

September 13, 2021

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

Re: File Code CMS-1751-P. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the 2022 Physician Fee Schedule (PFS) and Quality Payment Program (QPP) proposed rule, published in the *Federal Register* on July 23, 2021 (86 Fed. Reg. 39104).

The AMA comments are guided by our AMA policies, informed by our members, and presented through a COVID-19 public health emergency (PHE) and health equity lens. In addition, our comments addressing individual Current Procedural Terminology® (CPT®) codes were developed in close collaboration with the AMA/Specialty Society RVS Update Committee (RUC). The AMA fully supports the RUC recommendations and urges CMS to accept these work RVUs and direct expense inputs while also carefully considering the RUC and specialty society comments on other individual codes.

At the outset, we wish to express our sincere support for your efforts to extend coverage of services that were added to the Medicare telehealth list on an interim basis in response to the COVID-19 PHE until the end of 2023 and recommend that these proposals be finalized. The AMA also recommends that the additional services added to the telehealth list during the COVID-19 PHE, particularly the CPT codes for telephone evaluation and management services (99441-99443), be included in the category of services which are proposed to remain on the telehealth list through 2023. These services have played a critical role in allowing physicians to continue to manage their patients' care while remaining at a safe physical distance from medical practice staff and other patients, as well as avoiding contact that can occur during transportation to and from medical appointments. As we continue to grapple with COVID-19 and its variants, it is critical that access to telehealth services continue beyond the PHE.

Additionally, the AMA urges CMS to apply the office visit increases to the office visits included in surgical global payment, as it has done historically. We continue to oppose 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 and compounds drastic cuts to many physicians. The AMA reiterates our concerns with the RAND reports, which the Agency should not rely on to pay surgeons at a different rate than other physicians. The AMA urges CMS to convene with the RUC and other stakeholders to discuss the global surgical codes issues and indicate specific codes which it believes are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period.

We are also deeply concerned about the growing financial instability of physician practices due to the severe reduction in revenue caused by the COVID-19 PHE. The looming payment cuts facing physician practices at the end of this year, including cuts due to budget neutrality, must be addressed to ensure that practices can remain fiscally viable. As we commented in response to the CY 2021 PFS, the AMA continues to urge CMS to work with Congress to address the budget neutrality issue. 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 greatly appreciates the active engagement between CMS and specialty societies to develop some of the initial seven MIPS Value Pathways (MVPs) that are proposed for the 2023 performance period. We continue to urge CMS to reimagine its approach to MVPs by moving away from reporting existing measures, establishing a far more flexible MVP framework, and collaborating with specialty societies to establish new and innovative quality and cost measures to improve patient care around an episode, condition, or public health priority. In addition, based on specialty societies' and stakeholders' experience with the initial round of MVP co-development with CMS, the AMA makes several recommendations to refine the process, including; (1) adding an MVP development criterion that MVP development be clinician-led; (2) establishing an informal process to ensure transparency and coordination among the relevant specialty societies in development of an MVP; (3) publishing CMS' intentions for future MVP development priority areas to encourage early specialty society collaboration; and (4) clear and timely feedback about why a candidate MVP submission has not been proposed for implementation.

The following outlines our principal recommendations to the 2022 proposed rule.

Calendar Year 2022 Updates Physician Fee Schedule (PFS)

- The AMA agrees with CMS that the United States Bureau of Labor Statistics (BLS) wage data continue to be the most accurate source for clinical labor pricing, however, CMS should maintain the data up-to-date and use the most recent year of available BLS data to determine clinical labor costs. A four-year transition to the updated labor pricing is reasonable in light of significant impacts of this change. In addition, increases in medical practice costs should be reflected in conversion factor updates.
- The AMA strongly supports the RUC recommendations on specific services that are potentially misvalued and the continued collaboration of the RUC and CMS to identify and review potentially misvalued codes.
- CMS should issue an Interim Final Rule to immediately implement and pay separately for CPT code 99072 with no patient cost-sharing during the PHE to address the significant financial pressures placed on physicians by the COVID-19 pandemic.
- The AMA strongly supports the proposal to extend coverage of services that were added to the Medicare telehealth list on an interim basis in response to the COVID-19 PHE until the end of

2023 and urges that it be finalized. The AMA also recommends that the additional services added to the telehealth list during the COVID-19 PHE, particularly the CPT codes for telephone evaluation and management services (99441-99443), be included in the category of services which are proposed to remain on the telehealth list through 2023.

- The AMA applauds CMS' proposal to expand the definition of telecommunications system for purposes of telehealth services to include audio-only communication technology for mental health services. CMS should leave the determination of when in-person care is necessary up to the discretion of the treating physician.
- The AMA continues to recommend that the COVID-19 PHE policy that allows "direct supervision" to include immediate availability through the virtual presence of the supervising physician using real-time, interactive audio/video communications technology be made permanent.
- The AMA urges CMS to clarify that the RTM codes are in fact general medicine codes and, as such, tasks performed by physical therapy assistants are billable when provided under the direct supervision of the physical therapist and under the physical therapist NPI number, making incident-to policy irrelevant.
- The AMA urges CMS not to require a modifier to be reported for split (or shared) visits. Requiring a modifier adds a level of administrative burden that the new E/M coding structure and guidelines were designed to alleviate. The AMA also urges CMS to work with the CPT/RUC Workgroup on E/M to create a proposal to the CPT Editorial Panel to clarify the reporting in CPT Guidelines.
- The AMA continues to oppose CMS' decision not to incorporate the revised office and outpatient E/M values in the global surgical codes and urges CMS to apply the office visit increases to the office visits included in surgical global payment, as CMS has done historically.
- The AMA urges CMS to reestablish the Refinement Panel process, or a similar process, to create an objective, transparent, and consistently applied formal appeals process, that would be open to any commenting organization, and provide stakeholders with multiple avenues of appeal.
- The AMA urges CMS to adopt its proposal to implement the reduced beneficiary coinsurance phase-in for colorectal cancer screening tests as required by the Consolidated Appropriations Act of 2021. Further, the AMA urges CMS to conduct patient education and outreach about the changes to their coinsurance for diagnostic colorectal cancer screenings until it is fully phased out in 2030.
- The AMA recognizes the value of nutrition support teams services and their role in positive patient outcomes and supports payment for the provision of their services but urges CMS to ensure that there is a reporting requirement for medical nutrition therapy (MNT) services to the treating physician.

Other Provisions of the Proposed Rule

- The AMA greatly appreciates and strongly supports the significant updates that CMS proposes to permanently update the Medicare Diabetes Prevention Program (MDPP), specifically the elimination of the Year 2 ongoing maintenance sessions, the redistribution of Year 2 payments to Year 1, and the waiver of the Medicare provider enrollment application fee. The AMA also recommends CMS to make an additional update to the MDPP by including virtual DPP providers permanently in the program.
- While the AMA appreciates CMS delaying the transition away from the GPRO Web-Interface until 2024 and allowing for a longer glide path, we remain concerned with the feasibility of having to begin reporting on one eCQM and all-payer data starting in 2023. We are also

disappointed that CMS plans to continue to move forward with its proposals to align MSSP quality scoring methodology with the MIPS methodology.

- The AMA supports patient-centered management of pain by clarifying, communicating, modifying, and/or expanding existing care management codes as needed to include patients with chronic pain and significant acute pain, in addition to patients with chronic diseases. The AMA urges CMS to prohibit Part D plans from imposing prior authorization and quantity limits on buprenorphine.
- The AMA urges CMS to finalize its proposal to require EPCS compliance by January 1, 2023, instead of January 1, 2022, and not to require long-term care facilities to comply until 2025. The AMA also urges CMS to finalize all proposed exemptions.
- The AMA strongly urges CMS to finalize its proposal to delay the penalty phase of the Appropriate Use Criteria (AUC) program until the later of January 1, 2023, or the January 1 following the end of the PHE. The AMA also urges CMS to reduce the burden of the AUC, particularly as the program has been superseded by the QPP. Finally, CMS should not move to the penalty phase of AUC until the claims data show a vast majority of all applicable advanced diagnostic imaging claims would meet the requirements to be paid.

Requests for Information

- The AMA supports advancements in data availability and integration for quality improvement and measurement through efforts such as data aggregation, but they must result in data that are easily accessible at the point of care and provide actionable information that can inform shared decision-making while also easing reporting burden.
- The AMA discourages CMS from strictly relying on dual-eligibility (DE) status when stratifying readmission or admission measures and we continue to believe that relying on algorithms for indirectly estimating race and ethnicity is not an appropriate solution.
- The AMA supports the OpenNotes effort. Yet, there are not sufficient policies, technologies, or the necessary data governance structures in place to support an OpenNotes mandate or imbedding OpenNotes in CMS' programs.

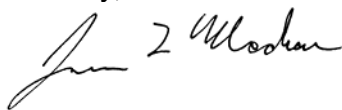
Calendar Year 2022 Updates to the Quality Payment Program (QPP)

- The AMA strongly urges CMS to automatically apply the Extreme and Uncontrollable Circumstances Hardship Exception for the 2021 MIPS Performance Period, so physicians are held harmless from the nine percent MIPS penalty due to the significant, ongoing disruptions that the COVID-19 PHE is having on physician practices.
- Following three years of unprecedented and significant disruptions to the health care system and MIPS due to the COVID-19 PHE, the AMA urges CMS to exercise every lever under its Extreme and Uncontrollable Circumstances hardship exception policy and related authorities to lower the performance threshold from the proposed 75 points and reweight the Cost Performance Category to the weight that it was prior to the PHE in 2019, which was 15 percent.
- CMS should establish a far more flexible MVP framework and create quality and cost measures based on clinical pathways and patient reported outcome measures (PROM) for diagnosis and treatment of specific medical conditions.
- Based on specialty societies' and stakeholders' experience with the initial round of MVP co-development with CMS, the AMA makes several recommendations to refine the process.

- The AMA urges CMS to encourage subgroup compositions of multiple specialties, across multiple locations, and in various sizes to achieve the MVP's goals of improving care and reducing avoidable costs.
- The AMA urges CMS to work with specialty societies and other MVP developers to develop and test new and innovative cost measures that are clinically appropriate for an MVP.
- The AMA urges CMS to finalize its proposal to provide detailed, comparative feedback to physicians who participate in the same MVPs. CMS should also provide easy, affordable ways for physicians to access and analyze Medicare claims data to identify opportunities to reduce spending, measure the impacts of care delivery changes, and quickly identify when services for patients need to be changed.
- The AMA continues to support CMS' goals of focusing the Promoting Interoperability (PI) program on interoperability and improved patient access to health information as opposed to burdensome, prescriptive data capture and measurement policies. We urge CMS to continue to limit regulatory requirements in the PI program as long as physicians can share data among themselves and with their patients.
- The AMA generally supports CMS' proposals around timeframes for Improvement Activities (IAs) nominated during a public health emergency, the revised criteria for IA nominations received through the Annual Call for Activities, and suspension of activities that raise possible safety concerns or become obsolete from the program. We also appreciate CMS' proposal for revised group reporting requirements for the 50 percent participation threshold to address subgroup reporting of IAs that may differ from the "parent" group.

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,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD

**2022 Physician Fee Schedule and Quality Payment Program Proposed Rule
Detailed Comments of the American Medical Association**

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I. CALENDAR YEAR 2022 UPDATES FROM THE PHYSICIAN FEE SCHEDULE (PFS)

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

1. *Clinical Labor Pricing Update*

- **Recommendation:** The AMA agrees with CMS that the United States Bureau of Labor Statistics (BLS) wage data continues to be the most accurate source to use as a basis for clinical labor pricing, however, CMS should maintain the data up-to-date and use the most recent year of available BLS data to determine clinical labor costs. A four-year transition to the updated labor pricing is reasonable in light of significant impacts of this change. In addition, increases in medical practice costs should be reflected in conversion factor updates.

CY 2022 marks the final year of the four-year market-based transition for supply and equipment pricing. The clinical labor pricing has not been updated since 2002. CMS proposes to update the clinical labor wage rates according to data from the BLS.

The AMA agrees with CMS that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and these data will appropriately reflect changes in clinical labor resource inputs for purposes of establishing practice expense relative values. However, we understand that there may be improvements in the methodology used in utilizing these data. For example, CMS utilizes the mean in its analysis, while the majority of the RBRVS data inputs are based on the median. **CMS should carefully consider comments regarding the appropriate application of the multiplier to include fringe benefits in the overall clinical labor costs. CMS should also carefully consider comments on specific clinical staff types and their labor rate costs.**

The total direct practice expense pool increases by 30 percent under this proposal, resulting in a significant budget neutrality adjustment. By increasing the clinical labor pricing, physician services with high-cost supplies and equipment are disproportionately impacted by the budget neutrality component within the practice expense relative values. The scaling of direct expenses, to 44 cents on every dollar fully recognized as direct costs, puts a huge and unfair burden on specialties that require expensive supplies and other direct costs to care for their patients. While the increase in clinical labor is appropriate, it is not appropriate that physicians and other qualified health care professionals, and notably from a few small specialties, are negatively impacted by the change.

CMS has requested comment on whether to implement a four-year transition to the new clinical labor cost data, much like the transition used in updating the supply and equipment price updates. **Such a transition appears reasonable, particularly because individual procedures will experience significant reduction. In the future, CMS should update pricing data on a more frequent basis for all inputs, so adjustments will not be so dramatic. The AMA also understands the underlying unfairness that the real increase in clinical labor costs is not recognized through an update to the conversion factor and calls on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2022 and all future years.**

B. Potentially Misvalued Services Under the PFS

- **Recommendation:** The AMA strongly supports the RUC recommendations on specific services that are potentially misvalued and the continued collaboration of the RUC and CMS to identify and review potentially misvalued codes.

1. RUC Progress in Identifying and Reviewing Potentially Misvalued Codes

Since the inception of the Relativity Assessment Workgroup (RAW), the RUC and CMS have identified 2,629 services through over 20 different screening criteria for further review by the RUC. The RUC has recommended reductions and deletions to 1,567 services, more than half of the services identified, redistributing \$5 billion annually. The RUC looks forward to working with CMS on a concerted effort to address potentially misvalued services.

2. Public Nominations of Potentially Misvalued Services

CMS received public nominations for six codes as potentially misvalued (CPT codes 22551, 49436, 55880, 59200, 66982 and 66986). CMS states that they are seeking comments on these services but currently there is no evidence that these services are misvalued. CMS is not proposing review of any new potentially misvalued codes. The RUC looks forward to continuing to work with CMS to identify and review any potentially misvalued services.

C. Telehealth and Other Services Involving Communications Technology

- **Recommendation:** The AMA strongly supports the proposal to extend coverage of services that were added to the Medicare telehealth list on an interim basis in response to the COVID-19 PHE until the end of 2023 and urges that it be finalized. Additional services that were added to the telehealth list during COVID-19, especially the three codes for telephone evaluation and management services, should be included in the category of services which are proposed to remain on the telehealth list through 2023. The current policy during the COVID-19 PHE allowing "direct supervision" to include immediate availability through the virtual presence of the supervising physician using real-time, interactive audio/video communications technology should be made permanent. CMS' proposal to expand the definition of telecommunications system for purposes of telehealth for mental health services to include audio-only communication technology should be finalized, but the determination of when in-person care is necessary should be left to the discretion of the treating physician.

1. Revised Timeframe for Services Added to the Telehealth List on a Temporary Basis

During the COVID-19 PHE, CMS added 135 services to the Medicare telehealth list on an interim basis. These services have played a critical role in allowing physicians to continue to manage their patients' care while remaining at a safe physical distance from medical practice staff and other patients, as well as avoiding contact that can occur during transportation to and from medical appointments. It is critical that access to telehealth services continue beyond the PHE. Besides their use to manage care for patients with respiratory and other symptoms that could reflect COVID-19, telehealth is being used for: patients with a variety of symptoms and acute and chronic conditions that can be evaluated and managed remotely; those who need hospice or palliative care; following up after hospital and emergency department services;

behavioral health and addiction treatment; and pain management. Provision of telehealth services to patients in their home or other location is a huge advantage for patients with mobility or functional impairments or other problems that make travel difficult, and it is preferable for immunocompromised patients and those with communicable diseases. It allows physicians to see patients who have functional impairments in their usual living environment, instead of examining them after what may have been an arduous and stressful travel experience to obtain in-person care. In addition, it allows physicians to see patients with sporadic symptoms when these symptoms occur and improves care for conditions where seeing the patient's living environment can inform treatment plans. Telehealth also facilitates team-based care by allowing other physicians, health professionals, caregivers, and family members to join patient visits from their own location.

In the 2021 final rule, several services that were added to the Medicare telehealth list during the PHE were permanently added to the Medicare telehealth list. CMS also created a new Category 3 for Medicare telehealth services added during the PHE for which there is likely clinical benefit but not enough evidence to determine if they meet Category 1 or 2 criteria for permanent coverage as telehealth services. The Category 3 services would remain interim 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.

The AMA strongly supported the establishment of Category 3 within the Medicare telehealth services list. Because 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 virus is no longer a threat, the AMA previously recommended that CMS consider extending coverage of the Category 3 services for a longer period. **With the emergence of new variants of the virus, continued resistance by certain individuals to mitigation measures such as mask-wearing, as well as continued vaccine hesitancy and even vaccine opposition, COVID-19 remains an extremely serious public health threat. The AMA continues to believe, therefore, that covering Category 3 services through the end of the year in which the PHE ends will not be sufficient to fully understand the impact of these telehealth services in the post-pandemic health delivery system. For this reason, the AMA firmly backs the proposal to extend interim coverage of the Category 3 telehealth services through the end of calendar year 2023 and urges that it be finalized.**

The AMA has participated in several research studies to better understand how the wide availability of telehealth services during COVID-19 is affecting medical practice and patient care. This research is described in materials submitted to the [Agency for Healthcare Quality and Research \(AHRQ\)](#) Center for Evidence and Practice Improvement in July 2021 in response to its key questions on utilization and effectiveness of telehealth services during the pandemic. The AMA collaborated with other organizations on surveys of patients and physicians conducted by The Telehealth Initiative and in the COVID-19 Health Coalition Telehealth Impact Study. The AMA also partnered with Manatt Health on research to develop a "[Return on Health](#)" framework. The Return on Health research goes beyond examining telehealth services in isolation to articulate the value of digitally enabled care that combines virtual and in-person services to increase overall health and generate positive impacts for patients, physicians, payers, and society. The additional time to examine the Category 3 services will allow better understanding not only of how they may best be utilized as telehealth services in patient care, but also how they may contribute to patient care that combines in-person and telehealth services in these hybrid models of care.

2. *Telephone Evaluation and Management Services in Table 11 (99441-99443) Need to Be in Category 3*

The AMA strongly opposes the proposal to implement the previous Administration’s plan to cease paying for the CPT codes for telephone visits at the end of the PHE. These codes, 99441-99443, should be included in Category 3 and payment should be maintained for them through 2023 like the other Category 3 services. To eliminate coverage for telephone services as soon as the PHE ends would be absolutely counter to this Administration’s goals for improving equity for minoritized and marginalized patient populations, as stated in President Biden’s Executive Order on Advancing Racial Equity and Support for Underserved Communities.

AMA policy calls for “coverage and payment of audio-only services in appropriate circumstances to ensure equitable coverage for patients who need access to telecommunication services but who do not have access to two-way audio-visual technology.” A key finding of the [COVID-19 Health Coalition Telehealth Impact Study](#) was that audio-only coverage is important to allow patients to access their physician when audio-visual service is not available. Analysis of the Coalition’s patient survey found that 20.6 percent of survey respondents over 65 accessed their most recent telehealth service through audio-only telephone. The AMA’s analysis of Medicare claims data for 2020 shows that Medicare spent \$736 million on the three CPT codes for audio-only visits over the entire year, which was 18 percent of total 2020 Medicare spending on telehealth services. Office visits for Medicare patients using audio-visual telecommunications accounted for 52 percent of 2020 Medicare telehealth spending. Overall, telehealth services accounted for 4.9 percent of Medicare spending in 2020.

While not a high percentage of office visits provided to Medicare patients via telehealth in 2020, access to audio-only services is critical for patients who do not have access to audio-visual telehealth services. Discontinuing payment for these services would exacerbate inequities in health care, particularly for those who lack access to broadband and/or audio-visual capable devices, including seniors in minoritized and marginalized communities where there were significant health disparities before COVID-19 that have become much worse during the pandemic. For example, according to the Federal Communications Commission, 628,000 tribal households lack access to standard broadband. Based on data from 14 participating states, the [Centers for Disease Control and Prevention](#) (CDC) reported that age-adjusted COVID-19–associated mortality among American Indian and Alaska Native persons was 1.8 times that among non-Hispanic Whites. Likewise, an October 2020 article in [Government Technology](#) reported that less than half the population in the parts of Alabama defined as the “Black Belt” have internet access, and two of these Alabama counties have no internet access at all. Marginalized urban communities have also been excluded from broadband service and need to rely on audio-only visits, because even when cities have broadband, many residents of these communities do not have access to it in their homes. A June 2020 report of the [National Digital Inclusion Alliance](#) describes data showing that the U.S. has more than three times as many urban as rural households living without home broadband of any kind.

Broadband and audio-visual telehealth services are clearly not accessible by all Medicare patients. We urge CMS to continue covering audio-only evaluation and management services through 2023 like the currently proposed Category 3 services. The AMA has adopted significant policy to address equity in telehealth. We recognize access to broadband internet as a social determinant of health and encourage initiatives to measure and strengthen digital literacy, with an emphasis on programs designed with and for historically marginalized and minoritized populations. We also support efforts to design telehealth technology, including voice-activated technology, with and for those with difficulty accessing technology, such as older adults, individuals with vision impairment and individuals with disabilities.

Finally, the experience physicians have had providing patient care since Medicare began paying for the CPT codes for audio-only visits demonstrates that these visits enhance quality and improve patient health outcomes. They do not diminish quality relative to audio-visual visits and, because some patients are more comfortable speaking with their physicians without video and the quality of telephone service may be better than they can obtain over the internet for audio-visual services, some patients report better health care experiences with telephone than audio-visual visits. The following are several examples provided to us by practicing physicians which illustrate in their own words that the clinical content of their audio-only patient visits is entirely comparable to in-person and audio-visual visits:

- “We talked about her appetite, which has been failing. She has lost weight and has a good scale to tell me her numbers. We talked about the possibility of depression, asked about her support systems, can she get out for a drive with her daughter? And how is she sleeping, does she have food? We talked about her cats, and which movies she is watching, and what medications she is taking. We checked in, just as we used to when she was able to come to the clinic, and last year when I was still able to see her at home. It was a full visit.”
- “Another example is an older gentleman, a veteran, who has been blind in one eye for decades due to a fishing accident. He has a terribly arthritic hip, and would like to have it replaced, but the surgeons say he is too old with too many other illnesses. He takes insulin for diabetes and lives alone ever since his wife died. Despite many ailments, his mind is very sharp. He is able to tell me his blood sugar readings, his blood pressure (on a home blood pressure cuff) and his weight. Over the phone we can have a lot of information exchanged that helps me make decisions with him about his medications, his overall health and his safety at home.”
- “Allowing patients to make this choice is important because it gives them a greater sense of autonomy. Using their preferred means of communication increases the connection between provider and patients which is likely to improve outcome.”
- “As a neurologist, I have done many 99441, 99442, and 99443 audio-only visits. This is essential even after PHE is over, as I serve a rural population of elderly who have no internet or video phone, and live 50-120 miles away with transportation difficulties and need care for their Parkinson’s or other progressive movement disorders e.g., PSP, MSA, as well as post stroke rehab follow-ups, headache, epilepsy, and four types of dementia.”

3. Additional Table 11 Services Should Be Included in Category 3

The AMA disagrees with the CMS proposal to limit Medicare telehealth coverage for the many services listed in Table 11 to the end of the PHE instead of extending coverage through 2023 as is proposed for the services currently included in Category 3. AMA analysis of 2020 Medicare claims indicates that although they only represented a small percentage of the total utilization of a number of the services in Table 11, there were instances in which physicians did need to utilize telehealth for their provision. The new patient home services codes in Table 11 were provided to more than 17,000 patients via telehealth, the nursing facility services to more than 142,000 patients, and hospital inpatient services more than 50,000 times.

Since all of these services have only been covered when provided via telehealth during the COVID-19 PHE, there has not been any experience to date with their telehealth utilization in Medicare outside the context of the PHE. As with the services that are already included in Category 3, CMS should allow time beyond the PHE for experience and evidence to be developed regarding telehealth use of the Table 11 services in clinical care. As noted earlier in this section, the AMA has been involved in research on the

use of hybrid models for delivering care through a mix of virtual and in-person services. Hospital inpatient services, for example, could involve such a hybrid approach and coverage of initial hospital services via telehealth should not be discontinued prematurely.

It is clearly desirable to have a physician see a patient in-person on the first day they are in the hospital, and it also makes sense that the physician would be better able to do subsequent visits by telehealth if they have seen the patient in-person on the first day. It is possible, however, that the physician who does the initial patient visit and the visit on the second day of the hospitalization are different physicians. It is also possible that determinations can be made via telehealth that the patient's condition warrants a hospital admission. The patient's condition can also change between the first and second day of hospitalization, or more information may be available on the second day due to test results becoming available. In these situations, it might turn out to be more important to have an in-person hospital visit on a subsequent hospital day than at the initial visit. It is not difficult to see that inpatient hospital care may lend itself to a hybrid of telehealth and in-person care where the initial hospital visit is not necessarily the one that is most important to provide in-person. CMS should continue to allow more flexibility to determine which hospital, nursing facility, home and other services can be provided via telehealth or in-person.

Telehealth can also be useful in preventing delays in care. For example, in cases when an in-person encounter for an initial hospital visit may not occur without significant delay due to the physician being tied up at another location for an extensive period of time, or located at a significant distance, the physician can expedite the evaluation and management of the patient hours earlier with a telemedicine encounter. Remote access to the electronic medical record, coupled with assistance from staff at the patient's side when needed, allow for valuable medical decision making and care that would otherwise have to be delayed.

In rural hospitals, there are many cases where a decision must be made whether to transfer the patient to another hospital. The best decision may require waiting to see whether the patient gets better or worse during the first day in the hospital and what their test results indicate. If the patient's condition is complex and the local physician does not feel competent to manage the initial day on their own, absent telehealth the patient would likely be transferred immediately. If a more experienced physician at a tertiary care hospital could oversee the patient's initial hospital care via telehealth, though, the patient could stay in the rural hospital until that initial process of treatment and testing is completed. Then, if the patient does need to be transferred, they could be treated in-person on the subsequent days by the physician who treated them via telehealth on the first day. If it turns out that the patient does not need to be transferred, the telehealth policy would have prevented an unnecessary transfer. For example, a neurologist reported to us that they are the only physician of that specialty in their community and providing initial hospital visits to neurological patients via telehealth when they are out of town allows them to avoid patient transfers.

Since the goal of Category 3 is not to make a permanent decision about a code but to allow time for information to be assembled, there is no reason to not allow that time. It is likely that some of the greatest benefits would be in small rural hospitals, and there would be at most a few such cases at any one hospital. It is problematic for CMS to require that evidence be provided to indicate that codes should be permanently added to the telehealth list right now when the rural hospitals whose patients may be most likely to benefit from the policy are not easily able to provide the requisite data, especially as COVID-19 cases have been rising in these communities due to the Delta variant.

We have also heard from physicians that hospital admissions for patients with mental health disorders sometimes need to be done via telehealth due to lack of availability of a psychiatrist to evaluate the

patient in-person. Likewise, new patient visits in nursing facilities need to be done via telehealth when the geriatrician is not available in-person. In these cases, other clinical staff who are present in the hospital or nursing home can assist the physician in obtaining information needed about the patient. Physicians have also provided new patient home visits to patients who could not leave home due to mental health conditions like severe depression but who lived too far away for the physician to travel to their home.

Finally, due perhaps to its code number being similar to the numbers assigned to certain critical care services, CPT code 99473 for *Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*, has been included in Table 11 under the heading Critical care services. This service was new in 2020 so there has been no experience with its provision via telehealth outside of the COVID-19 PHE. It should be included in Category 3 so that additional experience can be gained with its provision via telehealth after the PHE. Rates of blood pressure control have been [moving in the wrong direction](#) and greater use of self-measured blood pressure monitoring is a key tool for reversing this trend.

4. *Direct Supervision by Interactive Telecommunications Technology*

The AMA continues to recommend, as stated in our [comments](#) on the 2021 Medicare physician payment proposed rule, that the current policy during the COVID-19 PHE allowing "direct supervision" to include immediate availability through the virtual presence of the supervising physician using real-time, interactive audio/video communications technology should be made permanent. At a minimum, the current policy should be continued through 2023 as is proposed for Category 3 Medicare telehealth services.

The fact that remote supervision may be inappropriate in some cases does not justify refusing to pay for it under any circumstance. In many rural and underserved areas patients may be unable to access important services if the only physician available 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 direct 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.

5. *Definition of Interactive Telecommunications System to Include Audio-Only Communication Technology for Mental Health Services*

The AMA applauds CMS' proposal to expand the definition of telecommunications system for purposes of telehealth services to include audio-only communication technology for mental health services. CMS should leave the determination of when in-person care is necessary up to the discretion of the treating physician. As we state above, the AMA strongly supports coverage and payment of audio-only services in appropriate circumstances to ensure equitable coverage for patients who need access to telecommunication services but who do not have access to two-way audio-visual technology. Increasing access to audio-only services for mental health care can help ameliorate inequities in health care, particularly for those who lack access to broadband and/or audio-visual capable devices, including seniors in minoritized and marginalized communities where there were significant health disparities before COVID-19 that have become much worse during the pandemic.

Based on our review of CMS' proposal, AMA believes it is CMS' intention to include services provided to patients with a substance use disorder (SUD) in the definition of mental health services for purposes of

the proposal to expand the definition of telecommunications services to include audio-only services. However, because SUD is not explicitly identified in CMS' discussion, the AMA encourages CMS to clarify that SUD services are considered mental health services for purposes of the expanded definition of "interactive telecommunications system" to include audio-only services under 42 C.F.R. § 410.78(a)(3). For example, counseling and therapy provided as part of the monthly codes for office-based management of patients with SUD (G2086, G2087, and G2088) should be able to be delivered as audio-only services.

6. Implementation of Provisions of the Consolidated Appropriations Act of 2021

CMS is also proposing to implement related provisions of the Consolidated Appropriations Act of 2021 which created an exemption from the geographic restrictions of section 1834(m)(4)(C)(i) of the Act and included the home as an originating site for telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE for COVID-19, so long as the treating physician had furnished in-person services to the patient for the first time in the last six months. While the AMA believes this statutory provision is an arbitrary restriction on patient access without any evidence demonstrating clinical benefit, we understand that CMS is simply implementing a Congressional mandate.

However, the AMA is with CMS' proposal to require that patients must have an in-person visit with their treating physician or a physician from the same practice every six months, based on its authority to require in-person visits at such times as the Secretary determines appropriate after the initial visit. This would create an additional arbitrary and burdensome requirement over and above the statutory requirement that a practitioner or physician must have furnished an in-person, non-telehealth service to the beneficiary in the six-month period prior to the first time such practitioner or physician furnishes an eligible telehealth service. While CMS has the authority to add additional requirements, it does not cite a rationale as to why this additional burden is appropriate other than by reference to the statutory requirement in 1834(m)(4)(C)(i). Instead, CMS states that "[w]e chose this interval because we are concerned that an interval less than six months may impose potentially burdensome travel requirements on the beneficiary, but that an interval greater than six months could result in the beneficiary not receiving clinically necessary in-person care/observation."

The AMA is not aware of any evidence that requiring an in-person visit every six months, in and of itself, provides a clinical benefit or would otherwise be an appropriate interval. Further, we agree with CMS' concern that implementing this requirement could have a negative impact on patients' ability to receive care given the lack of regular access to mental health care in certain geographic areas. Requiring additional travel that may not be feasible for many could force patients to forgo care they would otherwise be able to access. The AMA believes treating physicians are in the best position to understand the clinical needs of their patients and to determine when in-person treatment is necessary, whether that is a greater or shorter interval than every six months. **The law gives CMS discretion to determine appropriate subsequent periods for in-person visits, including determining that a regulatory requirement for follow up is unnecessary. CMS should take advantage of its regulatory flexibility to ensure that patients can gain access to these services to the greatest extent possible and leave the determination of when in-person care is necessary up to the discretion of the treating physician.**

In addition, the introduction of a requirement of recurring in-person visits for mental health patients could introduce even more administrative confusion given the lack of a similar burden placed on patients receiving telehealth services for a diagnosed SUD. While the different burdens placed on the use of

telehealth services for the first time to treat patients with SUD and patients for mental health services are entirely arbitrary, we understand these are statutorily mandated. Imposing different requirements on the necessity of recurring in-person visits for SUD services and mental health telehealth services would be an additional arbitrary burden and would create additional and significant administrative burdens on physician practices. We urge CMS to avoid creating arbitrary requirements on select telehealth services and adding regulatory complication for practices that may impact their ability to provide timely and effective care.

