

Every physician matters, each patient counts.

September 9, 2024

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

Re: File Code CMS–1807–P. Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

On behalf of the nearly 25,000 physician, resident, and medical student members of the Massachusetts Medical Society (MMS), I appreciate this opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (MPFS) and Quality Payment Program (QPP) proposed rule, published in the *Federal Register* on July 31, 2024 (89 Fed. Reg. 61596). The MMS largely supports the comprehensive comments submitted by the American Medical Association (AMA). Our comments, which are guided by thoughtfully developed MMS policy priorities and advocacy initiatives, highlight specific areas of support, concern, and recommendation regarding the proposed rule. Primary areas of focus in our comments include:

- 1. Concern about Medicare Physician Fee Schedule payment rates that are insufficient to support and sustain practices and patient access
- 2. Disagreement regarding how the new E/M codes are fundamentally different than the office/outpatient E/M codes in that they are performed remotely rather than in person and require fewer direct cost inputs
- 3. Support for continued the telehealth flexibilities with an eye toward making them permanent
- 4. Support for CMS' goal to advance access to behavioral health services but disagreement regarding the proposal for a set of G-codes in order to accomplish this aim
- 5. Support for CMS' proposals to delay in-person visit requirements for telehealth services for mental health conditions and to extend virtual direct supervision in RHCs while continue to allow RHCs to furnish non-behavioral health visits via telecommunications technology
- 6. Support for CMS' proposals to expand telecommunications flexibilities for OTPs and to establish payments for social determinants of health (SDOH) risk assessment and new FDA-approved opioid agonist and antagonist medications
- 7. Support for CMS' proposal to pay for pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV) prevention
- 8. Concern regarding MIPS performance thresholds and quality and cost measure evaluation

- 9. Recommendation to reevaluate incentives for APM participation and to offer better opportunities for physicians to participate in Alternative Payment Models (APMs)
- 10. Recommendation that any new payment model must prioritize the financial sustainability of primary care practices by ensuring that payments are adequate, predictable, and free from the constraints of budget neutrality.

The MMS' comments and recommendations are informed by our policies, our membership, and our commitment to providing high quality, equitable care to all patients. The MMS' recommendations are outlined in more detail below. We also urge the Department to carefully consider the extensive and thoughtful commentary provided by the American Medical Association.

1. <u>MEDICARE PHYSICIAN FEE SCHEDULE PAYMENT</u>

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

CMS is proposing a 2.8 percent cut to Medicare physician payments starting January 1, 2025, despite estimating that the costs of practicing medicine, as measured by the Medicare Economic Index (MEI), will *increase* by 3.6 percent. As such, while the costs of paying clinical and administrative staff, rent, and purchasing equipment and supplies are projected to rise by 3.6 percent, physicians' payments will decrease by nearly three percent. Yet, this proposed rule is silent on the impact of the growing gap between what Medicare pays for care and what it costs to provide that care. The 2025 cuts compound across-the-board cuts in 2021, 2022, 2023, and 2024; are not sustainable for physicians and their patients; and, risk jeopardizing the Administration's priorities and access to critical services. It is far past time for CMS to join the chorus of authorities on the Medicare program in expressing concern about the ability of patients to continue to receive high-quality care as physician payments erode year after year. We urge CMS to call on Congress to enact a permanent, annual inflation-based update to Medicare physician payments tied to the MEI. At a minimum, CMS must be fully transparent with the public about the impact of these payment cuts by including the expiration of temporary statutory increases to the conversion factor in the specialty impact table. If those cuts affect the conversion factor, they will also affect specialists' payment rates.

