products well-ahead of the CMS' proposed August 2, 2022 date.** The AMA is concerned that the current proposed 23-month timeline is insufficient. For one, CMS is not considering the impact of the COVID-19 pandemic's long-term recovery on physicians' medical practices, which will extend at least through 2021. Second, historically, CMS has required physicians to adopt new EHR editions on January 1st of the performance year. Hundreds of thousands of physicians have already incorporated this date into their EHR adoption plans. This consistency allows both EHR vendors and physicians to use lessons learned from their previous EHR edition migrations. Third, while CMS states that physicians can use their current 2015 EHRs until August 2, 2022 and that the 90-day PI reporting can take place after the required EHR switchover, CMS does not consider how adopting a new EHR mid-year will impact other CMS reporting program requirements. For instance, physicians participating in PI are also likely participating in the Quality component of MIPS. An arbitrary

[20] https://library.ahima.org/doc?oid=64036#.X1-OOWhKiud

[21] https://www.ehra.org/sites/ehra.org/files/EHR%20Association%20Response%20to%20ONC%20Proposed%20Rule%20on%20Interoperability%20Information%20Blocking%20and%20Certification%20Program.pdf

EHR changeover date during a 365-day quality reporting period will cause disruption, hardship, and potentially impact physicians' MIPS scores. Likewise, any EHR upgrade could implicate the integrity and availability of patient information; rushing the transition process could threaten this integrity and availability, potentially jeopardizing patient safety. **To limit any unnecessary complications, patient safety issues, or burden, the AMA strongly urges CMS to not require physicians to use 2015 Edition Cures EHRs before January 1, 2023.**

F. Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

- **Recommendation**: The AMA greatly appreciates and strongly supports the significant flexibilities that CMS has provided for MDPP suppliers during the COVID-19 PHE, in particular allowing patients to receive MDPP services more than once during their lifetime and allowing access to sessions provided on a virtual basis. The AMA recommends that these flexibilities be made permanent so Medicare beneficiaries can access MDPP more than once-per-lifetime, receive their first MDPP class virtually and use virtual means to report weekly body weight measurements. The AMA recommends that CMS allow all MDPP sessions to be provided through virtual modalities on a permanent basis, and for virtual providers to be allowed to provide MDPP services.

Once-Per-Lifetime Limit

From the beginning of the MDPP, the AMA has been seriously concerned about the once-per-lifetime limit of the Medicare benefit. Weight loss is extremely difficult and complex, and some patients may need multiple attempts to be successful at either achieving or maintaining weight loss. These difficulties, and the need to lift the once-per-lifetime limit, will not end when the pandemic ends. **The AMA recommends that the once-per-lifetime limit on MDPP participation be permanently eliminated.**

The AMA appreciates that CMS is waiving the once-per-lifetime limit for patients who were participating in an MDPP program and who had sessions that were cancelled or suspended by the novel coronavirus restrictions. We are very concerned, however, that CMS proposes to not allow such a waiver for participants in future PHE events if they elect to continue to receive sessions virtually. Weight loss, the key metric of the MDPP, is difficult and no easier as individuals age and have multiple chronic conditions. Much like quitting smoking, individuals may try multiple ways to lose weight before making lasting changes. In addition to COVID-19 PHE event, there are also lifetime events that may interrupt participation such as surgery or death of a family member.

In contrast to the MDPP limit, the Medicare coverage policy for obesity counseling specifically acknowledges the science showing the need for repeated use of healthy lifestyle counseling for weight management in its current coverage policy for obesity counseling. The Medicare obesity counseling benefit states that, "For beneficiaries who do not achieve a weight loss of at least 3kg during the first 6 months of intensive therapy, a reassessment of their readiness to change and BMI is appropriate after an additional 6-month period." Similar to Medicare coverage of obesity counseling and tobacco cessation, CMS should provide Medicare beneficiaries additional opportunities to participate in and benefit from MDPP. The stress and strains on the health care system from the COVID-19 PHE will continue once the PHE is lifted, and it may be a challenge for those patients that previously participated to maintain the MDPP program goals.

Virtual MDPP Services

As noted above, the AMA strongly supports the CMS policy during the COVID-19 PHE of allowing nearly all MDPP services to be provided through virtual modalities such as distance learning and online sessions. **As the AMA has previously recommended, we strongly support the current proposal to also allow the first core MDPP session to be provided virtually during a PHE. We urge CMS to finalize this proposal and to make it effective immediately instead of waiting until 2021.** The prohibition on providing the first core session virtually has effectively prevented new patient cohorts from starting the program during the pandemic. **The AMA also supports the proposal to allow patients to report their weight through virtual means, such as Bluetooth-enabled scales, during a PHE.**

The AMA strongly disagrees with the CMS decisions to only allow MDPP services to be provided virtually during a PHE and to prohibit providers of virtual-only DPP services to enroll as MDPP suppliers. Instead, the AMA recommends that CMS allow all MDPP sessions to be provided through virtual modalities on a permanent basis in order to provide the greatest access to services for all Medicare beneficiaries regardless of where they live, income level, race or ethnicity. The COVID-19 PHE has clearly demonstrated that marginalized citizens, especially older adults and older adults of color, are extremely vulnerable to a severe impact from novel viruses and has reinforced the need to prevent diabetes in these populations.

The AMA strongly advocates for inclusion of virtual providers, especially in the case of the PHE and any future 1135 waivers. The virtual providers have consistently demonstrated the ability to meet the rigorous standards set by the Centers for Disease Control and Prevention (CDC), which CMS recognizes as the basis for approving MDPP suppliers. It is contradictory to assign importance of CDC recognition to some CDC DPP providers while excluding others. The rule says another reason for excluding virtual providers was because they would not be able to offer in-person services when the PHE ends. During the COVID-19 PHE, we have all been able to experience firsthand the true value of the health care innovation represented by DPP providers that offer virtual learning opportunities. To force MDPP participants to return to in-person sessions does not recognize the reality of human behavior. Just because the PHE ends does not mean it is appropriate for everyone to resume their pre-COVID lifestyle. People participating in the MDPP might have individual health reasons to continue to limit their contact with others, functional challenges that make it difficult to travel to in-person sessions, or have caregiving responsibilities at home.

The MDPP already provides patients with flexibility to change MDPP suppliers as their personal needs change. So, there is no reason to not allow virtual-only DPP providers because beneficiaries could switch to an in-person program after the PHE if they choose. If a beneficiary begins a distance learning program where the actual site location is 75 miles from their house, they should not be expected to start attending in-person after the PHE is over. They should be able to complete the program with their original program supplier, especially because there will be some beneficiaries who have no access to an in-person program after the PHE ends. **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.**

Additional Recommendations to Improve the MDPP

The AMA participated in the initial model with the Y-USA that formed the basis for the CMS decision to expand the MDPP model, and has continued its active involvement in educating physicians and health care systems about the MDPP and promoting supplier enrollment in the expanded model. The AMA now has six years of experience working with physician practices and health care systems to implement diabetes prevention strategies, including referrals to MDPP. Systematic screening of patients for prediabetes and abnormal glucose metabolism is an important aspect of preventing type 2 diabetes and optimizing participation in the MDPP. Robust MDPP participation is necessary for CMS to realize the cost savings that were estimated by the CMS Actuary for the expanded MDPP model.

The AMA's work with health systems has identified barriers that physicians and care teams face when they seek to follow the standards of care and clinical guidelines for screening. A major barrier is that the CMS coverage policy for HbA1c tests does not include the indication of prediabetes or abnormal glucose screening. HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for at least 10 years. 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 October 2019 request to the CMS Coverage and Analysis Group 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 United States Preventive Services Task Force and the 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.

Two other key issues continue to inhibit more robust supplier enrollment and participation in this model as it is currently being implemented: the way payments are structured and persistent differences between the original CDC model that was tested and the CMS expanded model. These problems and their solutions are described in detail in a letter of May 13, 2020, from the Diabetes Advocacy Alliance to the Center for Medicare and Medicaid Innovation (CMMI) with which the AMA concurs:

- CMMI should modify the expanded model to become a one-year program, with payment levels at least equivalent to the levels provided in the CMMI pilot test. Average payments per participant in the first year were estimated (pre-COVID-19) at 56 percent of what was paid in the one-year pilot program.

- CMMI should modify the expanded model to change its fasting plasma glucose (FPG) range of 110-125 mg/dL for beneficiary eligibility to align with the FPG range specified in the National DPP's Diabetes Prevention Recognition Program standard of 100-125 mg/dL.

The AMA is committed to preventing new cases of type 2 diabetes by addressing prediabetes and assisting physicians and clinical teams in delivering effective preventive care. We strongly encourage CMS and CMMI to adopt these recommended improvements.

III. Calendar Year 2021 Updates to the Quality Payment Program (QPP)

The AMA appreciates the additional time afforded to physicians for the 2019 data submission and continues to closely monitor how the unprecedented pandemic will impact the QPP scores. We offer several specific recommendations to the QPP proposals below.

A. MIPS Value Pathway (MVP) Development

The AMA supports CMS' aims in MVP to reduce burden and focus reporting on an episode of care and patient outcomes. The high-level framework outlined in the 2020 final rule, as well as the development criteria proposed in this rule, are an important step in the right direction. However, we believe that the MVP approach needs to be structured appropriately to effectively improve the relevance of MIPS to clinical practice and reduce unnecessary paperwork burdens. Specifically, we support postponing implementation due to the COVID-19 pandemic and recommend creating a transition period, focusing on measures that are meaningful to physicians and patients, and ensuring the development criteria are fair and transparent rather than creating a "moving target."

Timeline for MVP Implementation

- **Recommendation**: The AMA supports CMS' proposal to delay the implementation of MVPs until the 2022 performance period in light of the COVID-19 pandemic. We also urge CMS to establish a transition period for MVPs.

The AMA agrees with CMS that due to the 2019 Novel Coronavirus (COVID-19) pandemic public health emergency and resultant need for clinician focus on the response, the timeline for MVP should be delayed until at least 2022. MVPs have the potential to be a positive turning point in MIPS but will require significant input from physicians in the development and corresponding changes in how they participate in MIPS within their practice. MVPs are a novel episode-based approach to MIPS, and we would be concerned that rushing forward could diminish both the MVP framework and development policies, as well as the success of the initial MVPs in achieving CMS' and the AMA's shared objectives of improving the clinical relevance of MIPS for both physicians and patients.

In addition, as CMS took a gradual implementation approach to MIPS in 2017 and 2018, CMS should also view the first two years of each new MVP as a transition period. It will take time to develop, refine, implement, and educate physicians about the specific features of an MVP. Physicians may also be concerned that by adopting the new MVP approach, they will be at risk for a substantial negative payment adjustment. **We urge CMS to hold physicians harmless from a penalty for the first two years of participation in a new MVP**. This transition period should be rolling and begin when a new MVP is introduced into the program. Although a handful of specialty societies are submitting an MVP proposal for potential adoption in 2022 or soon after, most physicians will not have an MVP option in the near term.

A transition period is critical for incentivizing specialists who have been participating at a group level but would move to sub-group participation in an MVP, which is potentially more administratively burdensome than reporting as a group. CMS should also consider the expenses to adopt and administer an MVP for physicians in small practices who have been reporting via claims. 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.

Implementing Meaningful Measures in MVPs: Population Health Administrative Claims Measures

- **Recommendation:** The AMA urges CMS to retain a robust list of Qualified Clinical Data Registry (QCDR) and MIPS quality measures. The AMA does not support the use of population health administrative claims measures as foundational to MVP proposals. If CMS moves forward, administrative claims measures should only apply to group practices and cannot be a requirement of MVP. Alternatively, CMS could make population health administrative claims measures voluntary and allow practices the option to self-designate whether they want CMS to calculate the measures on their behalf. The Quality Category comments contain the AMA's specific concerns with the HWR measure.

The AMA is concerned with CMS' continued emphasis that MVPS must include population health administrative claims measures as a foundation to MVPs. We do not believe organizations will develop MVPs if CMS moves forward to require population health administrative claim measures. The proposed measures also move the MVP away from incorporating the patient's voice, measuring clinical conditions and outcomes, and generating real-time feedback.

Over time, measure developers have moved away from administrative claims measures due to concerns over attribution, retrospective analysis, the inability to measure individual physicians, and outcomes. Organizations have shifted to the development of electronic clinical quality measures (eCQM) and Qualified Clinical Data Registries (QCDRs) due to the shortcomings with administrative claims measures, including the inability to move to clinically meaningful outcome measures. QCDRs and eCQMs electronic tools provide for a much richer data source than administrative claims measures. For example, it is very difficult to get to intermediate outcomes, such as diabetes HbA1c levels or blood pressure level measures, without requiring additional data collection. Therefore, CMS will be left to select measures that may be sufficient from the community or population perspective but are not appropriate to attribute to an individual physician or practices. If this happens and the measures are so far removed from clinical practice, the measure will not provide meaningful or actionable data at the point of care.

To date, we have yet to see a reliable attribution model developed for any existing administrative claims measures. CMS also relies on retrospective attribution which greatly decreases the ability of a physician or a practice to drive improvements in care, as they will not be working with a pre-determined set of patients. We are also concerned that the measures may incentivize the provision of poor care or lead to other unintended consequences.[22] For example, the literature is beginning to show that readmission measures, which are based on administrative claims, may be leading to increased mortality.[23]

[22] *See* AMA 2020 Physician Fee Schedule Proposed Rule Comments and 2019 Inpatient Prospective Payment System (IPPS) Proposed Rule Comments for our detailed analysis and concerns with the All-Cause Readmission measure.

[23] Gupta, Ankar, et al. Association of the Hospital Readmissions Reduction Program Implementation with Readmission and Mortality Outcomes in Heart Failure. JAMA Cardiol. 2017. doi:10.1001/jamacardio.2017.4265. Published online November 12, 2017.