CMS has also asked for input concerning whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service. We believe this should be acceptable and is consistent with traditional billing practices for purposes of determining whether a patient has an established relationship with a physician or practitioner. We urge CMS to provide as much flexibility it can in order to ensure that patients do not lose access to needed care due to lack of availability of their typical physician. Demands for constant availability of the same physician could accelerate stress and burnout. Patients could lose out on access simply because their regular treating physician is busy with other patients, away from the practice due to illness or vacation, or even retired from practice. CMS should further ensure physicians are empowered to use locum tenens when they are individually unable to care for their patients. Generally, a Medicare patient should not be penalized because of a physician’s lack of availability, so CMS should use every authority possible to ensure these patients can access care, including by going outside the practice if necessary.

D. Remote Therapeutic Monitoring (CPT® codes 989X1, 989X2, 989X3, 989X4, and 989X5)

- **Recommendation:** The AMA urges CMS to clarify that the Remote Therapeutic Monitoring (RTM) codes are in fact general medicine codes and, as such, tasks performed by physical therapy assistants are billable when provided under the direct supervision of the physical therapist and under the physical therapist NPI number, making incident-to policy irrelevant.

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
989X1	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment	0.00 (PE Only)	0.00 (PE Only)
989X2	device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days	0.00 (PE Only)	0.00 (PE Only)
989X3	device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days	0.00 (PE Only)	0.00 (PE Only)
989X4	Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes	0.62	0.62

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
989X5	each additional 20 minutes (List separately in addition to code for primary procedure)	0.61	0.61

The AMA appreciates that CMS is proposing the RUC recommended work RVUs of 0.62 and 0.61 for CPT codes 989X4 and 989X5, respectively, as well as the RUC recommended direct PE inputs without refinement for both codes. CMS states "...according to RUC documents, primary billers of RTM codes are projected to be nurses and physical therapists." The AMA notes an error in the original Summary of Recommendation Forms SORs submitted by the RUC. The SOR's should have stated "Nurse Practitioner" in the utilization section, not "Nursing." Primary billers of RTM codes are not nurses and physical therapists, rather they will be a range including physiatrists, nurse practitioners, and physical therapists.

For all the codes in the family, the clinical staff type of RN/LPN/MA will be typical, because it was estimated that most of the services will be reported by physicians or nurse practitioners. However, physical therapists would supervise physical therapy assistants or physical therapy aides when they provide this service. The AMA believes these codes should remain general medicine codes and tasks performed by physical therapy assistants are billable when provided under the direct supervision of the physical therapist and under the physical therapist NPI number, making incident-to policy irrelevant. Separate CPT or HCPCS II (G) codes are not warranted to merely address which clinical staff type is utilized in assisting the physician or other qualified health care professionals who provide the service. With this clarification, there should be no need to "remedy the issues related to the RTM code construction in order to permit practitioners who are not physicians or NPPs to bill the RTM codes."

CMS should clarify its position so that the RTM codes may be used by certain qualified health care professionals, such as physical therapists. CMS has created confusion among these stakeholders in providing the following rationale:

- CMS claims that physical therapists cannot bill the new RTM codes, even though the codes were created to be used by physicians and QHPs (including physical therapists) by specifically placing the codes in the medicine section of CPT.
- CMS explains that because the new RTM codes are modelled on the Remote Patient Monitoring (RPM) codes, "incident to" services became part of the all five codes 989X1-989X5 and because only physicians and certain other practitioners are authorized to furnish and bill "incident to" services physical therapists and other practitioners, who are not physicians or NPPs cannot report the services.
- CMS goes on to say that the codes would have to be designated as care management services (like RPM codes 99457 and 99458) to allow for general supervision rather than direct supervision for "incident to" services and because the codes are not E/M codes, they cannot be designated as care management services and would require direct supervision.

We urge CMS to clarify that these codes are in fact general medicine codes and, as such, tasks performed by physical therapy assistants are billable when provided under the direct supervision of the physical therapist and under the physical therapist NPI number, making incident-to policy irrelevant.

CMS is seeking comment on the typical type of device(s) and associated costs of the device(s) that might be used to collect the various kinds of data included in the code descriptors (for example, respiratory system status, musculoskeletal status, medication adherence, pain) for the RTM services. The AMA encourages CMS to review what was submitted with the AMA recommendations and in comments that are submitted by national medical specialty societies and other health care professional organizations.

989X2

The AMA also disagrees with the refinement to the direct inputs for the PE-only code 989X2. CMS is not proposing the RUC’s recommendation for a new supply item, *Remote respiratory therapy system*, stating that this \$25 monthly rental fee would not be paid as a direct cost under the PFS.

The AMA recommends that CPT code 989X2 include a new supply input, *Remote respiratory therapy system fee*. This system and its related technology are required in order to appropriately perform the RTM services. The monthly fee per patient comprises the leasing of the Bluetooth sensors (2 provided in each rental) placed on top of the patient’s inhalers (typically 1 daily use inhaler and 1 rescue inhaler) as well as use of the app technology for tracking.

CMS states that the Agency has historically “considered most computer software and associated licensing fees to be indirect costs.” The AMA believes this an inaccurate assertion. While this may have been the case with generic software like Microsoft Office, it is not true for procedure-specific software. There are currently 110 codes for 2022 that include “software” direct inputs. CMS is not setting a precedent of including software and associated licensing fees in codes like 989X2. The 42 CMS codes containing software are listed below:

CMS Code	EQUIPMENT Description
ED009	computer and VDT and software
ED020	computer workstation, nuclear pharmacy management (hardware and software)
ED040	genetic counseling, pedigree, software
ED051	multimodality software
ED058	CAD Software
ED060	sheer wave elastography software
ED063	Sequence data analytics (alignment/variant calling) and reporting software
EP090	IkoniLan Software
EQ008	ECG signal averaging system, w-P-waves and late potentials software
EQ013	EEG analysis software
EQ018	EEG, digital, standard testing system (computer hardware & software)
EQ027	Farnsworth-Munsell 100-Hue color vision test w-software
EQ070	barostat system, with hardware & software
EQ075	breast biopsy imaging system, stereotactic (imager, table, software)
EQ087	cognitive abilities testing software (Woodcock Johnson)
EQ135	impedance recording workstation w-software
EQ187	nutrition therapy software (Nutritionist Pro)
EQ196	pH recording workstation w-software (Bravo)

EQ197	pH recording workstation w-software (Digitrapper)
EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)
EQ212	pulse oxymetry recording software (prolonged monitoring)
EQ218	range of motion (spinal) device and software (Myo-Logic)
EQ222	rhinomanometer system (w-transducers and software)
EQ284	reader software, CASCADE (Caldwell Labs)
EQ298	Coronary CTA Post Process Software
EQ303	dermal imaging software
EQ305	Diabetes education data tracking software
EQ307	Electrophysiology, Pulmonary Vein Processing Software
EQ312	INR analysis and reporting system w-software
EQ315	Left Ventricular Function Software
EQ329	ZEPHR impedance / pH reflux monitoring system with data recorder, software, monitor, workstation and chart
EQ330	EEG, digital, testing system (computer hardware, software & camera)
EQ380	flow cytometry analytics software
ER019	densitometry unit, fan beam, DXA (w-computer hardware & software)
ER030	film dosimetry equipment-software (RIT)
ER055	radiation therapy dosimetry software (Argus QC)
ER070	portal imaging system (w-PC workstation and software)
ER077	image-acquisition software and hardware (Brainwave RealTime, PA, Hardware)
ER081	Calcium Scoring Software
ER112	Software and hardware package for tumor and other distribution Quantitation
ES029	video system, capsule endoscopy (software, computer, monitor, printer)
ES049	incision programming software

CMS is proposing to value the practice expense for the PE-only codes using crosswalk methodology. CPT codes 989X2 and 989X3 would be crosswalked to reference code 99454 *Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*. While we acknowledge that using a crosswalk could result in similar total resource costs, the AMA questions the use of a crosswalk to CPT code 99454 which would overvalue the PE for 989X2 where the only input is the monthly fee of \$25.

The AMA urges CMS to accept the RUCs recommendation that CPT code 989X2 warrants inclusion of a monthly fee for the remote respiratory therapy system and its related technology including leasing of the Bluetooth sensors and use of the app technology for tracking. This fee represents a per-patient, single-use item, and thus is appropriately included as a direct supply. **The AMA recommends that CMS negate the need for a crosswalk by accepting the new supply item, *Remote respiratory therapy system fee as a direct practice expense input for CPT code 989X2*.**

E. Comment Solicitation for Codes Involving Innovative Technology

CMS asks a series of questions to “...help us better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. The AMA appreciates that the Agency takes the importance of payment for AI seriously and is actively engaged in gathering information from stakeholders to determine accurate resource costs. The AMA recognizes that considerations around AI delivery are complex and their impact on payment relevant. For example, applications may change our very understanding of “work done by machines” in complicated ways. At the same time AI applications offer medical advancements and innovation to serve as an additional tool in the overall toolkit of physicians and other health care professionals to improve patient care and outcomes. AI is transforming quality, efficiency, accessibility, and patient, as well as physician, experience within the health care system. It is gaining traction in everyday practice and physicians should be compensated appropriately for the expense of applying AI to enhance patient care.

While we appreciate and support CMS’ commitment to gathering additional information on innovative technologies including software algorithms and AI, we recommend that, in addition to the questions posed here, CMS engages in a broader RFI independent of the Physician Fee Schedule to ensure all impacted stakeholders have a chance to comment. Seeking input from a broader array of stakeholders may provide the Agency with additional insight and information that it may not receive in response to the physician fee schedule and allow for additional time to consider that information.

1. *To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work?*

The AMA commends CMS for exploring the important and wide-reaching topic concerning innovative technologies such as software algorithms and AI and their relationship to physician work. The AMA is also anticipating important developments in this evolving area of digital medicine and has developed resources related to the questions posed in the Medicare PFS proposed rule for 2022. The AMA’s work in this area is guided by subject matter experts in AI, who have experience integrating digital medicine services and tools into clinical practice. These AI experts are consulted through the AMA convened Digital Medicine Payment Advisory Group (DMPAG). One of the goals of the DMPAG is to advise the AMA on approaches to establish a clear pathway to clinical integration of digital medicine to ensure access to high quality and safe clinical care for patients and their physicians that promote improved health outcomes.

The DMPAG has participated in the AMA’s CPT Editorial Panel process because it has identified limitations in the terminology used to date to describe AI services in the CPT code set. The AMA acknowledges that impacts on work are possible, but this will vary based on the role AI plays in the clinical encounter. Terminology such as substitutes or supplements is not appropriate, rather, the AI application’s contribution to clinical work depends on the level of autonomy of the application and could lessen or increase physician work, depending on the clinical situation to which the application is applied. AI technologies are expanding in clinical use, but until they become more commonplace, making determinations about how they impact physician work across the Medicare Physician Payment Schedule is not possible. An appropriate starting point is for health care professionals to gain a better understanding of how to accurately describe these services and procedures in a way that defines elements of differentiation between AI services.

New resources currently under review by the AMA's CPT Editorial Panel are intended to establish foundational definitions relevant to the CPT code set. Most AI is a resource for physicians to assist in their work and detect clinically meaningful data. AI or software algorithms do not replace physician work. AI that performs a service independent of a physician represents a new service distinct from physician work and based on the clinical procedure or service provided to the patient.

The AMA is encouraged that the Agency has put this question forward so that it can serve as a starting point for a fruitful dialog about the future of AI in health care. The AMA reiterates that the appropriate terminology is being carefully considered at the CPT Editorial Panel. We recommend that the Agency work directly through the established CPT Editorial Panel process and refrain from making decisions about payment for AI and software algorithms until guidance on terminology can be established.

- 2. How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries?*

The AMA believes it is too early in the diffusion of these technologies to make broad determinations. On the one hand, it may seem that an AI application performing clinical tasks or making clinical decisions lessens the quantity of physician work. On the other hand, this additional software acquired information may prompt additional physician tasks. For instance, integrating the determinations of the AI algorithm into the broader clinical presentation requires careful consideration. There may be instances where the new data are contradictory or inconsistent with other clinical data or the physician's clinical intuition, increasing the intensity of decision making. As CMS acknowledges above, there may be additional work in explaining to the patient that a digital application is being used and the way the application operates. It is possible that the total time may decrease at the same time as the intensity increases, thereby maintaining or increasing the total work involved.

- 3. How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?*

Costs for innovative digital technologies vary based on the individual application and the business model of the associated technology company. This is true across services, specialties, types of practice and patient cohorts. As such, determinations about cost will require individual per-code or per-encounter analysis. As experience with these applications grows, trends may become apparent such as how physician offices pay for technology, including hardware, software as a medical device, servers, support services, and maintenance. Trends may also begin to emerge regarding which, if any, costs will decrease, increase, or stay the same over time. While it may be some time before software algorithms and/or AI have a large-scale impact on cost structures in the physician office setting it is important that physicians' offices are compensated for the resources to provide individual AI services. The AMA has found that many AI applications and software can be accounted for as a direct practice expense within the practice expense component of CPT codes and that many of the existing business models are analogous to direct practice expense already accounted for in the PFS. There are relevant payment solutions to be gleaned from what already exist within the PFS payment methodology and the AMA will outline some potential solutions and relevant examples that may be applicable in payment determinations.

Licensing agreements are a business model used for many types of software products across the business landscape. When a health care organization pays a licensing fee to use AI analysis software for a specific medical service this is unique from a general software license used in the everyday functioning of a medical office. Software used for scheduling and billing are not applied to specific medical services and are, therefore, considered indirect expenses within the PFS. In contrast, an AI software license fee is integral to the specific medical service and can be allocated to the individual patient receiving that service. As such, the licensing fee is a direct practice expense. Because the license for AI software or algorithm is purchased and then used to provide the medical service to many patients over time it is analogous to a direct practice expense equipment item in the Medicare PE methodology. An apt example within the PFS of a licensing business model used in the delivery of a specific service and defined as a direct practice expense is EL024, *Image Checker CAD (9.4) License for One FFDM (for mammography room)* included in the PE allocated to:

- 77065 - *Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral.*
- 77066 - *Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral.*
- 77067 - *Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed.*

Computer-aided detection (CAD) refers to pattern recognition software that identifies suspicious features on a radiological image. CAD is a particularly apt example as it is a form of algorithm, analogous to AI. In the Medicare PFS Final Rule for 2017, the Agency described equipment item EL024 for mammography services as the “License required for using CAD. This is a one-time fee.” A formula within the CMS PE methodology is applied to all equipment items to compute the equipment cost per minute of use. This one-time licensing fee can be treated as the purchase price of the equipment (\$35,000) and is not literally a one-time fee but rather is amortized over the useful life of the equipment which was determined to be 5 years for the CAD license. For CPT code 77067, CAD is used for 16 of the 31 minutes that a mammography technologist spends to perform the imaging study at a rate of \$0.1356 per minute. This calculates to \$2.17 in equipment costs for the use of CAD which factors into the total direct PE costs for this service of \$48.52. This amount is one input within the PE Methodology used to calculate the overall PE relative value unit (RVU) for CPT code 77067.

Not all software included as an equipment direct practice expense has its payment based on a licensing structure. For instance, there are many instances of software included as a direct practice expense equipment item for medical services. There are 42 equipment items listed in the table below that include software as the equipment item directly or as part of the equipment item. This demonstrates that, although some more administrative types of software are accurately categorized as indirect practice expense, software that is central to the specific procedure being performed is accurately categorized as a direct practice expense.

Software as Equipment Item

CMS Code	EQUIPMENT Description	Useful Life	Price	Cost Per Minute
ED009	computer and VDT and software	5	\$7,100.00	\$0.028
ED020	computer workstation, nuclear pharmacy management (hardware and software)	5	\$13,400.00	\$0.053

ED040	genetic counseling, pedigree, software	5	\$950.00	\$0.004
ED051	multimodality software	5	\$13,767.50	\$0.055
ED058	CAD Software	5	\$43,308.12	\$0.168
ED060	sheer wave elastography software	5	\$9,600.00	\$0.038
ED063	Sequence data analytics (alignment/variant calling) and reporting software	5	\$28,800.00	\$0.112
EP090	IkoniLan Software	5	\$50,000.00	\$0.189
EQ008	ECG signal averaging system, w-P-waves and late potentials software	5	\$17,155.87	\$0.068
EQ013	EEG analysis software	5	\$82,000.00	\$0.311
EQ018	EEG, digital, standard testing system (computer hardware & software)	7	\$21,000.00	\$0.068
EQ027	Farnsworth-Munsell 100-Hue color vision test w-software	7	\$626.50	\$0.002
EQ070	barostat system, with hardware & software	5	\$23,625.00	\$0.094
EQ075	breast biopsy imaging system, stereotactic (imager, table, software)	5	\$192,334.16	\$0.729
EQ087	cognitive abilities testing software (Woodcock Johnson)	5	\$558.00	\$0.002
EQ135	impedance recording workstation w-software	5	\$63,988.40	\$0.242
EQ187	nutrition therapy software (Nutritionist Pro)	5	\$595.00	\$0.002
EQ196	pH recording workstation w-software (Bravo)	5	\$11,490.00	\$0.046
EQ197	pH recording workstation w-software (Digitrapper)	5	\$11,490.00	\$0.046
EQ198	pacemaker follow-up system (incl software and hardware) (Paccart)	7	\$215,466.63	\$0.658
EQ212	pulse oxymetry recording software (prolonged monitoring)	5	\$537.75	\$0.002
EQ218	range of motion (spinal) device and software (Myo-Logic)	5	\$28,731.69	\$0.111
EQ222	rhinomanometer system (w-transducers and software)	7	\$18,984.93	\$0.061
EQ284	reader software, CASCADE (Caldwell Labs)	5	\$3,728.05	\$0.015
EQ298	Coronary CTA Post Process Software	5	\$65,000.00	\$0.246
EQ303	dermal imaging software	5	\$4,500.00	\$0.018
EQ305	Diabetes education data tracking software	5	\$500.00	\$0.002
EQ307	Electrophysiology, Pulmonary Vein Processing Software	5	\$109,774.01	\$0.416
EQ312	INR analysis and reporting system w-software	5	\$19,765.00	\$0.078
EQ315	Left Ventricular Function Software	5	\$45,000.00	\$0.174
EQ329	ZEPHR impedance / pH reflux monitoring system with data recorder, software, monitor, workstation and chart	5	\$22,250.00	\$0.088
EQ330	EEG, digital, testing system (computer hardware, software & camera)	7	\$43,810.37	\$0.138
EQ380	flow cytometry analytics software	5	\$23,600.00	\$0.094

ER019	densitometry unit, fan beam, DXA (w-computer hardware & software)	5	\$67,339.18	\$0.255
ER030	film dosimetry equipment-software (RIT)	5	\$30,840.00	\$0.120
ER055	radiation therapy dosimetry software (Argus QC)	5	\$21,000.00	\$0.083
ER070	portal imaging system (w-PC work station and software)	5	\$489,940.00	\$1.856
ER077	image-acquisition software and hardware (Brainwave RealTime, PA, Hardware)	3	\$108,807.00	\$0.610
ER081	Calcium Scoring Software	5	\$55,000.00	\$0.208
ER112	Software and hardware package for tumor and other distribution Quantitation	5	\$40,535.75	\$0.157
ES029	video system, capsule endoscopy (software, computer, monitor, printer)	5	\$10,181.55	\$0.040
ES049	incision programming software	5	\$10,012.50	\$0.040

Analysis Fee

In the analysis fee business model, the purchaser (physician practice, hospital system, patient, etc.) pays a set amount per analysis at the time of use. The concept of an analysis fee fits well into the PFS practice expense methodology. Different than a licensing fee as described above, the analysis fee included in the RUC recommendation for CPT code 92229 *Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral* is a one-time fee that is not used for a certain amount of minutes per service, but rather is allocable without amortization to the distinct patient at the time that they receive the service. The physician’s office incurs the expense only when they use the application. For this reason, the practice expense associated with the AI application is analogous to a disposable medical supply, a direct practice expense in the PFS PE Methodology. The same as a disposable supply, it can only be used once per patient to provide a distinct service and is assigned a specific purchase price in the Medicare direct PE inputs medical supplies listing.

Like an analysis fee, CPT code 95905 *Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report* is an example of a code that includes the type of supply analogous to the analysis fee supply. Supply item, SD223 *electrode, array, nerve, preconfigured* provides electrodiagnostic testing using algorithms that can drive stimulus delivery, measure, and analyze the response, and report study results at the point of care through a single use, preconfigured array. Like 92229, the technology can be used in the primary care setting without specialized training for clinical staff.

Subscription

Industries in every sector of the economy have adopted subscription business models for everything from meal prep kits to clothing. This successful business model is expanding to health care settings, especially for digital medicine health solutions such as AI. The most common subscription structure involves the physician’s office purchasing a subscription for an allowable number of studies per time-period (i.e., capitated per week, month, year). This expense can be accounted for as a direct practice expense on a per service, per patient basis by dividing the subscription cost for the agreed amount of time by the typical number of patients receiving the service in the agreed amount of time. If the appropriate software specific purchasing information were provided for RUC review, a per unit cost could be calculated analogous to a

disposable medical supply. This approach would be very similar to the simple calculations that are done to determine the monthly cost per unit of a supply item for time-based CPT codes.

Data Processing Center

External electrocardiographic recording is structured where the physician's office performs one component of the service and an outside entity that can report services to Medicare directly, in this case a IDTF data processing center, performs the other component of the service. The family of services is a relevant example of the way that sets of codes can be structured to allow for direct practice expenses to be accounted for, even for a supply that spans two distinct sites of service. The following CPT codes utilize new technology supply item, *extended external ECG patch, medical magnetic tape recorder (ECG patch)* that patients wear for a physician determined period of time:

- 93241 - *External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*
- 93243 - *External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*
- 93245 - *External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*
- 93247 - *External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*

The ECG patch is applied by clinical staff in the physician's office. However, the patch is typically provided by the IDTF to the practice rather than purchased by the practice itself. The work of the clinical staff in the physician's office to register, sync, apply and activate the patch is performed through reporting a different practice expense only CPT code than the code that includes the patch itself. Typically, the patch is removed by the patient themselves and delivered to the IDTF. An electrodiagnostic technologist at the IDTF performs several clinical activities to prepare the patch for scanning analysis and initiate algorithm processing. A cardiovascular technician at the IDTF completes the scanning analysis by reviewing data, rhythms, and beats to identify the various types of abnormalities (blocks, ectopics, AF, tachycardias, etc.) identified by the algorithm to include in the report. The ECG patch can clearly be categorized as a direct practice expense as it is a disposable medical supply. It can only be used once per patient to provide a distinct service.

AI technologies are developing quickly and along with that the cost structures used to bring AI enabled services and devices to the health care market will continue to develop and evolve. The PFS is already structured to allow for incorporation of AI as a direct practice expense and the AMA is confident that CMS can rely on mechanisms within the current system for coverage and payment of AI that can improve patient outcomes. The AMA hopes that CMS will be agile and responsive to innovation as it is critically important that AI technology developers and the physicians and other qualified health care professionals providing quality patient care, see progress on payment policy. Ultimately, even if AI is capable of "thinking" like a physician it is still a physician who decides when to use AI and how to best treat patients based on the totality of data collected.

4. *How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services*

involving software algorithms and/or AI? Additionally, to what extent have services that involve innovative technology such as software algorithms and/or AI affected access to Medicare-covered services in rural and/or underserved areas, or for beneficiaries that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions/frailty, etc.) in obtaining health care?

Digital health technologies, including AI-based systems, hold great promise to help advance the quadruple aim of enhancing the patient experience, improving population health, reducing costs, and improving the work life of health care providers, including clinicians and staff. Innovative technologies, including software algorithms and AI, can increase access to appropriate care such as recommended screenings or specialty care that would otherwise require additional visits and/or travel for patients and their families.

For example, screening for diabetic retinopathy using automated point-of-care retinal imaging, billed using CPT code 99229, is currently covered by CMS. This allows practices that did not have the capacity to perform screening to now provide this important service to patients. In the near future, similar augmented/artificial intelligence tools will have the potential to help physicians provide additional necessary screening, diagnostic, and treatment services to individuals in underserved areas who otherwise might be unable to access these services.

However, we stress that the development and adoption of AI tools and other innovative technologies into clinical practice remains a work in progress. While we see great promise in the potential of innovative technology to expand access to care to individuals living in rural and underserved areas and beneficiaries who face other barriers to care, as well as augment physician work in ways that could potentially reduce burden, more evidence is still needed for all but a few already rigorously studied widely reported clinical scenarios to measure the impact of these emerging technologies across multiple settings and in diverse populations. The AMA is pleased that CMS is seeking information on the ability of these tools to expand access to care and supports the collection of additional data to better understand the impact AI and other innovative technologies have on access to care.

- 5. Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? As we are considering appropriate payment for services enabled by new technologies, there are considerations for program integrity. For example, section 218(b) of the PAMA required that we establish an Appropriate Use Criteria Program to promote appropriate use of advanced diagnostic imaging services provided to Medicare beneficiaries. To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?*

The AMA is not aware of any evidence to suggest that unique concerns about overutilization, fraud, waste, or abuse exist in services that are driven by or supported by innovative technology such as software algorithms and/or AI. As a result, we believe that CMS and OIG use their established authorities to investigate and enforce fraud, waste, and abuse.

The AMA would not support an expansion of the AUC program to any new services or service categories at this time due to the significant challenges and burdens associated with its implementation for advanced diagnostic imaging services, which has been continually delayed since CMS first outlined a programmatic framework in the 2015 Medicare Physician Fee Schedule proposed rule. Please review the AMA's

detailed AUC comments, which appear later in this letter for more information. In addition, we specifically caution against viewing AUC as a fraud and abuse mechanism. The purpose of AUC is to drive behavior change related to low-value services as determined by clinical guidelines developed by provider-led entities, not to act as a means to identify and mitigate fraud and abuse. We recommend that CMS work with specialty societies and other stakeholders to determine more appropriate guardrails for detecting and mitigating fraud and abuse of these new services.

6. *Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?*

The AMA commends CMS for seeking greater clarity on the potential impact of innovative technology such as software and/or AI on access to health care and health equity. AMA policy supports the development of thoughtfully designed, high-quality, clinically validated health care AI that:

- is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
- is transparent;
- conforms to leading standards for reproducibility;
- identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and
- safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.

When developed with these principles in mind and incorporated into clinical practice appropriately, we believe that innovative technology including products incorporating AI can help improve quality of care and increase health equity.

However, we note that many of these products are novel and not yet in widespread use so their impact on quality of care or health equity is not yet entirely clear. While we believe these products can be used to provide higher quality of care to a greater number of patients, we strongly support CMS and other regulators interest in gathering the data necessary to calculate the performance and impact of innovative technology moving forward. Given that the approaches to design and implementation, as well as the underlying data provenance, will vary by necessity, it will be important to gather additional evidence on the development and impact of the use of specific technologies.

Advancing equity in health requires the understanding and acceptance of the harmful impacts of historical and contemporary racism on our individual and collective ability to strive for and achieve a reality in which we all have the resources, conditions, opportunities, and power to thrive and achieve optimal health. The AMA is strongly committed to achieving these goals and addressing related issues, including the potential of AI to introduce inappropriate bias into clinical decision making.

The AMA is greatly concerned with the potential for software and AI to introduce bias into the medical system when these products are not developed with a comprehensive data set or do not provide a clear

description of the limitations of an application. Algorithms are only as good as the data on which they are trained and operate and can be subject to bias arising from several directions and due to many causes: limitations in the geographic origins and ancestral representativeness of the data collected, missing data; small sample sizes; the implicit biases and inaccurate or inexperienced judgments of clinicians; or differential care delivered in different clinical settings to different populations of patients. As a result, technical solutions to mitigate bias before, during, or after an algorithm processes data may not be sufficient to ensure that an algorithm benefits patients as intended. Instead, there must be a focus on ensuring the data used to train algorithms are free from bias, including inappropriate reliance on race or ethnicity.

Therefore, it is our belief that the best way to control for bias is during algorithm conceptualization and development, including ensuring appropriate and unbiased data are used for training. While potential bias can be discovered and ameliorated after the product is in use, ideally developers will have a comprehensive product development plan in place that helps ensure it is free of inappropriate bias throughout the total product lifecycle and, most importantly, before it is marketed. We follow with interest the progress being made to develop tools to detect algorithmic bias and anticipate that market authorization and favorable coverage decisions will in time require use of such tools by developers.

We applaud CMS' commitment to understanding these issues. The AMA believes it is the FDA, not CMS, that is best positioned to evaluate an AI product's potential for introducing inappropriate bias into clinical decision making, especially bias which could influence outcomes for minoritized groups, and that such evaluation should be incorporated into the requirements to be met by AI developers seeking authorization to market. Products that are found to potentially introduce bias should not be granted marketing authorization nor should they be covered by CMS.

F. Evaluation and Management (E/M) Visits

1. Split (or Shared) Visits

- **Recommendation:** The AMA urges CMS not to require a modifier to be reported for split (or shared) visits. Requiring a modifier adds a level of administrative burden that the new E/M coding structure and guidelines were designed to alleviate. The AMA also urges CMS to work with the CPT/RUC Workgroup on E/M to create a proposal to the CPT Editorial Panel to address the following questions and to clarify the reporting in CPT Guidelines. It is important that physicians can focus on one consistent set of guidelines in reporting their services.

CMS has requested comments on developing additional policy for split (or shared) visits performed in a facility setting, including:

Qualifying Time

CMS is seeking public comment on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) emergency department visits, since those visits also have a unique construct.

Same Group

CMS is seeking public comment on whether they should further define “group” for purposes of split (or shared) visit billing. While CMS is not proposing a definition in this proposed rule, they have considered several options, such as requiring that the physician and NPP must be in the same clinical specialty, in which case they would use the approach outlined in the CPT E/M Guidelines; that is the NPP is considered to be in the same specialty and subspecialty as the physician with whom they are working. CMS is also considering an approach under which they would align the definition of “group” with the definition of “physician organization” at § 411.351. The term “physician organization” is defined at § 411.351 for purposes of section 1877 of the Act and regulations in 42 CFR part 411, subpart J (collectively, the physician self-referral law).

Medical Record Documentation

To ensure program integrity and quality of care, CMS is proposing that documentation in the medical record must identify the two individual practitioners who performed the visit. The individual who performed the substantive portion (and therefore bills the visit) would be required to sign and date the medical record. CMS is proposing to revise the regulation at § 415.140 to reflect the conditions of payment for split (or shared) visits.

Claim Identification

CMS is proposing to create a modifier to describe split (or shared) visits and proposing to require that the modifier must be appended to claims for split (or shared) visits, whether the physician or NPP bills for the visit. Currently, CMS cannot identify through claims that a visit was performed as a split (or shared) visit, which means that they would know that a visit was performed as a split (or shared) visit only through medical record review.

2. Critical Care Services (CPT codes 99291-99292)

CMS proposes to adopt the CPT guidelines for the reporting of critical care services. The AMA supports this consistency. CMS, however, goes on to propose that physicians would no longer be able to report other Evaluation and Management Services on the same date as a critical care visit. This is contrary to CPT specific instruction (CPT 2021 Professional, page 31) which states, “Critical care and other E/M may be provided on the same patient on the same date by the same individual.” **We urge CMS to reconsider this proposal. Although, not typical, instances occur where a patient may be seen on an inpatient floor, emergency department, or even a physician office and then later require critical care services on the same date. These are separate services and should be reported and paid.**

Additionally, CMS proposes to prohibit practitioners from reporting critical care visits during the same time-period as a procedure with a global surgical period and will not pay for any critical care for a patient who has undergone a procedure or surgery, regardless of who performs it. **The AMA urges CMS to reconsider this proposal. CMS should maintain the current policy as described in the Medicare Claims Processing Manual.**¹

¹ Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners
<https://www.cms.gov/files/document/medicare-claims-processing-manual-chapter-12>.

G. Office Visits Included in Codes with a Surgical Global Period

- **Recommendations:** The AMA continues to oppose 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 urges CMS to apply the office visit increases to the office visits included in surgical global payment, as it has done historically. The AMA reiterates our concerns with the RAND reports, which the Agency should not rely on to pay surgeons at a different rate than other physicians. The AMA asks for CMS to convene the RUC and other stakeholders to discuss the global surgical codes issues and indicate specific codes which it believes are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period.

The AMA refers to the RUC recommendations previously communicated with the Agency and strongly believes that it is appropriate to apply the increased 2021 valuation of the office E/M visits to the visits incorporated in the surgical global packages and disagrees with the CMS proposal to not apply the office E/M visit increases to the visits bundled into global surgery payment. An example of the shortcomings of this policy decision became apparent during discussion of CPT code 67141 *Prophylaxis of retinal detachment (e.g., retinal break, lattice degeneration) without drainage; cryotherapy, diathermy* (RUC recommended work RVU = 2.53 and 2-99213 office visits) at the October 2020 RUC meeting. The RUC questioned whether the specialties had considered changing the global period to a 000-day global given that the intensity will be low and the office visits in 2021 will be of a different value. The specialties explained it is routine and typical that the two postoperative visits occur as part of the work within the 10 days after the procedure. Hence, the survey code 67141 is a good fit for the 010-day global and is in alignment with the other retinal laser codes and ophthalmic laser codes for other diseases. Relativity is therefore better maintained by keeping as a 010-day global even though the intensity is low. The RUC noted that these codes are being valued too low considering that office visits for the surgical global period are not going to be increased to the 2021 office E/M codes. Considering that the 99213-office visit in 2021 is valued at 1.30 RVUs, two 99213 office visits are valued higher than the 2.53 value of this code. Consequently, the CMS policy is disadvantageous to the eye surgeons and an example of shortcomings and rank order abnormalities the flawed policy creates. The Agency's position implies that the physician work for office visits is not the same when performed in a surgical global period, which is an inaccurate assumption. An excerpt from the RUC comment letter to CMS on the CY 2021 Proposed Rule is attached in which the RUC recommends that CMS apply the office visit increases uniformly across all services and specialties. CMS should not hold specific specialties to a different standard than others. **The AMA strongly urges that CMS apply the office E/M visit increases to the office visits included in surgical global payment, as it has done historically.**

In addition, the AMA is including below an excerpt from our 2020 Medicare Physician Fee Schedule proposed rule comment letter that remains just as relevant today. We strongly urge CMS to review these comments and reconsider its decision that treats office visits differently depending on whether they are billed as a standalone visit or within a global surgical period.