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

Moreover, cuts to Medicare physician reimbursement impede the Biden-Harris Administration's policy priorities. The Biden-Harris Administration has prioritized ending cancer as we know it through the Cancer

Moonshot. Yet in 2024, payment for a bilateral screening mammography, which is a diagnostic test that screens for breast cancer and is recommended every other year for women between the ages of 40 and 74, dropped 2.5 percent compared to 2023. Multiple agencies across the U.S. Department of Health and Human Services (HHS) have committed to strengthening primary care. Yet in 2024, payment for an office visit with an established patient needing a moderate level of medical decision-making fell 0.7 percent and would fall 4.1 percent below the 2021 payment rate in 2025 after several consecutive years of cuts (see table below). The Biden-Harris Administration has stood up a whole-of-government initiative to improve maternal health. Yet in 2024, the bundled payment for obstetrical care throughout the prenatal, childbirth, and postpartum period was cut 0.6 percent compared to 2023. While Medicaid, not Medicare, is the single largest payer of maternity care in the U.S., Medicaid payments are typically a percentage of Medicare and, according to the American College of Obstetricians and Gynecologists, the rates are on average only 82 percent of Medicare payment. In effect, a cut to Medicare payment for maternity care is a cut to the already low Medicaid maternity care payment.

CMS' statements in this rule about prioritizing behavioral health, advanced primary care, health equity, and cancer prevention are at odds with the proposed Medicare payment rates that would cut physician payment nearly three percent next year. We strongly urge CMS to acknowledge the negative effects of the proposed payment cut on Medicare beneficiaries in the final rule and encourage Congressional action to reverse it.

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

The MMS appreciates and supports CMS' decision to defer implementation of MEI changes to the distribution of RVU components (work, practice expense, and professional liability insurance) within the Resource-Based Relative Value Scale (RBRVS). The MMS agrees that CMS should allow for the review of data from the Physician Practice Information (PPI) Survey *before* implementing any re-weighting that would result in significant redistribution within physician payment.

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

b. Invoice Submission Process

CMS discusses the invoice submission process for use in updating supply and equipment pricing, stating "We welcome public comments on this general topic of more comprehensive updates to supply and equipment pricing, and we may consider comments we receive to inform future rulemaking." The MMS supports a deliberate, systematic approach to supply, equipment, and clinical labor updates. CMS also specifically requests feedback "regarding scheduled, recurring updates to PE inputs for supply and

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

2. <u>TELEHEALTH SERVICES</u>

Based on the most recent March report from the Massachusetts Center for Health Information and Analysis, in 2022, telehealth spending reported by commercial, Medicare Advantage, and MassHealth plans totaled \$1.6 billion (2.4% of total health care spending in the state). Overall, telehealth spending in 2022 remained significantly higher than the \$3.0 million reported in the pre-pandemic year 2019 in Massachusetts. However, it has also become clear that telehealth has improved access to services for patients, particularly to behavioral health services.

Spending for telehealth services delivered by "other professionals" (non-physician providers), which includes occupational and physical therapists, nurse practitioners, physician assistants, and certain behavioral health providers, represented about half (53.8%) of all telehealth spending in 2022, consistent with prior years.

In particular, it is notable that 10 diagnosis categories accounted for more than two-thirds of telehealth spending for commercially insured Massachusetts residents and, of these diagnosis categories, 9 of the top 10 diagnosis categories were behavioral health conditions, consistent with trends in the types of providers who are providing a large portion of their services via telehealth.

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

a. <u>New CPT Codes for Synchronous Audio-Video and Audio-Only Evaluation and</u> <u>Management (E/M) Services</u>

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

- 9X075-9X078 E/M services for *new patients* delivered via an interactive *audio/video* telecommunications system.
- 9X079-9X082 E/M services for *established patients* delivered via an interactive *audio/video* telecommunications system.
- 9X083-9X086 E/M services for *new patients* delivered via an interactive *audio-only* telecommunications system.
- 9X087-9X090 E/M services for *established patients* delivered via an interactive *audio-only* telecommunications system.