If CMS insists on moving forward with administrative claims measures to provide more accurate assessment of physicians, the AMA recommends that each measure demonstrate the following:

- **High level of reliability:** Physician performance on any administrative claims measure should not be used for payment or be publicly reported unless a minimum reliability of 0.80 can be demonstrated and the risk adjustment model is developed, tested, and released for comment prior to implementation. Social risk factors must be adequately addressed in the model before it is implemented. Testing should be completed at the individual and group level, among groups of various sizes. Statisticians and researchers generally believe coefficients at or above 0.80 are considered sufficiently reliable to make decisions about individuals based on their observed scores, although a higher value, perhaps 0.90, is preferred if the decisions have significant consequences.[24, 25]

- **Robust testing of the validity of the measure:** The attribution approach must be tested to demonstrate that the assignment of a measure to specific physicians, groups, and specialties is clinically appropriate and tied to the physician's or group's ability to meaningfully influence the outcome. Correlations between quality and cost measures to demonstrate the validity of the measure when applied to a specific physician, group, or specialty must be evaluated. CMS should demonstrate when measuring cost measures in conjunction with quality results in the intended outcomes.

- **Timely and relevant information:** Notification in real time of which patients will be attributed to a physician or group for any of these measures could help reduce costs and avoid unnecessary services such as a readmission. Timely and relevant information is critical for physicians and practices participating in MVPs.

We do not believe CMS considered that implementation of population health measures will further diminish the viability of small practices. Most of the promising strategies related to addressing population health, such as hiring nurse coordinators may be a violation of the Stark and Anti-Kickback statutes. Therefore, the only way to work around the statute is to become employed by a hospital. Individual and small practices also do not typically have a large enough patient sample size to calculate a reliable score.

MVP Principles, Process and Criteria

The AMA appreciates the opportunity to provide feedback on the revisions to the principles and the proposed process and criteria on which MIPS Value Pathways (MVP) would be assessed. While some of the information and criteria as proposed would be useful to collect and evaluate, CMS does not provide a sufficient level of guidance on how the responses would be evaluated or prioritized. There is great risk that this process would create a catalog of information with little to no direction on how it would be applied. This scenario already occurs with the Measures Under Consideration (MUC) process where

[24] Webb, Noreen, et al. Reliability Coefficients and Generalizability Theory. Handbook of Statistics, Vol. 26. 2006 Elsevier B.V. DOI: 10.1016/S0169-7161(06)26004-8. http://web.stanford.edu/dept/SUSE/SEAL/Reports_Papers/ReliabCoefsGTheoryHdbk.pdf.

[25] Del, Siegle. Instrument Reliability. Educational Research Basics. University of Connecticut. Accessed 09/05/2020. http://researchbasics.education.uconn.edu/instrument_reliability/.

measure developers develop measures in good faith using the requirements as outlined by CMS, yet selection of the measures remains a "moving target." The MUC process is very subjective, open to interpretation, and lacks full transparency. The AMA urges CMS to avoid replicating this process with MVP.

The AMA offers the following feedback on the principles and criteria:

1. Second Principle/Subgroup Reporting: The AMA appreciates CMS' recognition of the importance of subgroup reporting in the second MVP guiding principle and urges the agency to provide specific information on its operationalization the final rule. Consistent with the AMA's previous comments, we continue to believe subgroup reporting will be crucial to MVPs as it would facilitate participation by specialists who may be practicing within multispecialty groups. Currently, a clinician has three options to choose among for MIPS data reporting: individually, as a virtual group (which is limited to solo practitioners and small groups), or as a group (which includes all MIPS eligible clinicians within a TIN). The AMA has heard from physicians who are part of a group practice that would like to report separately from the larger group and instead partner with their colleagues in the same or similar specialty. **We support allowing an option for a portion of a group to report as a separate subgroup for purposes of MVP or traditional MIPS.** This would allow a specialty in a multispecialty group to form a subgroup to report on MVPs that are more clinically relevant to that particular specialty.

   We understand that CMS faces challenges in implementing a subgroup level reporting option in MIPS. To ease the transition, CMS should consider offering this option in MVP before expanding to the traditional MIPS program. Noting that MVPs will be built around an episode of care or condition, and most likely involve reporting via a registry or QCDR, multispecialty groups will find it challenging to engage in MVP unless members of the group are able to form sub-groups based on their combined interest in participation in an MVP track. Many MIPS-eligible physicians are part of a multispecialty group and, based on 2018 QPP Experience Report, 53 percent of eligible clinicians received their final score based on participation in a group. It will not be simple to move from participating in a group practice to participating as a sub-group, and CMS must give physicians as much time as possible to plan and make the business case for participating in CMS as a sub-group. **Therefore, we urge CMS to provide specific information about how subgroups can form and opt-in to MVPs within the final rule.**

   Physicians in the group who are not affiliated with the subgroup that is participating in an MVP should retain the option to participate as a group practice in traditional MIPS or select another MVP. We urge the agency to look to its "split-TIN" policy for certain Advanced APMs, where some of the clinicians billing under the group's TIN participate in the model while others do not. In this case, the portion of the group that is not participating in the model has the option to participate in MIPS as a split-TIN and can submit measures via another data submission mechanism. This will minimize the burden on multispecialty groups who have a subgroup interested in an MVP.

2. Fifth Principle/Digital quality measures: The AMA urges CMS to continue to advance the field of measurement and evaluations on the quality of care provided to patients. We are encouraged to see the addition of a fifth principle that states, "MVPs should support the transition to digital

quality measures." We strongly support a shift to measures that are derived from electronic data generated at the point of care as we believe that these types of measures are more meaningful and actionable to physicians and patients. We do not, however, support CMS' current definition of digital quality measures. **While administrative claims are in fact digital in nature, and administrative data itself can enhance a physician's view of their patients' longitudinal care, we do not believe that measures based solely on data pulled directly from claims should be included in the definition. Claims based information for purposes of quality improvement and comparisons lacks granularity and untimely.**

We also request clarification on how this new principle fits with the statement made in Section IV.3.a.(1):

> "Over time we intend to provide greater amounts of population health measurement data using administrative claims information while decreasing the amount of clinician reported measurement data used for MIPS."

This statement is alarming, as we believe that inclusion of additional population administrative claims-based measures is contrary to the program's intent and would further minimize the meaningfulness and relevance of MIPS. Efforts around improving the nation's data infrastructure must emphasize information that is derived at the point of care. **Therefore, if this fifth principle will serve to encourage the inclusion of increasing numbers of administrative claims-based measures in MVPs, then the AMA does not support the addition of the fifth principle to the list.**

3. Measure and Activity Selection: Regarding the proposed criteria by which measures and activities are selected, the AMA appreciates CMS' recognition that physician input is critical and we support a collaborative process that allows MVPs to be largely developed and proposed by medical specialty societies. Consistent with past comments, the AMA believes that MVPs provide a more holistic track for physicians by allowing for attestation for promoting interoperability and automatic full credit for improvement activities, implementing quality measures that are meaningful to physicians and patients as long as they are not based on administrative claims, and allowing innovative and flexible approaches to measuring costs. However, we believe that significant refinement and clarification of the intent of the proposed criteria are necessary prior to their use.

   It is unclear how the criteria will be used in aggregate to evaluate MVPs. In the current form, the criteria emphasize questions or items that are extremely subjective and duplicative, does not assess overall burden of reporting a proposed MVP, and is less likely to produce information that is meaningful to physicians and patients. Most of the questions solicit information, but no guidance is provided on how the responses would be evaluated if provided. For example, several questions ask whether there are opportunities to improve the quality of care and value in the area being measured, whether the quality measures meet the current program requirements (e.g., demonstrates a performance gap), and if topped out measures can be avoided. All of these questions capture similar information, and we believe that refinements should be made to simplify what is asked. The AMA also asks that CMS clarify the language around what it would approve or disapprove.

4. Patient Reported Outcome, Experience or Satisfaction Measures: Another proposed question that raises concern is whether the MVP would include patient-reported outcome, experience or satisfaction measures. The AMA seeks clarification on the extent an approval of an MVP would be withheld if the response to the question was "not at this time." The AMA seeks more detail on what information CMS would use to ensure that the proposed measure is attributed to the physician or group that can meaningfully influence the outcome, is closely linked to structures and processes that are actionable by physicians, is feasible to implement without unnecessary burden, and produces reliable, valid outcomes. At the individual physician level, we are concerned that it may not be feasible to reliably measure patient experience, such as through CAHPS and/or PROs or satisfaction measures. If that is the case, would a specialty's MVP be rejected, and would an individual physician be prohibited from reporting on the MVP?

   We also very much caution CMS with moving forward with a single question or brief survey to measure the quality of patient experience and satisfaction due to the diversity among physician practice settings and specialties. Patient experience encompasses the range of interactions that patients have with the health care system, including their care from health plans, doctors, nurses, and staff in hospitals, physician practices, and other health care facilities. Patient satisfaction is related to whether a patient's expectations about a health encounter were met.[26] When the Physician Quality Reporting Initiative (PQRI) started, the AMA extensively explored ways to identify and develop universally applicable patient satisfaction measures. However, we found universal measures to be difficult to define in a way that clearly links to measuring an outcome. CMS should invest time and money in expanding GPRO types of measures rather than a one-size-fits-all-measure approach. It also is inappropriate to apply the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) across all specialties. There are site and specialty specific CAHPS surveys due to the clinical uniqueness of medical encounters. Therefore, we would not support mandatory MVP adoption of a single measure that was then aggregated and scored across all physicians. As we have highlighted, the measures associated with an MVP should be specifically tailored to what is most important to measure with the clinical condition.

5. Consistent Denominator: The criteria states that MVPs must be "consistent across the measures and activities within the MVP" which we do not support. Maintaining the denominator criteria across quality measures or all categories would greatly limit the applicability of MVPs to specialists and sub-specialists. Specialists most likely would not have enough patients who meet the denominator across all four MIPS categories. The criteria would also require physicians to report on all four categories for the full calendar year and eliminate the option for physicians to only report on PI and IA for 90-days. Having to report on IA and PI for more than 90-days would greatly increase administrative burden. However, we potentially would consider reporting on PI and IA for more than 90-days within an MVP if CMS modified the category requirements and moved away from treating the two categories as separate. Furthermore, the criteria would lead to significant work by measure developers to modify existing measures and/or create new ones to fit MVP requirements, which we believe is not necessary. It also would significantly delay the availability of MVPs because organizations would have to develop and propose new measures.

[26] What is Patient Experience? Patient Experience Defined. About CAHPS. Agency for Healthcare Research and Quality. https://www.ahrq.gov/cahps/about-cahps/patient-experience/index.html. Accessed 09-05-2020.

6. Capturing the patient voice: While we support having patients at the table during the development of MVPs, CMS must recognize that the burden of participation in the development of quality measures and now, MVPs continues to increase. CMS must ensure that the criteria used to select MVPs are well-defined and applied consistently with a transparent process. This approach will minimize the number of proposals where organizations spend time and resources but may ultimately be rejected by CMS. For instance, it is unclear what CMS defines as "capturing the patient voice" and the level of required patient involvement, if at all. The AMA has several questions about these criteria:

    - Is having a patient involved in the measure development process sufficient?
    - Must a patient have a role in the development of an MVP?

    Therefore, we seek clarification and ask CMS take into consideration that the definition it finalizes may delay inclusion of MVPs in MIPS. Given that some MVPS may be based on existing MIPS measures and patients may not have been involved in the development process, we need additional clarification from CMS.

7. Incorporating QCDR Measures into MVPs: The AMA supports the inclusion of QCDR measures into MVPs. We believe that many of the measures developed and maintained by QCDRs are clinically relevant, would enable reporting across specialties and sub-specialties on quality measures that the current MIPS quality measures do not allow, and promote quality improvement since participants are able to benchmark and track performance against their peers. However, we are concerned by the requirements CMS has laid out for incorporating new QCDR measures into MVPs. If the QCDR requirements are finalized as proposed, it will take years to implement MVPs that incorporate QCDR measures. Therefore, we request that if a steward develops and proposes an MVP including new QCDR measures, CMS should allow provisionary approval of measures until the QCDR can meet the testing requirements. Please see *Quality Category, QCDR Testing Timeline* section comments for more specifics on QCDR testing.

8. Accept and Pilot Test New Cost Measures for MVP: CMS should partner with specialty societies to develop, validate, and implement new cost measures for MVPs. CMS should allow physicians to pilot test innovative and flexible approaches to measuring costs involved in an episode or condition, through MVPs. CMS should also allow for the development and testing of new risk adjustment and attribution methods. For instance, non-patient-facing clinicians may not be attributed to episode-based cost measures but may wish to develop and test a cost measure around appropriate use criteria and clinical decision support. This can ensure that evidence-based screenings and treatments are provided while also preventing inappropriate costs.

    While we continue to support development of episode-based cost measures through the CMS and Acumen LLC process, the limited inventory of episode-based cost measures in MIPS will restrict the availability of MVPs for the next several years.[27] There are currently 18 episode-based cost measures in MIPS and five in development. By comparison, there are 219 quality measures and 106 improvement activities. There are 46 specialty quality measure sets and many more sub-

[27] "To Succeed, MIPS Value Pathways Need More Episodic Cost Measures," Health Affairs Blog, November 14, 2019. DOI: 10.1377/hblog20191107.686469

specialty designations recognized by CMS. MACRA sets a "target of an estimated ½ of expenditures under Parts A and B with such target increasing over time as appropriate" for the MIPS cost measures. CMS is much more likely to reach this target for episode-based cost measures if the agency works with specialty societies to develop, validate, and pilot test new episode-based cost measures as part of MVPs. In addition, we recommend testing the CMS developed measures against specialty society developed cost measures to determine the best approach to measuring and comparing cost.

