

October 5, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

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

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) physician fee schedule (PFS) proposed rule for calendar year (CY) 2021.

**The AHA appreciates CMS's effort to continue certain pandemic-era policies that have helped our members ensure access to care for patients during the COVID-19 public health emergency (PHE).** In particular, we support CMS's proposal that would allow physicians and non-physician practitioners to continue providing direct supervision via interactive telecommunications technology; we urge the agency to make permanent this policy. We also appreciate CMS's proposals to permanently retain some of the telehealth services it added to the Medicare telehealth list of services during the PHE and temporarily retain other services it added during the PHE. The AHA also supports



CMS's proposal to delay until CY 2022 at the earliest implementation of the Merit-based Incentive Program's Value Pathways (MVP) approach.

**However, we are concerned about other proposed policies, particularly those made more problematic by the ongoing COVID-19 pandemic.** The proposed significant reduction to the Medicare conversion factor that is a result of CMS's proposal to implement the evaluation & management (E/M) revaluation and other changes in a budget-neutral manner would significantly strain the finances of hospitals and health systems. These facilities are already buckling due to the PHE; the agency's proposal would further jeopardize access to care for numerous patients. In addition, we are concerned by the proposal to create a new MIPS Advanced Payment Pathway (APP) that asks all MIPS alternative payment models (APMs) to report the same six quality measures. If implemented, this policy would lead to a misalignment between APMs and the quality measures to which they are held accountable.

We also have serious concerns about the proposed changes to the Medicare Shared Savings Program (MSSP) quality measurement approach and urge CMS not to finalize its proposed policies to remove the pay-for-reporting year and eliminate the web interface reporting option. Finally, we caution against aggressive implementation of the requirement governing the electronic prescribing of controlled substances as in addition to facing the challenges of the PHE, providers are struggling to stay abreast of and meet the numerous health information technology requirements CMS is developing.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Shira Hollander, AHA's senior associate director of policy, at [shollander@aha.org](mailto:shollander@aha.org), regarding the payment provisions, or Akin Demehin, AHA's director of policy, at [ademehin@aha.org](mailto:ademehin@aha.org), pertaining to the quality provisions.

Sincerely,

/s/

Ashley B. Thompson  
Senior Vice President  
Public Policy Analysis & Development

*Enclosure*

## AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS

### PAYMENT FOR EVALUATION AND MANAGEMENT (E/M) VISITS

Over the past two years, CMS has redesigned the coding, documentation and payment policies for office/outpatient E/M visits. CMS last year in the CY 2020 PFS final rule adopted several policies that altered the E/M visit code set, in the process establishing separate payment for two new add-on codes: one for prolonged visits and a second for visit complexity. CMS also finalized increases to the RVUs for most of these codes, effective Jan. 1, 2021. In this rule, CMS proposes to revalue additional services that are closely tied to these office/outpatient E/M visits.

CMS states that the E/M visit payment policies finalized last year and the additional proposals this year necessitate a budget neutrality adjustment resulting in a net decrease to the Medicare conversion factor of 10.61% for CY 2021. However, CMS proposed this conversion factor cut without any clear, transparent explanation into how it was calculated. Moreover, while these changes may be budget neutral for Medicare as a whole, they would not be budget neutral for individual providers, including hospitals and health systems, unless they have the exact national average RVU mix, an unlikely occurrence. **Thus, we are extremely concerned about the impact that a payment cut of this magnitude would have on patients' access to care.**

**Our concern is greatly heightened by the fact that this cut is coming at a time in which the nation's health care system is already under unrelenting financial pressure due to the ongoing COVID-19 PHE.** Specifically, the AHA [estimates](#) that hospitals and health systems will lose more than \$300 billion before the end of this year due to the pandemic. A cut of the magnitude proposed by CMS, which would have a disproportional impact on hospitals and health systems given that most directly employ providers or contract for their essential services, would exacerbate these already extreme financial challenges that our nation's providers face. Indeed, the practitioners who have put themselves on the front lines of the COVID-19 pandemic – such as anesthesiologists, critical care and emergency medicine providers, respiratory specialists, radiologists, lab pathologists and many others – are the very ones who face the most significant financial losses from this policy, a troubling way to treat those providers who have already sacrificed so much. Providers are also still trying to navigate the drastic utilization changes caused by the cancellation of elective procedures, changes in acuity of patients due to many putting off care so as not to risk COVID-19 exposure, and changes in insurance coverage due to unprecedented levels of unemployment.