1. *CMS History of Valuing Office Visits in the Post-Operative Period*

The relativity of the RBRVS must retain integrity and ensure that office visits with patients are valued consistently, regardless of specialty. The new office visit framework requires physicians to report on either time or medical decision making. The surveys of these new codes indicated a high level of consistency in the work required for office visits by each specialty. CMS has acknowledged this

equivalent work for nearly 30 years. Each time stand-alone office visits increased since 1992, the visits bundled into the surgical global period also increased. The following are the three instances of these increases:

- 1997 First, Five-Year Review of the RBRVS;
- 2007 Third, Five-Year Review of the RBRVS; and
- 2011 Elimination of consultation codes led to budget neutrality adjustments to office visits.

2. *Problems with the RAND Reports*

The Medicare Access and CHIP Reauthorization Act (MACRA) required CMS to collect data on the number and level of post-operative visits for surgical global codes provided to Medicare beneficiaries. The statute stipulated that CMS use these data and other available data, as appropriate, to improve the valuation of surgical global services. To comply with these requirements, CMS contracted with the RAND Corporation. The AMA reiterates our concerns with these reports below, which we initially raised in our 2020 Medicare Physician Fee Schedule proposed rule comment letter and which have not been fully addressed by the Agency.

Previously, CMS has appropriately aligned the changes in valuation of the office visits in the surgical global period with the valuation of the stand-alone office visits. This time, responding to political pressure from certain stakeholders and the RAND analysis of incomplete claims data, CMS now pays surgeons at a different rate from other physicians and distorts the relativity within the established RBRVS. **The AMA recommends that CMS instead indicate specific codes which it believes are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period.**

RAND Report 1: Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-Day Global Periods

Since July 1, 2017, Medicare practitioners in nine states have been required to report on the postoperative visits they furnish during the global period of specified procedures using CPT code 99024 Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure. The 299 010-day or 090-day surgical global procedures included in this initiative are those that are furnished by more than 100 practitioners, and either are nationally furnished more than 10,000 times annually or have more than \$10 million in annual allowed charges.

The AMA does not believe that this dataset can reasonably be used to forecast any overall trends, given the limited and likely intermittent participation of eligible physicians as well as the current difficulty the CMS and RAND researchers have implied in matching up procedures to CPT code 99024. Only 46 percent of practitioners were expected to submit tracking code 99024 through June 2018. 54 percent of physicians eligible for this data collection project were either not aware of the requirement to participate or were unable to participate for another reason. In addition, only 17 percent of eligible physicians were classified as “robust reporters,” indicating that a majority of those that did participate did so intermittently or did not begin until partway through the reporting period. If most of the eligible providers did not participate, the median count of post-op visits would be zero irrespective of what study participants reported, and the mean number of visits would be greatly understated.

Participation also varied widely by both specialty and state. Primary care physicians only participated at a rate of 16 percent and NPs/PAs only at a rate of 23 percent; these providers collectively account for nearly 40 percent of the 40,000 eligible providers in the nine states and perform a large proportion of the 010-day global services included in the study. The participation rate by state varied widely, with the highest participating state, North Dakota, participating at a rate four times higher than that of the lowest participating state, Nevada (per figure 3.2 in report).

Furthermore, the dataset that includes only practices with 10 or more practitioners is potentially not representative as most physicians are in practices that have fewer than 10 providers. The AMA 2020 Physician Practice Benchmark Survey² indicated about one-third (33.6 percent) of physicians worked in practices with fewer than 5 physicians. Another 20.0 percent worked in practices with 5 to 10 physicians, for a total of 53.7 percent who worked in practices with 10 or fewer physicians.

We do not agree with the RAND conclusion that only 39 percent of 090-day global visits and four percent of 010-day global visits were performed. Many flaws exist in the computation to arrive at these figures. First, 54 percent of physicians in the nine states who were eligible to participate, did not do so. RAND inappropriately assumes that each of these physicians did not provide any office visits in any surgery's global period. Second, RAND includes ½ day work proxies for 99238 in the denominator of expected visits. The ½ 99238 in the CMS time files are simply proxies for additional work preparing the patient for discharge from the outpatient setting. Physicians would never report a 99024 for this work. Third, the study used physician time files that are several years old. Modifications to cataract surgery and other procedures' post-operative visits in 2019 and 2020 dramatically change the results of this computation. If RAND utilized the robust reporters only; eliminated the ½ 99238 from the expected visits; and utilized the 2020 CMS time files, we compute that 51 percent of the expected visits were captured in the reporting of 99024.

RAND used the following definition to categorize study participants as robust reporters, "ten or more 90-day global procedures performed and half of those procedures include at least one reported visit reported during the global period." This definition is flawed as it excludes any providers that only perform 010-day global procedures. In addition, most providers that joined the reporting initiative after the first day of the survey period would still be counted as robust reporters, when they participated in at least roughly half the reporting period. If RAND improved the definition of robust reporters, the number of reported visits compared to expected visits would be greater than 51 percent.

The top three 010-day global codes, 17000, 17004 and 17110, make up 65 percent of the utilization for all 010-day global services in the study. These three codes are typically performed by the same specialty, dermatology, and are all from the same destruction of benign or premalignant lesions code family. As all RAND analyses that refer to 010-day global services overall are volume-weighted, the findings are dominated by these three services and, therefore, are not representative. For 090-day global codes, cataract surgery (codes 66982, 66984) and hip/knee arthroplasty (codes 27130, 27447) collectively account for 28 percent of the volume. As stated, cataract surgery was reviewed recently, and the postoperative visits now align with the 99024 claims data collected.

The RAND researchers indicated that they attempted to expand their analysis to differentiate between visits not performed at all versus visits that were performed, but under an expanded definition. For example, tracking code 99024 was reported 15,955 times for 010-day global services shortly after the end of the global period (days 11-15), which if added to the visits reported within the 010-day global period,

² <https://www.ama-assn.org/about/research/physician-practice-benchmark-survey>.

would increase the total number of visits by 37 percent and the ratio of observed visits versus expected visits would have increased by approximately 50 percent. Furthermore, when examining visits reported by other providers using either 99024 or a separately reported E/M service, the total number of postoperative visits would increase by another 75 percent. If these numbers are applied to only eligible physicians who were robust reporters, the ratio for observed versus expected increases dramatically. If the top three codes (17000, 17004 and 17110), are excluded from the 010-day global analysis; and the more expanded definitions of a visit are included; and the analysis is limited to robust reporters, then the 010-day global codes do in fact appear to typically include a post-operative visit.

RAND Report 2: Survey-Based Reporting of Post-Operative Visits for Select Procedures with 10- or 90-Day Global Periods

To comply with MACRA's requirements, CMS also contracted with RAND to conduct a survey to collect additional data on post-operative services, including the level of post-operative services. RAND launched a pilot of the survey in fall 2017 with a sample size of 557 practitioners and received only a single complete response. Following this setback, CMS and RAND decided to greatly narrow the scope of their survey initiative to only three high-volume services, cataract surgery (only CPT code 66984), hip arthroplasty (only CPT code 27130) and complex wound repair (CPT codes 13100, 13101, 13120, 13121, 13131, 13132, 13151, and 13152).

RAND's main conclusion in the second report was that the average visits were somewhat shorter than anticipated for cataract surgery (16.4 minutes vs 19.4 minutes) and hip arthroplasty (22.9 minutes vs. 29.6 minutes) and longer for complex wound repair (21.8 minutes vs 16 minutes). However, RAND misinterpreted the findings of their survey data as they compared only the survey physician time "on the day of the visit" to the CMS physician time file, where the pre-service and post-service time of E/M services is not specific to the date of the encounter, and inappropriately excluded nurse practitioner (NP) and PA time from their visit time comparison analysis. Additionally, in 2019, time is not the only factor relevant in selecting a code level.

RAND categorized NP/PA survey data as "staff time" and incorrectly observed that "...such staff time would be considered as part of PE in the RUC process and not contribute to the physician time component nor to the level of the visit." While this is the case for work performed by clinical staff, this is never the case for qualified health care professionals who can separately report Medicare services. The researchers did not account for Medicare rules on "incident to" and split/shared E/M services. When a nurse practitioner or physician assistant assists with an office visit, both the work of the physician and the work of the NP/PA is used to select the level of the visit if the requirements for "incident to" are met and the patient is an established patient.

RAND's survey for hip arthroplasty showed that for 37.4 percent of the surveyed physician visits, part of the visit logged by the physician included work performed by an NP/PA. The survey data also showed that of those visits, the NP/PA spent an average of 16.9 minutes. This survey data only included NPs and PAs that "assisted in the visit"; the survey respondents were explicitly instructed to "not include NPs, PAs and other staff who are billing for this visit separately." Therefore, it was made clear to the survey respondents that they should only include time estimates for work that was solely reported under their claim. As an NP or PA assisted 37.4 percent of the reported physician visits and the NP/PA spent an average of 16.9 minutes helping to provide the visit, the average hip arthroplasty visit would include 6.3 minutes ($16.9 \text{ minutes} \times 0.374$) of NP/PA time. Adding the 6.3 minutes to the day of physician time of 22.9 minutes would equal 29.2 minutes, which is very similar to the average CMS time cited in the study of 29.6 minutes. Similarly, seven percent of complex wound repair visits included NP/PA assistance

averaging 19.1 minutes. This time should have been included with the wound repair time comparison analysis.

The RAND survey also collected time data before and after the date of the encounter. The researchers observed that “If this time were to be added to the time spent on the day of the visit, it would increase time spent related to the visit by 30 percent to 40 percent depending on the procedure.” As the current pre-service and post-service CMS times are not specific to the day of service, this survey time should have also been included in the analysis to have made a like to like comparison. Comparing day-of service time to the CMS time file was not accurate.

Certain aspects of the survey methodology were concerning. Survey respondents were provided with completed examples of the surveys. The researchers correctly observed “that providing sample surveys could potentially affect survey responses,” yet the survey method still included this tool to help the survey respondents understand the survey burden. This same task could have been accomplished with blank copies of the survey without risking the integrity of the survey data. In addition, each survey respondent was requested to provide survey data on five of their visits, though based on the survey instructions, the respondents would have been reporting on five different patients. These five visits could have been disproportionately only one or two types of visits (i.e., the first hospital visit or the first office visit) and therefore, would not be representative.

Most importantly, the new E/M office visit framework allows for a physician to report a 99212 if 10 minutes is spent on the date of encounter. Most surgical post-operative office visits are attributed as 99212 in the surgical global period in determining physician work, physician time and practice expense. The new coding structure renders this RAND report moot.

Rand Report 3: Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods

This third study utilized the reverse building block methodology to estimate the change in Medicare payment based on RAND’s summary data from the first study. The analysis included in this study is extremely flawed, as the researchers completely disregarded the “robust reporters” concept highlighted in the first study and made no attempt to filter out the 54 percent of eligible providers that did not participate in the data collection initiative. When 54 percent of eligible providers were assumed to never perform post-operative visits simply because they were not aware or were unable to participate in the data collection project, the median number of visits for many surgical global codes would be zero irrespective of what participating physicians reported. Also, as no specialty achieved a 100 percent participation rate, all codes included in the study would have been undercounted in the study to some extent.

The analysis included in this study applied the four percent observed versus expected ratio from 111 010-day global services and the 39 percent observed versus expected ratio from 185 090-day global services to all surgical global services (over 4,200 codes). Applying an overall ratio from a pool of data where all non-participants were categorized as physicians who never perform post-operative services is not appropriate.

This study included a major error, where immediate post-service time was incorrectly included as a part of post-operative visit time for the analysis. The researchers stated that they “computed the total postoperative visit time by subtracting pre- and intra-service time from the total physician time.” However, this method would have included immediate post-service time, which does not coincide with any bundled visits, as part of the bundled post-operative visit time. 010-day global services typically

include 10 to 20 minutes of immediate post-service time and 090-day global services typically include 25 to 45 minutes of immediate post-service time. This time reflects work after skin closure in the operating room and through discharge from recovery, which is distinctly different from E/M postoperative visits in the hospital or office.

The AMA does not agree with any suggested methodology that uses “reverse building block methodology” to systematically reduce a work RVUs for services. We believe that reverse building block methodology, or any other purely formulaic approach, should never be used as the primary methodology to value services. It is inappropriate as magnitude estimation was used to establish work RVUs for services since the publication of the first Medicare physician payment schedule in 1992. This methodology, for example, ignores the care coordination work that is performed during the surgical global period, with evidence from the RAND survey of hip arthroplasty.

Implementation of the methodology outlined in this RAND report would result in unreasonable reductions in total Medicare payment for many surgical specialties, putting at risk access to care for Medicare beneficiaries (e.g., payment reductions of -18.4 percent for cardiac surgery and -18.1 percent for surgical oncology).

In summary, the result from the RAND studies cannot be used to justify distorting the relativity of office visits within the RBRVS. The RUC recommended submitting recommendations to CMS to apply the RUC office visit recommendations to both the stand-alone E/M office visit codes and the E/M office visit component of the codes with global periods (010, 090, and MMM). The AMA urges CMS to finalize a policy that adopts this recommendation.

H. Refinement Process/Appeals Process

- **Recommendation:** The AMA urges CMS to reestablish the Refinement Panel process, or a similar process, to create an objective, transparent, and consistently applied formal appeals process, that would be open to any commenting organization, and provide stakeholders with multiple avenues of appeal.

In 2016, CMS permanently eliminated its Refinement Panel process by making the nomination requirements so specific that no services could be eligible going forward. At that time, CMS designated the Refinement Panel only to review Interim Final values and simultaneously discontinued the concept of Interim Final values beyond CY 2016. In the CY 2016 Proposed Rule, CMS states their belief that since proposed work RVUs will now be published in the Proposed Rule, the Refinement Panel process will no longer be necessary. The Agency had asserted that the opportunity for stakeholders to provide comments on codes in both the Proposed and Final Rules “...will allow a better mechanism and ample opportunity for providing any additional data for our consideration, and discussing any concerns with our interim final values, than the current refinement process.” While the change to including proposed work RVUs in each year’s NPRM continues to be strongly supported by the AMA, we do not agree that these process changes had made the Refinement Panel process obsolete. These separate processes are not mutually exclusive and could be undertaken in tandem to provide stakeholders with multiple avenues of appeal.

For two decades, the CMS Refinement Panel Process was considered by stakeholders to be an appeals process and CMS deferred to the vote conducted by the Refinement Panel in finalizing values. In the last few years of the Refinement Panel’s existence, CMS modified the process to only consider codes for which new clinical information was provided in the comment letter. CMS also began to independently review each of the Refinement Panel decisions in determining which values to finalize. In many cases, the

Refinement Panel supported the original RUC recommendation and the commenter's request, yet CMS chose instead to implement CMS' original proposed modified value. The complete elimination of the Refinement Panel discontinued CMS' reliance on outside stakeholders to provide accountability through a transparent appeals process. **The AMA urges CMS to consider these issues and create an objective, transparent and consistently applied formal appeals process that would be open to any commenting organization. This recommendation was previously made to CMS by the AMA and 89 national medical organizations on August 23, 2016.**

I. Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting

- **Recommendation:** To help address the significant fiscal pressures placed on physicians by the COVID-19 pandemic, we urge CMS to immediately implement and pay for CPT code 99072 to compensate practices for the additional supplies and new staff activities required to provide safe patient care during the PHE. **CMS should issue an Interim Final Rule to immediately implement and pay separately for CPT code 99072 with no patient cost-sharing during the PHE.** Payment for these additional costs should be fully funded and not be subject to budget neutrality. CMS could use remaining money from the CARES Act funding to pay physicians for these costs and/or recognize the decreased expenditures during the early months of the pandemic to waive budget neutrality.

The AMA appreciates that CMS is soliciting comments about PHE-related costs that could be accounted for by establishing new payment rates for new services to inform future rulemaking. However, we do not believe that CMS has the luxury of waiting for future rulemaking as physicians continue to incur increased expenses to safely care for patients during the surging fourth wave of the COVID-19 PHE. **Instead, CMS should withdraw its previously finalized policy implementing CPT code 99072 as a bundled service on an interim basis in the 2021 Medicare Physician Payment Schedule final rule and issue an interim final rule to separately pay for CPT code 99072.** We reiterate the [recommendation](#) made by the AMA and 127 other state medical associations and national medical specialty societies that CMS immediately implement and separately pay CPT code 99072 to recognize the increased expenses due to infection control practices necessary to safely immunize and care for patients during this PHE.

Physician practices incur significant costs in implementing the increased infection control measures required to provide safe in-person care during the COVID-19 PHE, including administering the COVID-19 vaccines. These costs include additional supplies (such as cleaning products and facial masks for both staff and patients), clinical staff time for activities such as pre-visit instructions and symptom checks upon arrival, and implementation of office redesign measures to ensure social distancing. These additional practice expenses are not included in many in-person services, including office and outpatient E/M services nor the new CPT codes for COVID-19 vaccine administration. The AMA does not agree with CMS' interim final decision to bundle these services as there is an existing CPT code designed to recognize the supplies and new staff activities required to provide safe care during the PHE—CPT code 99072.

The AMA believes implementation of payment for CPT code 99072 will support the Administration's goal to mount a safe, effective, and comprehensive vaccination campaign—a goal strongly supported by the AMA. The [National Strategy for the COVID-19 Response and Pandemic Preparedness](#) directs the Department of Health and Human Services to ask CMS “to consider whether current payment rates for vaccine administration are appropriate or whether a higher rate may more accurately compensate providers.” The practice expenses necessary to safely administer the COVID-19 vaccines, including

additional supplies, pre-visit instructions and symptom checks upon arrival, and office redesigns to ensure social distancing, are not included in the new CPT codes for COVID-19 vaccine administration because CPT code 99072 recognizes these additional costs.

We recognize and appreciate the significant support and flexibility CMS has provided to physician practices. **However, it is imperative that CMS specifically compensate physicians for the additional expenses involved in treating patients during the PHE.** Separate payment for these increased expenses to safely immunize and provide in-person care for patients during the COVID-19 PHE is also essential to protect the viability of our nation's health care workforce and alleviate the financial strain physicians face. In July and August 2020, the AMA surveyed 3,500 physicians who provided at least 20 hours of patient care per week prior to the pandemic. Practice owners [reported](#) an average increase in PPE spending of 57 percent since February 2020, with 25 percent of owners saying that PPE expenses have risen at least 75 percent. Nearly all (99 percent) surveyed physicians have implemented infection control protocols, such as pre-visit screening phone calls, screening for COVID-19 symptoms/exposure and checking patient temperatures upon office arrival, and limiting the number of patients in the waiting room. To address the financial impact of these new protocols related to the PHE, the CPT Editorial Panel approved CPT code 99072 on September 8, 2020. According to [CPT guidance](#), 99072 is used to report the additional supplies, materials, and clinical staff time over and above the practice expense(s) included in an office visit or other non-facility service(s) when performed during a PHE, as defined by law, due to respiratory-transmitted infectious disease.

In its [comment letter](#) on the proposed rule for the 2021 Medicare Physician Payment Schedule, the AMA/Specialty Society RVS Update Committee (RUC) requested that CMS immediately implement and pay for CPT code 99072 to recognize the additional supplies and new staff activities required to provide safe care during the PHE. This recommendation was based on extensive research and analysis by the RUC Practice Expense Workgroup during the COVID-19 PHE, which included responses from 50 national medical specialty societies and other health care professional organizations to a practice expense survey and more than 800 submitted invoices. The Workgroup's report, analysis, background information, and practice expense spreadsheet describing the \$6.57 in direct costs for the code are included in Attachment 05 of the RUC comment letter to CMS.

The AMA continues to urge CMS to pay for CPT code 99072 with no patient cost-sharing during the COVID-19 PHE. Payment for these additional costs should be fully funded and not be subject to budget neutrality. CMS could use remaining money from the Coronavirus Aid, Relief, and Economic Security (CARES) Act funding to pay physicians for these costs and/or recognize the decreased expenditures during the months of the pandemic to waive budget neutrality. Your support will ensure that physicians receive the critical financial resources needed to maintain intensive infection control measures during the COVID-19 PHE.

J. Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

- **Recommendation:** The AMA urges CMS to adopt its proposal to implement the reduced beneficiary coinsurance phase-in for colorectal cancer screening tests as required by the Consolidated Appropriations Act of 2021. Further, the AMA urges CMS to conduct patient education and outreach about the changes to their coinsurance for diagnostic colorectal cancer screenings until it is fully phased out in 2030.

The AMA thanks CMS for implementing the provisions in the Consolidated Appropriations Act of 2021 that gradually reduce the beneficiary coinsurance amount from 20 to zero percent when a screening colonoscopy becomes a diagnostic procedure according to Medicare due to removal of polyps during the procedure, for example. AMA policy supports the elimination of cost-sharing for additional procedures done during a screening colonoscopy.³ Colorectal cancer is the [second leading](#) cause of cancer deaths in the U.S. and 60 percent of colorectal cancer deaths could be prevented with screening. However, physicians and patients have long expressed confusion and concerns about being billed for services that they expected would be covered at no cost to them. There is [substantial evidence](#) that inadequate insurance coverage is associated with lower rates of screening. Moreover, barriers to colorectal cancer screenings are more common among people with fewer financial resources, leading to disparities in care.

Because the reduction in a patient's coinsurance for diagnostic services furnished in the same clinical encounter as the colorectal cancer screening test is gradual and could lead to confusion, we urge CMS to conduct extensive education and outreach to inform patients about their out-of-pocket costs. This will have the added benefit of increasing awareness of the importance of colorectal cancer screening.

K. Vaccine Administration Services: Comment Solicitation: Medicare Payments for Administering Preventive Vaccines

- **Recommendation:** The AMA refers to the RUC recommendations about immunization administration as the RUC reviewed these codes at the April 2021 meeting. We urge CMS to use the RUC recommendations to value these services based on the RBRVS principles.

The RUC submitted recommendations for Immunization Administration codes 90460, 90461, 90471, 90472, 90473, 90474, G0008, G0009 and G0010 in May 2021. The Immunization Administration recommendations related were submitted to the Agency by the RUC. **The AMA urges CMS to use the RUC recommendations to value these services based on RBRVS principles.**

The AMA objects to the reliance on data from the Outpatient Prospective Payment System (OPPS) in establishing relative values for the Medicare Physician Payment Schedule. 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.

³ **H-185.960 - Support for the Inclusion of the Benefit for Screening for Colorectal Cancer in All Health Plans**

1. Our AMA supports health plan coverage for the full range of colorectal cancer screening tests.
2. Our AMA will seek to eliminate cost-sharing in all health plans for the full range of colorectal cancer screening and all associated costs, including colonoscopy that includes a "diagnostic" intervention (i.e., the removal of a polyp or biopsy of a mass), as defined by Medicare. To further this goal, the AMA will develop a coding guide to promote common understanding among health care providers, payers, health care information technology vendors, and patients.

L. Physician-led Team-based Care

- **Recommendation:** The AMA recognizes the value of nutrition support teams services and their role in positive patient outcomes and supports payment for the provision of their services but urges CMS to ensure that there is a reporting requirement for medical nutrition therapy (MNT) services to the treating physician.

1. *Medical Nutrition Therapy Services and Related Services*

Currently, regulations require that referrals for medical nutrition therapy (MNT) services must be made by the treating physician. The treating physician is defined as the primary care physician or specialist, coordinating care for the beneficiary with diabetes or renal disease. This safeguard in part was put in place to ensure coordination of care by the primary care physician or specialist for beneficiaries with chronic diseases in order to assure quality. However, CMS is proposing to eliminate the requirement that a referral be made by the treating physician for MNT services.

The AMA recognizes the value of nutrition support teams services and their role in positive patient outcomes and supports payment for the provision of their services. However, the AMA is concerned that if the referral requirement is eliminated the physician will no longer receive adequate information about the treatment and status of patients. Collaboration is the process of healthcare providers working “with a physician to deliver health care services within the scope of the practitioner’s professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed.”⁴ Care coordination between the hospital or post-acute care provider and the primary care provider is the goal and a standard of care in today’s medical environment and it is vital to have treating physicians be a part of coordinating care.

Though it is true that there are multiple efforts to help with the exchange of patient information between health care settings, if physicians are removed from the referral process there is a chance that physicians will not be properly communicated with, which would ultimately result in a lower quality of patient care. To ensure that Medicare beneficiaries will receive high quality services it is important that their care is coordinated by a physician-led team. As such, if CMS pushes forward and removes the physician referral requirement, it is imperative that safeguards are put in place to ensure that the referral loop is closed, and physicians are informed in a timely and thorough manner how their patients are doing.

If physicians are removed from the referral loop, it is important that reporting requirements are put in place. There should be required reporting back to the physician by the registered dietician or nutrition professional at the onset of the therapy, and periodic updates to the physician during the course of treatment. Ultimately, the primary care physician or specialist is primarily responsible for coordinating all the patient’s care and must be kept up to date on all critical services and resulting outcomes.

2. *Billing for Physician Assistant (PA) Services*

Every member of the care team plays an important role and patients benefit when every member of the team, including physician assistants (PAs) and physicians work together sharing information, and their unique skills toward high quality patient care. However, every team needs a leader and physicians bring

⁴ <https://www.law.cornell.edu/uscode/text/42/1395x>.

with them the highest level of education and training, making them uniquely qualified to lead the health care team. Every state in the country requires PAs to practice with some level of physician involvement. It is imperative, therefore, that any changes to the billing authority of PA's as proposed in the PFS does so within the parameters of these state laws and ensures such billing authority does not negatively impact the quality of patient care.

To date, PA services have been covered under Medicare Part B only when billed by the PA's employer, with a few narrow exceptions. Medicare Part B payment could be made to the qualified employer of a PA and the PA could furnish services under a W-2 employment relationship, an employer-employee relationship, or as an independent contractor through a 1099 employment relationship. The regulation also specified that a group of PAs that incorporated to bill for their services were not a qualified employer. However, section 403 of the Consolidated Appropriations Act, 2021 removed the requirement to make payment for PA services only to the employer of a PA effective January 1, 2022.

The PFS is looking to implement the change from the Consolidated Appropriations Act, 2021 which will allow PAs to bill the Medicare program, be paid directly for their services, reassign their rights to payment for their services, and incorporate as a group comprised solely of practitioners in their specialty and bill Medicare. This change will impact only the statutory billing construct for PA services. It did not change the statutory benefit category for PA services, including the requirement that PA services are performed under physician supervision or collaboration and in accordance with state scope of practice laws, nor did it change the statutory payment percentage applicable to PA services.

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. As such, PAs should be authorized to provide patient care services only so long as the PA is functioning under the direction and supervision of a physician or group of physicians. The typical PA program is only 27 months in length with 2,000 clinical hours.⁵ In comparison, physicians are required to attend four years of medical school, three-to-seven-years of residency training, and 10,000-16,000 hours of clinical training.⁶ Moreover, there is a large difference in rigor and standardization between medical school and residency and PA programs. PAs 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.

The vast majority of states' regulations reflect the necessity for oversight of PAs and the importance of physician-led care. In 48 states a PA's scope of practice is determined with the supervising or collaborating physician at the practice site. Moreover, in 34 states PAs are supervised by physicians and in 16 other states PAs are subject to other forms of collaborative or alternative agreements.⁷ Thus, as the billing abilities of PAs change it is important to ensure that this change does not impact the care the patients receive or the scope of practice requirements that are in place.

⁵ <https://www.physicianassistantedu.org/>.

⁶ <https://www.ama-assn.org/system/files?file=corp/media-browser/premium/arc/ama-issue-brief-independent-nursing-practice.pdf>.

⁷ <https://www.ama-assn.org/system/files/2020-02/state-law-physician-assistant-scope-practice.pdf>.

3. *Payment for the Services of Teaching Physicians*

The AMA applauds the decision to allow teaching physicians to use audio/video real-time communications technology to supervise residents during the pandemic and include the total time considered for visit level selection. We would like to see these changes adopted permanently.

The current flexibilities due to the COVID-19 PHE allow 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 temporary change in supervision is consistent with the current primary care exception, which allows teaching physicians to direct the care furnished by residents, reviewing the services physically provided by residents during or immediately after the visit using remote audio/video real-time communications technology. During the PHE, CMS has 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 PHE and sees the benefit of permanently maintaining the ability for all teaching physicians to supervise residents via audio/video real-time communications technology. The AMA believes implementing these supervision expansions in accordance with Accreditation Council for Graduate Medical Education (ACGME) policy, taking into account program, specialty, patient, and trainee factors, will enable residents to provide additional services while still garnering the oversight needed from their teaching physicians.⁸

Since a teaching physician is still required to review resident physicians' interpretations and services, and ACGME has strict limits concerning direct supervision by 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 through which to supervise residents will increase the ability to provide residents with timely feedback while taking into account patient, resident, and teaching physician safety by decreasing 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. Decisions about appropriate supervision and the type of technology used 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. 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 using 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' levels of education, competence, and experience, and any other applicable

⁸ <https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRResidency2020.pdf>.

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 if ACGME requirements are met and the use of audio/visual real time communication equipment is individualized to support the needs of residents, teaching physicians, and their patients, this tool will be an effective way to 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.

Currently, payment for teaching physician services will be made when the teaching physician renders sufficient personal and identifiable physician's services to the patient including exercising full, personal control over the management of the portion of the case for which payment is sought. In the case of E/M services, the teaching physician must be present during the portion of the service that determines the level of service billed. The PFS is proposing that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included since the Medicare program makes separate payment for the program's share of the resident's graduate medical training program, which includes time spent by a resident furnishing services with a teaching physician, under Medicare Part A. The AMA supports this proposal and believes that adequate payment will still be provided for teaching physician services.

4. *Primary Care Exception Policy*

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 31, 2020, 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 1, 2020, COVID-19 IFC, CMS further expanded the list of services included in the primary care exception during the COVID-19 PHE. As such, during the PHE the list of services that residents could furnish without the physical presence of the teaching physician was temporarily expanded to include all levels of an office/outpatient E/M visit, among other services. However, upon the conclusion of the PHE, CMS is planning to revert to the original standards and no longer include levels 4-5 office/outpatient E/M visits in the primary care exception.

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 may be 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 used 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 COVID-19 PHE, the AMA believes that the expanded list of services should be maintained permanently.

Additionally, CMS is proposing that under the primary care exception, only medical decision making (MDM) be used to select office/outpatient E/M visit level. CMS believes that because residents are in

training, they may need more time than is reflected in the code descriptor to furnish a visit that has a low-level of medical decision making and as such, CMS believes that MDM is a more accurate indicator of the appropriate level of the visit relative to time in the context of the primary care exception for services furnished by residents and billed by teaching physicians in primary care centers.

II. OTHER PROVISIONS OF THE PROPOSED RULE

A. Medicare Diabetes Prevention Program (MDPP)

- **Recommendation:** The AMA greatly appreciates and strongly supports the significant updates that CMS proposes to permanently update the Medicare Diabetes Prevention Program (MDPP), all of which address the challenges faced by MDPP suppliers: the elimination of the Year 2 ongoing maintenance sessions, the redistribution of Year 2 payments to Year 1, and the waiver of the Medicare provider enrollment application fee. The AMA recommends CMS make an additional update to the MDPP by including virtual DPP providers permanently in the program. Additionally, the AMA recommends additional changes which when viewed through a health equity lens, will positively impact the prediabetes and diabetes epidemic facing the country.

1. *Supplier Updates Included in Proposed Rule*

The AMA supports the three key changes included in the PFS to update the Medicare Diabetes Prevention Program. First, CMS proposes to eliminate the ongoing maintenance session for Medicare beneficiaries beginning with the MDPP on or after January 1, 2022. The change reflects the feedback from Medicare DPP suppliers that the mandatory ongoing maintenance sessions—unique to the Medicare DPP and not a component of the CDC’s National DPP lifestyle change program—are not widely attended by Medicare participants, are burdensome to administer, result in low payment compared to the cost of delivering, and thus, are a deterrent to DPP supplier organizations from enrolling in Medicare. The ongoing maintenance sessions, or Year 2 of MDPP, were not tested in the DPP model test; no clear evidence exists that a second year reduces the risk of developing diabetes. MDPP suppliers had to demonstrate capacity to deliver Year 2 sessions to those who had successfully achieved a five percent weight loss, yet there was no curriculum to follow for these classes. The AMA strongly supports the elimination of Year 2, which will allow the MDPP suppliers to better align their Medicare DPP program with the National DPP in terms of class structure and session content.