The new telemedicine E/M codes streamline reporting, creating code descriptors so that modifiers become unnecessary to report these services. This fundamental change to the code descriptors leads to

administrative simplification, providing a consistent mechanism for all payors to recognize the newer modalities of synchronous audio-video and audio-only E/M services. Much like the distinct E/M codes for office/outpatient, inpatient hospital, home visits, and nursing facility visits, the new codes provide the ability to distinguish the distinct resource costs required to provide the services. In addition to providing the benefit of consistency, reducing administrative burden, and describing accurate resource costs, the new coding structure for synchronous audio-only visits provides additional differentiation on the time ranges, consistent with how audio-only visits are being addressed today. These audio-only codes differentiate new and established patients, unlike the previous telephone E/M codes (99441-99443).

b. <u>Telemedicine E/M Services are not Duplicative of Office/Outpatient E/M Services</u>

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

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

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

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

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

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

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

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

Furthermore, CMS raises a concern that:

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

Section 1834(m) is a payment rule for services that are identified as telehealth services and furnished to telehealth eligible individuals. The payment rule specifies that if a service is a telehealth service that is furnished by a physician or practitioner through a telecommunications system to a telehealth eligible individual then the payment amount to the physician or practitioner for that service must be an amount equal to the amount that the physician or practitioner would have been paid if the services were furnished in person. If a service is not identified as a telehealth service, the rules and limitations under section 1834(m) do not apply to that service.

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

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

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

be applicable when a 9X075-9X090 code outside of the telehealth benefit is furnished that originates from a patient's home or a health care site.

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

In the proposed rule, CMS states:

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

As noted above, the MMS believes it is within CMS' statutory authority to pay for E/M services delivered remotely via interactive remote audio/video or audio-only telecommunications systems outside of section 1834(m) of the Act. If CMS were to recognize and pay for CPT codes 9X075-9X090, it would substantially mitigate the concerns about the expiring waivers to section 1834(m) of the Act as the office/outpatient E/M services are likely the largest single category of services paid under the Medicare telehealth benefit. For these services, the 9X075-9X090 codes would be available for use as an alternative to the office/outpatient E/M services leaving a much smaller universe of services on the telehealth services list that would no longer be payable when waivers under section 1834(m) of the Act expire on December 31, 2024.

c. <u>Telehealth Budget Neutrality Issues</u>

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

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

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

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

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

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

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

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

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

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

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

If CMS were to begin paying for audio-only E/M services in 2025 for the first time without having previously paid for them, it would have been consistent with CMS' historical policy to apply a budget

neutrality adjustment for unbundling audio-only E/M service from other E/M services. However, CMS has been paying separately for audio-only E/M services under current policy for several years and any additional spending has been incorporated into the base level of payment CMS uses for its budget neutrality calculations.

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

d. Expanded Coverage for Audio-Only Communication Technology

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

CMS now proposes to extend its policy allowing use of audio-only technology when any telehealth service is furnished to a patient in their home, not just for those related to mental health or substance use. The same conditions would apply; that is, the distant site physician can use audio-video technology, but the patient cannot or does not consent to its use. For audio-only services, CPT modifier 93 must be appended to the claim to verify that the service meets these conditions. **The MMS applauds the proposal for Medicare to cover audio-only services and urges CMS to finalize it.** Broadband and audiovisual telehealth services are not accessible by all Medicare patients. Access to broadband internet is a social determinant of health, and discontinuing audio-only coverage would exacerbate health inequities, including for historically marginalized, minoritized, and underserved populations. Physicians have also made it clear that audio-only services can enhance quality and improve patient health outcomes. Some patients would want to obtain all their health care services over the phone, in the nearly five years since CMS has been allowing payment for audio-only services, it has become clear that these services play an important role in digitally enabled hybrid models of in-person and virtual care.

e. Direct Supervision via Communications Technology

The MMS supports the CMS proposal to permanently allow physicians to be immediately available for direct supervision via audio-video, real-time communications technology for a subset of services that require direct supervision and appreciates the proposal to continue to allow virtual provision of direct supervision for other services through 2025. The MMS has recommended in previous comment letters that the policy be made permanent. The fact that remote supervision may be inappropriate in some cases does not justify refusing to pay for it under all circumstances. In many rural and underserved areas, patients may be unable to access important services if the only physician available must supervise or deliver services at multiple locations and may not be available to supervise services in-person when all patients need them. Under these circumstances, failure to allow use of audio-video communications technology for direct supervision could mean that a patient would be unable to receive the service at all, rather than forcing in-person supervision to occur. Both patients and CMS rely on physicians' professional judgment to determine the most appropriate services to deliver, and the same principle should apply to how supervision is provided.