In addition to the PHE, there are other factors that would heighten the impact of the proposed cuts. Specifically, Medicare payments have not kept up with inflation such that the proposed CY 2021 conversion factor of \$32.26 is *less* than the 1994 conversion

factor of \$32.9050, which is equivalent to approximately \$58.50 in today's dollars.<sup>1</sup> Additionally, many other payers tie their fee schedules to the Medicare physician fee schedule; providers' losses under Medicare's proposed policy would thereby be compounded by losses from other payers.

**While we are deeply concerned about the payment reductions that arise from CMS's proposed conversion factor cut, we support the payment increases that result from CMS's proposals to increase the work RVU (wRVU) amounts for E/M codes.** These revaluations ensure that increased funding can and will reach some of our communities' most vital providers, including those that provide primary care and behavioral health services. They also reflect CMS's effort to update what they believe to be the outdated E/M visit code set. **Thus, we urge the agency to finalize this proposal while working to reduce the degree to which it redistributes funds among providers. Specifically, we recommend CMS work with Congress to secure a waiver of budget neutrality for the PFS for at least CYs 2021 and 2022.** Doing so would allow CMS to protect patient access to care by increasing payments for E/M visit codes without an overall cut to payments in excess of 10 percent. This balance would help ensure Medicare maintains a robust network of providers of all specialties at a time when such access has never been more important.

Additionally, because wRVUs are utilized not simply by Medicare, but by private parties nationwide as a reliable, impartial metric for evaluating the compensation that hospitals and others pay physicians, dramatic changes in Medicare wRVUs can lead to significant and costly unintended consequences. For example, viewed through the lens of the Stark Law, a precipitous drop in wRVU-based Medicare revenue paid for physician services could drive hospitals across the country to perceive a need to renegotiate physician employment and service agreements, agreements under which value is often measured on a dollars-per-wRVU basis. Absent a clear statement from CMS that Medicare wRVU rates are not a benchmark for Stark Law standards like "commercial reasonableness," "fair market value," and/or "takes into account the volume or value of referrals," standards that have been rendered ambiguous by recent court decisions, the proposed changes will unfairly expand the uncertainty and risk that hospitals face when they pay physicians who provide patient care on their behalf. It would be incredibly difficult for hospitals to have to renegotiate every single contract with every single provider due to the COVID-19 pandemic and the extremely short time period between the final PFS rule – whenever it is published – and Jan. 1, 2021. In fact, many of these contracts require 90-180 days of notice before one or both parties can make a change; even if the final rule were published on Nov. 1, those deadlines will have passed.

If CMS cannot secure a waiver of budget neutrality from Congress, we urge the agency to delay the implementation of the revaluation of the E/M and related visit codes and the

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<sup>1</sup> Using the [U.S. Bureau of Labor Statistics inflation calculator](#), the conversion factor in 1994, \$32.9050, is worth approximately \$58.50 today.

corresponding budget neutrality adjustment so as not to hinder the ongoing work hospitals and health systems must do in response to COVID-19.

We also urge CMS, whenever it implements these adjustments, to phase them in over a 2-4 year period. This is a request AHA has previously made on a variety of issues in order to moderate substantial fluctuations in payment rates to promote predictability and reliability for providers. Indeed, such an approach would be consistent with previous actions taken by the agency when incorporating significant new data into the PFS. For example, CMS implemented a four-year transition period in the CY 2007 PFS final rule when changing to the “bottom-up” practice expense methodology, as well as a similar, four-year transition period finalized in the CY 2019 PFS final rule when incorporating new supply and equipment values based on the StrategyGen survey.