In tandem with the elimination of year 2 ongoing maintenance sessions, CMS proposes to redistribute a portion of the payment from those sessions to the core and core maintenance session performance payments. Low payment for the delivery of initial DPP sessions has plagued MDPP suppliers from the inception of the expanded model. The redistribution of payments should help assuage this concern, in part, for suppliers. The AMA supports the redistribution of money to Year 1 in light of the discontinuance of Year 2 and appreciates this change.

CMS notes in the proposed rule “beneficiary acquisition and retention as a leading barrier” to MDPP supplier enrollment. Even with the proposed redistribution of Year 2 payments to Year 1, MDPP suppliers are not paid for their efforts to introduce individuals to the benefits of the diabetes prevention program, to recruit potential beneficiaries to join, and to provide additional program supports to participants. As proposed, higher payments to suppliers would continue when an MDPP participant achieves the five percent weight loss goal in addition to attending at least 2 classes. Continuing to base payments to the suppliers contingent on the beneficiary achieving a weight loss goal, attending a specific

number of sessions or any other performance goal is not consistent with the MDPP pilot, which paid providers for delivering the service. Additionally, other preventive health programs, namely smoking cessation and obesity interventions, do not pay providers based on the beneficiary achieving a particular outcome. CMS should not base MDPP payments to suppliers on outcomes either.

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

Finally, CMS proposes to waive the Medicare provider enrollment application fee (\$599) for all organizations applying to be MDPP suppliers, effective January 1, 2022. Given the low enrollment and the low Year 1 payments per participant to date, potential MDPP suppliers have been hesitant to enroll since they would not have a clear path to recoup their application costs. The Medicare provider enrollment application fee has been cited as a barrier to enrollment for potential MDPP suppliers. CMS' waiver of the Medicare provider enrollment application fee will alleviate this barrier; this proposed change is supported by the AMA.

Despite the three key proposed changes to the MDPP supplier program, there are still several changes to the MDPP that should be made. Since CMS has established that indeed it does possess the requisite authority to make necessary updates to the program structure (as seen with the elimination of Year 2 ongoing maintenance sessions) and to revise the payment structure to make the MDPP more appealing to potential suppliers, the AMA asks for CMS to similarly include the following changes to the MDPP.

2. Supplier Updates Still Needed

Virtual MDPP Services

The AMA strongly supported the CMS policy during the COVID-19 PHE allowing nearly all MDPP services to be provided through virtual modalities such as distance learning, online sessions, and virtual weight reporting. The AMA strongly advocates for the permanent inclusion of virtual DPP suppliers in Medicare, which have consistently demonstrated the ability to meet the rigorous standards set by CDC. It is arbitrary to assign importance of CDC recognition to some CDC DPP providers while excluding others. We have all been able to experience firsthand the true value of the health care innovation represented by DPP providers that offer virtual sessions before and during the COVID-19 PHE. A virtual DPP provider conducted a retrospective analysis of Medicare-aged adults' participation in their virtual DPP. The results demonstrated that 92 percent of participants completed 9 or more lessons.⁹ Virtual DPP has proven successful for Medicare-aged beneficiaries and should also be permanently incorporated. The AMA urges CMS to include virtual providers in MDPP.

⁹ "Outcomes of a Digital Health Program with Human Coaching for Diabetes Risk Reduction in a Medicare

Elimination of the High Categorical Risk Level Enrollment Screening for Medicare DPP Suppliers

CMS continues to maintain the high categorical risk level enrollment screening for potential Medicare DPP suppliers. This serves as an especially high barrier to entry for community-based organizations interested in becoming Medicare DPP suppliers. In addition, health care organizations that already deliver other health care services and then elect to deliver MDPP are classified in high categorical risk level for these select services. This is not only cumbersome, but it also lacks sound justification and a rational basis. The hurdles associated with this high categorical risk encompass and exceed those of the limited and moderate categorical risk levels. Under the high categorical risk category, suppliers are subject to expensive and burdensome fingerprinted-based background checks that are usually reserved for the home health agencies and Durable Medical Equipment, Prosthetics, Orthotics, & Supplies (DMEPOS) suppliers. The high categorical risk level is excessive for this community-based, preventive health program. The AMA urges CMS to revise downward this risk level screening which will undoubtedly allow more National DPP providers to apply to become Medicare DPP suppliers.

Removing the high categorical risk is consistent and necessary with what CMMI has already identified needs to happen to advance health equity. In the recent Health Affairs blog, the authors noted. “It (advancing health equity) requires engaging providers who have not previously participated in value-based care initiatives and ensuring that eligibility criteria application processes encourage care for historically disadvantaged populations, including racial, ethnic and rural communities, those with disabilities, and those who previously may not have had care relationships.”¹⁰ No more poignant example can be made than the potential MDPP community-based suppliers that are ready to serve minoritized and marginalized individuals, but for the high categorical risk level enrollment screenings they are unable to navigate or overcome. The AMA strongly urges CMS to remove the high categorical risk level for MDPP suppliers.

3. Medicare Beneficiary Updates Urgently Needed to Support Health Equity

The AMA notes that the proposed changes to the MDPP in the PFS are designed to benefit MDPP suppliers. The AMA is disappointed that the proposed rule lacks any targeted changes that will directly impact the MDPP experience for Medicare beneficiaries. It is essential that CMS propose and implement changes to the MDPP that directly impact Medicare beneficiaries, because low enrollment in the MDPP highlights the fact that millions of people with prediabetes are not receiving this preventive intervention. There are millions of marginalized and minoritized Medicare beneficiaries who are in locations that lack in-person MDPP suppliers. As examined through a health equity perspective, the need to immediately update the MDPP is dire. The COVID-19 PHE has only exacerbated the inequities in MDPP and the areas where a focused response is urgently needed. The data here underscores how critical it is to address beneficiary issues in the PFS for MDPP:

- 74 percent of the MDPP participants were female. Of those participants, 75 percent of the beneficiaries were White, and 77 percent are not Hispanic or Latino.
- In a review of AMA professional claims for 2020 for a five percent sample of Medicare beneficiaries, the total allowed frequency for HCPCS code G9873 (first MDPP core session) was just 13 people. That extrapolates to a frequency of 260 participants in the full fee-

Population.” Castro Sweet CM, et al. J Aging Health. 2017 Jan 1:898264316688791.

¹⁰ “Innovation At The Centers For Medicare And Medicaid Services: A Vision For The Next 10 Years” Health Affairs Blog, August 12, 2021. DOI: 10.1377/hblog20210812.211558.

for-service population for 2020. The number of people who participated in the MDPP is dramatically low given that prediabetes impacts 88 million American adults.¹¹

- Less than 2,500 Medicare beneficiaries participated in the MDPP from April 2018 to December 2019. The Medicare DPP is not reaching the millions of seniors with prediabetes.
- These low participation numbers for the MDPP expanded model are especially striking in light of the participation of about 8,000 Medicare beneficiaries in the CMMI pilot model. If the expanded model were better designed, it is anticipated that there would be significantly greater participation in the nationwide expanded model than in the limited pilot test.

The COVID-19 PHE has only exacerbated the inequities in MDPP and the areas where a focused response is urgently needed. Of the small number of people who are enrolling, Black, Latinx, Asian, American Indian, Pacific Islander, and Native Alaskan individuals are largely left behind. The problem of prediabetes has continued to get worse for diverse communities:

- The percentage of adults with diabetes increased with age, reaching 26.8 percent among those aged 65 years or older.
- New diabetes cases were higher among non-Hispanic blacks and people of Hispanic origin than non-Hispanic Asians and non-Hispanic whites.¹²

Given these statistics and the Administration's commitment to addressing health equity issues, the AMA urges CMS to include the following changes geared to the MDPP beneficiary in the final rule:

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. **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. The AMA is 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 six months of intensive therapy, a reassessment of their readiness to change and BMI is appropriate after an additional six-month period." Similar to Medicare coverage of obesity counseling and tobacco cessation,

¹¹ National Diabetes Statistics Report, 2020. Centers for Disease Control and Prevention, available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

¹² National Diabetes Statistics Report, 2020. Centers for Disease Control and Prevention, available at <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

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 are reoccurring and will continue once the PHE is lifted. It is understandable that it may be a challenge for those patients that previously participated in MDPP to maintain the program goals. They should be afforded the opportunity to access the MDPP again.

Access to Virtual Services

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 option for virtual MDPP services during the pandemic should be made permanent. The expansion to virtual DPP during the pandemic represents innovation and adaptability. Once the pandemic concludes, it is very plausible that Medicare beneficiaries may prefer to enroll in a virtual preventive program to avert the onset of diabetes. Some of the functional challenges that make it difficult to travel to in-person sessions, such as transportation and caregiver obligations, may persist after the COVID-19 pandemic concludes.

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

Elsewhere in this proposed rule, CMS proposes continuing payment for Category 3 services added to the Medicare telehealth list through the end of 2023, a proposal that the AMA strongly supports. If CMS does not think it has sufficient data to maintain coverage of virtual MDPP sessions permanently, then at a minimum the coverage should parallel that of Category 3 telehealth services. This would allow more time to develop additional evidence of the effectiveness of virtual MDPP sessions in preventing progression from prediabetes to diabetes.

Cover HbA1c for Prediabetes Screening

As cited by the United States Preventive Services Task Force (USPSTF) updated recommendation for prediabetes screening, HbA1c testing has benefits for patients and physicians.¹³ The HbA1c does not require fasting, and the glucose concentrations in A1c lab results are not affected by stress, and therefore, HbA1c is both more convenient for patients and more reliable than a fasting plasma level or an oral glucose tolerance test. Although HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for at least 10 years, CMS does not reimburse for the HbA1c

¹³ US Preventive Services Task Force. Screening for Prediabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;326(8):736–743. doi:10.1001/jama.2021.12531.

test for screening for prediabetes, although the results from HbA1c can be used to qualify for the Medicare DPP. The lack of Medicare coverage, or payment, for the screening HbA1c test disadvantages Medicare beneficiaries compared to those with commercial insurance, which typically does cover the HbA1c test for screening, and precludes patient referrals to the MDPP. The AMA reiterates its previous requests that CMS expand Medicare Part B coverage of HbA1c testing to include the indication of screening for prediabetes or abnormal glucose. This coverage policy would allow physicians to better adhere to the clinical recommendations issued by the 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.

B. Medicare Shared Savings Program (MSSP)

- **Recommendation:** While the AMA appreciates CMS delaying the transition away from the GPRO Web-Interface until 2024 and allowing for a longer glide path, we remain concerned with the feasibility of having to begin reporting on one eCQM and all-payer data starting in 2023. We are also disappointed that CMS plans to continue to move forward with its proposals to align MSSP quality scoring methodology with the MIPS methodology.

In the 2021 Medicare Physician Fee Schedule Final rule, CMS finalized 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) set starting in 2021 with mandatory participation starting in 2022, as well as align the MSSP quality scoring methodology with the Merit-based Incentive Payment System (MIPS) methodology. Given stakeholder feedback and the impact the pandemic has had on practices and patient care, CMS is now proposing to delay mandatory APP reporting until 2024. However, starting in 2023 ACOs that are still utilizing the GPRO web-interface to report must begin to report at least one eCQM to satisfy MSSP quality requirements. While the AMA appreciates CMS delaying the transition away from the GPRO Web-Interface until 2024 and allowing for a longer glide path, we remain concerned with the feasibility of having to begin reporting on one eCQM and all-payer data starting in 2023.

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. We urge CMS to utilize the interim period to consult with the ACO community and patient representatives to determine the best-balanced measure set.

Aggregating eCQM data at the ACO level is not appropriate and, in some cases, not technically feasible at this time. CMS should work with ACOs and the EHR vendor community to find solutions to these data aggregation problems, and until these solutions are widely available, eCQMs should not be mandated for

ACOs. At a minimum, we urge CMS to provide ACOs with one additional year beyond what is proposed for a full transition to mandated eCQM reporting, permitting use of the Web Interface reporting mechanism through 2025 and removing the requirement to report one eCQM prior to full implementation. According to a National Association of ACOs (NAACOS) survey of ACOs, nearly half of ACOs' participating practices use 11 or more EHRs and the biggest barrier cited for movement to eCQM reporting was the lack of EHR standardization. Further, nearly 70 percent of survey respondents reported that their ACO does not have software in place to assist with integrating and extracting quality data from their participating Trial Innovation Networks' (TINs') EHRs. Data completeness standards will be difficult if not impossible for some ACOs to operationalize as CMS has clarified that ACOs will be responsible for de-duplicating patient data when submitting aggregate QRDA III files to CMS. At the current time, it is unclear whether there is a way to achieve this goal from a technological standpoint. QRDA III files are aggregate files with no patient identified.

We also urge CMS to remove the all-payor requirement for ACOs reporting eCQMs and would support a similar policy under MIPS. Alternatively, we urge CMS to require reporting on a sample of ACO assigned patients meeting the denominator criteria. We feel this is a more reasonable expansion of the criteria and more aligned with the goals of the MSSP. We continue to believe that a sampling methodology focused on ACO assigned patients is more appropriate for assessing ACO quality and will provide more accurate evaluations of quality.

We are also disappointed that CMS plans to continue to move forward with its proposals to align MSSP quality scoring methodology with the MIPS methodology. It is inappropriate to compare ACO quality performance to MIPS quality performance scores. Instead, we urge CMS to revert to the previous methods for evaluating the MSSP quality performance standard, which is used in calculations to determine shared savings/losses for ACOs. We also stress the importance of providing ACOs with their performance benchmarks prior to the beginning of the performance year.

While the AMA appreciates CMS now proposing to allow pay-for-reporting for new ACO participants, we are disappointed CMS has not continued the policy for new measures and when measures undergo significant change. Providing pay for reporting is critical to ACO's success on reporting on new measures. The policy allows ACOs 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, including exacerbating inequities or increasing disparities 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 a measure is not only assessing true quality but also how the quality data are captured.

1. *Shift to MIPS MCC for MSSP*

- **Recommendation:** The AMA does not support the proposed shift to the MIPS MCC measure from the current ACO MCC measure for MSSP.

The AMA does not support the proposed shift to the *MIPS Multiple Chronic Condition (MCC)* measure rather than continue to use the current *ACO MCC* measure for MSSP. As we have stated before, the AMA strongly believes that attribution must be determined based on evidence that the accountable unit is actually able to meaningfully influence the outcome, which aligns with the National Quality Forum

(NQF) report, *Improving Attribution Models*.¹⁴ It appears that CMS assumes that ACOs are able to influence or control care decisions in practices with whom they contract and while that may be true for their participating beneficiaries, ACOs may not necessarily have the ability to meaningfully influence treatment decisions for those individuals outside of their purview.

In addition, we believe that the rationale for this change to “to reduce the potential confusion around performance scores and feedback for MIPS eligible clinicians who might otherwise have been scored on both measures with different results” is not based on any actual data analysis and is likely flawed. We do not believe that the broader denominator that will be produced when applying the MIPS MCC measure to ACOs will be reflective of MIPS eligible clinicians’ performance since many ACOs contract with a broad set of provider types that may or may not be aligned. The AMA urges CMS to complete analyses such as comparisons of the measure denominators and resulting performance scores for ACOs and the associated eligible clinicians to determine whether the assumption that scores will likely be similar is correct prior to finalizing this change.

C. Chronic Pain Management

- **Recommendation:** Support patient-centered management of pain by clarifying, communicating, modifying and/or expanding existing care management codes as needed to include patients with chronic pain and significant acute pain, in addition to patients with chronic diseases; creating optional bundled payments for comprehensive management of patients with significant chronic pain; and removing barriers to effective management of acute and chronic pain. CMS should prohibit Part D plans from imposing prior authorization and quantity limits on buprenorphine.

CMS is soliciting comments on whether it should create separate coding and payment for chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether these services are already appropriately recognized in the payment system. It notes the intersection between the problems with pain care and the worsening epidemic of drug overdose deaths, primarily due to illicitly manufactured fentanyl, other synthetic opioids, and methamphetamine. The AMA agrees with CMS’ observation that untreated and inappropriately treated pain may translate to increased Medicare costs as more patients experience functional decline, incapacitation, and frailty.

The AMA greatly appreciates the discussion in the proposed rule regarding the need for Medicare payment policies to better support management of patients’ pain. Any new payment policies developed by the Agency should not be limited to management of chronic pain but should also focus on improving support for acute pain, as well as pain related to the treatment of cancer, sickle cell disease, and for those in need of hospice and palliative care. Increased support for the comprehensive management of acute pain and postoperative pain can be expected to improve patient outcomes in terms of function as well as mental health and lead to greater emphasis on individualized patient-physician shared decision making. Importantly, it can also reduce the number of patients whose pain progresses from an acute to a chronic condition. We know that patients with chronic pain and those with co-occurring OUD make frequent visits to multiple physicians and to emergency departments, experience a great deal of stigma, and are more likely to require expensive treatments. Patient outcomes will be better and Medicare spending will

¹⁴ National Quality Forum. *Improving Attribution Models*. Final Report. August 31, 2018. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88154>. Last accessed December 18, 2018.

be lower if Medicare payment policies enable physicians to help *prevent* patients from developing chronic pain and OUD, rather than only paying for treatment *after* patients' medical diagnoses and treatments become more complicated.

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

CMS has recognized the need to provide additional, flexible monthly payments to physicians for patients who have chronic diseases and behavioral health conditions through its payment policies for the Chronic Care Management, Principal Care Management, and Collaborative Care Management codes. The types of activities these codes support—care management by a nurse or other member of the practice staff, time spent by the physician outside of face-to-face visits with the patient, and consultations with a specialist—are equally important for managing patients with acute or chronic pain. When a patient seeks help from a physician for pain, the physician should be able to have a care manager follow up with the patient to determine if the prescribed therapy is working, the physician should have time to make appropriate adjustments to therapy as needed, and the physician or care manager should be able to consult with a pain specialist when standard approaches are not feasible or effective. These services have been found to reduce net Medicare spending for patients with chronic diseases and behavioral health problems, and the AMA expects that they will also reduce net Medicare spending for patients with pain.

Although one approach to paying for these services would be to create a parallel set of codes for management of pain, the AMA believes it would be better to either clarify or modify the existing codes so they can support services for patients with chronic pain or significant acute pain as well as those with a chronic disease or behavioral health condition. Like many other chronic conditions, untreated or undertreated pain can place patients at risk for functional decline. Using the existing codes would avoid any concerns about overpayment for patients with both a chronic disease and pain, while also making it more feasible for small practices to employ care management staff and provide customized care management services for all the patients who need them. In some cases, physicians and other health professionals may simply be unaware that existing codes can be applicable to pain care services, so this information should be provided through the AMA, CMS, and other communications. For example, the guidelines for Cognitive Assessment and Care Plan Services code 99483 include “chronic pain syndromes” in the “assessment of factors that could be contributing to cognitive impairment.” Although the particular specialty expertise that might be obtained by reporting the Interprofessional E-Consultation codes is not listed in the service description, these codes could be reported by physicians who consult with a pain specialist about their patient's pain. Transitional Care Management could also potentially include pain management following inpatient care to help prevent acute pain from progressing to chronic pain.

Providing monthly payments to physicians by expanding the use of the existing care management codes to include pain would support most of the services CMS lists as needed for effective patient-centered management of pain, including:

- Assessment and monitoring;
- Administration of a validated rating scale(s);
- Development and maintenance of a person-centered care plan;
- Overall treatment management;
- Facilitation and coordination of any needed behavioral health treatment;
- Medication management;
- Patient education and self-management;
- Crisis care;
- Specialty care coordination such as complementary and integrative pain care, and substance use disorder (SUD) care; and
- Other aspects of pain and/or behavioral health services, including care rendered through telehealth modalities.

In addition, we also suggest providing the option to manage the care of a patient with significant chronic pain through a monthly bundled payment, such as the payment CMS developed for managing office-based treatment of SUD. This approach appears to be just as appropriate for supporting treatment of patients with pain as it is for supporting treatment of SUD. A comprehensive approach that gives physicians the flexibility to focus on providing all the care that patients with painful conditions require instead of the fragmented care that can result from reporting each individual element of care on a piecemeal basis could significantly improve patient health outcomes while preventing increased Medicare costs associated with the many complications that can arise due to untreated or undertreated pain.

In addition to paying adequately for patient-centered management of pain, the AMA urges CMS to abandon its [past policy proposals](#) that promote reducing prescription opioid prescribing without regard to how well patients' pain is managed, such as its frequent proposals to evaluate quality performance based on the number of prescriptions for opioid analgesics that exceed arbitrary thresholds of dose or duration. These policies not only create the risk of undertreating pain, but they lead to sub-optimal outcomes while increasing stigma and barriers to care. **Payment policies in all the health programs managed by CMS, including Medicare Advantage and Medicare Part D, need to be aligned in supporting comprehensive multimodal, multidisciplinary, restorative pain care.** This includes removing administrative and financial barriers (e.g., prior authorization, inappropriate specialty tiering in formularies, prohibitive cost-sharing) as well as supporting payment policies that will promote optimal pain care.

Physicians have reduced opioid prescribing by more than 44 percent since 2012, but other forms of pain relief remain unavailable or unaffordable for many patients. The barriers to patient-centered pain care are pervasive and harm patients. Multidisciplinary and multimodal approaches to acute and chronic pain are often not supported, leaving physicians with few options to treat often challenging and complex conditions. Part D plan and network pharmacy limits on the duration of prescriptions, dose changes, and other restrictive barriers to obtaining properly prescribed pain medications has limited access to pain care. Without access to sufficient pain care, many patients face unnecessary medical complications, prolonged suffering, and decreased function. There are also troubling reports of patients dying by suicide when denied access to the care prescribed by their physician. Besides removing arbitrary limits on patients' access to opioid therapy when it is effective in improving patient health outcomes, Medicare should work to significantly improve affordable access to the many different non-opioid options, including non-opioid medications and non-pharmacologic treatments for pain, restorative therapies, interventional procedures, behavioral health approaches, and complementary and integrative health strategies.

The discussion in the rule mentions the use of buprenorphine to treat patients with OUD, but the AMA and the HHS Inter-agency Pain Management Best Practices Task Force also support efforts to increase the use of buprenorphine in the treatment of pain. Buprenorphine is approved by the Food and Drug Administration for the treatment of pain, and it is safer than morphine, hydrocodone, and oxycodone because it has a reduced potency for respiratory depression. Prior authorization requirements for buprenorphine should be removed to facilitate its use in treating pain as well as OUD. The AMA stresses again that without CMS action to remove these barriers, comprehensive pain care options for patients will remain limited and lead to suboptimal outcomes.

Part D drug utilization management strategies including prior authorization and quantity limits are being misapplied to buprenorphine with disastrous effect. Physicians treating patients who had been using illicitly manufactured fentanyl, for example, have had success with buprenorphine prescriptions greater than 24mg, but often face quantity limits that prevent patients from accessing the dose needed to manage their OUD. CMS should prohibit these limits.

D. Electronic Prescribing of Controlled Substances (EPCS)

- **Recommendation:** Finalize CMS proposal to require EPCS compliance by January 1, 2023 instead of January 1, 2022, and not to require long-term care facilities to comply until 2025. Finalize all proposed exemptions including for physicians who issue 100 or fewer Part D controlled substance prescriptions annually, practice in disaster areas, or request a waiver due to circumstances affecting their ability to adopt EPCS such as lack of broadband access. CMS should also exempt those who issue prescriptions for medications to treat opioid use disorder from the requirement for EPCS. Finalize the plan to notify those who are not in compliance with the EPCS requirement but not to impose penalties for non-compliance.

The SUPPORT Act required that Medicare Part D prescriptions for controlled substances be prescribed electronically starting on January 1, 2021 and required the Drug Enforcement Administration (DEA) to modify the biometric component of the multifactor authentication requirements within its EPCS standards. The DEA has not yet revised these standards. CMS is also required to specify circumstances when the EPCS requirement may be waived, establish exceptions to the requirement, and determine penalties for non-compliance. CMS is continuing to encourage EPCS adoption and notes that EPCS increased from 38 percent of prescriptions in 2019 to 70 percent in 2021.

Previous CMS rules pushed back the deadline for EPCS compliance until January 1, 2022, and CMS is now proposing to push it back further to January 1, 2023. For patients in long-term care facilities, the compliance deadline would be 2025. CMS also proposes that the threshold prescribers would need to meet for compliance is 70 percent of their controlled substances being e-prescribed. CMS also outlines exceptions and waivers from the requirement for those who issue 100 or fewer Part D controlled substance prescriptions annually, those in disaster areas, as well as those who request and receive from CMS a waiver due to circumstances that prevent EPCS such as lack of broadband access. The AMA deeply appreciates CMS' recognition of how difficult it would be for medical practices to implement EPCS systems during the COVID-19 PHE. **We strongly support the proposal to defer the EPCS compliance deadline until 2023 and urge that it be finalized.**

We also appreciate CMS' acknowledgement of the uncertainty facing practices that may be considering EPCS adoption but do not yet know when or how the DEA requirements for multifactor authentication will be modified. We remain hopeful that, once issued, these modifications will streamline implementation of EPCS for practices, make it easier for EPCS to be integrated into physicians' regular

workflows, and lower its cost and administrative burden. There may also be time needed for EPCS vendors to adjust their products to comply with the revised DEA regulations, so we recommend that CMS continue to monitor this situation and take it into account in its EPCS compliance policies.

The AMA agrees with the rationale that CMS has provided for all its proposed exceptions to the EPCS requirement. We particularly appreciate the flexibility that the proposed individual waiver request process allows. **The AMA recommends that all the proposed exceptions be finalized.**

One important goal of the SUPPORT Act was to increase Americans' access to evidence-based treatment for OUD, and several provisions were specifically intended to increase access to buprenorphine for use in treating patients with OUD. **Consistent with this aim, and to minimize regulatory burdens for physicians who provide office-based treatment to Medicare patients with OUD, the AMA recommends that CMS create an additional exception to the EPCS requirement for physicians who issue prescriptions for buprenorphine.** If a physician issued 150 Part D prescriptions for controlled substances, for example, but 75 were for buprenorphine, then they would fall under the low prescription volume exception because the buprenorphine prescriptions would not be included in the count of eligible prescriptions.

Finally, the AMA strongly supports the CMS proposal not to impose penalties on physicians for non-compliance with the EPCS requirement. The CMS plan to send a letter informing them that they are not in compliance, explain the benefits of EPCS, and provide a link to the CMS portal to request a waiver from EPCS is an excellent plan and the AMA urges that it be finalized.

E. OUD Services Furnished by Opioid Treatment Programs (OTPs)

- **Recommendation:** Finalize the proposals to reimburse OTPs for take-home provision of the new 8mg naloxone product and to continue to allow audio-only communications for counseling and therapy services.

CMS has been allowing OTPs to submit an add-on code, G2215, to the weekly bundled payments they receive for patients being treated for OUD to indicate that the patient has been provided with a take-home supply of nasal naloxone. The pricing for this add-on code is based on an assumption that the patient is provided with a box of two 4mg nasal spray products.

As the Food and Drug Administration has now approved a higher strength nasal naloxone spray with 8mg of naloxone, CMS proposes to create a new G-code describing a take-home supply of the higher dose product. **As the drug overdose epidemic has evolved and many patients are experiencing overdoses from illicitly manufactured fentanyl, it is important that patients with OUD have access to the new, more potent overdose reversal drug. The AMA strongly supports this CMS proposal and urges that it be finalized.**

CMS is also proposing that after the COVID-19 PHE, patients receiving treatment at OTPs would be able to continue to receive their counseling and therapy services via audio-only telephone. The AMA believes it is vitally important to continue to provide patients with access to telephone services. As we have noted elsewhere in this comment letter, it is AMA policy that broadband access is a social determinant of health. Far too many historically minoritized and marginalized patients are unable to access audio-visual telecommunications. We also agree with commenters that patients receiving treatment for OUD face enormous stigma and are certainly among those who have been historically and are

currently marginalized. **We urge CMS to finalize this policy and allow audio-only counseling and therapy services to continue to be furnished by OTPs after the COVID-19 PHE.**

The CMS proposals for documenting provision of audio-visual and audio-only services by OTPs are not entirely clear and have the potential to cause confusion and be administratively burdensome to implement. It plans to require that modifier -95 be reported when audio-visual technology is used for the service described by the counseling and therapy add-on code, G2080. It also proposes that after the PHE, OTPs furnishing counseling and therapy services via audio-only, whether as part of the bundled service or an add-on, would need to document in the patient's medical record that this was done and rationale for doing so. On top of this documentation in the record, it proposes to require a modifier to be reported. **The AMA recommends that CMS reconsider and simplify this plan. We are concerned that these various documentation requirements could potentially dissuade OTPs from making audio-only services available to their patients due to either the administrative burden or fear of enforcement action.** The clear intent of the proposal put forward by CMS is to remove barriers to care provided by OTPs and the AMA urges simplification to achieve this important goal.

F. Appropriate Use Criteria

1. Delay AUC Penalty Phase

- **Recommendation:** The AMA strongly urges CMS to finalize its proposal to delay the penalty phase of the AUC program until the later of Jan. 1, 2023, or the Jan. 1 following the end of the PHE. The AMA will continue to advocate for a delay until CMS can adequately address technical and workflow challenges with its implementation and any interaction between the QPP and AUC.

The AMA appreciates CMS' recognition that the COVID-19 PHE has adversely impacted physicians' ability to prepare for AUC implementation and strongly supports CMS' proposal to delay the start of the AUC penalty phase until the later of Jan. 1, 2023, or the Jan. 1 after the PHE. As outlined in our joint [letter](#) with the American Hospital Association, due to the ongoing COVID-19 pandemic, physicians, hospitals and other providers have been unable to sufficiently engage in the Education and Operations Testing Period to adjust workflows, train staff, and gain necessary experience to comply with the program.

To help "flatten the curve" and to comply with directives from federal, state, and local authorities, hospitals and physician practices severely limited all non-emergency surgeries and postponed other non-urgent procedures. While these steps enabled the country to combat the extraordinary circumstances presented by the virus, they significantly limited the provision of diagnostic imaging services. In addition, responding to the challenges of the PHE required providers to significantly reallocate resources. In order to meet patient safety needs, providers underwent a massive expansion of telehealth services. Physicians, hospitals, and health systems allocated extensive information technology resources so that first-rate patient care could occur remotely. Due to the surging fourth wave of COVID-19 cases and hospitalizations and the ongoing demands of meeting patient care needs, physicians are still not in a position to devote the necessary resources to ensure a successful implementation of the AUC program.

2. *Reduce AUC Reporting Burden*

- **Recommendation:** CMS must reduce the burden of AUC, particularly as the program has been superseded by the QPP, which holds physicians accountable for value and unnecessary resource use directly through quality and cost measures in the Merit-based Incentive Payment System, as well as financial risk in alternative payment models.

In addition, the AMA continues to have foundational concerns about the burden of AUC and how best to implement the program, including the proper, standardized procedures for transmitting information from the ordering to the rendering provider, efficient reporting of the required data on claims, and understanding aspects of the program requirements and exceptions. In the sections below, the AMA responds to the adequacy of CMS' proposed claims processing edits to address specific circumstances, such as modified orders. However, we urge CMS to take substantial steps to alleviate the burden of AUC and improve its relevance to physicians and Medicare. The AMA realizes the law requires that each claim identify the specific G-code representing the consulted Clinical Decision Support Mechanism (CDSM) for a particular imaging service; however, **given the burden, CMS may need to consider discussing potential legislative fixes with Congress or limiting reporting to the priority areas. CMS should also exempt physicians who are taking on financial risk in alternative payment models and allow compliance via means other than claims, such as qualified clinical data registries.**

More broadly, we have significant concerns about numerous workflow challenges and questions that will result from the AUC program requirements. Ordering physicians must be able to easily identify the diagnoses and specific advanced diagnostic imaging services to which the AUC requirements apply so that they can consult the CDSM at the time of ordering. Ideally, they would be prompted to consult the CDSM upon ordering a service to which the requirements apply. Information regarding the CDSM consultation will then somehow need to be communicated between ordering and furnishing providers, as the physician ordering the imaging service in most cases will be different than the physician performing the imaging. Thus, not only must the claim change but also all methods used to send an order (electronically or otherwise).

While a standard and technological solution for transferring this information from ordering to furnishing providers (Integrating the Healthcare Enterprise Radiology Technical Framework Supplement Clinical Decision Support Order Appropriateness Tracking) is [in development](#), it is in an immature, pilot stage, meaning that providers will most likely need to rely on manual workflows to exchange these data during the implementation of the AUC program. Additionally, providers will need to determine optimal procedures for these communications. For example, will ordering providers send the applicable G-codes and modifiers to the furnishing physician, or will they simply send the information in text format that the furnishing provider will need to translate into the code and modifier? These communications and reporting burdens will be further compounded when different providers are responsible for the technical and professional components of the imaging service, as the ordering physician will need to send the CDSM consultation information to two separate providers to be reported on the technical and professional claims.

3. *Comprehensively Address the Lack of Awareness and Readiness for AUC Implementation*

- **Recommendations:** CMS should not move to the penalty phase of AUC until the claims data show a vast majority of all applicable advanced diagnostic imaging claims would meet the requirements to be paid. CMS should not retire or redefine Modifier MH at the outset of the program as it is a failsafe so furnishing professionals do not need to delay care if an

ordering professional has not provided or cannot provide AUC consultation information. CMS should provide quarterly claims data updates about AUC reporting uptake and common errors. The AMA also urges CMS to initiate an education and outreach campaign about AUC akin to its efforts for operationalizing the new Medicare Beneficiary Identifier (MBI).