The AMA is also concerned about the following proposed MVP question: "If there are not relevant cost measures for specific types of care being provided (for example, conditions or procedures), does the MVP include broadly applicable cost measures (that are applicable to the type of clinician)?" It implies that if an episode-based cost measure is not available, the MVP must include a broadly applicable cost measure, including the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures. The AMA has long opposed the inclusion of the TPCC and MSPB measures in MIPS as they hold physicians accountable for costs outside of their control, do not align with quality measures, and face reliability and validity problems. Attribution is also a challenge for many specialties. MVP developers should not have to rely on these problematic measures to advance their MVPs. Instead, CMS should work with the specialty societies to share the costs and burdens of developing new cost measures applicable to MVPs, such as a measure that evaluates the cost-effectiveness of Medicare diabetes prevention efforts in preventing type 2 diabetes. We urge CMS to revise this proposed question to indicate CMS is willing to partner with specialty societies to develop and pilot test new measures that are not currently on the list of MIPS episode-based cost measures.

9. Reporting Burden: **We also note that the criteria do not assess the degree to which the construction of the MVP would reduce reporting burden**. Given that burden reduction was one rationale for moving to MVPs, we believe that it should be included as a specific item within the criteria. Assessment of potential unintended consequences through the implementation of an MVP should also be incorporated, including the degree to which misinformation would be provided through the current benchmarking approach, particularly for cost measures where low cost implies higher quality or whether the inclusion of the clinically relevant, yet topped out measures could provide context to costs.

10. Actionability and Informed Decision Making for Physicians and Patients: The criteria should also assess the degree to which an MVP provides the context and information related to the care provided by a specialty or sub-specialty in a way that is understandable and useful to both physicians and patients. For example, measures that are based primarily on population health and administrative claims would be less actionable for physicians and would not facilitate informed decision-making for patients.

11. Process to Solicit MVP Candidates: While a rolling review process would expedite MVP selection, CMS must ensure that the evaluation is as objective as possible and completed in coordination with the relevant specialties and sub-specialties. Medical specialty societies often report that submission of measures to the MUC process lacks transparency, feedback on why measures were not selected is often perfunctory, and the CMS/contractor responses clearly indicate that the relevant clinical expertise was not consulted during the review. A repeat of this

process must not occur as MVPs are selected. Medical specialty societies must be at the table as any applicable MVP is evaluated and can provide substantive input on the proposals. The input cannot be achieved with one advisory committee, technical expert panel or interdisciplinary committee and CMS must not limit these reviews to one group. The AMA can assist in ensuring that the appropriate specialties and sub-specialties are consulted during the evaluation.

CMS must ensure that any potential MVP is thoroughly vetted across specialties and other stakeholders. While some MVPs may be easily constructed and finalized, we believe that thoughtful consideration and review will be needed for many of these MVPs and the process to approve them must not be rushed. Ensuring the integrity and usefulness of each MVP must be prioritized over expediting their incorporation into the program.

Eliminating review of MIPS measures by the MAP would also significantly accelerate the timeline for measure implementation and help achieve CMS' goal of moving to "Meaningful Measures." For instance, the AMA initiated development of pre-diabetes measures (a MIPS measure gap area and public health priority) roughly two years ago and submitted them for the 2019 Measures under Consideration (MUC) list for implementation in 2021 MIPS. However, due to CMS' testing requirements they were rejected and the earliest these measures may make it into MIPS is 2022 (5 years after initial development). Pre-diabetes and similar important preventive services could be good focus areas for MVPs.

In addition, the lack of reliable MAP processes leads to inadequate review of the measures—especially in the context of considering appropriateness based on program requirements—and unpredictable MAP proceedings and reports issued with limited time to comment. If CMS continues to insist that measures (and future MVPs) must undergo MAP review and requires testing at the time of submission for the MUC list, we recommend the following issues be addressed to improve the MAP process:

- The MAP treats measures undergoing maintenance/updates as if they are under development despite the fact that CMS has data about and experience with the measure, which, if shared, could lead to a more focused and meaningful discussion.
- Stakeholders often only have one week to 30 days to comment on MAP recommendations—depriving stakeholders and the programs of a thorough review and constructive feedback.
- Opportunity to re-review and consider measures after MAP-flagged issues have been addressed by the measure steward.
- Consider new measures (and future MVPs) in the context of the entire program, specifically the existing measures and whether new measures are warranted.
- The deliberations of the MAP coordinating committee and workgroups are highly dependent upon who has a seat at the table. If a measure within a particular specialty area is being reviewed, and that specialty is not represented on the committee or workgroup, legitimate issues may be overlooked, and measure review may be inadequate. The MAP must bring in subject matter experts by specialty if they cannot seat every specialty on the workgroup.
- Notices of opportunities for measure developers or stakeholders to publicly comment are sometimes inadequate. Agendas are all too often unavailable until on or close to the day of a MAP meeting. The order of review of items on the agenda frequently deviates from the published schedule, making it difficult for those not present, including clinicians and the public, to participate or provide comments.

MVP Co-Development: The AMA greatly appreciates that CMS is taking a collaborative approach to co-developing MVPs with physician specialty societies. We also understand that CMS will propose approved MVP candidates through rulemaking. What is less clear from the proposed rule is whether CMS and the co-developing societies will have the opportunity to reach agreement about the MVP measures before the MVP is proposed, assuming it is approved by CMS. **We strongly urge CMS to reach consensus with the co-developing specialty societies about the measures included in the MVP before it is proposed in rulemaking.**

Because the MVP would bear the name of the co-developing specialty society, it is of the utmost importance that there is no surprise about what measures will be included in the MVP when it is listed in the proposed rule. For these reasons, we have concerns with the following sentence: "Since MVPs must be established through rulemaking, as described at § 414.1305, CMS will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the proposed rule." In the final rule, CMS should clarify that the agency will communicate with the co-developer and reach agreement about the measures that would appear in the MVP candidate if it were to be approved and proposed in the following rulemaking cycle.

In addition, we understand CMS has received a number of viable MVP candidates during the previous rulemaking cycle which were not at that time aware of several proposed criteria, such as the patient voice. Specialty societies have devoted significant time and resources to developing MVP candidates. We urge the agency not to start at square one as it resumes co-development for the 2022 rulemaking cycle. Instead, CMS should work with the co-developers to identify any relevant information that would was not initially included as part of the MVP candidate but is necessary to the agency's decision about whether to approve the MVP candidate. Co-developers should have sufficient time to respond and supplement their original proposal according to the new criteria.

B. Merit-based Incentive Payment System Alternative Payment Model Performance Pathway (APP)

The AMA does not support CMS' proposal to eliminate the Merit-based Incentive Payment System Alternative Payment Model (MIPS APM) Scoring Standard and transition all MIPS APM quality measures to the APP measure set. It is unclear how CMS determined that the APP measures are more appropriate than the current measures APMs are evaluated on. The one size fits all approach does not take into consideration the spectrum and variability between the MIPS APM programs or create a set of measures that better inform patients. Many important measurement areas are not captured, such as patient safety. For example, it does not make clinical sense for Bundled Payments for Care Improvement Advanced, or BPCI-A, to be compared and measured on the same set of measures that apply to Comprehensive Primary Care Plus (CPC+) participants. However, it would potentially make sense to utilize the same measure set for CPC+ and Primary Care First (PCF) model participants since they are both primary care focused programs. Quality measurement within APM programs must focus on measures most appropriate to the program and ensure holding organizations accountable for cost does not lead to stinting on care. Therefore, the quality measures must match the goals of the APM.

We also do not support CMS' alternative proposal to allow individuals physicians to opt out of reporting the APP and to report under the standard MIPS requirements and scoring. While the MIPS quality measures may be more appropriate than the pre-defined APP measure set, it is subjecting APP

participating physicians to both the MIPS program, as well as the APM scoring standard. This is burdensome on physicians. Furthermore, we do not support eliminating some of the scoring flexibility provided to APMs, such as pay-for-reporting.

The proposed MIPS APM quality changes are significant and come at a time when APM entities and associated physicians are continuing to deal with challenges and uncertainty caused by the COVID-19 pandemic. **We urge CMS to postpone such drastic and significant changes to the way quality is measured, assessed, reported, and scored under APMs.**

C. Merit-based Incentive Performance System (MIPS)

1. Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

- **Recommendation**: The AMA strongly urges CMS to extend the extreme and uncontrollable circumstances hardship exception flexibilities due to the COVID-19 public health emergency (PHE) through at least 2021.

The AMA greatly appreciates CMS' rapid and flexible response to the public health emergency by adopting MIPS extreme and uncontrollable circumstances hardship exception policies in both 2019 and 2020. **We strongly urge CMS to continue to provide flexibility to physicians by extending these policies through 2021 in the final rule.** Physicians need flexibility and minimal administrative burdens to ensure they are able to continue to meet the needs of patients while confronting new COVID outbreaks and slowing the spread of the virus. Physician practices have been under severe distress and experienced unprecedented practice disruptions during 2020. While the duration of the pandemic is unknown, it is reasonable to expect ongoing impacts from the novel coronavirus into 2021 and months or years of recovery.

Following Medicare and CDC guidelines during the public health emergency, many practices delayed or cancelled care, resulting in reduced revenues for physicians and a changing care delivery system. While many practices have received payments from the CARES Act Provider Relief Fund and loans from the Medicare Advance Payment Program, they remain in financial distress. We are deeply grateful to CMS for being a leader in expanding access to telehealth for Medicare beneficiaries, which physicians quickly implemented in order to continue furnishing care. However, some care cannot be furnished by telecommunications and to resume in-person care, practices have had to institute new safety and cleaning protocols, which limits the number of patients that can be seen a day. Some patients also continue to delay in-person visits or procedures due to fear of infectious disease exposure. Patients with comorbidities and social risk are likely to suffer adverse outcomes due to delaying or not receiving care.[28] Physicians may

[28] Kaiser Health News, "Nearly Half of American Delayed Medical Care Due to Pandemic": https://khn.org/news/nearly-half-of-americans-delayed-medical-care-due-to-pandemic/; The British Medical Journal, "Delayed presentation of acute ischemic strokes during the COVID-19 crisis": https://jnis.bmj.com/content/early/2020/05/27/neurintsurg-2020-016299; US National Library of Medicine National Institutes of Health, "Hospitalization for Ambulatory-care-sensitive Conditions in Taiwan Following the SARS Outbreak: A Population-based Interrupted Time Series Study": https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135451/.

need to devote additional resources to caring for these patients in 2021 and future years. CMS will not have a clear picture of how 2020 MIPS participation and performance was impacted by the COVID-19 public health emergency until mid-way through 2021 or later, but we caution against waiting until then to make a decision about extending the MIPS extreme and uncontrollable circumstances flexibilities. The earlier CMS announces an extension of these flexibilities, the more physician practices can plan and determine the best way to allocate resources toward patient safety, keeping their doors open, continuing to combat the COVID-19 pandemic, and ongoing participation in MIPS.

2. MIPS Performance Threshold and Additional Performance Threshold

- **Recommendation:** The AMA strongly supports CMS' proposal to lower the previously-finalized 2021 performance threshold due to the disruptions caused by the COVID-19 PHE. While we appreciate CMS' proposal to reduce the threshold from 60 points to 50 points, we encourage CMS to consider maintaining the performance threshold at 45 points, which is the performance threshold in 2020. We also urge CMS to similarly reduce the additional performance threshold.

The COVID-19 public health emergency is an ongoing crisis and continues to strain physician practices which are facing reduced revenues and increased expenses to implement new safety protocols. In light of these hardships, CMS proposes to lower the performance threshold to avoid a corresponding MIPS penalty from the previously finalized 60 points to 50 points. We agree with CMS that some clinicians will not have sufficient measures and activities to participate in MIPS in 2020 and will opt out of MIPS entirely or specific MIPS categories through the extreme and uncontrollable circumstances hardship exception policies. It would be difficult to re-enter the program at a much higher performance threshold after a gap due to the pandemic. Additionally, clinicians on the frontlines combatting COVID-19 have not had time to focus on MIPS. We also believe some physicians will have opted out of participating in 2019 due to the overlap of the start of the public health emergency and the data submission period in early calendar year 2020. Finally, none of us know what the future will bring, how long the pandemic will continue to spread in communities throughout the country, and the long-term impacts of COVID-19. **For these reasons, we strongly support CMS' proposal to lower the performance threshold for 2021 and urge CMS to maintain the threshold at 45 points.**

Maintaining the performance threshold at 45 points will also help small and rural practices, which are at risk of closing due to their financial distress and have even fewer resources to devote to participation in MIPS. In addition, stability is essential as the final rule may not be released until as late as Dec. 1, 2020, giving physicians only one month to familiarize themselves with changes to the program that could result in significant penalties.

Similarly, we urge CMS to lower the additional performance threshold to ensure it is obtainable by physicians in all specialties, practice sizes, and geographic locations who continue to confront challenges posed by the ongoing COVID-19 pandemic. We disagree with CMS that it is necessary to maintain the additional performance threshold at 85 points to incentivize high performers. We question whether keeping the threshold at 85 points would actually discourage physicians from fully participating in MIPS if they believe the threshold to earn an exceptional bonus is unattainable due to the pandemic and significant uncertainty about benchmarks, attribution, and measure denominator requirements. Although we cannot predict the status of the public health emergency in 2021, it is reasonable to assume based on currently available information that physician practices will continue to be impacted by the pandemic into

2021 and will need months if not years to recover. We strongly urge CMS to err on the side of providing more flexibility and incentives to encourage participation in MIPS while physician practices continue to fight COVID-19.

3. Quality Category

- **Recommendation:** The AMA believes that MIPS continues to miss opportunities to drive improvements in patient outcomes and cost savings through the siloed approach of prioritizing population health administrative claim-based measures and outcome measures paired with unrelated cost measures.