CMS has identified a subset of services requiring direct supervision for which it proposes to allow virtual direct supervision on a permanent basis. These are services that CMS views as being typically performed in their entirety by auxiliary personnel, including services described by CPT code 99211 which by definition "may not require the presence of a physician or other qualified health professional." The MMS agrees with the proposal to permanently allow virtual direct supervision for a subset of services.

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

f. Supervision of Residents by Teaching Physicians via Communications Technology

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

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

Accreditation Council for Graduate Medical Education (ACGME) <u>rules</u> allow for audio-visual supervision of residents and its guidelines state that direct supervision can occur when "the supervising physician or patient is not physically present with the resident and the supervising physician is concurrently monitoring the patient care through appropriate telecommunication technology." ACGME also provides more specific guidance for each <u>specialty</u>. In accordance with ACGME guidance, the MMS acknowledges and supports individually tailoring the virtual supervision of each resident according to their level of competency, training, and specialty since this would enable residents to provide additional services while still garnering the support needed from their teaching physicians.

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

g. Frequency Limitations on Certain Medicare Telehealth Services

The MMS supports the CMS proposal to continue lifting the telehealth frequency limits on subsequent inpatient and nursing facility visits and critical care consultations through 2025 but urges CMS to *permanently* lift these restrictions. The environment for telehealth services has transformed in the many years since CMS first imposed the frequency limits for these services. Digitally enabled services provided by the more than 300 hospitals participating in CMS' Acute Hospital Care at Home program allow patients to receive hospital-level care in their own homes, including through virtual visits with their physicians. These programs free up inpatient hospital beds for the patients who really need them and cannot be cared for at home. Limitations on the number of nursing facility visits that can be provided in-person. Amid workforce shortages of physicians and other health professionals who treat nursing facility patients, it has become difficult in some communities to find nursing facility patients can allow their physicians to practice more efficiently and allow them to be available for in-person visits with those patients who cannot be effectively treated in a telehealth visit.

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

h. <u>Reporting of Physician Home Addresses</u>

As noted in prior comments, the MMS has been, and remains, concerned about any potential requirement for physicians to report their home address and supports CMS' proposal to not require such reporting at least through 2025. Specifically, the MMS advised CMS to permanently allow physicians to render telehealth services from their homes without reporting their home address on their Medicare enrollment form while continuing to bill from their currently enrolled location. Physician privacy and safety is of utmost concern, and we fear the unintended consequences of this personal information becoming available to the public, especially in the current times of unprecedented violence against health care professionals. For example, physicians who provide behavioral health services may conduct telemedicine visits from their home and the nature of the medical conditions treated by these physicians may introduce a heightened level of safety concerns that outweigh any potential benefit to CMS from having data on physicians and other health care workers demonstrate that they have never been at a greater risk of injury due to work-related violence. Any effort towards preserving the privacy and safety of health professionals must be a top priority for CMS.

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

i. Additions to the Medicare Telehealth List

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

basis, it proposes to add the codes for PrEP for HIV as permanent telehealth codes. The MMS supports these proposals.

3. COVERAGE OF DENTAL SERVICES

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

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

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

We likewise appreciate the Agency <u>previously stating</u> that it would closely study the trends in utilization and payment for these services. We call for CMS to make this information available to the public and to publish data regarding the impact that reimbursing these dental services has on clinical outcomes for Medicare-covered services, which we believe is necessary to demonstrate that these dental services meet the definition of being inexplicably linked to these Medicare-covered services.