**At the very least, we urge CMS to delay the implementation of the visit complexity HCPCS add-on code (GPC1X) finalized by the agency last year.** In the rule, the agency recognizes that stakeholders are confused about the definition and use of this HCPCS code and that this uncertainty could make the code susceptible to overuse. CMS’s own utilization assumptions envision certain specialties billing the code with 100% of visits. Despite a year of concern and requests for clarification from stakeholders, CMS did not provide answers in this rule and instead asked “what aspects of the definition of HCPCS add-on code GPC1X are unclear, how we might address those concerns, and how we might refine our utilization assumptions for the code.”

CMS should not implement a new code with this degree of uncertainty, especially in a year rife with uncertainty. Instead, CMS should use this time to develop far more detailed coding and billing guidance on how to use the HCPCS G code when it is eventually implemented, so as to ensure its accurate use by providers. Because the HCPCS code carries a net PFS impact of more than \$3 billion, delaying its implementation would enable CMS to lessen its conversion factor reduction. While we continue to urge CMS to work with Congress to secure a waiver of budget neutrality, if that becomes impossible, delaying this HCPCS code would at least soften the blow of the budget neutrality adjustment.

## **TELEHEALTH AND OTHER COMMUNICATIONS TECHNOLOGY-BASED SERVICES (CTBS)**

CMS proposes several changes related to telehealth and CTBS. These changes build on the numerous, critical telehealth flexibilities that CMS provided during the PHE, which have enabled our members to better serve their communities. **The AHA and our members appreciate the speed at which the Administration has acted during the COVID-19 pandemic to allow hospitals to preserve their in-person capacity for the sickest patients while meeting other patients’ needs via telehealth.**

One of the most salient features of telehealth is the access to care it creates for broad swaths of patients. Telecommunications technology connects patients to vital health care services through videoconferencing, remote monitoring, electronic consults and wireless communications. It increases patients' access to physicians, therapists and other practitioners, helping ensure they receive the right care, at the right place, at the right time. This is especially true in areas of the country where recruiting and retaining providers is challenging, such as in rural areas, where providers cannot meet standard or surge demand with current capacity. Telehealth fundamentally changes that equation.

During the pandemic, our members have utilized critical flexibilities CMS established to reach even more patients. This shift in care delivery is producing high-quality outcomes for patients and could outlast the public health emergency if the appropriate statutory and regulatory framework is established. In an August 2020 [letter](#) to you, U.S. Rep. Kevin Hern and 49 of his Congressional colleagues summarized the great strength of telehealth:

Throughout the current, unprecedented crisis, Americans have seen the benefits of expanded telehealth services. Not only do these services help to facilitate public health mitigation strategies by increasing social distancing, but these services allow patients to maintain continuity of care to help avoid additional negative consequences from delayed preventive, chronic, or routine care. Further, telehealth services can help to increase participation for those who are medically or socially vulnerable, those who do not have ready access to providers, and those for which an in-person visit is not practical or feasible.

As an example of the impact made by pandemic-borne flexibilities, one of our members reported a 10-fold increase in access to specialties while reaching 39% more zip codes in their state using telehealth. They received extremely high patient satisfaction ratings from the patients who utilized these telehealth services; one such patient, a farmer, relayed how he conducted a visit with his physician via his smartphone while on his tractor, a process that would normally take three hours for an in-person visit. Many other AHA members also indicated they observed greatly improved health outcomes for patients who no longer cancelled or missed their appointments due to the ability to connect remotely with their providers.

The COVID-19 pandemic spurred to action another of our members, who set up a virtual hospital with significant telehealth capabilities when the pandemic first hit. The program's original objectives were to provide proactive management of COVID-19 patients across the care continuum, keep significant numbers of patients out of emergency departments and hospitals, and preserve and increase inpatient bed capacity for those who needed it. These objectives were met with great success; nearly 18,000 patients were treated in the virtual hospital as of August 2020, with only 3%

requiring transfer to a brick-and-mortar site. A significant number of hospitalizations were avoided, making the program very cost effective.