Although the requirements for consultation and reporting of AUC were enacted by Congress in 2014 and CMS has attempted to implement these policies in a deliberative fashion, we are very concerned that many physicians remain unaware of the underlying program requirements. Our concerns are underscored by CMS' claims analysis finding that only 9-10 percent of claims would have been paid in 2020 had AUC been in effect. Put differently, 90-91 percent of Medicare claims for advanced diagnostic images would have been rejected and unpaid. If the AUC program had been fully implemented during 2020, the impact on furnishing providers would have been nothing short of disastrous from the resulting massive cash shortfall and/or the administrative hassles of resubmitting or appealing denied claims. **CMS should not move ahead with the AUC penalty phase until the vast majority of applicable claims would meet the requirements to be paid.**

The AMA also urges CMS not to retire or redefine Modifier MH to report unknown CDSM consultation status, as it is a failsafe so furnishing professionals do not need to delay care if an ordering professional has not provided or cannot provide AUC consultation information. The MH modifier protects furnishing providers from the untenable position of choosing between delaying a patient's medically necessary imaging service or risking claim nonpayment. Without this failsafe, Medicare beneficiaries' imaging services would be delayed by at least the time needed for the furnishing provider to contact the ordering provider for AUC consultation data. Patients' wait times could be further—and significantly—extended in situations where the ordering provider does not have a CDSM and/or is unaware of the AUC program requirements. **The potential for negative clinical impacts on Medicare patients due to care delays necessitates the continued availability of the MH modifier.** Moreover, we do not support CMS' proposal to redefine Modifier MH from the current identification of claims where AUC consultation information is not provided to a new definition where AUC consultation is not required. We believe this will generate much confusion and furnishing professionals may continue to use the modifier in its current context. Instead, CMS should create a new modifier for those situations where AUC consultation is not required.

CMS should release more detailed data about the claims that were compliant with AUC and the other 6-7 percent of claims that included some relevant AUC information. The AMA is specifically interested in what percentage of the claims used *Modifier MH – Unknown if ordering professional consulted a clinical decision support mechanism for this service, related information was not provided to the furnishing professional or provider*. If it was a significant percentage, we believe citing 9-10 percent of claims as compliant is disingenuous, as it likely indicates that the ordering and furnishing professionals have not yet established a standardized process for communicating AUC information with the advanced diagnostic imaging order, and that many, if not most, of these claims would have been denied if the failsafe MH modifier had not been available. **CMS should also release claims data analyses on a quarterly basis during 2022 to inform stakeholders about the rate of uptake of AUC reporting, such as it did during the MBI implementation, and common errors in reporting that would result in claims not being paid.**

One key aspect of ensuring a seamless rollout is outreach and education, and the AMA is extremely concerned that the lack of education to date about the program exacerbates the administrative burdens associated with AUC and creates the potential for confusion and difficulty processing claims. We recommend the Agency increase its efforts to inform physicians about AUC and use as a guide its training

and resources for operationalizing the new MBI, which included webinars, a frequently asked questions document, regular correspondence with tips and resources to understand the new identifier, and a transition period. Additionally, given the substantial complexities and severe lack of awareness about the AUC program, CMS should also establish an ombudsman similar to the MBI provider ombudsman who was devoted to educating physicians about the program and who physicians could contact for help settling any implementation problems that arose.

4. *Allow Flexibility for Modified Orders*

- **Recommendation:** CMS should allow flexibility when the furnishing professional uses his or her professional judgment to modify an order.

The AMA appreciates that CMS is proposing flexibility when a furnishing professional using his or her professional judgment decides to modify an imaging order. We agree that, in these circumstances, neither the ordering professional, nor the furnishing professional, should be required to consult AUC for the additional services. CMS does not provide enough data, however, to substantiate its claim that modified orders are infrequent. Moreover, the proposed workarounds in the claim submission process are confusing and appear to require the furnishing provider to *report erroneous information* regarding CDSM consultation on the claim. In cases when the furnishing professional modifies the order by addition, it seems that the AUC consultation information provided by the ordering professional must appear on the claim lines of both the originally ordered image and the additional image to avoid failing AUC claims processing edits. When the furnishing professional modifies the order by substitution, CMS appears to require that the AUC consultation information provided by the ordering professional with the original order be reported on the claim line for the substituted image. While we strongly support the underlying intent of offering flexibility, the proposed operational solution does not accurately reflect the actual CDSM consultation, with a resulting potential for these errant data to negatively impact ordering providers when CMS eventually uses the AUC program to identify outliers subject to prior authorization. **If CMS chooses to proceed with the proposed claim submission adjustments for revised imaging orders, the AMA requests clarification on (a) how AUC data should be reported on claims for revised/additional imaging orders and (b) how CMS plans to mitigate any negative downstream effects on ordering physicians whose CDSM data were erroneously reported on claims to accommodate this particular scenario.**

Again, we reiterate our concerns that this program is overly burdensome and convoluted. If CMS is trying to change the behavior of the ordering physician, there are far more straightforward options, including exempting ordering professionals who are taking on financial risk in an alternative payment model and allowing reporting via mechanisms other than claims, such as qualified clinical data registries.

5. *Improve the Extreme and Uncontrollable Circumstances Hardship Exception*

- **Recommendation:** CMS should harmonize the AUC hardship exceptions, including the Extreme and Uncontrollable Circumstances Hardship Exception, with the QPP hardship exceptions and allow both ordering and furnishing physicians to attest annually to a hardship rather than on every claim.

We greatly appreciate that CMS recognizes the need for an Extreme and Uncontrollable Circumstances hardship exception due to the COVID-19 pandemic after the PHE expires, as the investments in new information technology and staff time necessary to comply with AUC will likely not happen until after

the PHE ends. However, we urge CMS to make it easier for physicians who need to avail themselves of this hardship. CMS should consider allowing for both ordering and furnishing physicians to attest once as to the existence of a certain hardship exemption rather than having a physician individually attesting on every claim, especially in extreme and uncontrollable circumstances of a natural disaster.

In order to promote administrative simplification, CMS also needs to align the hardship exceptions in the QPP with the AUC program, including the exemptions for new physicians for one year and for low volume of Medicare patients. The AMA does not understand why CMS established different exemptions for closely related and similarly burdensome programs. Allowing for new physicians or low-volume physicians to be exempted from participating in MIPS but not from the AUC program with its highly complex and potentially expensive requirements is inconsistent, confusing, and burdensome.

6. *Deny or Return Claims that Fail AUC Claims Processing Edits*

- **Recommendation:** We strongly urge CMS not to fully implement AUC until the Agency is certain that the vast majority of claims will not be rejected or denied due to either (1) AUC reporting errors or (2) claims processing issues. CMS should initially return claims for correction and resubmission and revisit this approach on a frequent basis—no less often than annually—after the first full implementation period. CMS should consider the preferences and concerns shared by the most impacted medical specialties.

There is unfortunately no good answer to whether CMS should deny or return claims that fail AUC claims processing edits. Instead, CMS should move ahead to implement AUC only when analysis of claims data during an Education and Operations Testing Period shows that the vast majority of claims would meet the AUC reporting requirements and be paid. However, if forced to choose between the two, we believe there are advantages to returning claims that can be corrected and resubmitted without having to go through the formal appeals process. The AMA urges CMS to revisit this decision frequently, at least on an annual basis, and to consider the preferences and concerns shared by the most impacted medical specialty societies.

Finally, the AMA again reiterates that the AUC program should be delayed until CMS is able to adequately address technical and workflow challenges with its implementation and any interaction between the QPP and AUC. We have outlined numerous recommendations throughout our comments to alleviate the extreme burden posed by this program and to harmonize it with the existing quality improvement and cost reduction requirements under the QPP. We also urge CMS to ensure that its systems do not result in unnecessary claims denials or rejections. The Agency should program the system to require advance diagnostic imaging claims to have a valid AUC modifier and a valid CDSM G-code to pass through processing. The system should identify Place of Service codes, i.e., inpatient or critical access hospital, that qualify a claim to automatically bypass AUC reporting requirements. Any analysis, e.g., whether the hardship exemption was appropriate, should be done on the back end. The system programming should be as simple as possible to cause the fewest rejections or denials.

7. *Exempt Critical Access Hospitals*

- **Recommendation:** CMS should clarify that advanced diagnostic imaging services either **ordered or furnished** in an outpatient department of a critical access hospital (CAH) are not subject to the AUC program.

The AMA appreciates that CMS has addressed situations where advanced diagnostic imaging services are not entirely furnished in a CAH setting. In such cases, CMS states that neither the professional component nor technical component claims should be required to include AUC consultation information and proposes establishing a modifier that would identify imaging claims that are not subject to the AUC program for this reason.

However, the AMA notes that similar operational challenges may arise when there is a “mismatch” in AUC exemption status between the **ordering and furnishing providers**—i.e., when the ordering provider is at a CAH but the furnishing provider is not. In such situations, the CAH ordering provider should rightfully be exempt from AUC requirements due to limited resources for technology investment. However, if the furnishing provider is not in a CAH, such claims would presumably be denied for lack of AUC program compliance. **We request that CMS expand its provisions for CAH imaging services so that claims where either the ordering or rendering provider is in a CAH are not subject to the AUC program.**

G. Indirect Compensation Arrangement

Historically, determining whether a physician has an indirect compensation arrangement (ICA) with a designated health services (DHS) entity has been a complicated, confusing, and time-consuming undertaking.¹⁵ An ICA is the only type of financial relationship that (a) is not expressly addressed or defined in the Stark Law statute, and (b) by regulation, requires application of a burdensome multi-prong test to determine applicability.

In December 2020, CMS published the final rule “Modernizing and Clarifying the Physician Self-Referral Regulations” (MCR Final Rule) and overhauled the ICA Definition—specifically, Prong Two—and its interaction with the Unit-Based Special Rules.¹⁶ The 2022 PFS Proposed Rule would again amend the definition of ICA under the Stark Law.

The 2022 PFS Proposed Rule multiplies the number of variables in the ICA definition and introduces new, defined terms into the analysis. Understanding the proposed changes to the ICA definition is challenging even for health care counsel experienced in the federal Stark Law and will likely confound the DHS entities and physicians required to comply with the statute. For example, how will the proposed changes to the ICA definition interact with the Stark Law’s flexibilities afforded to “group practice” compensation (which are not necessarily limited to personally performed services)?

In the proposal, CMS relies heavily on public comments the Agency received almost five years ago to justify their belief that unit of service-based compensation formulas in arrangements for the lease of space and equipment are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. We strongly disagree and believe that the previous predictions of substantial increased abuse have not come to fruition. Further, we believe that CMS has the ability to provide additional flexibility to adapt to changing circumstances and developments in the health care industry. The AMA urges CMS to consider that as physicians continue to battle against the COVID-19 pandemic, with increasing surges across the U.S., proposing additional complex changes to the ICA definition—just months after CMS overhauled the ICA definition in December 2020 via the MCR Final Rule—creates a burden on physicians and DHS entities who will now

¹⁵ CMS has altered the ICA definition multiple times since 2004.

¹⁶ Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (2020 Final Rule) 85 FR 77492. <https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf>.

have to pause and reassess how this additional round of proposed changes, if finalized in their current form, impact their arrangements. This burden will likely be even greater for physicians in small and rural areas whose patients may rely on receiving certain services locally.

III. REQUESTS FOR INFORMATION

A. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs

Data Aggregation

The AMA supports advancements in data availability and integration for quality improvement and measurement through efforts such as data aggregation, but they must result in data that are easily accessible at the point of care and provide actionable information that can inform shared decision-making while also easing reporting burden. Many third-party aggregators such as clinical registries and health information exchanges (HIEs) have demonstrated the great potential that can be experienced through data sharing, such as increasing transparency on patient interactions across the health system to promoting initiatives that inform public health, but we strongly recommend that CMS consider the following issues if they move forward with this effort.

Hospitals, practices, third-party aggregators, and others must have sufficient time and guidance to implement digital quality measures (dQMs) prior to any required reporting of the data and/or measure scores. The recent experience encountered by accountable care organizations (ACOs) with the Medicare Shared Savings Program (MSSP) changes as outlined in the [letter to Secretary Becerra](#) dated May 4, 2021, from multiple health care organizations including the AMA serves as an example on how reporting requirements that are not adequately researched or delineated can create confusion and expend unnecessary and costly resources. Specifically, as ACOs attempt to be responsive to the shift to reporting of electronic clinical quality measures (eCQMs) or the Merit-based Incentive Payment System clinical quality measures (MIPS CQMs) using all payer data, each are encountering multiple challenges, including:

- The significant number of vendor systems from which the data are collected and across multiple practices;
- The extent to which the ACO may or may not have permissions to access and report data on patients beyond their assigned beneficiaries;
- How to best complete patient matching across all participating practices; and
- How to best clean and validate these data, including the extent to which the ACO can assume responsibly for that reporting and validation and likely includes thousands of patients for a single measure.

Perhaps more importantly, many must build the necessary internal infrastructure or identify and pay an external vendor to assist in the data aggregation and reporting and many are spending hundreds of thousands to over a million dollars to enable this transition. These unexpected costs, particularly with little advance warning, will likely require ACOs to shift resources that would traditionally have been used to improve patient care and should not be replicated again.

The AMA also does not believe that it is realistic to assume that any one hospital or physician practice will be asked to coordinate and share data with only one entity unless CMS served as the sole third-party aggregator. Rather, it is not unreasonable to expect that one provider will need to interact and establish data sharing with multiple third-party aggregators and it will further add to the costs and challenges of

data sharing. We urge CMS to explore the potential impact that these requirements may have and develop solutions that will minimize costs, address user resistance, and ensure that the reporting burden and expenses do not increase for those entities at the point of care. This analysis should be broad and include those groups that will serve important roles both in providing important data and driving improvements in individuals' health such as public health agencies. In addition, creating some governance and defining a minimum set of standards and capabilities for these data aggregators could minimize the reporting burden experienced by hospitals, practices, and others, particularly if they must interact with more than one group. This information will also ensure that third-party aggregators are able to demonstrate and offer the services that will be required for quality measure reporting such as robust processes around patient matching, ensure adequate privacy and security of the data, and demonstrate data accuracy and validation. Hospitals, practices, and others must be able to ensure that those aggregators with whom they partner will meet CMS expectations/requirements.

In addition, the broader implications to quality measurement if data aggregation is supported must be considered. While the expansion to the broader population could provide a snapshot of care within a community, it is likely not representative of the care provided by the hospital or other providers. It is important to note that the IQR or MIPS is a Medicare program so organizations naturally focus their efforts on Medicare patients, causing them to target services and interventions for their assigned Medicare patient population. The issue with payer mix will become more complicated as CMS moves to measure providers on more outcome and intermediate outcome measures. The AMA performed a query of 2016 National Ambulatory Medical Care Survey (NAMCS) data, looking at blood pressure control rates and on a national level the rates are different by insurance types demonstrating that payer mix and associated patient populations will affect scoring. As a result, performance on quality measures could be skewed based on inequities and differences in patient mix. This misrepresentation does not serve to drive change in a meaningful and useful way and potentially penalizes providers treating more vulnerable populations.

1. *CMS is seeking feedback on developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.*

The AMA supports the two-pronged approach of alignment of the individual measures and specifications separate from the necessary data elements. This division is useful, as it would allow a staged approach to implementation of aligned measures based on the degree to which data elements are standardized and demonstrated to be available within a specific setting or for a specific CMS quality program. We encourage CMS to be thoughtful on when a dQM might be proposed for inclusion in a quality program and perhaps create thresholds by which these determinations would be made. For example, once a data element that captures a patient-reported outcome result relevant to inpatient care is created, it must first be incorporated into the United States Core Data for Interoperability (USCDI) and relevant implementation guides and have a certain percentage of all electronic health record vendors in the inpatient setting in collaboration with hospitals and others demonstrate that the data element is feasible to collect. At that point, any dQM that seeks to include this data element would be pilot tested in the inpatient setting and provide information on whether the required data elements and resulting measure score are reliable and valid. The dQM could then be considered for CMS inpatient quality programs and others.

We also encourage CMS to continue to advance a dQM that provides more clinically meaningful data within one setting or program even if the measure cannot be aligned across programs initially. Rather, the goal should be to work with the other relevant settings and programs to enable them to also leverage the advanced data as quickly as possible while not holding up the implementation of dQMs that may ease reporting burden and inform patient care.

While we also support the concept of a broad dQM portfolio that can be used by multiple end users, we encourage CMS to identify what has limited our ability to create that portfolio to date and actively address those challenges and barriers. One approach may be to identify one or two dQMs that are ready to be implemented across multiple programs, agencies, and settings and determine what actions or efforts are needed to ensure widespread adoption and success.

2. *CMS is seeking feedback on changes needed to advance to digital quality measures by 2025.*

The AMA appreciates CMS' acknowledgement that it will work with stakeholders to achieve interoperable data exchange and that to transition to full digital measurement requires its programs, where possible, to ensure alignment of: (1) measure concepts and specifications including narrative statements, measures logic and value sets; and (2) the individual data elements used to build these measures specifications and calculate the measures. Further, the required data elements would be limited to standardized, interoperable elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. However, the AMA believes to realize the full extent of digital quality measurement requires rethinking Electronic Health Record (EHR) certification.

While health IT certification was initially designed to evaluate a product's ability to meet Meaningful Use (MU) requirements, the usability and interoperability of EHRs going forward must be improved, which in part will require the Office of the National Coordinator for Health Information Technology's certification program to be refocused. Many demands by clinicians, hospitals, and other providers to improve EHRs (e.g., better usability, easier access to meaningful information, less time spent documenting or redocumenting data) can be addressed by examining key aspects of eCQMs or dQMs. A more robust approach to certification should focus on the quality, exchange and usability of data and aligned with measure reporting requirements. Generally, this includes:

- Capturing information relative to the clinical needs and goals of patients while leveraging alternative sources of data, instead of direct human documentation, as frequently as possible;
- Using data models that retain the intended meaning of information, including attributes about the data (e.g., provenance);
- Reporting and exchanging information in a structured format using standard terminology where possible; and
- Demonstrating the usability by focusing on integration of the data into their products and the degree of clinical workflow changes that may or may not be needed at the point of care.

Said another way, EHRs that improve the capture, management, and communication of clinical information will better accommodate the actual needs of providers and their patients, ensure the accuracy of quality measurement, and support a broader array of measures. We regularly hear that vendor certification timelines do not always match with CMS quality reporting requirements, such as the MIPS reporting requirements. In addition, vendors are not required to complete robust testing of measure and updates every year and as a result the test cases are insufficient to truly ensure that the measure can be "easily" and "accurately" reported. Currently, all of this is placed on measure developers and participating practices when it should really be a vendor's responsibility. **Therefore, prioritizing testing and certification that validates strict conformance to the principal aspects of dQMs will improve overall EHR user experience and reduce vendor development burden.**

A key component of the quality data infrastructure requires that payers utilize a single source for code and terminology mappings to ensure greater consistency with measure calculations and comparisons of performance (data mapping). Currently, vendors, practices, health systems, and consultants perform their own mapping, which leads to data inconsistencies and is a reason why no two EHRs can reliably calculate comparable results.

Work is needed to ameliorate data mapping issues by building upon the strengths of existing terminologies. For example, linking a terminology based on a comprehensive ontological model (e.g., SNOMED-CT) and foundational code sets (e.g., CPT) would allow for the seamless collection of information from the clinician at the bedside, the ability to capture and automate coding for fees and billing, extend the capabilities of clinical decision support systems (CDS), save countless hours of manual coding, and reduce errors in the process. Both terminologies provide unique advantages to end users, are fit for the purpose they are used, and together optimize data for clinical care, research, and administrative uses. Data maps, both new and existing, should be leveraged to resolve issues around efficiency and consistency of measures across EHRs and providers. The AMA has already initiated a close collaboration between SNOMED-CT and CPT terminologies.

Importantly, not only should a complete record be accessible, but also the data contained therein must be consistent, understandable, and usable (data consistency). For this to occur, data must be in a recognizable electronic package (data structure or syntax) and maintain a consistent meaning (data semantics). Just as the English language is built from words and grammar, the translation from data to knowledge can only occur if the meaning of data is consistent. However, levels of semantic interoperability vary greatly in the health care system. Most providers agree that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care. As a practical matter, the more data exchanged that lacks both semantic and syntactic interoperability, the less useful it is to providers and patients.

In order to improve electronic capture, calculation and reporting of quality measures, CMS should incent the use of standardized semantic content from recognized developers. In the development and specification of a quality measure intended for use in CMS programs, the clinical concepts used in the measure could be derived from recognized clinical content models. For example, if a measure is looking at blood pressure, and using the concepts as defined in one of these models, CMS-recognized data aggregators and registries could be given incentives to use those concepts and avoid variation in data management. Incorporation of data requires the development, maintenance, and refinement of administrative codes such as ICD, foundational code sets such as CPT, and clinical vocabulary standards such as SNOMED CT, LOINC, and RxNorm. CMS should promote collaborative efforts across these different coding systems and ensure consistency when data are exchanged.

- 3. CMS is seeking feedback on leveraging advances in technology (e.g., Fast Health Interoperable Resources Application Programming Interfaces or FHIR APIs) to access and electronically transmit interoperable data for dQMs and other reinforcing activities to support quality measurement and improvement.*

Quality measurement can be labor-intensive, fragmented, and inconsistent. It is also largely retrospective. Eliminating unnecessary or duplicative work and expenditures related to quality measurement can result in cost savings and free up invaluable time for patient care. Physicians need more automated, unified, accurate, prospective, and timely quality measurement and reporting. Moreover, CMS bases many of its performance incentives on insufficiently validated data processed through systems that are prone to error. This undermines CMS' goal of rewarding high quality care and support for value-based arrangements.

Furthermore, electronic clinical data requires the validation of clinical data sources—increasingly outside the “four walls” of the medical office—prior to use in quality and incentive programs.

Yet, due to the variability in technology and health care technical standard implementation, we are not yet at a point of achieving standardization nor sufficiently able to leverage advanced technology to accommodate dQMs. The best chance to accelerate adoption of dQMs across parties is to incent technology developers to develop a uniform set of tools in a common, secure environment to facilitate better data flow. Digital quality systems can enable rapid feedback and integrated content development across clinical guidelines and decision support, quality measures, and data specifications—each informing the other. However, **the AMA believes there are fundamental overarching goals that CMS should consider as it looks toward a dQM future. These include:**

- Timeliness of the data and the reporting—moving from batch transactions measured in months to near real-time;
- Facilitating the reuse of data already captured in the EHR, reducing physician and administrative burden; and
- Supporting the opportunity for all stakeholders to interoperate at scale.

Several entities are using or considering FHIR as an approach to develop clinically relevant measures that reduce burden, enhance accuracy, and drive quality improvement. The use of FHIR-based APIs may also allow data verification at hubs such as health information exchanges (HIEs) to a degree not practical for physician offices. HL7’s efforts to incorporate clinical quality language (CQL) used to specify dQMs is more precise, provides new options for measure logic, and reduces the opportunity for interpretation errors. Moreover, dQMs allow for preprogrammed packages ready for execution within a digital-ready data environment. dQMs are quicker to disseminate than measures with narrative specification which must be interpreted, programmed, and tested before use.

The AMA has identified several benefits in leveraging FHIR and CQL for digital quality measures. These benefits include:

- Defining quality measures as computable artifacts;
- Automating data collection and quality measure reporting;
- Easing the burden of identifying quality measures applicable to specific patients;
- Facilitating the exchange of gaps in care and quality measures;
- Closing clinical and information gaps prospectively versus retrospectively; and
- Minimizing the burden of manual data abstraction for measure reporting.

However, we stress that CMS must address several fundamental issues prior to moving physicians and other providers to dQM reporting and tying payment and/or quality rating systems to dQM performance. Including that:

- Challenges persist related to level of maturity of FHIR implementation overall. Not all resources are normative/mature; for others, significant work is needed to support dQM use cases;
- Adoption of US CORE profile capabilities by EHR vendors is not yet widespread enough to attempt full migration to FHIR. This is not expected to occur until 2023. CMS should promote alignment between QI CORE and US CORE;
- Digital clinical data are frequently in disparate, non-standard formats. As previously discussed, CMS should incent the use of standardized content;

- Generating the necessary data to support dQM implementation is not practical for most medical practices at this time and readiness is highly variable; and
- Smaller health systems and those serving underserved populations will need resources and technical support. CMS should make supporting these health care facilities a priority.

B. Closing the Health Equity Gap in CMS Clinician Quality Reporting Programs

In recognition of persistent health disparities and the importance of closing the health equity gap, CMS requests information on several CMS programs to make reporting of health disparities based on social risk factors, race, and ethnicity more comprehensive and actionable for hospitals, providers, and patients.

Specifically, CMS is seeking comment on the following:

1. *The potential future stratification of quality measure results by race and ethnicity. Specifically, the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.*

The AMA believes that continued stratification of quality data by dual eligibility and race and ethnicity remains insufficient and while the expansion to disability provides useful information, CMS must make significant efforts to advance the data that are used to identify health care inequities. For example, quality measures should account for risk factors such as lack of access to food, housing, and/or transportation that affect patients' ability to adhere to treatment plans. Continued reliance on existing data that have known deficiencies is not acceptable and we must advance to more accurate and relevant data.

The AMA discourages CMS from strictly relying on dual-eligibility (DE) status when stratifying readmission or admission measures. While the 2016 Assistant Secretary for Planning and Evaluation (ASPE) report to Congress on social risk factors and their impact on measures in CMS value-based purchasing programs¹⁷ may have identified dual eligibility as a strong predictor for disparities, a recent study found that due to the differences in the DE population stratifying by DE-only within the confidential hospital Disparities Report is misleading and further exacerbates inequities, which is counter to the goals of quality and its related incentives to close or minimize health care inequities.¹⁸ The potential addition of race and ethnicity data using the indirect estimation approach, while potentially informative for quality improvement purposes, should not be used for any other purpose.

The AMA also believes gathering additional information on clinical algorithms in use today and the impact of including race and ethnicity into their calculations is of utmost importance. Collection of additional information on these specific algorithms is an essential early step towards identifying where racism and bias may exist in clinical decision-making tools and how they should be addressed to ensure clinical care and health of historically marginalized communities are not negatively impacted by their application. Given that the approaches in design and implementation, as well as underlying data

¹⁷ U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>. Washington, DC: 2016.

¹⁸ Alberti, Philip., Baker, Matt., Dual Eligible Patients Are Not The Same- How social risk may impact quality measurement's ability to reduce inequities.

provenance, vary, it will be important to seek further input from organizations that have expertise in equity and direct experience with development and use of specific algorithms.

The usage of race and ethnicity as variables, and how both are defined, varies among the clinical algorithms in use today. This is attributable in part to changes in protocols over time, as some of the clinical data registries from which algorithms are derived are more than several decades old. There is also variation among multiple health data systems in how the data are collected (are race and ethnicity patient or investigator/clinician reported?) and the number of choices provided to the reporter. Furthermore, because race is a social construct, there is significant variability in how “races” are defined by society, lawmakers, and others—including individuals themselves. These definitions have changed and evolved in usage and application over time and do not always correspond with biology and genetic ancestry. Accordingly, their inclusion as variables creates challenges in developing meaningful consensus definitions, especially as our society diversifies over time, further clouding how we define these variables.

The AMA House of Delegates in November 2020 passed historic new policy directing our organization “to collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors.”¹⁹ The AMA is currently undertaking an effort to convene a variety of organizations to gather more information about the use of clinical algorithms and create an action plan for how to address these problems.

We believe that, in addition to efforts like our own, the AHRQ is ideally situated to conduct and fund additional research into the use of race and ethnicity data in clinical settings and algorithms, their potential contribution to medical racism and/or bias in clinical decision-making, and the methods needed to eliminate such racism.

A new report finds that bias in algorithms is making health care delivery more biased along racial and economic lines, opposed to making health care delivery more objective and precise.²⁰ Perhaps the most well-known example of an algorithm that contributed to inequitable care is the Optum algorithm which used health care cost as a proxy for health, resulting in lower risk scores being assigned to Black patients who were equally sick to similarly White patients.²¹ While assigning higher risk scores to patients who have higher health care costs may have seemed reasonable to the developers because higher health costs are often associated with greater needs, doing so failed to account for the systemic and long-standing inequities in care that have resulted in fewer expenditures on Black patients. This resulted in further inequitable care, including excluding Black patients from care management programs that dedicate additional resources to coordinate care for higher risk programs.

CMS states that its contractors have identified two algorithms to indirectly estimate the race and ethnicity of Medicare beneficiaries. One approach uses Medicare administrative data; first name and surname matching, derived from the U.S. Census and other sources; with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or API. The second approach combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses Bayesian

¹⁹ [AMA Policy Racial Essentialism in Medicine D-350.981](#).

²⁰ Ziad, Obermeyer et al, “Algorithmic Bias Playbook,” Center for Applied AI at Chicago Booth. June 2021. <https://www.chicagobooth.edu/-/media/project/chicago-booth/centers/caai/docs/algorithmic-bias-playbook-june-2021.pdf>.

²¹ Obermeyer et al, “Dissecting racial bias in an algorithm used to manage the health of populations,” *Science* (Oct 25, 2019), <https://science.sciencemag.org/content/366/6464/447>.

updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups. The second algorithm has two versions, the latter of which has higher levels of validation.

Estimating an individual's race and ethnicity based on name and geography is inappropriate. Women and children often take the names of their husband and father, respectively. Particularly for women, estimating one's race/ethnicity based on surname simply does not make sense. Such estimation would also be insufficient for adopted individuals who take their adoptive family's surname. Additionally, there are discrepancies in how individuals self-report their race on the U.S. Census questionnaire, which would be used in each of the algorithms contemplated by CMS.²²

Therefore, we continue to believe relying on algorithms for indirectly estimating race and ethnicity is not an appropriate solution. If CMS plans to use proxies for race and ethnicity data to help identify and address inequities in care delivery and health outcomes, it must be based on self-reported data. A study by Jarrin, et al explores the accuracy of Medicare's administrative data variables for race and ethnicity data compared with the gold-standard of self-reported data and found inaccuracies, especially related to classification of American Indians/Alaskan Natives and Asian/Pacific Islanders.²³ We also question the accuracy of the algorithms and appropriateness outside of the hospital setting due to concerns of sufficient sample to make such estimations. As we highlighted, it is unclear how well such algorithms capture varied patient populations. In fact, the algorithms under consideration by CMS "are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial." To use an algorithm that is not accurate for multiracial individuals when the country's multiracial population is only growing (the multiracial population has jumped 276 percent between the 2010 and 2020 census) is counterproductive.²⁴ We urge CMS to focus on longer-term strategies that will truly drive improvements as opposed to spending time on resources to implement "quick fixes" and utilize proxies. The methodologies chosen to stratify and present data for purposes of improvement are multifaceted and it is a complex topic. Therefore, it requires more research to develop an evidence-based approach to account for social risk-factors and reduce inequities.

2. Current data collection practices by hospitals to capture demographic data elements.

As CMS begins to consider addressing health inequities and the potential development of a Hospital Equity Score, CMS must consider the potential unintended consequences and provide supportive education to ensure that this score does not exacerbate inequities and that institutions are appropriately educated on best practices for data collection and/or program implementation. As noted above, perhaps the most well-known example of an algorithm that contributed to inequitable care is the Optum algorithm, which used health care cost as a proxy for health, resulting in lower risk scores being assigned to Black patients who were equally sick to similarly situated White patients.²⁵ While assigning higher risk scores to patients who have higher health care costs may have seemed reasonable to the algorithm developers

²² <https://www.npr.org/2021/08/13/1014710483/2020-census-data-us-race-ethnicity-diversity>.

²³ Jarrin OF, Nyandeghe AN, Grafova IB, Dong X, Lin H. Validity of Race and Ethnicity Codes in Medicare Administrative Data Compared With Gold-standard Self-reported Race Collected During Routine Home Health Care Visits. *Med Care*. 2020 Jan;58(1):e1-e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433. <https://pubmed.ncbi.nlm.nih.gov/31688554/>.

²⁴ <https://www.census.gov/library/stories/2021/08/improved-race-ethnicity-measures-reveal-united-states-population-much-more-multiracial.html>.

²⁵ Obermeyer et al, "Dissecting racial bias in an algorithm used to manage the health of populations," *Science* (Oct 25, 2019), <https://science.sciencemag.org/content/366/6464/447>.

because higher health costs are often associated with greater needs, doing so failed to account for the systemic and long-standing inequities in care that have resulted in fewer expenditures on Black patients. This resulted in further inequitable care, including excluding Black patients from care management programs that dedicate additional resources to coordinate care for higher risk patients.

Not only is it important to ensure that the risk factors by which a measure or summary score is stratified or calculated accurately represent the characteristics of patient populations as discussed above, CMS must also be thoughtful on the set of measures on which these comparisons are made. It should not be assumed that a score derived from all the outcome measures in a quality program, for example, can be used to identify meaningful differences in performance that are due to health care inequities. CMS should determine what quality metrics would be most informative and not just from those measures that exist but also consider whether additional measures must be developed and implemented. If measure gaps are identified, they must be filled prior to the development of any Hospital Equity Score.