As with all clinical care, to only focus on narrow and disconnected components and not on increasing preventive services and processes directly linked to outcomes limits physicians' ability to truly drive improvements in the long term. For example, in a recent retrospective review of commercial administrative claims, researchers identified that within at least five years prior to the initial diabetes diagnosis, health care costs begin to rise and continue to increase once the diagnosis is confirmed.[29] This finding supports efforts to identify and address the early warning signs of prediabetes – all of which would be addressed through process measures and not through measurement of outcomes. By focusing on the downstream effects of clinical care rather than these upstream opportunities, the U.S. health care enterprise will never truly achieve our collective goal.

These concerns are further validated through the continued efforts by CMS to remove quality measures from MIPS with no thoughtful consideration of whether there are relevant replacements, if the measure is truly topped out and not just representative of top performers or one data source, and the inclusion of measures where clinical experts question their underlying evidence and validity. We continue to see proposals to remove quality measures from this program, yet on review of what is submitted to the Measures Application Partnership (MAP) and included in proposed rules, there appears to be an increasing emphasis on population health and not measures that are derived from clinically rich electronic data at the point of care. Physician specialty organizations also report that it has become increasingly difficult to have a measure selected for inclusion in the Measures Under Consideration (MUC) process and rejections are often arbitrary, use boilerplate language that lacks detail on the true concerns with the proposed measure, and do not appear to be aligned with the MUC criteria. For example, the American Society of Retina Specialists (ASRS) submitted electronic clinical quality measures (eCQMs) during the most recent MUC cycle, which served to fill a gap in available measures for this sub-specialty and addressed the high priority area of care coordination by ensuring appropriate follow-up. All were rejected with minimal feedback and demonstrated a lack of understanding and clinical expertise on the topic. In addition, while ASRS attempted to develop an outcome measure addressing a key safety issue in retina care for consideration, most providers had performance scores at or near zero, leading to an insufficient distribution of rates that would not be easily implemented in the current MIPS benchmarking approach. Each year, the MAP is asked to consider smaller and smaller numbers of quality measures for potential implementation in MIPS, yet CMS continues to remove measures without a clear understanding of the disconnect and increasing lack of relevance of the program to clinicians.

[29] Khan T, Yang J, Wozniak G. Trends in Medical Expenditures Prior to Diabetes Diagnosis: The Early Burden of Diabetes [published online ahead of print, 2020 Feb 3]. Popul Health Manag. 2020;10.1089/pop.2019.0143. doi:10.1089/pop.2019.0143

Weight in the Final Score

- **Recommendation:** The AMA strongly urges CMS to maintain the weight of the quality category at 45 percent of the final MIPS score for the 2021 performance year in light of the unknown impact of the COVID-19 pandemic on the cost measures, frontline physicians' focus on continuing to care for patients during this crisis, and to provide physicians more time to familiarize themselves about their resource use.

CMS was granted increased flexibility in the Bipartisan Budget Act of 2018 (BBA) to set the performance threshold and category weights, and the AMA urges CMS to follow congressional intent. Altering the category weights before the cost category has been sufficiently refined leads to less stability with the program, adds complexity, and is counter to the Patients Over Paperwork initiative. The measures under the cost category are new. In addition, many have questionable reliability, and it is unknown how the COVID-19 PHE will impact costs, including the addition of payment for telehealth. Physicians need time to review their cost data and opportunity to make improvements in practice. CMS is discrediting the effort, time, and money required to make changes into practice based on administrative claims measures. **We urge CMS to maintain the quality performance category final score weight at 45 percent in 2021 while the agency reviews the impact of COVID-19 on the cost measures.**

Quality Performance Collection Types

- **Recommendation:** The AMA recommends CMS postpone transitioning away from the GPRO web-interface and associated measures until 2023.

While only about 20 percent of users of the GPRO Web-Interface participate in MIPS, the AMA does not support CMS' current timeline to eliminate this collection type. CMS provided no advance notice on this proposal, and practices will only have one month to transition to a new collection type, upgrade their IT systems and begin reporting on all-payer data due to the timing of the release of the final rule in the middle of a global pandemic. We recognize that practices can report on the same measures through other collection types, but CMS' proposal and argument within the rule fail to recognize the time it takes to transition, and the costs required to upgrade reporting tools.

We also believe the timing is poor given CMS plans to transition the program to MVP. Practices will essentially have to transition multiple times over the next few years, which is extremely burdensome, costly and does not allow for continuity with reporting quality measures. Continuity is necessary for comparisons, improvement and to allow patients to make informed decisions about care.

Topped-Out Measures

- **Recommendation:** We urge CMS to maintain topped-out measures that have a linkage to cost measures or MVPs so the program begins to measure value. We also urge CMS to revise the existing quality measure benchmark methodology to incorporate more of a manual+data driven approach, which will allow for less clustering of data.
  The AMA remains concerned with CMS' handling and evaluation of topped-out measures.

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. For example, when we examine the changes in rates on these measures over time, many measures demonstrate gaps in care and sufficient variation initially; however, physicians were able to improve performance across reporting periods. We are 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 of their patients, especially as we begin to measure cost of care. We also believe 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 medical record* measure, which was developed by CMS, has been listed as topped-out since 2017 but remains in the program. We recognize that it is a widely reported measure, but CMS must be consistent with its policies. Otherwise, it is providing the perception that is biased towards its own measures and not transparent with evaluation.

In addition, 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. The lack of measures for which a specialty can report must also be considered. We do not see any discussion what the potential impact might be to any specialty within the proposed rule.

Furthermore, the AMA continues to hear from physician specialty organizations that the program includes measures that are not based on strong clinical evidence and remain in the program because it appears they address a high priority area. As specified, these measures yield results that are not clinically valid. For example, the American Academy of Orthopedic Surgeons (AAOS) and the American Association of Neurological Surgeons (AANS) recently expressed concerns with *MIPS 459: Back Pain After Lumbar Discectomy/Laminectomy*, which is currently under consideration for endorsement by the Core Quality Measures Collaborative (CQMC). At its highest level, the measure is fundamentally flawed in that it uses an inappropriate patient-reported outcome to evaluate the procedure at hand. More specifically, the measure considers chronic low back pain to evaluate the effectiveness of lumbar discectomy/laminotomy even though these procedures are performed for leg pain and neurogenic claudication (pain, tingling, weakness/heaviness in legs) and not for low back pain. The measure also relies on a visual analog scale (VAS) score whereas most centers use a numeric rating score (NRS). These scores are collected differently (e.g., the VAS is a pain thermometer, making it difficult to assign numeric values for analysis). The NRS is utilized most in the current spine literature. Additionally, the measure relies on specific targets for pain that have no basis in literature (i.e., "For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) post-operatively."). These thresholds are problematic and assume improvement is possible when it may not be clinically achievable. While a VAS or Numeric Rating Score (NRS) less than 3.0 may be a reasonable target, a change of 5 points is a very aggressive target that would be challenging to achieve in a very high percentage of cares. Minimal clinically important difference (MCID) for NRS leg pain is 1.6 and substantial clinical benefit (SCB) is only 2.5 (reference attached). A change of 5 points would only be achieved in a very small minority of cases.
To date, CMS has been unable to benchmark this measure under MIPS due to low reporting rates, which is very likely due to the lack of clinical relevance and validity of the measure results. While we highlight

only one measure, it is not the only measure where medical specialties question the relevance and validity of the set of quality measures available for reporting. CMS must ensure that all measures within the program meet the minimum set of criteria and be responsive to feedback from specialties.

Lastly, **CMS must consider the extent to which the expansion to telehealth in many of the quality measure denominators will impact benchmarking and the reliability and validity of the measures.** While these changes on the types of visits for inclusion are noted in the proposed rule, their potential impact is not discussed and thought should be given to what additional information will be needed to ensure the reliability and validity of these measures and how benchmarking may be affected.

CMS must work to ensure that there is enough evidence-based, reliable and valid measures available for physicians to report. Otherwise, there is significant risk that any potential usefulness of this program to advance the quality of care provided to patients will be eliminated.

We once again offer the following recommendations to improve the process:

- **Process Measures**: Process measures, for which there is strong evidence that fulfillment of the measure intent, such as providing or not providing a specific treatment, will improve patient outcomes or safety, should be retained. CMS should exercise caution in measure removal until possible unintended consequences of removing each measure has been explored. The unintended consequences of removing key topped-out measures are unknown. If a topped-out measure directly impacts outcomes and is no longer reported, its removal may cause negative effects on patient care.
- **Outcome Measures**: There are very few outcome measures in the program, and it is difficult to measure through a quality measure. A specialty should not be penalized because it has good outcomes on a procedure. Instead, CMS should incentivize and encourage good patient care.
- **Analysis**: Physician performance can vary by practice setting, patient population, geography, years in practice, volume of cases of a particular condition, or how long the physician has been reporting. We urge CMS to examine the breadth and depth of reporting based on the number of physicians who successfully report on a measure and the length of time a measure is reported on within a given performance year.
- **Benchmark Methodology**: We urge CMS to revise the existing quality measure benchmark methodology to incorporate more of a manual driven approach which will allow for less clustering of data.
- **Consultation with Measure Stewards and Specialties**: CMS should consult with measure stewards and specialties to determine whether a measure is in development that could replace the topped-out measure. If a measure is almost ready for implementation but needs a little more time, then it should be kept in the MIPS program until it can be replaced.
- **Performance Results**: Performance results of a measure being considered for removal should be examined for any evidence of variation among subgroups defined by the above factors and other nonclinical factors. For example, are primary care physicians who treat patients in the nursing home showing different results on their diabetes patients because they care for sicker, frail, and elderly patients?
- **Reporting Options**: CMS should refrain from removing or classifying a measure as topped-out until it is topped-out across all reporting options. If the reporting mechanism produces

substantially different results, it may indicate an issue with the measure itself (e.g., the ability to accurately capture quality, potential bias in inclusion/exclusion).

- **Data Sources**: We encourage CMS to compare the scores to other current data as a possible way to verify if the scores are reflecting true performance. For example, if a study or clinical registry shows a gap in care remains, then the performance scores in MIPS may not reflect performance across all physicians. The results of these subgroup analyses should also be shared with the relevant stakeholders.

- **Recommendation:** Maintain topped-out scoring policy and flexibility CMS proposes for the 2021 performance period to future years. We urge CMS to reconsider utilization of 2020 or 2021 data for topped-out policies due to the pandemic.

Due to COVID-19, CMS proposes to not limit the number of measure achievement points for measures which have not been topped-out for at least two years as published in the 2020 MIPS performance period historic benchmarks and the AMA is supportive of the proposal. The AMA does not believe topped-out measures should be capped at seven points because for many specialties, topped-out measures continue to remain meaningful measures to report and practices should not be penalized for reporting on them. We urge CMS to extend the policy of not capping achievement points for topped-out measures into 2021 and future years.

Furthermore, **given the impact the COVID-19 pandemic has had on care, we recommend CMS to not utilize 2019, 2020 or 2021 data for determining topped-out measure status or setting historic benchmarks**. Care has been drastically altered due to the pandemic and the data should not be utilized for determining true or baseline performance. We very well may see that measures that have historically been topped-out may no longer be topped-out, for years to come due to the impact the pandemic has had on care.

Complex Patient Bonus for the 2023 MIPS Payment Year

- **Recommendation:** The AMA urges CMS to increase the composite score complex patient bonus. We also urge CMS to expand favorable scoring policies to small practices throughout the MIPS categories. Limiting the favorable scoring to the quality category is insufficient.

Based on the first year of MIPS data, there is evidence that physicians and practices that treat a higher percentage of patients with social risk factors performed worse than those practices that did not treat a high number of patients with these risk factors.[30] There is also evidence that MIPS adversely effects independent and safety net physician practices.[31] CMS should not develop a program that creates winners and losers based on the size of a practice or the patients that they treat. If not addressed, we predict there will be more physician consolidation in the marketplace.

[30] 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

[31] 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

We also strongly encourage CMS to continue to identify new data sets and strategies to better represent the clinical and social complexity of the patients seen by physicians or practices participating in MIPS. Adjustment based on the Hierarchical Condition Category (HCC) and the number of dual eligible patients serves as an acceptable proxy to capture the clinical complexity of the patient panels for a physician or practice. However, this approach does not sufficiently identify those patients with social 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.

We are concerned that the current approach CMS utilizes for determining the complex patient bonus for 2022 and 2023 performance periods is compromised and unreliable due to COVID-19. The formula CMS relies on to evaluate patient complexity utilizes a lookback period (i.e., the previous 12 months) to determine which variables should be considered for risk adjustment. Due to this lookback period, the disruptions to patient care as a result of the pandemic in 2020 will continue to distort and compromise the data in 2021. We are hearing about many barriers to resuming patient care, including fear among patients that they may be exposed to the virus, the difficulty and expense of procuring personal protective equipment, limited access to testing, and health insurance coverage losses due to layoffs and unemployment. This is magnifying existing barriers to care, such as transportation to make and keep appointments.

Performance Period Benchmarks for 2021 MIPS Performance Period

- **Recommendation:** The AMA supports CMS' proposal to use performance period benchmarks for the CY 2021 MIPS performance period rather than baseline period historic data due to the COVID-19 pandemic. The AMA agrees with CMS' concerns that 2019 performance data may not be a representative sample of historic data because of the flexibilities CMS instituted regarding submission of 2019 data. CMS must also explore the impact the use of 2019, 2020 and 2021 data will have on setting benchmarks and risk-adjustment models and consider scoring based on pay-for-performance.