What's more, the patients who were transferred were often able to bypass busy EDs, and by the time they arrived at the facility, the hospital already had their essential information due to their prior virtual care. Patients were extremely satisfied with the program, including the 97% of patients who remained at home and whose anxiety about this novel disease was very well-managed due to regular connection with a provider. Every patient discharged from the virtual hospital was set up with a follow-up appointment with a primary care provider, the majority of which were completed virtually. For many of these patients, that primary care visit was the jumping off point to ongoing access to care they had never had before. This member is now expanding its virtual hospital beyond COVID-19 care to assist those with chronic conditions.

**Given these and the millions of other successful telehealth encounters that have occurred since March – and in the years prior – the AHA implores CMS to work with Congress to eliminate the 1834(m) geographic and originating site restrictions, which would allow patients to receive telehealth services in their homes, residential facilities and other locations.** Without this change, much of the progress that has been made over the past months to significantly increase patient access to care will disappear, since the status quo limits telehealth to rural areas of the country and requires patients to be at certain facilities to receive care. The PHE clearly demonstrated the need for access to telehealth in non-rural areas and in the safety of patients' homes, and we urge CMS to work with Congress to ensure federal policy reflects the realities of today's health care environment.

**Similarly, we urge the agency to extend coverage of, and payment for, all telehealth services to new patients.** If CMS deems a service safe to be delivered via remote connection, it should not arbitrarily limit access to such services. This is especially important for patients who, without telehealth, might not otherwise be able to obtain care, such as patients in rural areas that lack primary care providers. CMS's own decision in the CY 2020 PFS to remove the history and physical examination elements of an E/M visit unless medically necessary demonstrates that the agency does not believe an in-person interaction is needed in every situation. That CMS did not limit this policy to established patients suggests that visits that do not require in-person interaction could be provided via telehealth to any patient – regardless of whether they are new or established.

We wish to underscore that any expansion of telehealth should be implemented with the explicit goal of addressing health equity and reducing health disparities. We are mindful that even though our recommended actions would protect access to care for millions of patients, challenges remain for the nation's minority communities. As such, telehealth must be employed with supporting policies to reach underserved populations, such as access to broadband and end-user devices.

As providers continue to explore the possibilities for improved patient care through telehealth and other virtual services, we urge CMS to do the same in an effort to best support providers' ability to deliver high quality care and improved patient outcomes. **This work must include a thorough and complete accounting of the costs that go into providing virtual visits and how such expenses relate to the need to maintain capacity for in-person services.** Armed with this information, CMS should ensure providers receive adequate reimbursement for the substantial upfront and ongoing costs of establishing and maintaining their virtual infrastructure, including secure platforms, licenses, IT support, scheduling, patient education and clinician training. Without adequate reimbursement of these costs, providers will be forced to decrease their telehealth offerings, thus returning many patients to the previous system of unequal access to care. Adequate reimbursement for virtual services also is key to ensuring providers have the means to invest in HIPAA-compliant technologies and to deliver these services with the highest attainable quality of care.

**As part of this effort, CMS should also consider which elements of the business of providing care, such as coding and billing, must move online in support of care that is provided via virtual connection.** For example, providers should be able to capture during telehealth visits diagnoses impacting risk adjustment so as to avoid having to conduct the same patient visit twice – once via telehealth and once in person to record all of the patient's conditions. Similarly, CMS should create a mechanism by which providers can collect and document vital signs obtained as part of the Annual Wellness Visits (AWVs) "Measure" component. We commend CMS for permitting beneficiaries for the duration of the COVID-19 pandemic to self-report vital signs when clinically acceptable. We urge the agency to continue this policy after the PHE ends and to disseminate guidance on what providers can do in situations in which patients cannot self-report. We also recommend CMS consider how to account for missing diagnosis data that will certainly occur as a result of the dramatic decline in utilization this year.

We again thank the agency for its unprecedented efforts to expand telehealth access during the COVID-19 pandemic and continue below with comments on specific proposals in the rule.