In addition, any consideration of such a measure must also be accompanied by significant resources and education. Often well-intended measures or tools create new problems and only health care facilities and physician practices that are well-financed and capitalized have the necessary resources to invest in quality improvement. For instance, the Hospital Wide Readmission program has substantially increased penalties for hospitals that serve a disproportionate number of low-income patients.²⁶ **CMS must provide adequate resources to help providers achieve better health outcomes for high-risk patient populations.** All patients with Medicare coverage do not have equal opportunities to achieve good health outcomes, so one-size-fits-all measures or programs are more likely to widen than reduce disparities.

The AMA strongly believes that inequities are best addressed through pilots and thoughtfully scaled initiatives and not within national accountability programs. As a part of the AMA's efforts to reduce health care inequities, we are currently in the process of developing a collaborative with health systems across the country that will leverage data-driven approaches to confront and overcome health disparities. The program, Quality and Safety for Impact on Racial Justice and Equity (FIRE), is designed to drive racial justice and equity in the health care arena by leveraging the foundational concepts of quality and safety improvement practices and making equity improvement an integral part of health care practice. The key objectives cross domains from patient care to operations to quality initiatives to culture and education. The framework for FIRE to guide the AMA's work is based on five key drivers:

- Driver 1: Integrate Equity into all Quality, Safety and Risk Analyses
- Driver 2: Use Equity-Informed High-Reliability Education
- Driver 3: Use Data to Support Equity Improvement
- Driver 4: Leadership Awareness and Engagement
- Driver 5: Organizational Accountability to Stakeholders

As we continue to collaborate with health systems and implement FIRE to determine any unintended consequences, the AMA continues to support efforts to pilot test innovative strategies to improve health equity and reduce disparities.

3. *Potential challenges facing clinicians with collecting a minimum set of demographic data elements in alignment with national data collection standards and standards for interoperable*

²⁶ Zuckerman, R. et al., Effect of a Hospital-wide Measure on the Readmissions Reduction Program. *N Engl J Med* 2017; Oct. 19, 2017. 377:1551-1558 DOI: 10.1056/NEJMs1701791.

exchange (such as the USCDI incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria).

Physicians need the best data available to make clinical decisions. Evidence indicating that a particular demographic characteristic is clinically important due to its association to a condition or support for a particular therapeutic intervention may signal utility of that data. Yet, as stated previously, demographic information is unlikely ever to be the best information available in determining a patient's individual priorities, goals, and concerns about their care. As CMS considers its policies on demographic data use, it must also consider the importance of patients' individualism. All patients deserve the opportunity to articulate their own personal health-related values to their physician. CMS should utilize a thoughtful review of its policy goals and balance those with the clear and real concerns of patients' data use. For example, patients might assume the care will be based on racial or ethnic stereotypes. This could cause individuals to second guess providing their full or accurate demographic data set to their physicians. **CMS must plan for situations where demographic data are limited or nonexistent; these plans must ensure physicians' payment, performance, or quality improvement metrics are not inappropriately impacted by choices patients make (e.g., resulting from small sample sizes or a lack of inhouse statistical expertise need to stratify performance data by demographic groups).**

While the USCDI v2 and the necessary certified health IT to support its use is expected to be available in early 2023, **CMS must consider and expect demographic data captured by certified health IT systems to vary by developer.** While large EHR developers may have well-designed or well-thought-out methods for data capture, our nation's physicians use a wide-array of EHR products—particularly physicians working in specialty or sub-specialty practices. Smaller EHR vendors often lack the resources to develop highly usable products. This leads to inconsistencies in data capture. For instance, the AMA is aware of products that will allow for free-hand text fields for demographic data capture rather than utilizing standardized, structured fields. What sounds like a small detail directly impacts the quality and consistency of demographic data. As CMS structures its programs, it must account for the inevitable variations in data capture and reporting because of health IT developer decisions. Similarly, these decisions are not easy or free to change. CMS should not expect or assume physicians must pay for modifications to their certified health IT. **Rather, CMS should coordinate with the Office of the National Coordinator for Health Information Technology (ONC) on health IT vendor policy levers to improve demographic data capture. These levers should not lead to physician burden or excessive costs.**

Additionally, the AMA is currently conducting a study on the collection and use of certain demographic information (race, ethnicity, and primary spoken language, abbreviated herein as REaL data). While the study is ongoing, preliminary findings indicate that organizational commitment to collecting REaL data is a key driver to effectively collecting data and minimizing collection errors. Collecting and using REaL data may not be top of mind for health care organizations, so there must be increased awareness and education among staff of why REaL data is important to collect and what it will (and will not) be used for. Accordingly, we suggest that improving the collection and use of REaL data must be recognized as a key organizational priority for health care providers to enact meaningful system-wide changes. CMS should consider positive incentives and provide educational tools to health care organizations to collect and use REaL data, while maintaining patient privacy protections and minimizing clinician burden.

Preliminary findings also have revealed that a variety of stakeholders are typically involved in the collection and use of REaL data, which makes understanding the entirety of the process challenging. Additionally, staff do not always know best or standard practices for collecting REaL data. Workflow changes—driven by organizational prioritization to improve equity through use of REaL data—are critical to improving REaL data collection. Engaging all key parties (front office, information

technology, analysts, clinicians, leadership, etc.) and creating feedback loops among parties can help to identify and address issues with data collection. Finally, preliminary survey results indicate that health care organizations need specific training and educational resources on collecting REaL data. Education and training should note that some patient communities may be resistant to providing REaL data. Staff needs to understand and respond (in a culturally appropriate manner) to these dynamics. CMS can help by creating educational resources, fact sheets, training videos, etc. on the importance of REaL data collection, as well as explain what the Agency does (and does not do) with the data. **The AMA further recommend CMS collaborate with ONC in the development of a voluntary certification program for certified electronic health record technology (CEHRT) that would enable physicians and health systems to adopt EHRs optimized for the collection of REaL data. In ONC’s 21st Century Cures Act (Cures Act) regulations, ONC proposed and finalized a voluntary certification program for health IT developers specific to pediatric care. The Cures Act directed the National Coordinator to encourage the voluntary certification of health information technology “for which no such technology is available or where more technological advancement or integration is needed.”²⁷ CMS can significantly advance the collection and use of REaL data by coordinating with ONC to improve CEHRT’s capability to meet patient and physician needs in this space.**

Given organizations are only learning about the importance of collecting REaL and the various challenges to data collection, **we believe it is premature to hold physicians and practices accountable for the collection and reporting of the data, including through some sort of quality measure or tying it to an accountability program, such as MIPS.**

IV. CALENDAR YEAR 2022 UPDATES TO THE QUALITY PAYMENT PROGRAM

A. MIPS Value Pathways (MVPs)

1. *Innovative Approaches to Measuring Value*

- **Recommendation:** CMS should establish a far more flexible MVP framework and create quality and cost measures based on clinical pathways and patient reported outcome measures (PROM) for diagnosis and treatment of specific medical conditions.

In response to the request for comment on “innovative approaches to measuring value that might include APM performance measurement approaches and using a single patient population both for MVP cost and quality measures in the future” (86 FR 39354), the AMA suggests that CMS relinquish its proposed attempt to contort traditional MIPS into MVPs as it results in a barely perceptible change to the program. Instead, the MVP framework should be flexible enough to allow specialty societies to co-develop with CMS a pathway that is similar to an APM in that it centers quality improvement, efficient resource use patient reported outcome and satisfaction and enhanced technology to care for patients with specific medical conditions. CMS should work with the specialty societies to develop quality and cost measures based on clinical pathways. This would be a more comprehensive method of measuring the quality of care than current measures, which apply only to a subset of patients and a subset of the services they receive. At the same time, it would be a more patient-centered approach than current measures, since it would permit customizing care delivery when patients are unable or unwilling to use the standard approaches to treatment that current measures are based on. In addition, the use of PROMs would also better assist with

²⁷ Cures Act, Sec. 4001.

measuring whether patients' goals are met and whether clinicians adhere to clinical pathways. This would help to reduce current inequities in care delivery and outcomes.

Since current quality measures are based on a portion of the evidence that is incorporated into the clinical pathways, a clinician could only perform well on the new measure if they also had good performance on current quality measures, and vice versa. However, unlike current measures, the new measures would automatically stay up to date when guidelines are revised based on new evidence, avoiding the delays that currently occur in quality measurement while individual measures are revised. To be clear, this alternative approach should not be thought of as additive to any of the existing categories or MVP Foundational Layer. Rather, specialty societies should be able to inform CMS how these measures would replace the traditional MIPS requirements in the new, more innovative MVP framework.

2. *MVP Development and Maintenance: MVP Development Criteria*

- **Recommendation:** Based on specialty societies' and stakeholders' experience with the initial round of MVP co-development with CMS, the AMA makes several recommendations to refine the process, including (1) adding an MVP development criterion that MVP development be clinician-led, (2) establishing an informal process to ensure transparency and coordination among the relevant specialty societies in development of an MVP, (3) publishing CMS' intentions for future MVP development priority areas to encourage early specialty society collaboration, and (4) clear and timely feedback about why a candidate MVP submission has not been proposed for implementation.

The AMA greatly appreciates the active engagement between CMS and specialty societies in the development of some of the initial seven MVPs that are proposed for the 2023 performance period. We have heard from several specialty societies that the initial outreach and subsequent communication from CMS was positive as CMS reached out to the specialty individually to schedule a call about a potential MVP, discussed the thinking behind the goal of the MVP and selected measures, and provided an opportunity to give input. However, we have also heard from specialty societies that they were not informed or engaged in any conversations and were unable to provide any input prior to publication of a clinically relevant MVP in the proposed rule. **Therefore, CMS should establish an informal process to ensure transparency and coordination among the relevant specialty societies in the early development of an MVP.**

It is especially important to alert specialties that CMS is considering working on a condition-focused MVP (e.g., stroke), because there are many physicians who may want to be part of the conversations. The AMA understands that CMS may not be aware of all the physicians who are engaged in the care and management of a condition, so we offer several suggestions to ensure all clinically appropriate stakeholders receive notice of MVP development. First, CMS could publish a list of MVPs under consideration on the QPP website along with the MVP developer to contact for coordination. Second, CMS could also publish a list of its MVP priority areas to alert specialty societies that they should begin to collaborate and engage with CMS to build out those MVPs. Third, CMS could require that MVP developers who submit an MVP around a condition or other broad clinical topic provide an opportunity for public feedback and input outside of the notice and comment period.

We have also been made aware of instances where third parties have developed and proposed MVPs to CMS, such as pharmaceutical, medical device and biotechnology industry. Currently, the AMA is unaware of CMS having restrictions within the CMS Measure Development Blueprint. We do not believe that use of industry-funded or backed measures or MVPs should be allowed within Medicare and other

CMS programs. The potential of a conflict of interest is too great; if real, such conflicts could result in measurement benefitting industry, not patients. We are also concerned that these third parties may not have the requisite clinical expertise and are unlikely to engage across the full range of physicians and stakeholders who should be involved in development of the MVP. Therefore, we recommend that CMS update the CMS Measure Development Blueprint to specifically state that measures financed exclusively by pharmaceutical, medical device or biotechnology companies are prohibited from CMS programs and request stewards to identify their funding source. At a minimum, for purposes of transparency, if a measure or MVP is funded by industry then there needs to be a disclaimer next to the steward's name highlighting their funding source. **The AMA also urges CMS to establish a new MVP development criterion that MVP-development be clinician-led.**

Finally, when CMS decides not to propose a candidate MVP for implementation, we urge the Agency to provide clear and timely feedback about why CMS is not moving forward with the MVP. MVP creation is a resource intensive process and developers would surely appreciate the feedback.

3. MVP and Subgroup Implementation Timeline

- **Recommendation:** The AMA supports CMS' proposal to introduce MVPs and a subgroup reporting option in 2023. Participation in MVPs and subgroups should be voluntary.

While the AMA appreciates that CMS proposes a gradual implementation timeline for MVPs such that they would first become an option in 2023, we do not support CMS' proposal to make MVP participation mandatory beginning in 2028. **We strongly urge CMS to ensure that MVP participation is voluntary and that physicians, group practices, and subgroups maintain the option to participate in traditional MIPS.** While the AMA continues to work closely with CMS and the specialty societies to improve the MVP framework and submit candidate MVPs that would be an improvement over traditional MIPS, there remain several outstanding questions and issues that CMS must get right in order to attract participation in MVPs. Throughout our comment letter, we recommend that CMS move away from thinking about MVPs as a collection of existing MIPS measures and instead test and adopt new, innovative approaches to measuring quality, cost, and health information technology, such as aligning with clinical pathways and patient-reported outcome measures. CMS must get these policy decisions right before considering a time horizon in which all eligible clinicians could participate in an MVP.

Mandating participation in 2028 is also counter to the goals of MVP, which is not to become a successor to traditional MIPS and risk carrying forward all its flaws and problems, but to become an alternative that is grounded in improving patient care around an episode of care, clinical condition, or other public health priority. We are extremely concerned that setting a drop-dead date for mandatory participation will take precedent over implementing well-constructed, innovative MVPs because CMS would be hamstrung by the need to rush to create enough MVPs—even if they are mediocre or sub-optimal—so that every eligible clinician can participate in an MVP.

Further, the AMA has logistical concerns about CMS' ability to adopt and implement an applicable MVP for all eligible clinicians. CMS' analysis estimates that approximately 10 percent of eligible clinicians will participate in an MVP in 2023. As required by statute, every eligible clinician must participate in MIPS or be subject to a penalty of up to nine percent of Medicare reimbursement. It would be extremely unfair and unreasonable to subject any physicians to an automatic penalty because there is no clinically relevant MVP option available to them. We believe this may be particularly true for subspecialists. For example, even though CMS proposes a lower joint repair MVP, not all orthopedic surgeons will be able to opt into this MVP as they may specialize in elbow or wrist surgeries. If CMS were to propose a

cataract surgery MVP, retina specialists would not be able to opt-in even though they are in the same specialty. We believe the same will be true in many specialties and it would be premature to establish a mandatory timeline before CMS understands whether it is even feasible to create a sufficient number of MVPs for all MIPS-eligible physicians.

The AMA also strongly urges CMS to create and maintain the subgroup option as a voluntary participation pathway in MIPS. The AMA continues to support a subgroup reporting option in MIPS, and we applaud CMS for tackling the operational and implementation hurdles the Agency faced to making this important participation pathway an option starting in 2023. However, just as CMS does not mandate individual or group practice participation, subgroup participation should not become mandatory. **We do not support requiring multispecialty groups to form single specialty subgroups in order to participate in MVPs starting in 2025.**

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 subgroup, and CMS must give physicians as much time as possible to plan and make the business case for participating in MVPs as a subgroup. In fact, CMS' analysis estimates that only 20 subgroups will form in 2023, and we believe limiting multispecialty practice participation in MVPs to single-specialty subgroups could have a chilling effect on MVP participation.

4. *Subgroup Composition*

- **Recommendation:** Because MVPs should focus on clinical conditions, episodes of care, and public health priorities, CMS should encourage subgroup compositions of multiple specialties, across multiple locations, and in various sizes to achieve the MVP's goals of improving care and reducing avoidable costs.

The AMA continues to believe subgroup reporting will be crucial to MVPs as it will 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 or who manage patient's care during an episode, such as surgeons and anesthesiologists, to report clinically relevant measures. We support allowing a subgroup option that allows a portion of a group to participate separately in an MVP.

We do not agree, however, that CMS should limit subgroup composition based on specialty, geographic location, size, or any other factors. One reason not to constrain the composition of subgroups is that MVPs are built around conditions, not specialties. For example, if a multispecialty group included a "stroke team" with neurologists, cardiologists, emergency physicians, neuroradiologists, etc., you would want the whole team to be able to form a subgroup for purposes of MVP participation. Also, imposing such limitations, particularly at the outset of this new reporting option, will increase the cost and burden of creating a subgroup, thus reducing participation. We strongly urge CMS to encourage multispecialty groups to form subgroups of the requisite specialists and locations to achieve the desired patient outcomes of the MVP. Artificial reporting barriers have plagued MIPS since its inception. Now is not the time to erect new hurdles when subgroups have the potential to promote more team-based care and give patients greater insights into the information they need to make care decisions.

5. *Scoring the Cost Performance Category in MVPs*

- **Recommendation:** Rather than focus on unfounded gaming concerns, CMS should work with specialty societies and other MVP developers to develop and test new and innovative cost measures that are clinically appropriate for an MVP. Specifically, CMS should provide specialty-specific and condition-specific Medicare claims data, MIPS cost performance data, as well as funding to help specialty societies in developing new cost measures as part of MVPs.

The AMA believes CMS' concerns about potential gaming by groups who elect to participate in an MVP to avoid being measured on cost are misplaced. First, we have heard numerous concerns from large, multispecialty practices that the burden to form a subgroup to select an MVP may outweigh the potential benefit. For example, not only would these large groups need to manage and invest in tracking different measures and data submission mechanisms for subsets of their physicians, but they would also be managing multiple applications to form subgroups, to apply for hardship exceptions as appropriate, and to file targeted reviews as necessary. In addition, these large groups would have to figure out how to manage multiple Medicare physician fee schedule payment adjustments for subsets of their physicians and whether this should factor into their compensation arrangements. We expect specialists within a large, multispecialty group that wish to form a subgroup and opt into an MVP will have to make the business case to the rest of the group about why they expect it will add value for their group and their patients. Second, we question why CMS would propose to mandate that large, multispecialty groups form subgroups to participate in MVPs if the gaming concerns loom large. Finally, the AMA reiterates our strong belief that it is far more important to ensure a high level of reliability to avoid inadvertently penalizing physicians, subgroups, or groups based on an outlier case than it is to score as many physicians as possible on cost.

Instead, CMS should focus on working with specialty societies and MVP developers to ensure there are clinically appropriate cost measures for MVPs. The AMA has heard numerous concerns from national medical specialty societies about the limited inventory of episode-based cost measures and their applicability to physicians who may choose to participate in an MVP. For example, the Emergency Medicine MVP includes the Medicare Spending Per Beneficiary measure, which evaluates Medicare spending prior to, during, and after an inpatient admission. Few emergency physicians may be attributed a sufficient case minimum of Medicare Spending Per Beneficiary (MSPB) episodes to be evaluated on this cost measure as they do not typically provide the plurality of care in the inpatient setting. This should not merit any concerns about gaming because the only cost measure in the MVP is not applicable to their practice. It is similar to traditional MIPS where few emergency physicians are scored on MSPB. CMS should work with the specialty societies and MVP developers to ensure that all physicians in all settings have an opportunity to be evaluated on relevant cost measures.

Specifically, the AMA recommends that CMS provide Medicare claims data, cost performance data, and funding to help specialty societies identify and develop clinically appropriate cost measures. The current process for obtaining Medicare claims data, such as through ResDAC, is time-consuming and expensive. More specialty-specific and condition-specific data from both the QPP and claims data sources will help specialty societies understand and target opportunities for a more cohesive, clinically relevant MIPS participation experience via the MVP. For example, in the Quality and Resource Use Reports (QRURs) that CMS used to generate as part of the Value-based Payment Modifier program, CMS included charts showing the midpoint and distribution of cost performance scores. CMS should provide these same charts, as well as breakdowns by measure and specialty. We understand the QPP data may be limited in

2019, 2020, and 2021 due to the Extreme and Uncontrollable Circumstances Hardship Exception policy in place due to COVID-19. However, we urge CMS to provide as much detail as possible.

6. *Enhanced Performance Feedback in MVPs and Request for Information on Actionable Feedback*

- **Recommendation:** The AMA urges CMS to finalize its proposal to provide detailed, comparative feedback to physicians who participate in the same MVPs. CMS should also provide easy, affordable ways for physicians to access and analyze Medicare claims data to identify opportunities to reduce spending, measure the impacts of care delivery changes, and quickly identify when services for patients need to be changed.

The AMA recognizes the challenge of balancing the goal of providing as much data as possible with the goal of enhanced usability and challenges related to CMS' limited resources. We support CMS' proposal to provide more detailed, comparative feedback to MVP participants. We have heard from physicians that the existing MIPS feedback reports are difficult to interpret in part because they lack comparisons, as well as sufficient definitions and summaries, to help identify trends across the data.

Regarding CMS' Request for Information on Actionable Feedback, we urge the Agency to present claims data in conjunction with more digestible elements, such as summaries, so physicians can easily understand what they are being measured on, how they are performing relative to other similar physicians, and what they are supposed to be doing with this data to improve overall value. With MVP, there will be opportunities to distill the data around an episode, condition, or specialty to help improve the actionability of the information. Also, to assist physicians with accessing and reviewing claims data, CMS should partner with its technical support contractors.

As CMS sees MVP as a pathway between MIPS and APMs, the Agency should look to the types of claims data analysis it currently provides to physicians in APMs as a guide. Claims data analysis is an essential factor in successful APM participation and introducing it in MIPS would help physicians to identify opportunities to improve care and reduce costs, while also enabling them to design effective APMs.

Rather than providing total utilization based on setting, such as inpatient or post-acute care settings, to be most useful data should be categorized based on the physician's level of influence over the expenditures or utilization. Five such categories are:

- a. Services their patients receive that are both *ordered and delivered* directly by the physician.
- b. Services delivered by *other* providers that are *integrally related* to services delivered by the physician. For example, anesthesia services are only delivered when a surgeon performs surgery.
- c. Services delivered by *other* providers that resulted from *orders* or *referrals* from the physician. This could include imaging and lab tests ordered by the physician directly as well as tests ordered by a specialist that the patient saw following a referral by the physician.
- d. Services delivered by other providers that were *related* to services delivered or ordered by the physician. For example, if the patient developed complications following a surgical procedure, the treatment of these complications would be related to the surgery performed by the surgeon, even if the surgeon did not directly treat the complications.
- e. All other services the patient received that appear to be *unrelated* to services delivered or ordered by the physician.

Collectively, these five categories add up to the total spending on all services a patient received. The services included in each category will differ for different types of physicians, so each specialty will need to define the categories for the types of patients and conditions they treat.

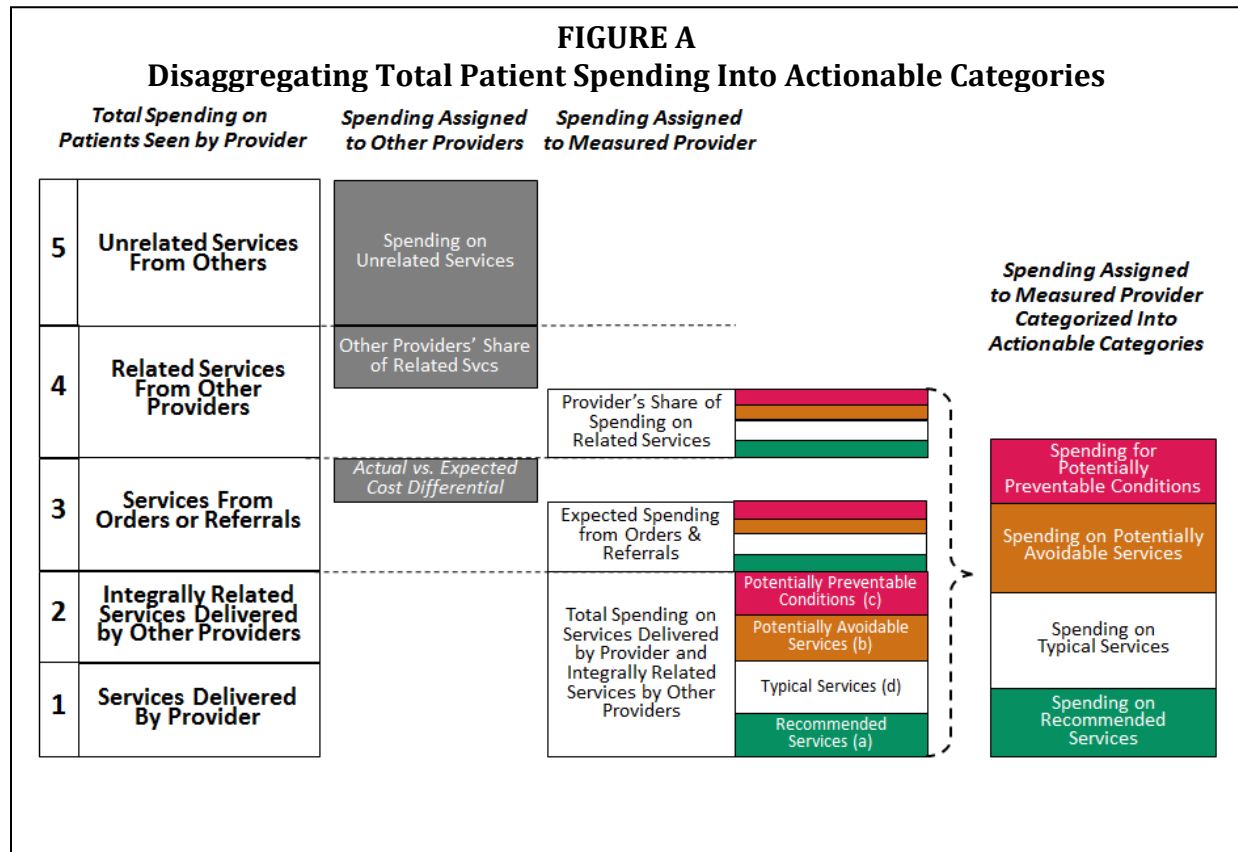
The five spending categories help identify which services physicians can control or influence, but they give only limited indications as to which aspects of spending could be *reduced* without harming patients' care. Consequently, it is desirable to further disaggregate spending into four subcategories:

- a. Services required to meet quality standards.
- b. Services that are potentially avoidable, e.g., services such as MRIs for lower back pain, cardiac stress tests, and Cesarean sections that may provide significant benefit to some patients but relatively little benefit to others and in some cases may result in harms to the patient that outweigh the benefits.
- c. Services needed to address potentially preventable conditions, i.e., situations where the *health condition itself* could potentially have been prevented if additional or different services had been delivered *at an earlier point in time*.
- d. All other services ("typical services"). Even if there is not enough evidence about appropriateness or preventability to classify them in the other three categories, variation among physicians in the number and types of "typical" services they use for similar patients could indicate opportunities for savings and areas where research to determine appropriate use criteria are needed.

Figure A illustrates how the total spending on patients seen by a physician would be divided into the five spending categories based on the level of the physician's control and influence over the services delivered to the patient and then further divided into the four subcategories.

Even with these better categorizations of services and spending, comparisons among physicians will not be useful in identifying opportunities for improvement unless they distinguish differences in utilization or spending that were associated with differences in the needs of the patients for whom the providers were providing care. Current risk adjustment systems do not do this effectively; the following methods should be used instead:

- **Disaggregating Spending into Subgroups of Patients with Similar Health Conditions.** Instead of using a *single* risk score to *adjust* spending, a better approach is to *compare* spending separately for *different subgroups* of patients, with each subgroup defined such that patients in that subgroup would be expected to need similar levels of services. Some risk adjustment systems have methods for grouping patients into clinically similar subgroups that can be used in this way for all types of spending.
- **Using Concurrent Risk Adjustment.** The patient categories should be based on complete information about the patient's health problems that occurred during the time period in which spending is being measured, rather than only the kinds of historical information used in purely prospective risk adjustment systems.
- **Using Clinical Information from EHRs and Registries in Addition to Claims Data.** In many cases, the key information that distinguishes differences in patient needs is not captured at all in claims data, and so clinical data will also be needed.
- **Disaggregating by Non-Health Factors to Identify Impacts on Spending.** *Disaggregating* spending into different categories of patients is also preferable to *adjusting* overall spending based on patient characteristics because it enables disparities between different groups to be measured and acted upon, rather than hidden inside a risk adjustment formula.



7. Foundational Layer- Population Health

The AMA is concerned with CMS' continued emphasis that MVPs must include population health administrative claims measures as a foundation to MVPs. CMS is essentially creating an entire new MIPS category that is outside the intent of the MACRA legislation by adding population health as a foundational layer to MVP. 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. CMS must also make significant efforts to advance the data that are used to identify health care inequities. For example, quality measures should account for risk factors such as lack of access to food, housing, and/or transportation that affect patients' ability to adhere to treatment plans. Collection of additional information is an essential early step towards identifying where racism and bias may exist in clinical decision-making tools and how they should be addressed to ensure clinical care and health of historically marginalized communities are not negatively impacted by their application. Continued reliance on existing data that have known deficiencies is not acceptable and we must advance to more accurate and relevant data. 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(s) 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.²⁸ For example, the literature is beginning to show that readmission measures, which are based on administrative claims, may be leading to increased mortality.²⁹

Furthermore, when it comes to purposes of public reporting or making comparisons, the AMA is concerned with CMS' approach to scoring since the methodology for scoring and setting benchmarks lumps all physicians together regardless of specialty, location, or practice size. The lumping approach does not provide physicians or patients with meaningful or accurate information to distinguish between good or poor care. We also 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-

²⁸ 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.

²⁹ 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.

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.

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.^{30,31}
- 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.

8. *CMS definition of population health measures*

- **Recommendation:** The AMA does not believe CMS' current definition of population health measures is sufficient and accurately distinguishes between other types of quality measures in the program and seek further clarification.

The AMA appreciates CMS' effort in seeking to define population health measures, but do not believe that this definition is sufficient to distinguish the current set of administrative claims-based measures that are currently considered to be population health focused from other measures in the program. There are many quality measures that are reported by registries, QCDRs, and others that have a broad population health focus such as Quality ID #113 Colorectal Cancer Screening. Is it CMS' intent to now label these measures as population health measures and potentially use them in the foundational layer of MVPs? Therefore, additional information or inclusion in the definition on the intended use and attribution approaches may be needed to provide further clarification and ensure transparency on CMS' intent.

³⁰ 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.

³¹ Del, Siegle. Instrument Reliability. Educational Research Basics. University of Connecticut. Accessed 09/05/2020. http://researchbasics.education.uconn.edu/instrument_reliability/.

9. *Acute Unplanned Cardiovascular Related Admission Rates for Patients with Heart Failure for MIPS*

- **Recommendation:** The AMA does not support inclusion of the *Acute Unplanned Cardiovascular Related Admission Rates for Patients with Heart Failure for MIPS* as a foundational layer to the program and/or a requirement.

The AMA continues to strongly believe that while it is useful to understand the rate of admissions for patients with heart failure particularly for quality improvement, measures used in accountability programs must be based on strong evidence, actionable to ensure that improvements can be driven by those held accountable, and proven to be reliable and valid at the levels to which the measure is attributed.

The AMA is concerned with the lack of evidence to support attribution of the measure at the individual physician level. Attribution must be determined based on evidence that the accountable unit is able to meaningfully influence the outcome, which aligns with the National Quality Forum (NQF) report, *Improving Attribution Models*.³² We believe that there are several concerns that are not adequately addressed including:

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

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

The AMA also notes that CMS only submitted face validity testing during the recent NQF review, and we encourage CMS to conduct further testing to demonstrate the validity of the measure as it relates to its application to each of the accountable units to which the measure is attributed. We recommend that CMS consider testing that demonstrates whether this measure attributed to physicians and practices is

³² National Quality Forum. *Improving Attribution Models*. Final Report. August 31, 2018. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88154>. Last accessed December 18, 2018.

correlated to other outcome measures such as the hospital wide readmission measure (HWR) or total per capita cost (TPCC) measure. Face validity alone should not be considered sufficient.

The AMA supports and is encouraged to see that social risk factors were tested and will be included in the risk adjustment approach. We strongly recommend that dual eligibility be included in the adjustment since the results demonstrate that it is strongly predictive of an admission. We remain concerned that CMS continues to test social risk factors after assessment of clinical and demographic risk factors, and it is unclear why this multi-step approach is preferable. On review of the Evaluation of the NQF Trial period for Risk Adjustment for Social Risk Factors report,³³ the approaches to testing these data should be revised to strategies such as multi-level models or testing of social factors prior to clinical factors and that as access to new data becomes available, it may elucidate more differences that are unrelated to factors within a physician's or practice's control. Additional testing that evaluates clinical and social risk factors at the same time or social prior to clinical variables rather than the current approach with clinical factors prioritized should be completed. This additional testing may provide support for inclusion of additional variables such as PCP density and further emphasize the need to include dual eligibility.

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

10. *All-cause Unplanned Admission for MCC for MIPS*

- **Recommendation:** The AMA does not support inclusion of the *All-cause Unplanned Admission for MCC for MIPS* measure as a foundational layer to the program and/or a requirement.

While this measure may be useful at the community or population level, the AMA does not believe that it is appropriate to attribute this utilization to a practice. Specifically, the lack of evidence to support applying this measure to practices is particularly concerning since much of what was provided in the evidence during the recent NQF review demonstrated that improved care coordination and programs focused on care management can lead to reductions in hospital admissions but required the involvement of multiple partners such as a disease management program, health system, and/or hospital. We do not believe that this measure applied at the TIN level has sufficient evidence to support the theory that physicians or practices, in the absence of some coordinated program or payment offset (e.g., care management fee), can implement structures or processes that can lead to improved outcomes for these patients.

³³ National Quality Forum. Evaluation of the NQF Trial period for Risk Adjustment for Social Risk Factors. Final report. July 18, 2017. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85635>. Last accessed December 18, 2018.

The AMA is yet again disappointed to see the minimum measure score reliability results of 0.413 for practices with at least 15 clinicians and 18 patients with multiple chronic conditions. We believe that measures must meet minimum acceptable thresholds of 0.7 for reliability. We acknowledge that this change would require a higher minimum sample size, which would reduce the number of TINs to which the measure would apply. Even with this change, we believe that a sufficient number of patients would still be included in the measure, and it would further ensure that the results yield more reliable and accurate representations of the quality of care provided.