We are disappointed that CMS did not take a proactive approach and outline policy adjustments given that the pandemic is expected to continue into 2021 and will impact historical data for use in future years. Care delivery and interactions with patients have been significantly disrupted and any data from these years are likely to not represent a true clinical performance. CMS must be cautious and avoid assessing and scoring performance on any data from 2019, 2020 and 2021, as data from each of these years are likely not a representative sample. This concern applies to all measures but we believe that **CMS must also consider not only those measures that use these data for measure denominators, such as the RSCR following elective primary THA and/or TKA but also for the HWR and cost measures, which use lookback periods (e.g., the previous 12 months) to determine what variables should be considered for risk-adjustment.** The disruptions to patient care and subsequent impact the pandemic has had on data submission will likely distort and compromise the data. **The problem extends to not only the measures that include an expanded performance period but also to measures that include a lookback period for risk-adjustment. As a result, we ask that any measure impacted by this issue be considered pay-for-reporting in the applicable performance period and full credit for the measure achieved.**

It also is unreliable to default to the use of 2018 data because CMS started paying for telehealth visits in 2020. Therefore, 2018 is no longer a representative sample to compare to 2020 or beyond.

MIPS Benchmark Methodology Analysis and Recommendations for Improvement

- **Recommendation:** We urge CMS to revise the MIPS benchmark methodologies to allow measure thresholds to incorporate clinical knowledge and evidence, consider the impact of random fluctuation, and be adjusted for practical considerations of comparison and relative performance. To address the shortcomings of the existing benchmark methodologies, we suggest that CMS implement a methodology that allows for manual manipulation of thresholds.

We recognize CMS is not seeking comment on the methodology it utilizes to calculate MIPS benchmarks for quality and cost measures, but we once again highlight the need for CMS to revise the methodology. A revised methodology will better allow CMS to handle random fluctuation in numbers due to small sample sizes, topped-out measures, better incorporate clinical knowledge, and move to one scoring methodology for MIPS and Physician Compare.

MIPS awards points to physicians based on their performance relative to decile-based categories calculated from historical data (when available), while Physician Compare Star Ratings use a five-point rating system. Therefore, our main concerns with the MIPS benchmark methodology are:

1. For topped-out or highly skewed data, thresholds are clustered close together (meaning that similar performance may not result in similar points awarded) and even relatively high performance can place a physician in one of the lower deciles. For example, a physician could score 88 percent and be in the 4th decile while another physician scores 92 percent and is in the 8th decile. Therefore, on the same measure two physicians can perform very similarly on the measure but may be awarded very different points;
2. There is a lack of consideration of the role played by random fluctuation, especially for small denominators;
3. Strictly data-driven thresholds may conflict with clinical knowledge and evidence of ideal performance or with practical considerations of quality;
4. There may be significant changes to the population of physicians and groups between the time that the historical data represents (2 years prior) to the time period to which the resulting thresholds are applied; and
5. Under certain circumstances, physician performance score under MIPS may differ significantly from their performance under the Physician Compare methodology, even for the same measure.

We urge CMS to revise the benchmark methodologies to allow measure thresholds to incorporate clinical knowledge and evidence, consider the impact of random fluctuation, and be adjusted for practical considerations of comparison and relative performance. To address the shortcomings of the existing benchmark methodologies, we suggest that CMS implement a methodology that allows for manual manipulation of thresholds. These adjustments would allow for enough flexibility to address the above issues when they arose. We acknowledge that this would add process to an already complex method, but we believe that what is most important is ensuring the fairness and clinical relevance of the measured benchmarks. We further acknowledge that there may be modifications to the

methodology other than what we suggest which may also address our concerns and welcome the opportunity to discuss further with CMS. Please see AMA's 2019 Physician Fee Schedule/ Quality Payment Program Proposed Rule Comments for more detailed analysis and recommendations on the issue.

Scoring Flexibility for Changes that Impact Quality Measures during the Performance Period

- **Recommendation:** The AMA is concerned with CMS' proposal to truncate the reporting period when updates occur to a quality measure during the performance period. We urge CMS to work with measure stewards and relevant specialties to evaluate the data to determine whether a cut off of nine months skews performance.

While we understand the need for additional flexibility in scoring when updates occur to a quality measure during the performance period, it is not clear how CMS will determine when it is appropriate to truncate the reporting period rather than suppress the measure. CMS provides no data or research to support a cut off of nine months. Decisions on whether a measure should continue to be used to evaluate physician performance and data not suppressed must be done in consultation with relevant specialties in addition to the developer. We also urge CMS to make this process as transparent and objective as possible to ensure that physician performance is not misrepresented, and its use does not lead to patient harm.

Proposed New 2020 Measures

1. *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) Eligible Clinicians*

- **Recommendation:** The AMA does not support CMS' proposal to include the RSCR THA and/or TKA for MIPS measure. If CMS finalizes the measure it must delay implementation of the measure, not include 2020 data, and provide advance notice given the measure utilizes retrospective data.

The AMA has similar concerns with this proposed measure as what we outline for the HWR measure. Specifically, the information provided at the time of the preliminary public comment in 2018 followed by the recent NQF review reinforced our concerns that there is insufficient evidence on how an individual physician or practice could reduce complication rates in these patients and the scientific acceptability of this measure is questionable.[32] The low minimum reliability score when applying this measure to eligible clinicians with more than 25 admissions was 0.582 for eligible clinicians and 0.463 for eligible clinician groups, which are well below the minimum acceptable threshold of 0.7.[33]

[32] Centers for Medicare and Medicaid Services. Development and Reevaluation of Outpatient Outcome Measures for the Merit-based Incentive Payment System. Public Comment Page: Currently Accepting Comments. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Outpatient-MIPS-MCC-Measure-Development.zip. Last accessed June 11, 2019.

[33] Centers for Medicare and Medicaid Services. Development and Reevaluation of Outpatient Outcome Measures for the Merit-based Incentive Payment System. Public Comment Page: Currently Accepting Comments. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Outpatient-MIPS-MCC-Measure-Development.zip. Last accessed June 11, 2019.

We also question whether the measure will reach acceptable reliability level given it utilizes retrospective claims data that includes data from 2020. Given elective procedures were halted for a period of time in 2020, we are extremely concerned the impact COVID-19 may have on volume and outcomes. **We do not believe any physician should be evaluated on outcomes that includes 2020 data due to the amount of obstruction that have occurred with care. Finally, information on how the measure would perform using the MIPS benchmark methodology and Physician Compare Star Ratings has not been provided.** All of the concerns must be addressed prior to finalizing this measure for inclusion in MIPS.

2. *Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups*

- **Recommendation:** The AMA does not support the HWR for MIPS measures until appropriate evaluation and potential refinements to the measure can be made. Physicians should not be held accountable for the HWR measure and the updated measure should be removed from the program.

While we are encouraged to see that CMS proposes to continue to only apply the revised Hospital-Wide Readmission (HWR) measure to groups of 16 or more clinicians and only those with a case minimum of 200 patients or greater, the AMA continues to have serious concerns with the measure that warrant attention and consideration. The HWR measure lacks transparent evaluation on whether it is appropriate to apply the readmission of one patient to multiple physicians since no evidence or testing was provided to support the attribution of this measure to the three distinct groups (discharge physician, primary inpatient care provider, and outpatient primary care provider) during the National Quality Forum (NQF) endorsement review. In addition, while we agree that there is evidence to demonstrate that improved care coordination and programs focused on discharge planning can lead to reductions in hospital readmissions, most of the evidence used to support attribution to physicians involves multiple partners and clinicians such as the health system, hospital, nurse, and/or pharmacist. Insufficient evidence was provided to support that physicians and practices using the proposed attribution approach in the absence of some coordinated program or targeted intervention led by the health system and/or hospital can implement structures or processes leading to improved outcomes for these patients.

The AMA questions the ability of the HWR to meaningfully distinguish better or worse performers based on the available benchmarks from the 2017 performance period. Performance ranged from 13.82 percent to 15.7 percent across the clinician groups to whom the measure was applied. Using the current benchmarking approach, there is a less than 2 percent difference in performance when distributed across the seven deciles and less than half a percentage point difference captured within each decile. Therefore, there is a need to examine the data to determine if additional reductions in scores can be made in readmissions since the readmission rates, including in the Inpatient Readmission Reduction Program are now somewhat stable. Minimal improvements (decreases in rates) are now seen for most, if not all of the readmission measures, but we are unable to know whether the rates have plateaued because there is no more room for improvement. Nor do we know if all of readmissions the measures capture are truly appropriate readmissions. This further leads us to question the utility of the HWR measure within MIPS.

Continuity of care also requires smooth transitions to prepare for patients' changing clinical and social needs, but the Stark law often impedes the continuity of care transitions. Specifically, in certain

circumstances, physicians are prohibited from employing promising care coordination strategies on behalf of their patients, e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient's care among a hospital, physician specialists, or a primary care physician due to concerns that this may induce future referrals to their own office to avoid an unnecessary readmission to the hospital. As a result, we do not believe that assignment of responsibility of the reduction of readmissions to multiple physicians and practices in MIPS is appropriate.

In addition, **the impact that social risk factors in the risk adjustment model could have on the absolute change of performance rates has not been fully explored.** These shifts could potentially influence the points physicians score in the Quality Category in MIPS and as a result, either positively or negatively impact the overall penalty or incentive they receive and the resources available for those whom serve larger numbers of disadvantaged patients. This information in addition to understanding how the measure performs using the MIPS benchmark methodology and Physician Compare Star Ratings since CMS utilizes two different methodologies for ranking and profiling physicians must be provided.

Therefore, **until appropriate evaluation and potential refinements to the measure can be made, physicians should not be held accountable for the HWR measure and the measure should be removed from the program.**

Data Completeness Criteria

- **Recommendation:** Reduce the data completeness criteria from 70 percent back to 60 percent for all reporting mechanisms. However, the AMA continues to believe 50 percent is a sufficient threshold.

For the 2020 performance period, CMS increased the data completeness to 70 percent of the MIPS eligible clinician, group, or virtual group's patients (and applicable Medicare Part B patients for Medicare Part B claims measures) that meet the measure's denominator criteria. The AMA continues to oppose this policy **and urges CMS to reduce the data completeness criteria back to 60 percent of eligible patients but continues to believe 50 percent is sufficient.** The increased reporting requirement is counter to the Administration's Patients Over Paperwork initiative. 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 and all-payer data.

We believe CMS did not take into consideration the following factors when increasing the data completeness threshold:

- The increased threshold is more difficult and burdensome for small and rural practices to meet.
- Some specialties provide services across multiple sites using the same National Provider Identifier (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. For instance, the ease of reporting is frequently based on the number of facilities for which the group provides services. For many measures, the radiology or pathology practice must rely on the

hospital to assist in data extraction from hospital systems for the group to report measures. The more facilities that a group works with, the harder it becomes. A good working relationship with hospital staff, particularly IT, is also key in successful extraction of data.

- If a group begins providing services to a new hospital or facility during the reporting year it can be difficult and burdensome to develop processes for reporting for that year. This factor alone could prevent a group from meeting a 70 percent threshold.
- We believe the average rate of reporting is actually less than 70 percent because the statistic does not include data on patients that are not captured in the registry or EHR.
- The time it takes to implement new measures or updates to measures into practice workflow or the registry or EHR and further discourages practices from reporting on new measures. EHR vendors often charge for any requested changes. CMS also does not release educational materials in a timely manner and often in the middle of the performance period.
- If vendors are cherry-picking cases on which to report, then CMS should implement corrective action plans with these vendors, rather than increase reporting burdens for all MIPS-eligible clinicians. Alternatively, CMS could institute requirements around randomized sampling of patients to guard against cherry picking. All physicians in MIPS should not be penalized and face unrealistic requirements for a bad actor.

Therefore, until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings, and providers, it is premature to increase data completeness and encourage reporting through a registry or EHR.

QCDR Testing Timeline

- **Recommendation:** We ask that CMS reconsider the proposed QCDR testing requirement that testing on reliability and validity for new measures must be submitted by the next self-nomination period. Due to QCDR's reliance on prospective data collection, QCDRs need two nomination cycles to produce the testing data.

While the AMA supports the testing submission extension that CMS provided to Qualified Clinical Data Registries (QCDRs), we ask that CMS reconsider the proposed requirement that testing on reliability and validity for new measures be submitted by the next self-nomination period. Many QCDRs are reliant on prospective data collection to generate the data required for reporting and testing; therefore, we do not believe that it is reasonable to assume that QCDRs will have 12 months of data available and analyzed by the next self-nomination period (currently, September 1). For example, if the measure is approved in 2020, then the QCDR has until the 2020 self-nomination period to complete testing, essentially two cycles. Finalizing this requirement could lead to increased fluctuations in the measures available to MIPS participants since QCDRs will likely not be able to complete testing in this time, leading to measures being removed after one year of implementation. Alternatively, they may be forced to use smaller sets of data to assess reliability and validity, which may skew results – not based on true concerns with the measure but based on what information was available for testing. As a result, **we strongly encourage CMS to require testing as the QCDR submits the measure for its third year in the program, which would lead to less unnecessary changes on the annual QCDR approved measures list.**

CAHPS Changes

- **Recommendation:** While the AMA supports the expansion of Medicare coverage to include telehealth services, we do not believe CG-CAHPS should be expanded at this time to include telehealth visits.

The AMA supports the expansion of Medicare coverage to include telehealth services and agrees that it would be useful to assess the effectiveness and patient satisfaction of these services over time. Yet, this does not appear to be what CMS proposes, rather the proposed new measure would assess usage of these new services. **Any change to CAHPS such as the addition of a measure must be completely transparent and the new specifications with results from reliability and validity testing should be made available.** For example, it is not clear what value add the inclusion of this new measure will provide – is it to determine whether patients understand that they are receiving services through these new communication vehicles, assess their satisfaction by using telehealth rather than a face-to-face visit, or is there some other purpose? To what extent do patients understand the differences between visits conducted through telehealth versus those that are in-person and can distinguish which type was appropriate based on their medical needs? In addition, will this new measure be used to assess physician performance and included in scoring for the measure? This proposal lacks enough information to determine whether its addition is appropriate, and the AMA does not support its inclusion at this time.