*Payment for Medicare Telehealth Services.* Over the past six months, CMS has added several services to the list of Medicare telehealth services for the duration of the PHE. In this rule, CMS proposes to permanently retain some of those newly approved services, including group psychotherapy, on the list on a Category 1 basis. **As we have in the past, we urge CMS to establish default coverage of all services that are safe to provide via telehealth, rather than covering only a small list of approved services. However, while the agency considers this change and learns more about the provision of care via telehealth, we strongly support your proposal to permanently retain some of the services authorized for delivery via telehealth during the PHE.**



CMS also proposes to create on a temporary basis a new Category 3 for adding services to the Medicare telehealth list. This Category 3 would be for services added during the PHE for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the services as permanent additions under the criteria for Category 1 or 2. **The AHA strongly supports the creation of Category 3. We urge CMS to go one step further and make Category 3 a permanent part of the Medicare telehealth list.** In the rule, CMS states that part of its motivation for creating Category 3 is to prevent a sudden disruption to clinical practice and patients' access to services when the PHE declaration expires. This builds upon the subregulatory process the agency adopted during the pandemic to rapidly add services to the Medicare telehealth list. **We recommend the agency permanently retain Category 3 and the accompanying processes outlines in this rule, and establish it as a subregulatory way to temporarily add services to the Medicare telehealth list.** Doing so would provide a much faster timeline than annual rulemaking allows, providing much-needed regulatory flexibility for the adoption of essential and innovative technologies in response to the emergence of new challenges.

Regarding the specific services CMS proposes to add to the Category 3 list, we thank the agency for including Levels 1-3 emergency department (ED) visits. **However, we urge CMS to also include Levels 4-5 ED visits on the Category 3 list of services.** When an ED provider begins a telehealth visit with a patient, they do not know in advance the level of visit. Including on the Category 3 list only some ED visit levels would create confusion for providers in a field where quick decision-making is critical. Allowing higher-acuity ED visits to be provided via telehealth does not mean those patients will wrongly be kept out of the hospital. In fact, it means just the opposite – that those patients could get immediate, on-demand access to emergency providers who can determine the appropriate course of care. Therefore, we urge CMS to add Levels 4-5 ED visits to the Category 3 list and consider adding them to the permanent Medicare telehealth list.

**We also recommend CMS add to the Category 3 list of services initial nursing facility visits.** As demonstrated by frequent, deadly outbreaks of COVID-19 at nursing facilities, the patients in these facilities are some of the most vulnerable in the nation. They are precisely those who should not be transferred between different health care environments due to the extremely unstable condition of most of these patients. Moreover, our members have indicated that providers are able to conduct more accurate and effective assessments of nursing facility patients in their own environments because this gives providers much more visibility into the patients' surroundings and living conditions. Thus, we urge CMS to add nursing facility visits to the Category 3 list and consider whether it could permanently add these visits to the Medicare telehealth list.

With regard to physical therapy (PT), occupational therapy (OT) and speech language therapy (SLP), CMS continues to believe it should not add these services to the

Medicare telehealth list because they are usually performed by PTs, OTs and SLPs who are not authorized to deliver Medicare telehealth services. We agree with the agency that adding PT, OT and SLP codes to the Medicare telehealth list at this time would be confusing. **In order to avoid that confusion, we strongly encourage CMS to work with Congress to secure authority to expand the types of providers that can deliver and bill for telehealth services to include, among others, PTs, OTs and SLPs.** These services have been among the most successfully delivered via telehealth during the COVID-19 pandemic; as such, data on their outcomes will be forthcoming. These data could support efforts by CMS to expand the eligibility to deliver telehealth services to additional practitioners.