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

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

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

B. Merit-based Incentive Payment System (MIPS)

1. Automatic Extreme and Uncontrollable Circumstances Hardship Exception for 2021 Performance Period

- **Recommendation:** The AMA strongly urges CMS to automatically apply the Extreme and Uncontrollable Circumstances Hardship Exception for the 2021 MIPS Performance Period, so physicians are held harmless from the nine percent MIPS penalty due to the significant, ongoing disruptions that the COVID-19 PHE is having on physician practices.

The COVID-19 PHE has been in effect prior to January 1, 2021 and is expected to remain in effect through at least the end of the calendar year. Although the rate of COVID-19 cases, hospitalizations, and

deaths decreased in the early summer, unfortunately those numbers are again surging in part due to the Delta variant. As in 2020, clinicians on the front lines do not have time to focus on MIPS, and patient case mix is changed, and utilization will vary geographically as physicians in hot spots once again delay or cancel non-essential procedures. We think all eligible clinicians and groups should be held harmless from a MIPS penalty in 2021 as they continue to confront this PHE. We urge CMS to make this determination sooner rather than later so physicians can focus on caring for patients during this crisis.

2. *Performance Threshold*

- **Recommendation:** Following three years of unprecedented and significant disruptions to the health care system and MIPS due to the COVID-19 PHE, the AMA urges CMS to exercise every lever under its Extreme and Uncontrollable Circumstances hardship exception policy and related authorities to lower the performance threshold from the proposed 75 points.

While CMS states that the statute would otherwise march onward toward full MIPS implementation and use of a prior year's mean or median as the performance threshold in 2022, the AMA contends the extraordinary circumstances of the COVID-19 pandemic warrant a change in course. **Specifically, the AMA urges CMS to exercise every lever under its Extreme and Uncontrollable Circumstances hardship exception policy and related authorities to lower the performance threshold from the proposed 75 points.** At a minimum, the performance threshold should remain at 60 points.

The COVID-19 pandemic has interrupted MIPS participation across three performance years so far, and the program is not even five years old. So, for more than 60 percent of the existence of the program, MIPS has been curtailed by the COVID-19 pandemic that is now in its fourth surge with cases, hospitalizations, and deaths increasing across the United States. The AMA greatly appreciates the flexibilities that CMS has put in place to hold physicians harmless from undue MIPS penalties during this time as physicians care for patients diagnosed with COVID-19, administer vaccines, and implement infection control practices necessary to continue to deliver care. We urge CMS not to flip a switch in 2022 as if the past three years have been business as usual. They have been far from it, and it is unfortunately reasonable to anticipate the PHE will extend into 2022.

Prior to the start of the PHE, the performance threshold was 30 points. Jumping from 30 to 75 points considering the three years of disruptions to MIPS is unreasonable. As a result, CMS should not move ahead with the proposed 75-point performance threshold and, instead, should establish a transition policy that recognizes the impact of the COVID-19 PHE.

The AMA is also concerned by CMS' analysis that the overall proportion of clinicians receiving a positive or neutral payment adjustment would decrease from 91.7 percent to 67.5 percent with implementation of the proposed policies. In a recent study, physicians from a sample of specialties and practices across the country spent an average of \$12,811 per physicians on MIPS-related expenses, including physician, health care professional, and administrative staff time, as well as IT and external vendor costs.³⁴ Physician practices also reported spending more than 200 hours per physician on MIPS-related activities, including tracking quality measures, attending training sessions, creating or implementing improvement activities, and collecting data or entering information into the patient's electronic health record. In particular, physicians spent more than 53 hours per year on MIPS-related

³⁴ Khullar D, Bond AM, O'Donnell EM, Qian Y, Gans DN, Casalino LP. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. *JAMA Health Forum*. 2021;2(5):e210527. doi:10.1001/jamahealthforum.2021.0527.

activities. If physicians see an average of 4 patients per hour, then these 53 hours could be used to provide care for an additional 212 patients a year—equal to more than a full week’s work for a physician. These substantial time and financial costs are not sustainable for physician practices and are detrimental to patient access. This is particularly true if these expenses and time-consuming efforts may still result in a physician receiving a negative MIPS payment adjustment due to a premature increase in the performance threshold following three years of flexibilities due to the COVID-19 PHE.

3. *Performance Category Weights*

- **Recommendation:** Following three years of unprecedented and significant disruptions to the health care system and MIPS due to the COVID-19 PHE, the AMA urges CMS to exercise every lever under its Extreme and Uncontrollable Circumstances hardship exception policy and related authorities to reweight the Cost Performance Category to the weight that it was prior to the PHE in 2019, which was 15 percent. At a minimum, CMS should maintain the weight of the Cost Performance Category at 20 percent.

The COVID-19 pandemic has interrupted MIPS participation across three performance years so far, and the program is not even five years old. So, for more than 60 percent of the existence of the program, MIPS has been curtailed by the COVID-19 pandemic that is now in its fourth surge with cases, hospitalizations, and deaths increasing across the United States. The AMA greatly appreciates the flexibilities that CMS has put in place to hold physicians harmless from undue MIPS penalties during this time as physicians care for patients diagnosed with COVID-19, administer vaccines, and implement infection control practices necessary to continue to deliver care. We urge CMS not to flip a switch in 2022 as if the past three years have been business as usual.

Moreover, the Cost Performance Category has been severely impacted by the COVID-19 pandemic, to the extent that CMS reweighted the category to zero percent of MIPS final scores in 2020. The AMA strongly supported this decision as we were very concerned that physicians would not be reliably and fairly scored on Medicare administrative claims-based cost measures due to geographic variation and changes in patient case mix. This means, however, that physicians have had one fewer year of reliable performance data to familiarize themselves with the new cost measures in order to prepare for an increase in the weight of the Cost Performance Category. Physicians need more time to understand this new category and the new measures, especially those developed in Waves 2 and 3, which have not yet been scored due to either the COVID-19 reweighting or because they are being proposed for the first time for 2022.

4. *Cost Performance Category*

New Episode-Based Measures for CY 2022 and Future Performance Periods

- **Recommendation:** CMS should exclude Part D prescription drug costs from MIPS cost measures.

The AMA strongly opposes including Part D prescription drug costs in Medicare cost measures. Inclusion of medications potentially penalizes physicians for something over which they have no control. Drug manufacturers and payers, in this case CMS and Medicare Prescription Drug Plans, negotiate formularies, coverage and price, not physicians. To hold physicians accountable for transactions that they are not a part of is fundamentally problematic. In this scenario, one presumes that patients and physicians

have information about coverage, formularies, out-of-pocket costs, and list prices at the point of care, which is not true in most cases. We believe this also assumes there is a viable, evidence-based, less expensive alternative option for patients. Finally, the addition of medication costs would add a lot of complexity to the measures at a time when they are still new and not well understood. CMS should not introduce the first chronic condition cost measures and include of Part D costs simultaneously, as it could compound the potential to inadvertently penalize physicians for costs outside their control.

Discussion of MAP Recommendations for New Episode-based Measures

- **Recommendation:** CMS should refine the development of cost measures to ensure alignment with quality measures and actionability.

We appreciate that CMS was responsive and tried to address the MAP's concerns about the proposed episode-based cost measures. Regarding validity, the AMA believes CMS and Acumen, LLC have an opportunity to refine their process in the future to not just look at correlation of quality and cost overall but also look at correlation for the outliers (e.g., physicians with low versus high cost or quality scores) or differences in case minimums. Regarding actionability of the Asthma/COPD and Diabetes measures, we do not believe that CMS directly addresses the concerns by listing several things that physicians can do without any data to support it. If the assumption is that if a physician knows their cost and quality data, they can move the needle in a meaningful way, then CMS and Acumen, LLC should try to begin to address actionability. For example, CMS could start looking at the correlations between cost and quality and determine whether there is anything useful that can be learned from the data.

Reliability and Case Minimums

- **Recommendation:** CMS should increase the case minimums for MIPS cost measures to improve reliability, particularly for the four proposed episode-based cost measures that demonstrate reliability below the modest 0.4 threshold set by CMS at the physician level.

The AMA continues to disagree with CMS that a 0.4 threshold for mean reliability is appropriate. The minimum case thresholds should be set at the level needed for reliability and CMS and Acumen, LLC should accept the fact that this will lead to fewer clinicians being attributed the measure. Further, four of the new measures demonstrate reliability below the modest 0.4 threshold set by CMS at the physician level. For the Asthma/COPD measure, 18 percent of TIN/NPIs had reliability rates below 0.4. For the Colon and Rectal Resection measure, even based on a proposed case minimum increase from 10 to 20 episodes, 24 percent of TIN/NPIs had reliability rates below 0.4 and the mean reliability was only 0.45. For the Diabetes measure, 21 percent of TIN/NPIs had reliability rates below 0.4. Finally, for the Sepsis measure, 20 percent of TIN/NPIs had reliability rates below 0.4. **We strongly urge CMS to increase the case minimums for these measures to improve reliability.** At a minimum, CMS should increase reliability in the first few years that a measure is introduced into the program to ensure that it is reliably and consistently measuring resource use during an episode of care.

Proposed Process for Cost Measure Development by Stakeholders

- **Recommendation:** CMS must ensure cost measures are developed with significant input from specialty societies and that field testing is conducted with an opportunity for stakeholder feedback. The AMA also urges CMS to add two standards for cost measure construction:

alignment of cost and quality and actionability. CMS should prioritize cost measure development as part of MVP development.

The AMA strongly encourages CMS to require broad stakeholder input and field testing in the development of cost measures by stakeholders. We have continued to be supportive of the measure development process established by CMS and Acumen, LLC to identify, specify, and test new episode-based cost measures as it prioritizes clinician engagement throughout the process. While we have urged the Agency to work with the specialty societies in developing and testing new cost measure concepts as part of MVPs, we are apprehensive of a stakeholder-drive cost measure development process outside of MVPs. Physicians and groups do not get a choice in which cost measures they are evaluated on in traditional MIPS. Rather, if they meet the case minimum, they are scored on the measure. **To minimize the potential for contractors or other third parties to develop cost measures without adequate input from specialty societies, CMS should require cost measure developers to demonstrate that they have the right clinical and methodological input during the process.**

Generally, the AMA believes the proposed standards for cost measure construction are reasonable. We urge CMS to add a criterion that developers demonstrate the relationship between cost and quality, as well as the actionability of the measure. It is not sufficient to include these in the prioritization criteria, as it is unclear from the proposed rule how the standards for measure construction and prioritization criteria overlap. We also urge CMS to minimize the number of cost measures in development at one time as it would be very difficult for specialty societies to comprehensively review multiple measures at one time.

Regarding the prioritization criteria, the AMA urges CMS to add a criterion that prioritizes cost measure development as part of MVP development and to provide comprehensive data and funding to specialty societies who are building MVPs. The limited inventory of cost measures hampers the ability of specialty societies to align cost and quality in a meaningful way in many MVPs. Specifically, the AMA recommends that CMS provide Medicare claims data, cost performance data, and funding to help specialty societies identify and develop clinically appropriate cost measures. The current process for obtaining Medicare claims data, such as through ResDAC, is time-consuming and expensive. More specialty-specific and condition-specific data from both the QPP and claims data sources will help specialty societies understand and target opportunities for a more cohesive, clinically relevant MIPS participation experience via the MVP. For example, in the Quality and Resource Use Reports (QRURs) that CMS used to generate as part of the Value-based Payment Modifier program, CMS included charts showing the midpoint and distribution of cost performance scores. This would be helpful, as well as breakdowns by measure and specialty. We understand the QPP data may be limited in 2019, 2020, and 2021 due to the Extreme and Uncontrollable Circumstances Hardship Exception policy in place due to COVID-19. However, we urge CMS to provide as much detail as possible.

CMS should also provide flexibility for cost measures developed by specialty societies as part of a candidate MVP. For instance, a specialty society may wish to leverage their QCDR for an appropriateness measure that is aligned with the applicable quality measures. This type of development could result in a greater number of clinically relevant cost measures for specialists at a quicker rate than developing claims-based measures and advance CMS' goal of moving toward value by linking cost and quality in MVPs.

Regarding the prioritization criteria around alignment with quality measures and Improvement Activities, the AMA urges CMS to allow for new quality measure development and to not solely focus on existing measures. Ideally, quality and cost would be developed at the same time to create the clinical coherence and validity that is needed, and it could then help to build an MVP. Finally, it is not clear how CMS

intends to use the prioritization criteria. Will CMS establish a list of prioritized cost measures that stakeholders can select for development? How will the Agency publicize this list? As CMS has done in advance of Wave 5, we believe CMS should solicit input from stakeholders about the measurement gaps in the Cost Performance Category.

Substantive Changes Criteria for Cost Measures

- **Recommendation:** The AMA agrees with CMS' proposal to establish a process for determining whether a substantive change has been made to a cost measure and urges CMS to add year-over-year impacts on performance scores that cannot be attributed to actual changes in performance as an indicator that substantive changes have occurred.

The AMA supports the intent and draft criteria for determining whether a substantive change has been made to a cost measure. We also encourage CMS consider a substantive change to be any modification to a measure that impacts performance scores that may likely be due to the changes in the measure construct or coding and not actual performance. For example, if year-over-year comparisons could not be attributed to actual changes in performance, it should be considered a substantive change.

5. *MIPS Final Score Methodology*

Cost Performance Category: Scoring Flexibility for Changes That Impact Cost Measures During the Performance Period

- **Recommendation:** The AMA urges CMS to finalize this proposal and to broadly define a significant change to include disruptions that would penalize physicians for things outside of their control, whether they impact attribution, reliability, validity, or actionability of the measure.

The AMA greatly appreciates CMS' decision to reweight the Cost Performance Category to zero for the 2020 performance period due to significant disruptions to clinical practice and service utilization during the COVID-19 PHE. We support CMS' proposal to suppress a cost measure when Medicare claims data used to calculate the score is impacted by significant changes that would lead to misleading or inaccurate results. We urge CMS to broadly define a significant change to include disruptions that would penalize physicians for things outside of their control, whether they impact attribution, reliability, validity, or actionability of the measure. Furthermore, the AMA continues to be concerned about geographic variation impacting cost measures, which use a national benchmark. We urge CMS to consider national disasters, such as wildfires and hurricanes, for example, as significant changes warranting measure suppression. Finally, similar to our recommendation for how to define substantive changes to cost measures, we urge CMS to evaluate year-over-year scoring variation and whether it can be attributed to changes in performance. If not, CMS should investigate whether a measure should be suppressed due to factors outside of the control of the physician.

6. *Promoting Interoperability Program*

- **Recommendation:** The AMA continues to support CMS' goals of focusing the Promoting Interoperability (PI) program on interoperability and improved patient access to health information as opposed to burdensome, prescriptive data capture and measurement policies.

We urge CMS to continue to limit regulatory requirements in the PI program as long as physicians can share data among themselves and with their patients.
The AMA welcomes the opportunity to provide feedback on the evolution of the PI program.

Proposals the AMA Supports

- *CMS is proposing to maintain the 90-day performance period for the PI category for CY 2022.*

The AMA supports CMS' proposal to maintain the 90-day performance period for the PI category for CY 2022. Allowing physicians to choose any continuous 90-day period provides physicians the ability to select the performance period that best meets their needs—giving them flexibility to focus on patient care while still meeting CMS reporting requirements. **We urge CMS to consider the long-term impact of the COVID-19 pandemic on physician medical practices, particularly those in small and rural settings, and to maintain the 90-day performance period in CY 2023.**

- *CMS is proposing to maintain the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure as optional, while increasing its available bonus from five points to 10 points for the EHR reporting period in FY 2022.*

The AMA supports CMS' proposal to maintain the PDMP Query measure as optional as many physicians and health systems remain incapable of interconnecting their health information technology (health IT) with PDMP systems. We also support increasing the available bonus from five points to 10 points as this provides positive incentives to connect EHRs to PDMPs without unduly burdening physicians who have little control over their EHR vendors' interoperability decisions. Finally, we continue to support CMS' innovative approach to this measure by allowing clinicians to use non-CEHRT in conjunction with CEHRT to accomplish a particular clinical goal. We encourage CMS to expand the ways in which eligible clinicians can use non-CEHRT in conjunction with CEHRT to meet the PI program's objectives.

- *CMS is proposing to remove attestation statements 2 and 3 from the PI Program's prevention of information blocking requirement.*

The AMA strongly supports CMS removing statements 2 and 3 from the PI Program's information blocking attestation requirement.

- *CMS is proposing to no longer require an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting.*

The AMA supports CMS' proposal to no longer require physicians to apply for the small practice hardship exception. An automatic hardship exception and reweighting will remove some burden for those physicians who fall into the exception's category. However, since those physicians may not know they are eligible for the hardship exception, we urge CMS to take all necessary steps to ensure those physicians are aware. For example, a physician may not be aware they are eligible and would receive the hardship if they simply do not report the PI category for MIPS. However, without knowing this, the physician's administrative staff or EHR vendor could report on behalf of that physician, cancelling the automatic exception and negating the needed flexibility the physician could have received. Physicians in small clinics are often extremely busy, under-resourced, and short-staffed. It may not be immediately clear they are eligible for the hardship exception and their practice may report on their behalf without being aware of the automatic exception. **We urge CMS to use several methods to communicate, in clear and**

unambiguous language, to eligible physicians what the exception means and that reporting any PI performance information will cancel their automatic hardship exception. CMS should communicate this through traditional mail, email, blog posts, social media, webinars, and provide physicians' professional societies (e.g., state and medical specialty organizations) language that can be forwarded to their membership.

Additional Recommendations from the AMA

- *CMS is proposing to modify the Provide Patients Electronic Access to Their Health Information measure to establish a data availability requirement beginning with encounters with a date of service on or after January 1, 2016, beginning with the EHR reporting period in FY 2022.*

The AMA appreciates CMS' objective to expand the timeframe for electronic health information availability to patients. We recognize CMS' intent of aligning its information access policies between providers and payers and to reduce the friction patients may face when accessing their medical information. While more can be done, the AMA is concerned there could be unintended consequences with requiring patient health information with encounter start date of January 1, 2016, be made immediately available starting with the CY 2022 EHR reporting period. Many physicians and health systems have digitized old medical records using digital imaging or PDF-style formats. These formats make it challenging to search for or protect specific information in EHRs that, by state or federal law, must be withheld upon request or when sending information to other individuals or entities. For instance, California state law requires physicians to withhold information about child abuse from being released. This information is often intermixed with other medical information inside various "notes" electronically contained within an EHR.

CMS' policy to make all information available would require physicians and health systems to manually review and redact certain information prior to the release of these notes. Due to the limitations of imaging or PDF-style formats used to document many of these notes, this process can be extremely time-consuming and costly. We are aware of a health system in California that has estimated it would take 60,000 workhours to manually go through EHR charts and to label or mark notes to prevent this information from being released. The AMA urges CMS to consider the limitations of EHR technology to support physicians and health systems' compliance with this proposed policy. **The AMA recommends CMS create flexibility that allows physicians to provide most of the information requested but still allows leeway for health information management personnel or a physician's professional judgment to determine when it is impractical for certain information to be made available in a "timely" manner. For instance, CMS should provide no less than a 48-hour window for physicians and health systems to review the patient's request for health information to determine whether the release will require manual redaction or extraordinary technical effort to accommodate state or federal law.**

- *CMS is proposing that MIPS eligible clinicians must report "yes" to being in active engagement with a public health agency to electronically submit case reporting of reportable conditions. If the MIPS eligible clinician fails to report on any one of the two measures required for this objective or reports a "no" response for one or more of these measures, CMS is proposing that the MIPS eligible clinician would receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Promoting Interoperability performance category.*

The ongoing PHE highlights the critical importance of the ability to collect, exchange and analyze public health data. Physicians have increasingly engaged with public health reporting systems past year. Yet, our nation's public health agencies' (PHA) information technology (IT) systems are, in many cases, antiquated and often unable to receive or incorporate data electronically. Like PDMPs, PHA data systems vary widely by state and jurisdiction. Physicians want to engage in standards-based exchange of public health data with PHAs—particularly when it comes to bi-directional data exchange. The AMA supports reporting to PHAs, particularly through electronic case reporting. However, current PHA data systems capabilities and the corresponding reporting landscape is challenging at best. We are encouraged that Congress recognized the need for investment in public health data systems and provided significant funding for modernization efforts in multiple COVID-19 relief bills. While this work is underway, and at a nascent stage, expansion of CMS' Public Health and Clinical Data Exchange objective should be considered in the context of the current state of PHA data infrastructure. **We urge CMS to not impose reporting obligations on clinicians before the technology can facilitate such reporting requirements.**

CMS' proposal to require "active engagement" with PHAs to meet measure requirements under the Public Health and Clinical Data Exchange objective is unclear. Historically, CMS has provided three options for active engagement (1) complete registration to submit data, (2) testing and validation, and/or (3) production. Furthermore, CMS has historically allowed physicians to demonstrate active engagement by using communications and information provided by a PHA or from the physician directly. Moreover, complete registrations with a PHA that occurred during previous reporting programs (e.g., Meaningful Use or Advancing Care Information) have historically counted toward a physician's active engagement. Additionally, CMS has historically provided several necessary exclusions for physicians who cannot meet this measure, including those that do not administer immunizations, those that operate in jurisdictions where immunization information systems are not capable of accepting the specific standards required to meet the CEHRT definition, or in jurisdictions where no immunization registry or immunization information system has declared readiness to receive immunization data.

The AMA believes more transparency is needed from CMS before finalizing this proposal. For physicians to successfully meet CMS' goals, while reducing physician burden, the AMA urges CMS to provide more clarity in its final rule. **The AMA strongly urges CMS to adopt the following recommendations:**

- CMS should retain the three historical options included above that physicians can use to meet "active engagement."
- Successfully demonstrating active engagement should be accomplished using communications and information proved from the physician *or* by the PHA. It is not practical for CMS to expect that physicians will "continue to ping" a PHA for a response in order to meet active engagement requirements. Physicians may not receive a response from a PHA in a timely fashion to meet the objective's requirements and therefore should be able to rely on their initial communication *to* the PHA to meet active engagement.
- Any efforts physicians have already made to meet active engagement requirements (e.g., active engagement in years prior to CY 2022) should enable physicians to demonstrate success under CMS' proposed Public Health and Clinical Data Exchange objective.
- CMS should continue to provide the same exclusions as those offered in the 2021 Performance Period³⁵ (established in the CY 2019 PFS final rule) to physicians who cannot

³⁵ CMS Guidance, Merit-Based Incentive Payment System (MIPS) Promoting Interoperability Performance Category. Measure, 2021 Performance Period, Objective: Public Health and Clinical Data Exchange, available at https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2021%20MIPS%20PI%20Public%20Health%20Registry%20Reporting.pdf.

meet active engagement requirements. We appreciate that CMS notes in its proposal that such exclusions will remain available. However, CMS must provide clearer and more actionable information to physicians on the use of these exclusions.

- **The AMA strongly urges CMS to reconsider its proposal to tie physicians' PI category success to the "all or nothing" approach proposed for the Public Health and Clinical Data Exchange objective requirements.** PHA reporting will be new for many physicians. It is likely that physicians will misunderstand active engagement or exclusion requirements. Missing even a small part of the objective's requirements would mean that a physician would receive a zero for the entire PI category—significantly impacting a physician's overall MIPS performance. Moreover, PHA data infrastructure is inconsistent, and thousands of physicians rely on their EHR vendor for IT support. EHR vendors may also lack the expertise to assist physicians in electronic PHA reporting. There are too many unknowns, missteps, potholes, and variables in electronic PHA reporting for CMS to directly tie PI success to such a complex and unproven set of requirements. **For those physicians who fail or are excluded from the objective, the AMA recommends that CMS instead not provide points in the Public Health and Clinical Data Exchange objective but continue to score the other PI objectives as they would normally do.**

Additionally, prior to finalizing this proposal, CMS should:

- Conduct and publicly release findings from a survey of state immunization registries to determine if there is readiness at the state level to conduct this level of exchange; and
 - Determine if states are willing to move towards electronic data exchange. Many state agencies continue to mandate manual reporting. If states continue to do this and CMS mandates electronic reporting, physicians will be burdened with the need to report in two different formats.
- *CMS is proposing to add a new SAFER Guides measure to the Protect Patient Health Information objective, beginning with the CY 2022 performance period/2024 MIPS payment year.*

The PI category was established to incentivize physicians to “adopt, implement, upgrade and demonstrate meaningful use of certified EHR technology.” While the AMA agrees that implementing safety practices for planned or unplanned EHR downtime is important, we believe the addition of a Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure is out of scope for the PI category.³⁶ Further, the SAFER Guides have not gone through a comprehensive review and update process since 2016—calling into question whether their content remains relevant. Additionally, requiring this type of annual assessment of all nine guides would place significant burden on physicians, particularly those with limited resources like small, solo, or rural practices—all while they are simultaneously trying to comply with technology upgrades required by the 21st Century Cures Act.

Furthermore, CMS states that “this measure would be required, but it would not be scored, and that reporting ‘yes’ or ‘no’ would not affect the total number of points earned for the Promoting Interoperability performance category.” CMS must be clear about its intent for including these guidelines and the actual impact to physicians' MIPS performance score. If CMS' goal is to improve the safe use of EHRs, it should not force an out-of-date set of guidelines to fit inside a program (i.e., PI category) that

³⁶ In 2017, the AMA submitted to CMS the recommendation that implementation of the SAFER Guides be included in MIPS as an optional Improvement Activity but this recommendation was not accepted.

was never meant to support guideline adoption. The AMA is very concerned that CMS' proposed approach will simply result in yet another check-the-box exercise.

Given these considerations, **the AMA does not support CMS' proposal to require physicians to attest to having completed an annual assessment of the nine SAFER Guides.** Instead, CMS should work with ONC to engage in an update of the guides, informed by stakeholder input, and undertake an education and awareness campaign to disseminate information to the field, including information tailored to small and medium-sized physician practices. **The AMA still encourages CMS to include the SAFER Guides as an option under the Improvement Activity category.**

7. Request for Information on Clinical Notes

CMS is requesting information on measures that will “further facilitate ensuring clinical notes are available to patients consistent with the goals of the OpenNotes movement.” CMS is also “seeking feedback on the development of a required and independently scored measure for the Promoting Interoperability performance category to allocate points for the use of ‘clinical note’ types supported by certified health IT” and seeks comment on the “types of clinical notes that are commonly sought, but not easily accessible to patients.”

The AMA supports the OpenNotes movement. In 2017, the AMA assisted in a case study with Beth Israel Deaconess Medical Center (BIDMC) in Boston, MA. While BIDMC had already been using OpenNotes for years, the clinicians in the Department of Obstetrics and Gynecology (OB/GYN) had not yet adopted OpenNotes. OB/GYN physicians were concerned that patient perceptions about their care might be affected if patients were able to read their own clinic notes. They were also uneasy about the potential impact on workflow. Yet, once OB/GYN physicians started using OpenNotes, most physicians did not see a difference in patient care and instead found the new approach useful for identifying inaccuracies or highlighting corrections that needed to be made to the visit record. In most situations, OpenNotes did not impact workflows and the process of documentation remained the same. For physicians who document their own visits, notes become available to patients as soon as they are finalized. However, using OpenNotes in the OB/GYN setting presented some specific risks. For example, the potential for someone other than the patient to find out about sensitive subjects such as prior pregnancy terminations, domestic abuse, sexual abuse, or substance abuse.

Additionally, we hear frequently from clinicians and patients that note-sharing in adolescent medicine can pose additional challenges, particularly with respect to parental access to the adolescent's patient portal or mobile application account. In many instances, documenting a teen's confidential information (e.g., sexuality or gender identity, drug or alcohol use, requests for contraception or abortion) within their medical record means that their proxy or parent could also have access to the information. Many teens' EHR portals are established by their parents. Some EHRs may allow clinicians to segment sensitive information and prevent it from being shared, but few have this functionality. Another possible method to address adolescent privacy would be for the physician to make the note “private” or “confidential.” Yet, that option is also not supported by many EHRs. The AMA is a strong supporter of data labeling and data segmentation efforts to protect privacy, which in turn will increase interoperability and patient safety. We are a founding member of the Protecting Privacy to Promote Interoperability Workgroup (PP2PI)—a collaboration of over 50 organizations assembled to address the problem of how to granularly segment sensitive data to protect patient privacy and promote interoperability and care equity. Among PP2PI's efforts is a focus on standards revision and stewardship of a national terminology value set to support sensitive health information exchange. PP2PI is working with ONC to identify policy drivers to spur widespread adoption of these efforts.

We reiterate that the AMA strongly supports the OpenNotes effort. However, there are not sufficient policies, technologies, or the necessary data governance structures in place to support an OpenNotes mandate or imbedding OpenNotes in CMS' programs. For instance, ONC's information blocking regulations are already being interpreted as a requirement for OpenNotes. This has led EHR vendors, health systems, and compliance personnel to "switch on" access to medical records without the needed guardrails to protect patient privacy or keep from harming patients. The AMA has received hundreds of letters from patients and physician describing the harm that has been caused by this policy approach. The AMA is currently working with ONC and the Office for Civil Rights (OCR) to evaluate guidance or regulatory changes necessary to protect data and patient safety. The joint work between ONC, OCR, and the AMA must be completed before CMS considers using its policy levers to incent further adoption of OpenNotes. **The AMA strongly urges CMS to work with ONC, OCR, and the AMA to accomplish our shared goals of patient access while also protecting patients from harm and ensuring their data privacy.**

8. *Improvement Activities*

General feedback on the Improvement Activities (IA) performance category

- **Recommendation:** The AMA generally supports CMS' proposals around timeframes for IAs nominated during a public health emergency, the revised criteria for IA nominations received through the Annual Call for Activities, and suspension of activities that raise possible safety concerns or become obsolete from the program. We also appreciate CMS' proposal for revised group reporting requirements for the 50 percent participation threshold to address subgroup reporting of IAs that may differ from the "parent" group.

However, we reiterate our previous comments that CMS should provide multi-category credit to eligible clinicians who report on closely related Quality, Cost, or Promoting Interoperability measures. For example, clinicians reporting on a Quality measure related to AUC should not need to separately report an overlapping AUC IA. This concept could be easily implemented into CMS' MVP proposals. Rather than eligible clinicians having to attest to IAs as part of their MVP reporting, the developer of each MVP should note to CMS which IAs clinicians are inherently performing as part of a particular MVP, and corresponding IA credit should be automatic. This is similar to how MIPS alternative payment models (APMs) and recognized patient-centered medical homes are currently scored in the IA performance category. Such an approach fosters a hybrid approach between MIPS and Advanced APMs and would reduce eligible clinicians' reporting burden while preparing them to participate in APM models (more fully discussed in our comments responding to CMS' MVP proposals). **The AMA again urges CMS to develop ways to automatically award IA credit to eligible clinicians performing activities that overlap with similar Quality, Cost, and PI measures.**

Proposal to modify IA_PSPA_6 (Checking PDMPs on 100% of opioid prescriptions and refills)

The AMA strongly opposes CMS' proposed change to IA_PSPA_6, "Consultation of the Prescription Drug Monitoring program." This IA currently requires eligible clinicians to attest to reviewing 75 percent of their patient population's history of controlled substance prescription using state prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. CMS is proposing to now require that eligible clinicians review the history of controlled substance prescriptions for 100 percent of patients using state PDMP data prior to the issuance of a CSII opioid prescription lasting longer than 3 days, with "exceptions for patients

receiving palliative and hospice care.” CMS does not state what such exceptions entail, nor does it instruct eligible clinicians on how to operationalize or document utilization of such exceptions.

At the very least, CMS must release guidance on the exceptions to this IA, being sure to explicitly designate certain patient populations as exempt from these PDMP checks (e.g., sickle cell patients, cancer-related care, and patients on long-term opioid therapy or receiving methadone for the treatment of opioid use disorder). More importantly, however, is that **this proposed change will not accomplish CMS’ intended policy goals of improved clinical care and outcomes for at-risk patients**, despite the CDC’s recommendations around use of PDMPs. Patients with painful conditions need to be treated as individuals. They need access to multimodal therapies including restorative therapies, interventional procedures, and medications. These include non-opioid pain relievers, other agents, and opioid analgesics when appropriate. Patients with sickle cell disease, cancer, terminal conditions, and those on long-term opioid therapy are often stigmatized, mistreated, and undertreated because of the CDC’s continued, narrow focus on prescription dose and duration.