In addition, the inclusion of telehealth services in CAHPS leads us to question how this expansion impacts the reliability and validity of the measure. As with any quality, population health administrative claims, or cost measure, we must understand the degree to which these new visits impact the integrity of the measure. CMS must ensure that measure results on patient satisfaction remain reliable and valid with the addition of telehealth services and that no modifications to the survey questions and resulting measures are required.

4. Cost Performance Category

i. Weight in the Final Score

- **Recommendation**: The AMA strongly urges CMS to maintain the weight of the cost category at 15 percent of the final MIPS score for the 2021 performance year in light of the unknown impact of the COVID-19 pandemic on the cost measures, frontline physicians' focus on continuing to care for patients during this crisis, and to provide physicians more time to familiarize themselves about their resource use. We also continue to recommend that CMS reweight the cost category to zero in instances where cost performance variation is due to factors outside the control of the physicians during this PHE.

The AMA greatly appreciates that CMS does not propose significant changes to the cost category for 2021 in light of the ongoing impact of the COVID-19 pandemic on physicians and Medicare beneficiaries. We are concerned there will continue to be disruptions to the cost measures in 2021 and possibly beyond due to the pandemic. **We urge CMS to maintain the cost performance category final score weight at 15 percent in 2021 while the agency reviews the impact of COVID-19 on the cost measures and to give physicians more time to become familiar with the sweeping MIPS cost performance category changes that took effect in 2020 during the pandemic.**

Because the cost measures rely on national average benchmarks, we are concerned that the physicians and practices who have been on the frontlines of testing, treating, and fighting COVID-19 in hot spots will be penalized. We believe this is particularly true with respect to the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures, which are blunt instruments that penalize physicians who care for patients with complications, admissions, and readmissions – unfortunately common scenarios during this public health emergency (PHE). On the other hand, many physician practices continue to face financial peril due to reductions in patient visits and surgeries resulting from stay-at-home orders and due to limited personal protective equipment, and they may not have a reliable case minimum for the TPCC, MSPB and episode-based cost measures. In addition, postponing preventive and routine care will skew patient attribution toward the sickest patients. **We understand CMS is monitoring the impact of the PHE on the MIPS cost measures and urge CMS to disclose those findings as quickly as possible. If the PHE causes disruptions to attribution and reliability, validity, actionability, or would negatively impact physicians on the frontlines of the COVID-19 pandemic, we urge CMS to reweight the cost performance category to zero.**

We also continue to have concerns about the effectiveness of the risk adjustment methodologies during a rapidly spreading pandemic that more severely affects economically and socially vulnerable patients, as well as patients with comorbidities. Evidence continues to show the virus has a disproportionate impact on racial and ethnic minorities, people facing homelessness, individuals in long-term care facilities, older adults, and individuals with underlying medical conditions.[34] CMS would need to carefully assess the current risk adjustment methods and their sensitivities to these variables. **While we appreciate CMS proposes to increase the patient complexity bonus from 5 points to 10 points in 2020, we do not believe this is sufficient. At a minimum, CMS should continue the increased complexity bonus into CY 2021**.

As outlined in more detail in our comments about the Quality Performance Category, the cost measures use a lookback period (i.e., the previous 12 months) to determine which variables should be considered for risk adjustment. Due to this lookback period, the disruptions to patient care as a result of the pandemic in 2020 will continue to distort and compromise the data in 2021. We are hearing about many barriers to resuming patient care, including fear among patients that they may be exposed to the virus, the difficulty and expense of procuring personal protective equipment, and limited access to testing. This is magnifying existing barriers to care, such as transportation to make and keep appointments.

Additionally, physicians continue to familiarize themselves with the cost measures but have only received detailed feedback on their attributed patient population and cost measure performance for CY 2018 and 2019, which is when the first wave of episode-based cost measures went into effect. However, CMS made substantial changes to the cost category in 2020, including adding 10 new episode-based cost measures and significantly revising the total per capita cost (TPCC) and Medicare Spending Per Beneficiary

[34] Centers for Medicare & Medicaid Services, Preliminary Medicare COVID-19 Data Snapshot, https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf; Centers for Disease Control and Prevention, COVID Data Tracker, Demographic Trends of COVID-19 cases and deaths in the US reported to the CDC, https://covid.cdc.gov/covid-data-tracker/#demographics; Mueller AL, McNamara MS, Sinclair DA. Why does COVID-19 disproportionately affect older people?. *Aging*. 2020;12(10):9959-9981. doi:10.18632/aging.103344; The New York Times, "The Fullest Look Yet at the Racial Inequity of Coronavirus," https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latinos-african-americans-cdc-data.html.

(MSPB) measures. These changes took effect during the PHE when physicians' focus shifted toward diagnosing and treating a novel coronavirus, rapidly implementing telehealth, and keeping their practices afloat. We greatly appreciate CMS recognized these trying circumstances and implemented a hardship exception for 2020, and we anticipate many physicians will opt out of MIPS entirely or for the cost category. **We therefore urge CMS not to increase the weight of the cost category to maintain stability in MIPS, to give physicians more time to familiarize themselves with the 2020 changes to the cost category, and considering the ongoing disruptions caused by the COVID-19 pandemic**.

ii. Addition of Telehealth Services to Previously Established Measures for the Cost Performance Category Beginning with the 2021 Performance Period

- **Recommendation**: We urge CMS to test and disclose the results of testing the addition of these services in the existing cost measures and to implement any necessary changes based on input from physician specialty societies regarding the impact of the addition of these services.

The AMA deeply appreciates CMS' efforts to expand Medicare patients' access to care during the COVID-19 public health emergency by allowing more telehealth services to be provided where the patient is located while reducing exposure to the novel coronavirus and conserving personal protective equipment. We understand the need to update the MIPS cost measures to account for the dramatic shifts in care delivery from in-person to via telehealth during the PHE. However, we are concerned that CMS has not tested and/or disclosed the results of testing the addition of these services to the existing cost measures. Does CMS intend to include telehealth services that are billed with modifier 95 and with place of service 02? Does the addition of these services penalize physicians who are in locations that experience COVID-19 outbreaks and therefore ramp up telehealth services to flatten the curve in their community? What is the effect of adding codes that were temporarily added to the Medicare covered telehealth list during the PHE but which may no longer be covered telehealth services after the PHE expires?

In addition, we urge CMS to implement changes based on feedback from physician specialty societies regarding the impact of the addition of these services, including services that were temporarily added to the Medicare covered telehealth list during the PHE, to previously established cost measures.

iii. Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) Clinician Measures

- **Recommendation**: In light of the National Quality Forum (NQF) Cost and Efficiency Standing Committee's preliminary recommendation to not endorse the MSPB clinician measure for MIPS and serious concerns expressed about TPCC leading them not to reach consensus, we again urge CMS to remove both measures from MIPS. At a minimum, CMS must address ongoing concerns with the measures' validity, reliability, and risk adjustment. These concerns are exacerbated by the disproportionate impact of the COVID-19 public health emergency on older, chronically ill, and minoritized and marginalized patients.

In the 2020 Medicare Physician Payment Schedule final rule, CMS finalized inclusion of the revised TPCC and MSPB measures for MIPS despite significant concerns raised by the AMA, specialty societies and other stakeholders, and the MAP Coordinating Committee, which did not support TPCC for

rulemaking "with potential for mitigation" and conditionally recommended MSPB for rulemaking pending NQF review and expressed concerns about the measure's risk adjustment and attribution. CMS finalized both measures for MIPS because, among other things, most clinicians do not have an otherwise-applicable episode-based cost measure as implementation of those measures remains gradual. We believe, however, that the TPCC and MSPB clinician measures are problematic and the rationale for including measures for the sake of measuring physicians does not outweigh the risks of including faulty measures that will not be actionable and valid for physicians, particularly as MIPS penalties are now fully implemented and can reduce Medicare payment rates by up to 9 percent.

The AMA reiterates our concerns that these measures hold physicians accountable for patients' medical conditions that are managed outside their organization and for costs they cannot influence like drug prices. We share the concerns raised by the NQF Cost and Efficiency Standing Committee about the measures' validity, reliability, and risk adjustment. The AMA also strongly supports the tenet that cost must be assessed within the context of the quality of care provided; yet both measures are not correlated to any one quality measure within the MIPS program.

Both measures are also subject to disruption by the COVID-19 pandemic on attribution, benchmarks, and risk adjustment. Based on preliminary Medicare claims data through July 18, 773,080 Medicare beneficiaries were diagnosed with COVID-19.[35] This translates to 1,208 COVID-19 cases per 100,000 Medicare beneficiaries. Preliminary Medicare data show 214,804 Medicare beneficiaries were hospitalized for COVID-19-related treatment, which equals 338 COVID-19 hospitalizations per 100,000 beneficiaries. Of those, 140,001 were in Medicare fee-for-service (FFS). Average Medicare payments per FFS COVID-19 hospitalization range from $5,190 to $70,388, and total Medicare FFS spending totals $3.5 billion. Minoritized and marginalized communities, as well as economically disadvantaged patients, have been harder hit. Whereas 230 white beneficiaries per 100,000 have been hospitalized, 870 Black and 588 Hispanic beneficiaries per 100,000 have been hospitalized. Compared to 785 Medicare only cases per 100,000, there are 3,098 COVID-19 cases among dual Medicare and Medicaid eligible patients.

As outlined in comments above urging CMS to retain the cost category weight at 15 percent of the MIPS final score, we believe modifications to TPCC and MSPB clinician are likely needed to adequately account for substantial changes in patient care and its disproportionate impact on older and minoritized patients during this public health emergency. **The AMA was disappointed that CMS did not propose any changes to the measures for 2020 or 2021 and continues to urge the agency to be more transparent about how it will reconcile these broad population-based cost measures with an ongoing crisis that has disproportionately and tragically impacted older, chronically ill, and minoritized and marginalized Americans.**

5. *Promoting Interoperability (PI)*

Health Information Exchange (HIE) Bi-Directional Exchange Measure

CMS is proposing to add a new HIE Bi-Directional Exchange measure to the HIE objective as an optional alternative to two existing measures: the Support Electronic Referral Loops by Sending Health

[35] Centers for Medicare & Medicaid Services, Preliminary Medicare COVID-19 Data Snapshot, https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.

Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. CMS is proposing the HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response.

The AMA welcomes CMS' proposal to add a new optional alternative measure to the PI Program's HIE objective. Many physicians find it challenging to meet the current HIE objective measures. The new optional measure provides physicians with a flexible and useful opportunity to receive 40 points within PI and, more importantly, allows physicians to meet an important objective using technology that interacts with certified EHR technology (CEHRT). **The AMA strongly supports CMS' proposal to allow physicians to report on the HIE Bi-Directional Exchange measure by a yes/no attestation. We are likewise encouraged by CMS' new direction in measure design that increases flexibility while reducing physician reporting burden.**

Additional clarity is welcome, however, on the proposed multi-part physician attestation. CMS is proposing that physicians attest they "participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period," and the HIE they participate in "is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners." The AMA interprets this as physicians attesting that they have the *functional capability* to conduct bi-directional exchange for all patients during the PI reporting period, not that physicians *must conduct* bi-directional exchange for all patients during the PI reporting period—something that may not be warranted for each patient over the course of a 90-day reporting period. Essentially, CMS is promoting the importance of HIE participation but not requiring bi-directional exchange unless warranted to support a patient encounter, transition, or referral (we note that physicians will be compelled by ONC's information blocking rule to conduct bi-directional exchange when warranted). The AMA supports physicians and patients making decisions around when exchange is necessary and recognizes the value of HIE participation. **Further clarity from CMS confirming this statement would be helpful.**

The AMA agrees that more should be done to promote bi-directional exchange between unaffiliated entities and between disparate EHRs. CMS' goal of achieving seamless interoperability is one shared by the AMA. We are encouraged by recent advancements in data governance and trust frameworks, technical improvements, standards developments, and CMS' own attention to more flexibility in these policy proposals. While interoperability is improving, we believe CMS should start with broad flexibility to encourage physician participation in HIEs. Limiting the proposed bi-directional measure to exchange with unaffiliated entities and between disparate EHRs may detract from CMS' goal of increasing HIE participation. Setting the bar too high could prevent physicians from trying. Rather, CMS should start with a focused goal of promoting exchange between unaffiliated entities first before layering on additional constraints. For instance, many physicians using the same EHR vendor's product report that they still—to this day—cannot conduct bi-directional exchange. Something as seemingly minor as a difference in EHR version limits interoperability between EHRs from the same vendor or within a vendor's own HIE.[36, 37] CMS' should use its policy levers to promote EHR vendors' own interoperability

[36] https://www.oig.hhs.gov/oei/reports/oei-01-16-00180.pdf
[37] https://www.computerworld.com/article/3397039/poorly-designed-systems-make-doctors-a-slave-to-their-ehr.html

between homogeneous products. **The AMA recommends that CMS limit its bi-directional measure conditions to that of exchange between unaffiliated provider entities regardless of whether they are using the same EHR product or participating in the same EHR-run HIE.** CMS could then consider increasing requirements to further bi-directional exchange once EHR vendors have achieved interoperability within their own product environments.

Future Direction of the Medicare Promoting Interoperability Program

The AMA supports CMS' goal of thinking creatively to reduce burden and promote interoperability. While we believe there are several opportunities for CMS to achieve these goals, we continue to believe a "less is more" approach to reporting will be the most effective. A fundamental component for the future direction of PI must include a reduction in physician reporting burden and more freedom in the choice of technology.