4. ADVANCED PRIMARY CARE MANAGEMENT (APCM) SERVICES

CMS should review the RUC's recommendations for a patient-centered medical home and consider its framework for tiering payment based on infrastructure capabilities. CMS proposes to incorporate some payment and service delivery elements from CMS Innovation Center models, including Comprehensive Primary Care Plus and Primary Care First (PCF), into three new APCM services, which could be furnished per calendar month, following the initial qualifying visit for new patients and obtaining patient consent. APCM services would include elements of existing care management codes, including chronic care management (CCM), transitional care management (TCM), and principal care management (PCM), as well as communication technology-based services (CTBS), including virtual check-in services.

Unlike existing care management codes, CMS is proposing that the code descriptors for APCM services would not be time-based. In addition, unlike the current coding to describe certain CTBS services, CMS is proposing that APCM services would not include timeframe restrictions, which CMS has heard are administratively burdensome. For example, virtual check-in services cannot be billed when there is a related E/M service within the previous seven days. CMS proposes that APCM services could not be billed by the same practitioner or another practitioner within the same practice for the same patient concurrent with these other services: CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient videos/images, virtual check-ins, and e-visits.

To bill for APCM services, CMS is requiring the following service elements and practice-level capabilities: 24/7 access to care and care continuity; comprehensive care management; patient-centered comprehensive care plan; management of care transitions; practitioner-, home- and community-based-organization coordination; enhanced communication opportunities; patient population-level management; and performance measurement. CMS does not propose that all elements included in the code descriptors for APCM services must be furnished during any given calendar month for which the service is billed but billing physicians must have the ability to furnish every service element. Participation in certain alternative payment models (APMs), including accountable care organizations, PCF, and Making Care Primary, satisfies some of the practice-level capabilities, such as population-level management and performance measurement. MIPS-eligible physicians must register for and report the Value in Primary Care MIPS Value Pathway (MVP) to satisfy the performance measurement service element to bill APCM services.

Given the substantial infrastructure requirements to bill the proposed APCM codes, the MMS urges CMS to review the RUC's recommendations for a patient-centered medical home and consider its framework for tiering payment based on capabilities of the practice, ranging from entry level to comprehensive. A tiering approach would enable more primary care physician practices, including independent physician practices, to qualify to report APCM.

5. ADVANCING ACCESS TO BEHAVIORAL HEALTH SERVICES

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

In 2018, the American College of Emergency Physicians submitted a <u>proposal</u> to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for the Acute Unscheduled Care Model. The model was specifically designed to allow emergency physicians to ensure safe discharges for patients to

their home and community after an ED visit, facilitate care coordination during the post-discharge period, and help avoid hospital admissions and repeat ED visits for patients seen in the ED. A key reason that the model was needed is because emergency physicians cannot report and be paid for transitional care or discharge day management services. As a result, there is a scarcity of resources available to help patients safely return to their home environment, connect them to primary care or other follow-up care services, ensure that they can obtain prescribed medications, healthy food, or caregiver services, and understand and follow discharge instructions. The PTAC recommended the proposal to the Secretary for implementation and said that it met all 10 of the PTAC's criteria, yet CMS has not tested or implemented the model. Instead of establishing G-codes, CMS could propose extending the use or revision of the existing CPT codes for transitional care or discharge day management services to help patients safely return to their home or community from the ED or other settings and coordinate needed support services following an ED visit.

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

a. <u>Digital Mental Health Treatment (DMHT) Devices</u>

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

CMS proposes a change in terminology to create a distinction between GMBT1 and the existing CPT codes 98975 and 98978. We are not sure that this distinction is necessary as the existing CPT terminology conforms with, and relates to, medical devices that are supported by ample evidence, have achieved medical device regulation designation, and were presented before the CPT Editorial Panel.