We agree that there may be value in encouraging clinicians to check state PDMPs; however, CMS is improperly conflating this intervention with the idea that it will reduce the number of deaths from opioid prescriptions. Preliminary results of a 50-state survey of state PDMPs by the AMA has revealed that while state PDMPs were checked more than 900,000,000 times in 2020—more than double the number of checks in 2018—more people died from drug-related overdoses. In other words, increasing the number of times a clinician checks a state PDMP does not reduce drug-related mortality and there is no meaningful data suggesting PDMPs improve the quality of pain care. Additionally, physicians have reduced opioid prescribing by more than 44 percent since 2012, but the drug overdose epidemic has gotten worse. This is because the overdose epidemic is not being driven by prescription opioid analgesics; rather, it is now mostly fueled by illicitly manufactured fentanyl, fentanyl analogs, heroin, methamphetamine, and cocaine. One study found “that, although the PDMPs’ intermediary purpose to reduce prescribing has been achieved by reducing opioid distribution by 7.7 percent, they have had inconsistent effects on prescription opioid overdoses, while increasing total opioid overdoses by 17.5 percent due to increasing mortality from the black market varieties by 19.8 percent” and concludes that “[s]ince PDMPs fail to achieve their ultimate goal of reducing opioid overdoses, [resources] should be re-appropriated to more-effective mechanisms to reduce addiction and overdose rates, such as providing access to prescription-quality opioids for medication-assisted treatment (MAT).”³⁷

In light of the above and CMS’ existing Part D Overutilization Monitoring System, which has been successfully dealing with patients receiving prescription opioid analgesics from multiple physicians and pharmacies at the same time, CMS should adopt an alternative approach to IAs intended to reduce deaths from the illicit and non-medical use of drugs. **Rather than continuing to focus solely on prescription dose and duration and perpetuating the “check-the-box” practices so common in federal reporting programs, the AMA recommends that CMS adjust this IA (or create a new IA) to encourage naloxone prescribing when clinically indicated and other evidence-based harm reduction strategies identified in a recent OIG Report on opioid overdoses.**³⁸ This strategy would also reduce inevitable

³⁷ Reason Foundation, *Prescription Drug Monitoring Programs: PDMP Effects on Opioid Prescribing and Drug Overdose Mortality*, by Jacob James Rich and Robert Capodilupo (July 2021), available at <https://reason.org/wp-content/uploads/prescription-drug-monitoring-programs-effects-on-opioid-prescribing-and-drug-overdose-mortality.pdf>.

³⁸ HHS OIG Data Brief, *Concerns Persist About Opioid Overdoses and Medicare Beneficiaries’ Access to Treatment and Overdose-Reversal Drugs*, OEI-02-20-00401 (August 2021), available at <https://oig.hhs.gov/oei/reports/OEI-02-20-00401.pdf>.

conflicts between compliance with CMS IA guidance and state laws around the required frequency of checks (i.e., checking PDMPs every 30/90/120/365 days as opposed to checks for every CSII prescription of a certain duration), as well as state law exceptions for PDMP checks in certain conditions—including those applicable to certain health conditions and problems related to technology implementation and operation.

9. *Changes to complex patient bonus methodology*

- **Recommendation:** Drop or delay the proposal to limit the complex patient bonus to clinicians who have a median or higher value for one or both of the two risk indicators.

The AMA recommends dropping or delaying implementation of the proposal to limit the complex patient bonus to clinicians who have a median or higher value for one or both of the two risk indicators. Although the data presented in Table 49 indicate that there is only a small difference in the MIPS scores for clinicians who had Complex Patient Bonuses (CPB) below the median using the current CPB methodology, it is not clear whether this would be true using the revised methodology or whether it will be true in the future as patient needs change and as other revisions are made to the MIPS program.

We believe CMS should proceed very cautiously before eliminating the distinction between clinicians who have relatively few complex patients and those who have larger numbers of such patients (but less than the median for other practices nationally). If the clinicians who are just below the median are discouraged from treating complex patients, access to care for those patients could be reduced, leading to greater disparities and inequities in health outcomes.

- **Recommendation:** Standardize the risk indicators using the median instead of the mean and using a more robust measure of variation than the standard deviation.

We do not support the proposed methodology for standardizing the scores for the risk indicators. Under the proposed approach, the risk indicators would be standardized using the means and standard deviations of the distributions, which are very sensitive to outliers. The proposed rule (at 86 FR 39443) indicates that CMS is proposing to use the median rather than the mean as the cutoff point for the bonus because outliers make the mean much higher than the median. This means that many clinicians who have risk indicators above the median would have a negative standardized value. CMS acknowledges this problem and proposes to offset it by adding 1.5 points to the score and zeroing any negative score, but it is not clear what the 1.5 value is based on or why the same amount should be used for both risk indicators, since the distributions of the values will differ dramatically (the dual proportion can only vary between 0 and 1, whereas the HCC score can be much higher than 1.)

If the means are significantly affected by outliers, the standard deviations of the distributions will be even more heavily impacted by these outliers. This would tend to compress the standardized scores for most clinicians into a very narrow range, so that only the small number of clinicians with the outlier values would receive high complex patient bonuses. Moreover, CMS has not provided any evidence that the impact of a risk indicator on quality scores is proportional to the number of standardized deviations from the mean rather than the absolute difference from the mean. CMS does not standardize HCC scores in this way before using them to risk adjust the cost measures in its other payment programs.

For example, the table below shows two versions of a hypothetical set of 10 average HCC risk scores, as well as the standardized scores and contribution to the CPB based on the HCC risk scores calculated with the methodology CMS has proposed. On the left side of the table, the 10th score is an outlier compared to

the others (4.8 is twice the highest other score). On the right side, the 10th score is not an outlier. The standard deviation on the left side is almost double what it is on the right side because the outlier dramatically increases the standard deviation. On the left side of the table, the high standard deviation makes the standardized scores for the non-outlier cases very small, so the CPB components (which include the 1.5 base) are all less than half of the maximum 10 points. However, the outlier case would easily qualify for the full 10-point cap based only on the HCC component. On the right side, because the mean and standard deviation are lower when there is no outlier, all the cases above the median get more points, and three of the cases would get 5 points or more from the HCC component.

In other words, under the methodology CMS has proposed, the CPB scores for most physicians would depend heavily on the HCC averages for the small number of other physicians who have very high HCC scores, rather than reflecting the real differences in the complexity a physician’s patients relative to most other physicians.

	<i>With an Outlier</i>			<i>Without an Outlier</i>			Difference in CPB
	Actual Average HCC	Standardized with Mean/SD	CPB	Actual Average HCC	Standardized with Mean/SD	CPB	
	0.8	-1.0	0.0	0.8	-1.6	0.0	0.0
	1.0	-0.9	0.0	1.0	-1.2	0.0	0.0
	1.2	-0.7	0.0	1.2	-0.9	0.0	0.0
	1.4	-0.5	0.0	1.4	-0.5	0.0	0.0
	1.6	-0.3	0.0	1.6	-0.2	0.0	0.0
	1.8	-0.1	1.1	1.8	0.2	2.2	1.1
	2.0	0.1	1.8	2.0	0.5	3.6	1.8
	2.2	0.3	2.5	2.2	0.9	5.0	2.4
	2.4	0.4	3.3	2.4	1.2	6.4	3.1
Outlier	4.8	2.7	12.2	2.6	1.6	7.8	-4.4
Mean	1.9			1.7			
Standardized Deviation	1.1			0.6			
Median	1.7			1.7			
Median Absolute Deviation	0.5			0.5			

To solve this, we recommend standardizing the risk indicators using more robust measures of central tendency and variation, such as the median and the median absolute deviation or the median positive deviation (i.e., the median absolute difference between the overall median and the actual values, either for all values or all values greater than the median). If CMS uses the median as the cutoff point for bonuses, standardizing the scores based on the median would avoid creating a negative score for any clinician who would be eligible for the bonus. More importantly, standardizing based on the median deviation (regardless of whether those below the median are included or not) would ensure that the clinicians in the highest quintile of CPB scores (who have significantly lower MIPS scores, according to Table 49) would receive a significantly higher complex patient bonus than those in lower quintiles.

Using the same hypothetical example as above, the table below standardizes using the median and the median absolute deviation instead of the mean and standard deviation. Under this approach, the CPBs are identical on the left and right sides of the table for everything but the outlier case. This is because the median and median absolute deviation are robust measures that are not affected by the outlier. If there is an outlier case, it gets a lot of points because it is an outlier, but it doesn’t affect the scores for the others.

	<i>With an Outlier</i>			<i>Without an Outlier</i>			Difference in CPB
	Actual Average HCC	Standardized with Median/MAD	CPB	Actual Average HCC	Standardized with Median/MAD	CPB	
	0.8	-1.8	0.0	0.8	-1.8	0.0	0.0
	1.0	-1.4	0.0	1.0	-1.4	0.0	0.0
	1.2	-1.0	0.0	1.2	-1.0	0.0	0.0
	1.4	-0.6	0.0	1.4	-0.6	0.0	0.0
	1.6	-0.2	0.0	1.6	-0.2	0.0	0.0
	1.8	0.2	2.3	1.8	0.2	2.3	0.0
	2.0	0.6	3.9	2.0	0.6	3.9	0.0
	2.2	1.0	5.5	2.2	1.0	5.5	0.0
	2.4	1.4	7.1	2.4	1.4	7.1	0.0
Outlier	4.8	6.2	26.3	2.6	1.8	8.7	-17.6
Mean	1.9			1.7			
Standardized Deviation	1.1			0.6			
Median	1.7			1.7			
Median Absolute Deviation	0.5			0.5			

- **Recommendation:** Increase the cap on the Complex Patient Bonus to at least 20 points and scale the formula so that individual clinicians in the upper quintile can receive at least a 15-point Complex Patient Bonus.

The AMA does not support a cap of 10 points on the Complex Patient Bonus. The data in Table 49 clearly show that there is a more than 20-point difference in the *median* MIPS scores for individual clinicians in the highest versus lowest quintiles of the CPB and a 16-point difference between those in the highest quintile versus the middle quintile. There is a 12-point difference in the group scores, but the group average likely masks larger differences for individual clinicians in those groups. Capping the Complex Patient Bonus at 10 points would fail to resolve nearly half of the current inequity.

However, increasing the cap means little if no clinician can ever reach it. Under the proposed methodology, a clinician would have to be more than two standard deviations above the mean risk indicator score on one risk indicator or more than one standard deviation above both risk indicator scores in order to receive the maximum 10-point Bonus. Because of this, it is likely that fewer than 10 percent of clinicians would receive the maximum bonus.

We recommend that the formula be scaled such that the median CPB for clinicians in the upper quartile of risk scores would be at least 15 points, and that clinicians with the highest risk scores be eligible to receive CPBs of at least 20 points.

- **Recommendation:** Standardize the dual eligible ratio using the median value in each state, rather than the national median or mean.

Since the dual eligible ratio for a clinician is based on the number of Medicaid-eligible beneficiaries attributed to the clinician, the dual eligible ratio will be lower for a clinician practicing in a state that has not expanded Medicaid, even if the clinician has the same proportion of low-income patients as a clinician in a state that has expanded Medicaid. This penalizes clinicians who serve patients in non-expansion states. (“...Medicare should exercise caution in implementing adjustment for dual status because Medicaid enrollment thresholds vary by state, and such adjustment could systematically penalize providers in states with less generous thresholds.” Johnston KJ, Joynt Maddox KE. “The Role of Social Cognitive, and Functional Risk Factors In Medicare Spending for Dual and Nondual Enrollees.” *Health Affairs* 38(4) April 2019.)

Ideally, a more comprehensive set of data on income and other social risk factors would be used to identify complex patients, rather than dual eligible status. Recent publications identified in the proposed rule (Johnston, 2020, UNC Rural Health Research Program, 2020) along with the ASPE report illustrate that there are many questions on what variables are useful indicators to understand patient complexity and how they may or may not contribute to a clinician's or practice's ability to provide the highest quality of care possible with the resources available. However, if dual eligible status is going to be used as one of the two measures of complexity, the dual eligible ratio needs to be adjusted to eliminate the current bias against clinicians practicing in non-expansion states. This could be done by standardizing the dual eligible ratio for a clinician using the median value in the clinician's state rather than using the national mean or median. The AMA is committed to working with CMS and others to share learnings and propose potential solutions to answering many of the questions that remain for handling complex patients as we evaluate quality and ensure CMS' programs do not exacerbate inequities or penalize physicians who treat a large portion of patients with social risk factors.

- **Recommendation:** Increase the average HCC score for a clinician based on the proportion of patients living in rural areas.

Although the proposed rule cites recent research showing that there are systematic differences in the ability of HCC scores to predict the needs of patients in rural versus urban areas, no changes in the methodology have been proposed to address this issue. If high-need patients in rural areas have lower HCC scores, as the research shows, then the average HCC score used in the proposed Complex Patient Bonus methodology will cause clinicians practicing in rural areas to receive lower CPBs than clinicians in urban areas even if their patients are similar.

We recommend that in calculating the risk indicators used in the Complex Patient Bonus, the average HCC score for a clinician should be increased based on the proportion of the clinicians' patients who live in rural areas.

- **Recommendation:** Report the magnitude of the Complex Patient unadjusted MIPS score.

The AMA opposes publicly reporting a clinician's MIPS score without any indication that the clinician was serving a high proportion of complex patients. This could discourage physicians from serving complex patients. Patients who use the MIPS scores to help them choose a physician should be informed that physicians with more complex patients may have lower overall quality scores or higher cost scores, and patients who have complex needs should be able to identify physicians with experience in treating them.

Small Practice Performance Category Redistribution

- **Recommendation:** The AMA supports CMS' proposal for redistributing performance category weights for small practices AND urge CMS to extend such reweighting policies to all physician practices regardless of size.

For small practices, CMS proposes when the PI category is reweighted, the quality performance category will be weighted at 40 percent, the cost category will be weighted at 30 percent, and the IA category will be weighted at 30 percent. When both the cost performance category and PI categories are reweighted, the quality category will be weighted at 50 percent and IA category will be weighted at 50 percent. Since the inception of the MIPS program, we have urged CMS to more evenly weight redistribution of MIPS categories and we appreciate and support CMS' proposal on reweighting categories for small practices.

However, we believe this policy should be extended to all practices regardless of size. Depending on a physician's specialty they may always have cost and/or PI reweighted given the measures do not apply to them and would also benefit from this more evenly distributed reweighting policy.

10. *Quality Category*

Increasing data completeness criteria to 80 percent in 2023

- **Recommendation:** The AMA does not support CMS' proposal to increase the data completeness criteria to 80 percent beginning with the 2023 MIPS performance period.

The AMA appreciates the proposal to continue the data completeness criteria at 70 percent for the upcoming 2022 performance period and urges CMS to reconsider increasing it to 80 percent beginning in the 2023 MIPS performance period.

As we have stated in previous comments, the increased reporting requirement is counter to CMS' goals of reducing administrative burden within the MIPS program. Physicians do not stop complying with quality protocol once they hit minimum threshold requirements. However, they may just stop submitting data to CMS due to the administrative burden of data collection and reporting, especially if reporting on patient reported outcome measures.

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

In addition, some specialties provide services across multiple sites using the same NPI/TIN but not all sites (including across sites of service) may participate in MIPS, the registry, or EHR that the physician opts to use for MIPS reporting. Specialties such as anesthesiology, radiology, gastroenterology, geriatricians, emergency medicine, and primary care physicians have these challenges with site of service differing; yet, the NPI/TIN remains the same. Therefore, until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings, and providers, it is premature to continue to increase data completeness and encourage reporting through a registry or EHR.

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

Case Minimum Requirements

- **Recommendation:** The AMA supports including some flexibility to enable larger case minimum requirements on a measure-by-measure basis. We urge CMS to evolve its benchmark methodology to better distinguish care and ensure it meets scientific evidence.

The AMA appreciates CMS' recognition that adequate reliability may not always be achieved using a case minimum of 20 patients across all quality measures and we support including some flexibility to enable larger case minimum requirements on a measure-by-measure basis. As we have stated previously, we urge CMS to ensure that all MIPS measures have high reliability, and this reliability standard should be higher than 0.7 not 0.4. While the 20-patient case minimum has been used since the beginning of this program, it remains unclear how CMS determined that this number produced adequate reliability across all the quality measures. In fact, if the current case minimum is based on assumptions and not actual measure score reliability testing, we urge CMS to revisit the current approach and modify the requirements to enable the proposed flexibility on a measure-by-measure basis for not just to new measures but to existing MIPS measures. Measure scores that are used for quality category scoring and public reporting must demonstrate sufficient reliability; otherwise, the scores will likely be misrepresentative of the actual quality of care provided.

We also note that this proposed approach does not solve the small numbers issue that can be encountered for some measures that may be important but occur infrequently. It may require collecting data across performance years and not benchmarking by decile but through identifying outliers or some other approach. We encourage CMS to explore other methods by which performance can be benchmarked. CMS must continue to evolve the program to enable the development of measures that can truly identify quality problems while still ensuring that they are reliable and valid. The AMA has repeatedly highlighted to CMS the need to evolve its benchmark methodology to better distinguish care and ensure meets scientific evidence.

Use of Performance Benchmarks for 2022 MIPS Performance Period

- **Recommendation:** The AMA supports CMS' proposal to use performance period benchmarks for CY 2022 MIPS Performance Period.

The AMA supports CMS' proposal to use performance period benchmarks for the CY 2022 MIPS performance period rather than baseline period historic data due to the COVID-19 pandemic. The AMA agrees with CMS' concerns that 2020 performance data may not be a representative sample of historic data because of the flexibilities CMS instituted regarding submission of 2020 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 do not support the proposal to expand the definition of the baseline period to calculate a benchmark. Expanding from two to three performance periods when a measure is suppressed creates instances where the underlying data are too retrospective and not reflective of current performance. Perhaps more importantly, this approach does not address the concerns of using a representative sample of historic data since many of the baseline periods would include data from 2019, 2020, and 2021 data—all of which are impacted by the COVID-19 pandemic. We encourage CMS to avoid the use of these data for benchmarking purposes.

Automatic Calculation of Outcome Based Administrative Claims Quality Measure

- **Recommendation:** The AMA does not support automatic calculation of administrative claims measures. If CMS insists on including administrative claims quality measures in MIPS, physicians must have the choice to elect an administrative claims measure whether it is an outcome or population health quality measure.

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 now digital quality measures (dQM), 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.

We are also concerned that the measures may incentivize the provision of poor care or lead to other unintended consequences, such as exacerbating inequities. As CMS highlights in the Health Equity RFI, within the 2022 Physician Fee Schedule Proposed Rule, the administrative claims readmission quality measures penalize institutions that treat a larger number of patients with social risk factors. The literature is also beginning to show that readmission measures, which are based on administrative claims, may be leading to increased mortality.³⁹

To date, we have yet to see a reliable attribution model developed for any existing administrative claims measures, which is why we only support the measures as satisfying MIPS requires if physician's have a choice and ability to opt-in to having the measure(s) attributed to them. 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. **Therefore, if administrative claims measures remain and/or are expanded within the program physicians should have the choice to elect to have administrative claim measure applied to them. Furthermore, to better assist physicians with assessing whether an administrative claims measure may apply to them we encourage CMS to use historical data to produce informational reports to individual physicians and practices.** Otherwise, physicians are left in the dark to determine whether a measure may be attributed to them or have the option to elect an administrative claims measure to satisfy MIPS or MVP requirements.

Criteria for determining whether a measure change is considered substantive

- **Recommendation:** The AMA supports the intent and draft criteria for determining whether a substantive change has been made to a quality measure. We also encourage CMS consider a substantive change to be any modification to a measure that impacts performance scores that

³⁹ 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.

may likely be due to the changes in the measure construct or coding and not actual performance.

Removal 3-point floor, except for small practices

- **Recommendation:** The AMA supports CMS' proposal to maintain a 3-point floor when scoring small physician practices on quality measures.

Minimum 5-point floor for reporting on new measures

- **Recommendation:** The AMA appreciates CMS instituting a policy to incentivize reporting on new measures but urges CMS to raise the floor to a minimum of 7 points to reporting on a new measure.

Since the inception of the MIPS program, the AMA has advocated for the program to provide incentives to report on new measures and we are glad CMS has finally proposed a policy. However, we believe a minimum 5-point floor is an insufficient incentive. As we have repeatedly highlighted, the methodology CMS has implemented for scoring and calculating benchmarks encourages practices to continuously report on measures they are familiar with given the MIPS quality benchmark methodology and scoring rules. Therefore, to encourage practices to take on the risk of reporting on a new measure and investing in new protocols and workflow, which often require IT and practice redesign costs, we urge CMS to consider a minimum point floor closer to the 10-point cap, such as 7-points.

Removal of bonus points for reporting on additional outcome measures

- **Recommendation:** The AMA does not support CMS' proposal to remove bonus points on additional outcome measures

Moving to high priority, such as outcome measures is an important goal, and physicians should continue to be recognized and compensated for this increased effort through bonus points. Therefore, the AMA does not support CMS' proposal to remove bonus points for reporting on additional outcome measures.

Removal of bonus points for end-to-end reporting

- **Recommendation:** The AMA does not support CMS' proposal to remove bonus points for end-to-end reporting

To encourage the use of electronic tools for reporting quality, the AMA urges CMS to continue to award bonus points for end-to-end reporting. Reporting electronically is extremely costly and CMS should reward physicians for utilizing registries, leveraging electronic capture, and reporting outside of claims. Physicians also need a glide path until more MVPs and digital quality measures (dQMs) are available especially in light of COVID-19 and the increased performance threshold.

Sunset of GPRO Web-Interface in 2023

- **Recommendation:** The AMA supports CMS proposal to delay elimination of the GPRO web-interface until 2023.

The AMA appreciates CMS responding to our 2021 Quality Payment Program Proposed Rule comments and re-considering the timeline to sunset the GPRO web-interface. Providing physicians with an

additional year to prepare for the transition and elimination of the GPRO web-interface will greatly assist physicians' practices, especially since practices are still on the front lines of handling the COVID-19 PHE. However, given the PHE has continued into 2021 with new a surge of cases throughout the country, we urge CMS to continue to monitor the pandemic and revisit the policy next year. At this time, it is unclear whether practices will have the bandwidth to make the transition to a new reporting tool in 2023.

COVID-Vaccination by Clinician Measure

- **Recommendation:** The AMA supports the inclusion of this measure once the underlying evidence becomes more stable and the measure is fully tested at the individual clinician level. We support voluntary reporting of the measure.

The AMA supports the intent of the *COVID-Vaccination by Clinician measure* and appreciates that it has been updated to capture whether a patient received a full course of the vaccine in response to feedback during the Measures Application Partnership (MAP) review. Prior to implementation of the measure in MIPS, it should meet the same minimum expectations as any measure, specifically that there is evidence to support the intent, the measure is feasible to collect and report, and that the performance scores are demonstrated to be reliable and valid at the individual clinician level.

In order to ensure that the measure is based on the most recent evidence, it should include all age ranges for which administration of this vaccine is approved (currently those aged 12 and older) and remain up to date on which vaccines for specific patient populations are approved for administration. Because the evidence to support this measure continues to evolve, we caution CMS on mandating reporting of this measure in future years. We believe that the measure specifications will not stay aligned with the most recent evidence throughout a performance period, leading to misrepresentations in performance based on out-of-date specifications and not true differences in quality. This will likely occur if additional vaccines become available or the appropriate age ranges are modified. Other factors such as the need for boosters could also increase the complexity of reporting this measure.

Because practices have not been the primary vehicle by which these vaccines have been administered to date, it remains unclear whether the measure would truly evaluate the quality of care delivered by that practice or how feasible it will be for practices to collect and report these data. In addition, as part of CMS' rationale for the structure of the measure it cites the flu vaccination measure. However, the current structure of the COVID-Vaccination measure is inconsistent with the influenza immunization measure that is in MIPS right now. The flu vaccine measure allows for patient decline of the vaccine, but the COVID vaccine measure does not. These concerns further validate our concern of mandating reporting of this measure in future years.

As a result, the AMA supports the inclusion of this measure once the underlying evidence becomes more stable and the measure is fully tested at the individual clinician level. We do not support mandatory reporting at any point in the near future.

Measures Proposed for Removal

- **Recommendation:** The AMA urges CMS to apply consistent standards for when a measure is proposed for removal. In addition, a high performance on one reporting option for a specific measure should not be considered an automatic trigger for removal. CMS should look at performance rates across reporting options before proposing to remove a measure from the program and the impact it may have on a particular specialty or sub-specialty.

For the 2022 performance year, CMS has proposed the removal of 19 quality measures. This is a substantial number of measures proposed for removal and may have significant consequences for practices attempting to avoid penalties in CY 2024. Clinicians need to be able to report measures that are clinically appropriate and for many practices, especially those in small practices without EHR, the removal of quality measures can inhibit their ability to reach the minimum measure requirement. Therefore, CMS must consider the availability of measures a specialty can report. For example, QPP317: *Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented* allows for many specialists to reach the required six measures. Many of the measures proposed for removal are also vital metrics that if not implemented in practices could potentially do harm to patients if not implemented in practices. For example, the removal of measures QPP14: *Age-Related Macular Degeneration (AMD): Dilated Macular Examination* and QPP19: *Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care* have large implications. Blindness due to diabetes and AMD are significant public health concerns and these measures call attention to the importance of HbA1c control for vision and regular eye exams for those with non-neovascular (dry) AMD before they progress to neovascular (wet) AMD. Without measures that span specialties and can be collected without EHR, CMS is disadvantaging clinicians in small and rural practices that are providing necessary care for patients. We are disappointed that CMS did not include any discussion on the potential impact a measure proposed for removal may have on a specialty within the proposed rule, particularly with the move to MVPs by potentially 2028.

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

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

The AMA also believes 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 consistently listed as topped out since 2017 but remains in the program. We recognize that it is a widely reported measure, but CMS must be uniform in its policies. Otherwise, it is providing the perception that CMS is biased towards its own measures and not transparent with its evaluation. Furthermore, because of the COVID-19 PHE in 2021, measure developers, qualified clinical data registries, medical societies, and others have had to delay measure development and testing. With CMS removing measures from the program and organizations unable to test and offer new measures to alleviate the strain for practices, at a minimum, CMS should delay the removal of MIPS quality measures. This

will allow QCDRs time to provide their users with better options. This will also allow a grace period for practices still feeling the effects of the PHE such as lowered patient volumes, staff shortages, and administrative help who will have to navigate the deletions of longstanding quality measures to the MIPS program.

Qualified Clinical Data Registry Participation Plan:

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

Starting with the 2024 MIPS performance period/2026 payment year, QCDRs that were approved but did not submit any MIPS data for either of the two years preceding the applicable self-nomination period must submit a participation plan for CMS approval. For example, for 2024 MIPS performance period, vendors will be required to have submitted performance data for the 2021 and 2022 MIPS performance period/2023 and 2024 payment years. Considering the COVID-19 PHE and the flexibilities CMS has set up through the Extreme and Uncontrollable Circumstances Hardship Exemption due to the PHE, we believe it is premature for CMS to institute such a policy at this time. Many QCDRs halted reporting at various times over the last couple years due to the stop in elective surgeries and surge in COVID cases, which has greatly impacted reporting. We urge CMS to revisit this policy.

C. Physician Compare Public Reporting

Delay Reporting of New IA Activities and PI Measures and Attestations Reported Via MVP

- **Recommendation:** The AMA supports CMS' proposal to delay reporting of new IA activities and PI measures. We also recommend CMS further delay MVP reporting until there are a more significant number of MVPs available for physicians to report on. Prematurely, publicly reporting MVP may confuse patients, especially since there is a disconnect between the scoring methodology used for MIPS/MVP and star ratings.

Adding Facility Affiliations to Individual Profile Pages

- **Recommendation:** The AMA is encouraged to see CMS take steps to add facility affiliation beyond hospital affiliation to individual profile pages.

A large percentage of physicians practice outside of the office and hospital setting and providing additional facility affiliation will be helpful to patients. However, we seek clarification on how CMS plans to obtain and verify the information. To date, CMS has not done a very good job on ensuring accuracy with individual physician practice information and expanding to include additional information may be premature given the ongoing inaccuracies with posting information on practice location and specialty.

Utilization data

Under section 104(e) of MACRA, beginning with 2016, the Secretary is required to integrate utilization data information on Physician Compare. To satisfy section 104(e) of MACRA, CMS previously implemented a policy to begin to include utilization data in a downloadable format in late 2017 using the most currently available data, and in an effort to continue to provide patients and caregivers with

meaningful information CMS is seeking comment on including utilization data on clinician and group profile pages. In addition, seeking comment on the potential types of utilization data that, if publicly reported, could help Medicare patients and their caregivers make informed health care decisions, as well as on technical considerations for presenting a specific affiliation between clinicians and diagnoses and/or procedures.

CMS is soliciting public comment pertaining to the potential addition of utilization summary data to the patient-facing profile pages of the Physician Compare tool. CMS notes their belief that "...utilization data may also have a place on clinician and group profile pages, if presented in a consumer-friendly way." The AMA commends CMS in general for exploring new ideas and opportunities to provide useful information to patients. However, we are concerned that since this utilization data would provide an incomplete and potentially inaccurate picture of the services each physician performs, that the data would often be misleading to patients.

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

CMS also notes that they may wish to apply a minimum experience level, such as the number of times a clinician performed a certain procedure or treated a certain condition. However, many types of services and diagnoses are distributed over large groups of procedure codes or diagnostic codes, respectively. Therefore, even if an individual physician regularly performs a type of service, the tool may incorrectly list them as having no experience since no single code exceeded a minimum threshold. For example, if a patient was preparing to undergo endovascular arterial repair (EVAR), they may be interested in looking up their vascular surgeon on the Physician Compare tool. However, as EVAR procedures are described by approximately 20 CPT codes, many vascular surgeons that regularly perform these major surgical procedures, even in the traditional Medicare population, may be listed by the tool as having had no experience performing EVAR procedures due to a minimum threshold requirement.

We are skeptical whether any type of disclaimer could avert the extensive confusion this unrepresentative information may produce. For all these reasons, the AMA urges CMS to exercise extensive caution if the Agency does opt to explore this concept further.

D. Advanced Alternative Payment Models (AAPMs)

1. Overview of the APM Incentive

- **Recommendation:** The AMA supports the proposal to take additional actions to identify changes that may occur in APM participants' organization affiliations so that their incentive payments may be correctly paid. CMS should consider developing a process that would allow physicians to notify CMS of changes in these affiliations earlier. The AMA also recommends that CMS work collaboratively with the physician community to improve payment model design and implementation so that more physicians have opportunities to

voluntarily participate in APMs that support the delivery of high-quality care to their patients.

CMS recognizes that under the Quality Payment Program, Qualifying APM Participants (QPs) eligible to receive an APM Incentive Payment from performance 2 years prior are sometimes disassociated from the practice where the payment was earned. The APM Incentive Payment is sent to the organization based on the TIN (Tax Identification Number) in CMS' system. The lag time between earning and paying the APM Incentive Payment should not cause a QP who has changed practices to be denied what they have rightfully earned. CMS addressed this issue in the 2021 PFS by establishing a process for QPs to update their enrollment information before APM Incentive Payments are made. In the current proposed rule, CMS seeks to revise section 414.1450(c) to first identify the TIN associated with a QP during the base year, and if necessary, identify a TIN associated with the QP during the payment year.

The AMA supports the clarifications CMS is making for the APM Incentive Payments to QPs. CMS should carry out its proposal to expand the search at each step to identify potential payee TINs that are so associated with the QP. Where more than one TIN is identified at a step based on paid claims during the applicable year, the proposal to allocate the APM Incentive Payment proportionately among the TINs according to the relative total paid amounts for Part B covered professional services is logical.

CMS should also consider and develop a process for a QP to proactively notify the Agency of a change from one practice to another. If a QP is able to route the APM Incentive Payment to a new TIN before it is paid, this will help ensure the payment reached the provider and should greatly reduce confusion and errors. Taken together, these proposals to identify and pay the appropriate TINs connected to a QP are important. The AMA supports these updates.

The AMA asks the Center for Medicare and Medicaid Innovation (CMMI) to explore ways to coordinate and increase model options across Medicare and Medicaid that will remove barriers that hinder physicians' participation APMs. The AMA has urged that incentive payments for APM participation be extended beyond the 2024 deadline that is included statutorily in MACRA. The extension of the APM Incentive Payments is vital for sustaining and expanding physician participation in APMs. Financing is important not just for QPs in existing APMs, but also for physicians entering APMs. We urge CMMI to allocate start-up funding to APM participants so they can invest in data analytic capabilities, care managers, training, and other practice changes that will lead to improved care delivery and more successful APM participation. Adequate resources will help physicians reduce health disparities in APMs instead of a one-size-fits all approach.

AMA policy opposes mandatory CMMI demonstration models. Instead, the AMA recommends that CMS seek innovative payment and care delivery model ideas from physicians and groups such as medical specialty societies that can guide the recommendations of the Physician-focused Payment Model Advisory Committee as well as the work of CMMI to propose models that are voluntary and can be appropriately tested. CMMI should focus on the development of multiple pilot projects in many specialties, which are voluntary and tailored to the needs of local communities and the needs of patients with different conditions. It is important to note that six years after the passage of MACRA, most physicians do not have the opportunity to participate in an APM designed for the kinds of patients they treat or the level of risk they assume. We ask CMS to improve the way CMMI designs and implements APMs so there is increased transparency and stability in the models being developed. Achieving the vision articulated recently by CMS for "a health system that achieves equitable outcomes through high

quality, affordable, person-centered care”⁴⁰ requires a collaborative approach that adheres closely to the perspective of physicians. Our physician members want to be able to jointly establish goals and processes to achieve consensus on new, voluntary models based on physician feedback, data, and involvement.

⁴⁰ Innovation At The Centers For Medicare And Medicaid Services: A Vision For The Next 10 Years, " Health Affairs Blog, August 12, 2021.DOI: 10.1377/hblog20210812.211558
<https://www.healthaffairs.org/doi/10.1377/hblog20210812.211558/full/>