Leveraging vendor-provided health IT utilization data to simplify physician reporting is one such conceptworth considering. We explored this idea in our QPP CY 2019 comments and in our response to ONC's EHR Reporting Program Request for Information. Currently, physicians shoulder the capture,documentation, and reporting for all PI requirements. EHRs are still built to track and record the process physicians take to meet measure requirements—making physicians feel they are just "going through the motions to check a box." The PI Program is designed to compel physicians to "use" the EHR, and therefore, prescribed EHR usage has become the focus of the program—contributing to physician reporting burden. A less burdensome approach offloads physician reporting and instead analyzes which EHR functions best serve patients and physicians.

CMS' proposed HIE Bi-Directional Exchange measure is a good start. Future measures should build on this attestation-based concept and should leverage EHR vendor-reported data. For instance, EHR vendors could report on the actual functionality the physician used to accomplish HIE measures. There are still gaps in our knowledge of what EHR functionalities best meet HIE needs. These include:

- Was Direct used (identifying the usefulness of that EHR function)?
- Did the physician's query find unique patient records (identifying patient matching/record completeness issues)?
- How many "places" did the system need to search (providing emphasis on HIE frameworks such as the Trusted Exchange Framework and Common Agreement [TEFCA])?
- Was any information discoverable but "blocked" (helping identify information blocking Actors)?

Instead of requiring the physician to do the work of documentation, the EHR vendor-reported data could expose health IT system efficiency, whether the EHR accommodated the needs of the physician, whether the EHR contributed to or detracted from patient care, areas where federal policy could address gaps, and whether the EHR supported the goal of interoperability—all of which are missing right now. **We urge CMS to consider how EHR vendor-captured data can reduce physician reporting burden.**

Reduce Burden and Burnout Through an Attestation Approach

The AMA appreciates CMS' continued engagement with physicians in burden reduction efforts.

We are also encouraged to see CMS is considering the need to transition away from prescriptive physician measurements. Currently, numerator and denominator reporting de-values clinical care, forcing physicians to distill their medical practice down to a simple mathematical fraction. Too often the rich clinical information generated from the physician-patient narrative is clouded by unnecessary additional "note bloat" in order to score PI points. **All PI measures should therefore transition to "yes/no" attestation. This must be done to put patients over paperwork. Any additional data on EHR use should be provided by the health IT vendor as previously discussed.**

Weaving physician yes/no attestation with vendor-provided reporting would be a powerful combination. It would reduce physician burden, facilitate return on investment discussions, and more accurately represent the real-world use of technology. The Health Information Technology for Economic and Clinical Health (HITECH) Act permits a professional to satisfy the demonstration of meaningful use of CEHRT and information exchange through attestation. HITECH also permits reporting via "other means specified by the Secretary," granting the Secretary the authority to allow third party-supported physician attestation. The AMA has worked with medical specialty associations to generate strong support for this strategy.

Removing the burden of PI reporting will also help alleviate physician burnout related to EHR use. Continuing to require prescriptive PI measurement detracts from clinical relevance of the patient encounter, adds burden, and focuses PI participation on documentation, reporting and compliance rather than improved patient outcomes. Furthermore, as technology continues to evolve, and current PI measures are likely to become quickly outdated or fail to promote innovative uses of digital health tools. In another approach, today's 2020 PI measures are still tied to the legacy of Meaningful Use (MU). Given the Administration's focus on Patients over Paperwork and emphasis on reducing physician burden, measures that track and monitor physicians' use of EHRs should be abandoned. Again, **we view CMS' proposed HIE Bi-Directional yes/no attestation measure as a step in the right direction.**

CMS should go further and create broad categories of PI objectives allowing physicians to attest "yes/no" <u>to the use of CEHRT itself</u> to achieve those categories. This will provide flexibility for patients and physicians to efficiently test new uses of technology—identifying what does and does not work while encouraging the use of EHRs. For example, CMS could create an objective called "Chronic disease management enabled by digital medicine." Measures could be developed that support physicians using not only emerging CEHRT functionalities, like application programing interfaces (APIs) and patient-generated health data (PGHD), but also could promote the use of digital health tools, such as remote patient monitoring services. We stress, however, that absent a yes/no attestation approach, any new objectives and associated measures should be optional to provide additional opportunities for physicians to be successful in the PI Program.

We also note that PI is not the only lever CMS has to drive interoperability, nor is it the most powerful. Physician compliance with MIPS information blocking requirements, ONC information blocking regulations, TEFCA, and the Health Insurance Portability and Accountability Act (HIPAA) patient right of access are themselves far better mechanisms to drive interoperability and promote patient access while reducing federal regulatory burden. The Administration's emphasis is clearly focused on comprehensive and bold regulation to move interoperability forward. **CMS should fully remove the tie between PI and the legacy MU program once and for all.** It anchors all of HHS and the Administration to a fundamentally flawed policy—a policy linked to an EHR grant program that no longer exists. MU was

intended largely to ensure physicians adopted and used EHRs. Since there are no funds involved, and adoption and use of EHRs is pervasive in the profession, it is illogical to link measures to whether EHRs are in use.

In sum, an innovative, attestation-based PI Program, combined with new information blocking policies, will give physicians new freedom to choose the technology they want to use and how to use it—which will better support patient care and long-term wellness. **The future direction of PI is prioritizing a yes/no attestation-based approach that reduces provider burden while getting physicians back to practicing medicine.**

Flexibility in the Use of Technology

Physicians need a new pathway to adopt and use innovative technology. There are several emerging applications (apps) and technology platforms that leverage Certified EHR Terminology (CEHRT) but are themselves not CEHRT. For instance, a hospital could develop a suite of apps that connect a physician with social workers and community-based organizations helping families transition to stable housing. These apps would connect and pull information out of a CEHRT's fast health care interoperability resources (FHIR)-based API. However, many CEHRT products do not allow information in apps to be written back to the medical record. Physicians working within this app environment could "meet" several PI measures but would not receive credit since documentation is not done within the CEHRT or captured in a numerator. We should also not expect CEHRT to facilitate every possible health or wellness scenario. Unfortunately, the tie of PI to CEHRT could disincentivize physicians from adopting new technologies that would aid in care coordination and patient engagement—as physicians often spend their limited resources on technology that will help with PI compliance, even if doing so means forsaking more innovative and helpful technologies.

A new PI direction will combine the flexibility for physicians to attest "yes/no" to using CEHRT, as discussed previously, while allowing for the use of technology that interacts with CEHRT to count toward PI. CMS' proposed HIE Bi-Directional and Query of PDMP measures are examples of this approach. It will also engage clinicians who are non-patient facing currently exempt from the category (e.g., radiologists who use imaging equipment, but not EHRs). Expanding measures to include non-CEHRT interactions aligns with the Administration's goal to promote a pro-competitive marketplace and will leverage the private sector's innovation and creativity as outlined by the White House Office of American Innovation.

6. Improvement Activities

Adding IAs Outside of the Annual Call for Activities Timeframe

CMS is proposing an exception to the IA nomination period timeframe such that during a PHE, stakeholders can nominate IAs outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, CMS would accept nominations for the duration of the PHE as long as the IA is still relevant. Additionally, CMS is proposing a change to establish a process to allow CMS to consider HHS-nominated IAs all year long in order to address HHS initiatives in an expedited manner. The AMA supports these proposals and appreciates that CMS has already recognized the importance of physician efforts to help with COVID-19 through its addition earlier this year of a new, highly weighted IA, providing credit to eligible clinicians participating in COVID-19 clinical trials. Indeed, we encourage CMS to create additional IAs in response to the COVID-19 PHE. Every physician has been affected by COVID-19, whether they are at the front lines providing care to infected patients, providing diagnosis or referrals, volunteering their clinical services at other care locations, offering expanded access to care to their practice population through telemedicine, or assisting with COVID-19 testing. Physicians have managed significant disruptions to their practice and navigated new technologies to continue to provide access to their patients during unprecedented times and should receive credit for doing so under very challenging circumstances. Physicians may also have been forced to curtail other activities that would have satisfied IA requirements. Accordingly, **we urge CMS to adopt more IAs related to the management of COVID-19. For example, practices providing COVID-19 screening, diagnosis, or treatment, whether in-person or via telemedicine, should satisfy IA requirements in full.**

IA Inventory

CMS is proposing to establish a new criterion for nominating new IAs, "Activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible." We support this proposal. However, **we encourage CMS to focus less on the criteria for nominating IAs and more on providing stakeholders with detailed guidance on submitting new IAs and thorough explanations of why activities are not adopted for inclusion in the IA inventory.**

The AMA has repeatedly raised with CMS that the agency's responses to IAs submitted by specialties and other stakeholders are vague and unhelpful (e.g., "your submission does not fit the IA acceptance criteria" and "your submission is a duplicate of a concept already in the inventory"). The AMA received one of the above responses for all 15 of the IAs we submitted in 2018 for the 2019 program year. These responses are extremely limited in explaining why CMS rejects proposals and whether (and how) they may be amended for inclusion in future MIPS performance years. Many specialties invest significant time and effort crafting IA proposals, including gathering sources of supporting validation documentation and the other elements requested on the submission form.

CMS guidance to date has not been helpful—points emphasized in webinars and information sheets indicate that CMS does not want duplicate activities, that the proposed activity should be feasible to implement, and that CMS should be able to validate the activity. The AMA and many specialties do not understand why many of their submitted activities fall short. Importantly, CMS does not explain how it defines "duplicate." For example, the AMA submitted an activity titled "Outbreak Control" in 2018 and

received a response stating that the activity was a duplicate. The activity was aimed at practice preparation for PHEs through activities such as vaccinations, community education, staff training on patient screening for disease, emergency preparedness plans, and emergency response drills—an activity we point out would have been quite timely for 2020. Upon review of the IA inventory to find a duplicate activity, the closest activity was IA_ERP_1, which is described as a minimum 6-month volunteer commitment for disaster or community emergency responder teams. This is not duplicative—as the activity we proposed was aimed at preparing the community and practice for an emergency as part of the practice's internal efforts (i.e., we did not intend for our proposal to require the physician to volunteer outside of the clinic for 6 months). Again, without additional guidance, it is difficult for stakeholders to know how CMS evaluates IA proposals. The AMA still is unclear of how it should modify its "Outbreak Control" proposal such that CMS does not classify it as duplicative.

We also question how CMS is evaluating proposals in light of CMS' criteria for new IAs. CMS' guidance on submitting IAs asks stakeholders to "focus on meaningful action from the [patient] and family's point of view," noting that the agency would "like to receive activities that would support the patient's family or personal caregiver, and activities that are representative of activities that the multiple individual MIPS eligible clinicians or groups could perform," are "feasible to implement" and have a high probability of improving beneficiary outcomes. It is very difficult to understand why activities meeting the above criteria are not accepted. For example, one of the AMA's proposals from 2018 would provide credit to physicians who engaged with their health IT vendors to learn about and discuss the availability and usage of patient-facing apps to facilitate beneficiary engagement and patient access. We believe that this should have been accepted for a number of reasons: (a) it met one or more of the criteria on the submission form; (b) CMS has placed a large emphasis on the importance of patient and caregiver access to medical information; (c) in its proposed rules, CMS has solicited ways to incentivize the use of health IT in IAs, including in 2019 since it removed the PI bonus, and this activity would utilize functionality that is new to 2015 Edition CEHRT; and (d) open APIs are one of CMS' two chosen methods of providing information to patients (which will only increase with the forthcoming implementation of the new information blocking and patient access rules). We are again left wondering what we should change in that submission to ensure it is accepted in the future.

If CMS will not provide more detail about what it wants from a proposal and will not accept proposals that meet the enumerated criteria, we suggest the agency provide more information about the types of IAs it does not want, so that stakeholders do not spend time cultivating proposals in those areas. We also urge CMS to issue additional guidance so that stakeholders can refine (or resubmit) their IA submissions in 2021. This is particularly critical given that there is now a 2-year lag between proposed and approved activities.

7. Physician Compare

- **Recommendation**: We appreciate CMS taking a slow and methodical approach to expanding the available data and ensuring any publicly reported information meets high reliability standards to better ensure Physician Compare does not lead to inaccurate distinctions about quality.

As CMS expands the website to include year three of data, we recommend the following:

- Align and move to one consistent data calculation between MIPS benchmark methodology and Physician Compare star ratings
- Only incorporate data used to calculate a physician's score: Regardless, if data is for star ratings, performance indicator or aggregate, CMS should only publicly release data that was used to assess physician performance under MIPS scoring.
- Create Separate Benchmarks for each reporting mechanism: CMS is mixing various reporting mechanisms when developing the benchmarks for Physician Compare, which CMS does not do when setting MIPS benchmarks. Therefore, CMS should create separate benchmarks for each reporting method instead of aggregating data from all reporting mechanisms.
- Move to the same number of achievable points across programs: Physician Compare places physicians into one of five categories to calculate star ratings, while the MIPS methodology uses nine categories (and point system) to score physicians on quality measures reporting to determine whether a physician will be subject to a MIPS penalty or eligible for an incentive.
- Retain only the "successful" performance indicator for PI: CMS should limit the PI performance category indicator to that which is only successful. CMS should refrain from including EHR utilization performance information on Physician Compare. EHR utilization performance is largely dependent on an EHR's functionality—or lack thereof. Information exchange is a complex interweaving of factors largely outside physician control, including: the availability of other providers to exchange information with; the number of data intermediaries; Health Information Exchange availability and costs; patient matching issues; vendor-initiated information blocking practices; and the unique ways EHR vendors send and receive data. It is inappropriate to list performance or compare physicians based on measures outside of their control.

Please see 2020 AMA Physician Fee Schedule/Quality Payment Program Proposed Rule Comments for more details on our analysis and recommendations to improve the Physician Compare Star Ratings methodology.