Starting January 1, 2025, the CPT code set does update guidelines for codes 98975, 98976, 98977, and 98978 to reflect changes to the devices in the marketplace. The guidelines allow for the reporting of RTM codes when the device also has a therapeutic intervention functionality. While we understand that the new G-codes are poised to include a broader range of services, the Agency should use caution in creating codes for a small number of devices that may not be covered through CPT coding, as it may cause confusion. As technology advances, it is important to synchronize terminology to ensure we

communicate effectively. We also remind the Agency that coding and valuation benefit from the clinical input of physicians and other qualified health care professionals that comes from the CPT and RUC processes. Lastly, creating a bifurcated code set does increase the administrative burden for practices. Since G-codes tend to be covered only by Medicare, it puts practices, especially pediatric practices, at a disadvantage. These practices primarily bill private payers and Medicaid, so having multiple codes for the same or similar services provides a challenge and often a delay in payment for services rendered.

6. <u>RURAL HEALTH CLINICS (RHCS) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCS)</u>

CMS should finalize its proposal to delay in-person visit requirements for telehealth services for mental health conditions until January 1, 2026, extend virtual direct supervision in RHCs through the end of CY2025 and continue to allow RHCs to furnish non-behavioral health visits via telecommunications technology. CMS proposes to extend existing telehealth flexibilities for RHCs through 2025, including delaying the requirement for patients with mental health conditions to have an inperson visit within six months of a telehealth visit, extending virtual direct supervision, and extending the ability for RHCs to serve as a distant site for non-behavioral health care visits to be furnished via telecommunications technology. As discussed in our comments on the telehealth proposals for the MPFS, CMS should consider providing permanent extensions of these policies, not just for one additional year.

7. <u>MODIFICATIONS RELATED TO MEDICARE COVERAGE FOR OPIOID USE DISORDER (OUD)</u> <u>TREATMENT SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS (OTPS)</u>

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

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

8. MEDICARE PART B PAYMENT FOR PREVENTIVE SERVICES

The MMS supports CMS' proposal to update and expand Medicare Part B coverage for colorectal cancer (CRC) screening tests. CMS is proposing to exercise its authority under section 1861(pp)(1)(D) to make significant adjustments in CRC screening to promote access and remove barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of CRC. In response to evidence supporting its efficacy and recommendations by the United States Preventive Services Task Force, CMS proposes to introduce coverage for Computed

Tomography Colonography (CTC). CMS also proposes broadening the definition of complete CRC screening in 410.37(k) to include a follow-on screening colonoscopy after a positive result from a Medicare-covered blood-based biomarker test.

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

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

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

Medicare Part B covers preventive vaccines for influenza, pneumonia, hepatitis B, and COVID-19, and there is no patient cost-sharing. For CY2025, CMS proposes to expand coverage of hepatitis B vaccinations to all individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. Additionally, CMS would allow roster billing for this vaccine by mass immunizers such that a physician's order would no longer be required. Also, for the first time since the law allowing coverage of drugs as "additional preventive services" was enacted in 2008, CMS is proposing to pay for a drug in this benefit category which, like other Medicare preventive services, would have no cost-sharing. Specifically, CMS proposes to pay for PrEP for HIV infection prevention once Medicare finalizes its national coverage policy. The MMS appreciates that CMS is updating these payment rates by the annual increase in the MEI and supports the proposal to expand Medicare coverage of hepatitis B vaccinations.

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

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

9. MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)

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

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

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

a. <u>Performance Threshold</u>

The MMS supports maintaining the performance threshold at 75 points in 2025 and is advocating for statutory changes that would freeze it at 60 points for at least three years. The MMS recommends CMS do everything in its authority to correct the well-documented problems with the MIPS program, including establishing a performance threshold that will not disproportionately penalize small practices and solo practitioners. While the MMS supports maintaining the performance threshold at 75 points during the 2025 performance period, we urge Congress to go further and freeze the performance threshold at 60 points for at least three years. A three-year, 60-point performance threshold would introduce much-needed stability into the program, affording all eligible clinicians flexibility following the five-year disruption of the COVID-19 public health emergency and Change Healthcare Cyberattack.