E. Advanced Alternative Payment Models (AAPMs)

APM Incentive Payment

- **Recommendations**: The AMA appreciates CMS' proposals to make APM incentive payments more efficiently and timely to qualifying APM participants (QPs) who are no longer affiliated with the TIN through which they achieve QP status. We caution against a 60-day cutoff or cutoff on Nov. 1 of the payment year and urge the agency to maintain flexibility to ensure the time frame is sufficient to conduct the necessary due diligence and outreach to disburse all earned APM incentive payments. If the agency believes a cutoff date is necessary, we urge CMS to make Dec. 31 of the payment year the cutoff.

We understand the agency has encountered challenges with disbursing APM incentive payments when QPs are no longer affiliated with the group through which they participated in the Advanced APM and became eligible for the 5 percent incentive payment. Many of these challenges can be traced back to the two-year lag between participation in the Advanced APM and the payment year. For example, in the

space of two years, physicians may switch practices, join new APM Entities, remain in the same APM Entity under a new billing tax identification number (TIN), or retire. We appreciate CMS' proposals to expedite payments to QPs who have a different business or billing arrangement in the payment year than in the performance year. We also continue to believe that making APM incentive payments earlier in the payment year will help to alleviate these challenges by shortening the two-year lag.

CMS also proposes to establish a cutoff date of Nov. 1 of the payment year, or 60 days from the initial round of APM incentive payments, whichever is later, as a point in time after which CMS would no longer accept requests and inquiries from QPs who have not yet received their payment. The AMA questions CMS' rationale that such a cutoff date is necessary to make correct payments for the relevant QPs as soon as possible. We are concerned that instead a 60-day window will result in fewer QPs receiving their APM bonuses. We urge CMS to reserve flexibility to conduct due diligence in locating physicians who earned the 5 percent bonus and disburse those payments. While this may be feasible by Nov. 1 or within 60 days in some years, we are not certain that will be the case in all years. For example, if an Advanced APM sunsets, there may be a greater number of QPs in a different billing arrangement in the payment year than the performance year. CMS should build in flexibility to account for these year-to-year variations in the APM landscape.

If CMS moves ahead with establishing a cutoff date, we urge the agency to establish Dec. 31 of the payment year as the deadline for inquiring about missing APM incentive payments. We believe this would be a stable and reasonable deadline for disbursing all APM incentive payments and consistent with statutory intent to reward physicians for their participation in an Advanced APM during the payment year.

QP Determinations

- **Recommendations**: As the QP threshold scores are set to increase in 2021 above an amount that is obtainable by most physicians and APM entities, we urge the agency to continue incentivizing participation in Advanced APMs by using every administrative lever to lower the thresholds and working with Congress to address the statutory QP cliff. We support CMS' proposal to more accurately calculate QP threshold scores, to establish a targeted review for QP determinations, and to make adjustments so that COVID-19 does not prevent a physician or group from becoming a QP in an Advanced APM.

The QP thresholds are set to significantly increase in 2021, yet the most up-to-date information available in the 2018 QPP Experience Report shows that many physicians participating in Advanced APMs will not be able to meet the increased thresholds.[38] For example, the average payment score for Medicare Shared Savings Program accountable care organizations (ACOs) was 44 percent, and the average patient score was 45 percent. Similarly, for the Next Generation ACOs, the average scores were 49 percent and 51 percent, respectively. Even more concerning are the average threshold scores for bundled payment model participants. The average payment and patient scores for the Comprehensive Care for Joint Replacement Payment Model were 12 percent and 5 percent respectively. CMS should ensure continued participation in Advanced APMs by reducing the patient count threshold to an obtainable level and by working with Congress to amend the statutory revenue threshold amounts.

[38] CMS, 2018 QPP Experience Report, https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1091/2018%20QPP%20Experience%20Report.pdf

We are pleased that CMS is proposing to update the methodology for calculating QP thresholds by excluding beneficiaries who are prospectively aligned to an APM Entity from the pool of attribution-eligible beneficiaries for other APM Entities in order to prevent diluting the QP threshold scores for participants in APMs that use retrospective attribution. The current methodology would include a beneficiary who is prospectively attributed to an APM Entity and as a result is precluded by the applicable rules for one or more APMs from attribution to other APM Entities in certain other APMs. This disadvantages the APM entities because their threshold score, or ratio of attributed to attribution-eligible beneficiaries, will be lower due to reasons outside the control of the physicians and APMs.

While we appreciate CMS' efforts to more accurately calculate QP threshold scores, we caution against foreclosing participation of beneficiaries in multiple APMs, whether the APMs use prospective or retrospective assignment. The AMA continues to believe patients benefit from receiving care in both bundled payment models and medical home or accountable care models, and that the Medicare program will see greater savings when beneficiaries participate in APMs that coordinate their primary care and specialty care needs.

The AMA supports CMS' proposal to establish a targeted review period for correcting QP determination errors made by CMS. We understand CMS' rationale for aligning the QP determination targeted review period with the MIPS targeted review period and we seek a clarification about how this will work in the event a physician wants to request a targeted review for both their QP status and their MIPS score. Would a QP be required to submit a separate targeted review challenging an error in their QP status calculation and a MIPS targeted review at the same time, or could one targeted review be submitted for both appeals? Would CMS prioritize the QP determination targeted review and respond to that appeal first? Ideally, the physician would know whether he or she is a QP and therefore excluded from MIPS first, as it could make the MIPS targeted review null and void.

Finally, in response to the COVID-19 PHE, CMS does not plan to amend the list of Advanced APMs in 2020 and would not revoke 2020 QP status in certain circumstances such as when an APM terminates its participation early due to the pandemic. The AMA supports these changes and urges CMS to extend them to the 2021 performance period. The COVID-19 pandemic is an ongoing crisis and may result in unintended negative consequences for Advanced APM and QP determinations in 2021, as well as in 2020.

APPENDIX I. Waiver Examples With and Without Authority

Topic	Description of Policy	Description of Waiver	Waiver Authority
Examples of Provisions Waived with Explicit Waiver Authority			
Telehealth	Medicare pays for services normally delivered face-to-face via telehealth. Section 1834(m) of the Act limits the originating site, the types of practitioners that may bill for telehealth services and requires real-time interactive audio/video telecommunications. HIPAA	Waiver applies to the originating site requirements, type of practitioners that can bill for telehealth and allows for audio only telehealth services. HHS Office for Civil Rights (OCR) will	Section 1135(b)(8) of the Act provides broad authority for CMS to waive section 1834(m) of the Act that applies to telehealth services in the context of this public health emergency (PHE) only. Section 1135 allows waiver

Topic	Description of Policy	Description of Waiver	Waiver Authority
	privacy and information security requirements apply to the telecommunications system.	exercise enforcement discretion and waive penalties for HIPAA violations against health care providers that serve patients in good faith through everyday communications technologies (Zoom, Facetime, etc…)	of specific HIPAA requirements although the requirement for the telecommunications system to meet HIPAA requirements does not appear to be among them.
Emergency Medical Treatment and Labor Act (EMTALA)	Requires hospitals to perform a medical screening exam on patients that present at a hospital with a dedicated emergency department and take appropriate action if the patient has an emergency medical condition or is in active labor.	Waives the enforcement of section 1867(a) of the Act to allow screening patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.	Section 1135(b)(3)(B) of the Act allows an individual to receive medical screening in alternative locations.
Conditions of Participation (CoP)	Health and safety requirements that apply to hospitals that participate in Medicare, Medicaid and other health insurance programs.	Under the "Hospital Without Walls" initiative, hospitals can provide hospital services in other health care facilities and sites that would not otherwise be considered to be part of a health care facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.	Section 1135(b)(2) of the Act allows for waiver of CoPs and similar requirements for an individual health care provider. Note: CMS is also waiving the provider-based rules in their entirety. These rules govern when patient care sites may be part of the hospital. The provider-based rules are conditions of payment, not participation and cannot be waived under section 1135(b)(2). However, CMS has undertaken rulemaking to change the provider-based rules. See below for more information.
Long Term	Must have an average length	Waives	Section 3710 of the CARES

Topic	Description of Policy	Description of Waiver	Waiver Authority
Care Hospitals (LTCH)	of stay (ALOS) of 25 days or longer. LTCH cases paid an LTCH rate that averages $42,678 if the patient meets specific criteria when transferred from a general acute care hospital. Otherwise paid an IPPS comparable amount (averaging $5,797). At least 50 percent of cases must be paid the LTCH federal rate for LTCH to retain LTCH status.	1. Criteria to receive the LTCH rate; 2. Requirement that LTCHs treat at least 50 percent of patients paid at the LTCH rate; and 3. Requirement to have an ALOS of 25 days or more.	Act allows waiver of the first two criteria but not the third. CMS is not counting cases admitted due to the PHE towards the 25-day ALOS. See below for more information.

Examples of Provisions where CMS Changed Temporarily Changed Regulations During the Public Health Emergency			
Provider-Based Rules	Rules under which a health care site may be considered part of the hospital.	CMS initially waived the provider-based rules in their entirety and then followed-up with an Interim Final Rule with comment (IFC) on May 8, 2020) that that specifies how the provider-based rules will be applied in particular circumstances.	There is no statutory authority to waive the provider-based rules that were developed under CMS' general rulemaking authority. There is no explicit statutory authority for the provider-based rules although section 404(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 establishes that a provider-based portion of the hospital must be within 35 miles of the main hospital campus. CMS has not explicitly indicated whether the 35-mile requirement is waived or remains in effect.
Rural Health Clinics (RHC)	RHCs receive an all-inclusive rate subject to a per visit payment limit. Under section 1833(f) of the Act, a provider-based RHC to a hospital with under 50 beds is exempt from national per visit payment limit.	CMS is using a bed count from before the PHE to determine whether RHC is provider-based to a hospital with fewer than 50 beds to be exempt from the national per visit payment limit.	There is no statutory provision that allows CMS to waive the 50-bed limit. CMS does have authority to determine how the 50 beds are counted. However, CMS indicates in the IFC that it does "not want to discourage [hospitals] from increasing bed capacity." This policy effectively allows RHCs to be provider-based to hospitals with more than 50 beds without explicit authority to waive that requirement of statute.

Topic	Description of Policy	Description of Waiver	Waiver Authority
Examples of Provisions Waived without Explicit Waiver Authority			
Accelerated and Advanced Payment Programs	Section 1815(e)(3) of the provides authority to make accelerated payments to inpatient prospective payment system (IPPS) hospitals. Regulatory and manual provisions dictate loan and repayment terms. 42 CFR §421.214 provides advanced payment to suppliers when a Medicare contractor transition interrupts payment. Implementing regulations for the advanced program do not cite CMS' statutory authority. A supplier does not include a "provider of services." Section 1861(u) of the Act defines a "provider of services" to include a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA) and hospice. Hospitals would include IPPS hospitals, LTCHs, inpatient rehabilitation facilities and inpatient psychiatric facilities (IPF) cancer hospitals and children's hospitals.	Section 3719 of the CARES Act expanded the accelerated program to children's hospitals, cancer hospitals and CAHs. Under 42 CFR §421.214, CMS is providing advanced payment to suppliers and providers of services other than those explicitly addressed by statute through the accelerated program. CMS has been inconsistent in whether the advanced or accelerated program applies to LTCHs, IRFs and IPFs. The accelerated payment program has more generous loan and repayment terms than the advanced program.	The statutory authority for the accelerated program is limited to IPPS hospitals, children's hospitals, cancer hospitals and CAHs. CMS does not have explicit statutory authority to expand the program to IRFs, IPFs and LTCHs although it has indicated through informal communications that these types of hospitals are subject to the accelerated program. The regulatory authority for the advanced program is limited to Part B suppliers that would not include IRFs, IPFs, SNFs, CORFs, HHAs and hospices even though CMS indicates in its official communications that these provider types are subject to the advance program.
LTCHs	LTCHs are required to have an ALOS of 25 days or more.	CMS has advised LTCHs not to count admissions or discharges in order to meet the demands of the emergency towards the 25-day average length of stay requirement.	Section 1861(ccc) of the Act requires the LTCH to have an ALOS of 25 days. There is no provision to waive this requirement. There is a parenthetical in the statute "as determined by the Secretary" after "average inpatient length of stay." This provision gives

Topic	Description of Policy	Description of Waiver	Waiver Authority
			Secretary authority to calculate the ALOS but not change the 25 days.
Sole Community Hospitals (SCH)	Under section 1886(d)(5)(D)(iii) of the Act, an SCH must be more than a specified distance from another hospital depending on the topography of where the SCH is located.	For a hospital classified as an SCH prior to the PHE, CMS is allowing a hospital to continue to be paid as an SCH even if it no longer meets these statutory requirements.	The SCH provisions are conditions of payment. There are no explicit statutory provisions to waive the SCH distance requirements.
Medicare Dependent Hospitals (MDH)	Under section 1886(d)(5)(G)(iv), an MDH must have fewer than 100 beds and Medicare utilization of 60 percent or more.	For a hospital classified as an MDH prior to the PHE, CMS is allowing the hospital to continue to be paid as an MDH even if it no longer meets these statutory criteria.	The MDH provisions are conditions of payment. There are no explicit statutory provisions to waive the 100-bed limit and Medicare utilization requirements.
Inpatient Rehabilitation Facilities (IRF)	To receive payment as an IRF, 60 percent of the IRF's patients must have a specific diagnosis requiring rehabilitation (the 60 percent rule). Also, IRFs are required to provide at least 3 hours of intensive therapy per day or 15 hours per week (the 3-hour rule).	CMS is waiving both the 60 percent rule and the 3-hour rule.	Both of these requirements are regulatory. Through an IFC published on April 6, 2020, CMS indicated that IRFs are not required to meet the 3-hour rule during the PHE in specific circumstances. Section 3711(a) of the CARES Act later waived the 3-hour rule. CMS did not undertake rulemaking to change the 60 percent rule and there is no explicit statutory authority to waive it.