In the regulatory impact analysis, CMS estimates there will be 686,645 MIPS eligible clinicians (ECs) in the 2025 performance period, the median final score will be 86.42, and 78 percent of MIPS eligible

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

CMS projects the median positive payment adjustment in the 2027 payment year based on 2025 performance will be 1.31 percent while the median penalty will be -1.48 percent. However, CMS expects that the median penalty will be -6.42 percent for solo practitioners and -5.88 percent for small practices because more solo practitioners and small groups are expected to receive the maximum negative 9 percent MIPS penalty.

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

b. Quality Measures with Substantive Changes

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

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

Ensuring that the scores used to evaluate physician performance and for benchmarking have sufficient denominator cases is critical. We encourage CMS to evaluate the potential impact on the measure score reliability due to any substantive change and/or the resulting truncation of data. We also encourage CMS to evaluate whether a coding update should be considered a substantive change based on whether changes

in performance scores are due to the modifications to the measure construct or coding rather than actual performance. For example, if year-over-year comparisons could not be attributed to actual changes in performance, it should be considered a substantive change and may require reliability of the measures scores to be reassessed.

c. <u>Proposed Cost Measures Should be Informational-Only for at Least Two Years</u>

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

10. ADVANCED ALTERNATIVE PAYMENT MODELS (APMS)

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

a. Qualifying APM Participant (QP) Determination and APM Incentive

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

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

The MMS recognizes these changes are set in statute; therefore, we urge CMS to leverage its expertise and authority to educate Congress on the adverse impact that allowing the QP thresholds to rise and the Advanced APM bonus to expire could have on Advanced APM participation. The MMS strongly

supports S. 3503/H.R.5013, *the Value in Health Care (VALUE) Act*, bipartisan legislation that would extend the original five percent APM incentive payments and freeze the 50 percent revenue threshold for an additional two years, among other changes that would stabilize and strengthen APMs.

The MMS appreciates important progress in the form of new voluntary models, including the Accountable Care Organization Primary Care Flex (ACO PC Flex) Model and the Making Care Primary Model. However, there are still many physicians who have no opportunity to voluntarily participate in an APM focused on the conditions that their patients have or the treatments they deliver, there is no nationwide voluntary primary care medical home model, and small, rural, and safety net physicians lack opportunities to transition to APMs.

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

As CMS looks to bridge the gap between MIPS and APMs, increasing data sharing and performance feedback is paramount for practices to monitor their performance and build confidence to move into APMs. Reducing the administrative burden of MIPS is also critical to allow practices to devote scarce resources to exploring APM opportunities, if available.

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

b. <u>Attribution</u>

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

The MMS appreciates that CMS is working to identify proposals that would allow Advanced APMs to include meaningful participation by more non-primary care specialists, and we generally support the proposed policy change. Although this is the second time CMS has proposed this change, we are unclear about its likely impact, which is not discussed in the regulatory impact analysis. It would be helpful for CMS to provide direct comparisons of the proportion of participants in each Advanced APM who are estimated to meet the thresholds required to achieve QP status under the current and proposed policies, and under both the performance year 2024 thresholds and the higher 2025 thresholds in current law.

11. <u>Request for Information: Advanced Primary Care</u>

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

The MMS recommends that any new payment model must prioritize the financial sustainability of primary care practices by ensuring that payments are adequate, predictable, and free from the constraints of budget neutrality. The MMS supports a model that integrates the flexibility of fee-for-service with the stability of prospective payments, all while reducing administrative burdens and safeguarding against unintended consequences that could undermine patient care.

CONCLUSION

As always, the Massachusetts Medical Society appreciates the opportunity to provide comment and work with CMS on our shared goal of providing the highest quality health care to patients. Should you have any questions, please contact Casey Rojas, Federal Relations & Health Equity Manager, at <u>crojas@mms.org</u> or (781) 434-7082.

Sincerely,

Wigh M Taylor

Hugh M. Taylor, MD President, Massachusetts Medical Society