*Communications Technology-based Services.* As detailed in our [comment letter](#) on the CY 2019 PFS proposed rule, the AHA strongly supports the CTBS services CMS created, including virtual check-ins, remote evaluation of pre-recorded patient information, e-visits and online assessment and management visits. **As such, the AHA supports CMS's proposed CTBS policies, including the proposed HCPCS codes for remote evaluation of patient information and virtual check-ins for use by practitioners who cannot independently bill Medicare for E/M services. We also support your proposal to allow patient consent for CTBS to be documented by auxiliary staff under general supervision.**

**We also greatly appreciate CMS's extension of CTBS services to new patients during the PHE. We strongly urge CMS to make permanent this policy.** Given that the purpose of many of the CTBS services is to assess whether a patient requires an in-person visit, it would be counterproductive to not extend such services to new patients. If a new patient needs an in-person visit, the CTBS visit can allow a provider to make that determination, and the provider can then establish a relationship with the patient when he or she comes in for the in-person visit. If the CTBS visit makes clear that the patient does not need an in-person visit, the CTBS visit would have saved the provider, patient and health system the costs of an in-person visit. In general, CTBS encounters are much lower resource encounters than telehealth or in-person visits; these should thus be made available to the greatest number of patients.

*Comment Solicitation on Continuation of Payment for Audio-only Visits.* During the PHE, CMS established separate payment for audio-only E/M services described by previously non-covered CPT codes 99441-99443. CMS also temporarily waived the requirement that telehealth services be provided by two-way, audio/video communication technology so as to add the audio-only E/M services to the Medicare telehealth list of services and permit other services on the list to be delivered via audio-only connection.

**The AHA enthusiastically supports CMS's ongoing efforts to reimburse audio-only services.** This flexibility has enabled our members to maintain access to care for numerous patients that do not have access to broadband or video conferencing technology. It has also protected the continuity of care when a video connection fails, a

situation with which the nation is now intimately familiar due to the COVID-19 pandemic. In those situations, if a provider and patient are connected via audio/video technology, and their video connection fails, they can default to an audio-only visit and pick up right where they left off. Additionally, audio-only behavioral health services have become extremely popular with patients who are more comfortable without hour-long, face-to-face visits.

We support the agency's consideration of coding and payment for an audio-only service similar to a virtual check-in, but we urge the agency to go further for the patients who most need these services. **Specifically, we urge CMS to work with Congress to allow, as clinically appropriate, Medicare coverage and payment for telehealth services that are conducted via audio-only communication.**

**Simultaneously, we urge CMS to maintain payment for CPT codes 99441, 99442, and 99443 as audio-only E/M services.** During the pandemic, CMS waived certain regulatory requirements to add these codes to the list of Medicare telehealth services. However, CMS could now remove these codes from the Medicare telehealth list and instead reimburse for them in a similar manner to how it covers and pays for CTBS. We understand the current statutory restrictions on CMS paying for Medicare telehealth services delivered via audio-only connection, but these three CPT codes were never designated as Medicare telehealth services until CMS exercised its authority to make them so. As such, we recommend CMS exercise its authority once again to remove these codes from the Medicare telehealth list for the time being and pay for them separately. We also recommend CMS consider what other services it could make available to patients by creating more codes for audio-only CTBS.

*Direct Supervision by Interactive Telecommunications Technology.* During the PHE, CMS allowed physicians and non-physician practitioners to provide direct supervision virtually, using interactive audio/video real-time communications technology. In this rule, CMS proposes to extend this policy through the calendar year in which the PHE ends or Dec. 31, 2021, whichever is later. **The AHA strongly supports the COVID-19 pandemic policy regarding direct supervision by interactive telecommunications technology and CMS's proposed extension of it. We urge the agency to make this policy permanent and stand ready to assist in determining appropriate guardrails for its operationalization.**

## **REMOTE PHYSIOLOGIC MONITORING (RPM) SERVICES**

The AHA appreciates that CMS provides guidance in the proposed rule related to remote physiologic monitoring (RPM) services. Addressing outdated policies that seek to limit, rather than enable, the use of information technology tools must be addressed. We concur with several of the agency's clarifications and offer suggestions on other proposals to ensure the full value of RPM can be realized for patients and providers.

In recent years, innovative technologies in health care, including RPM tools, have been increasingly used to expand access to care and improve outcomes for patients. The data generated by these devices give clinicians a vital lens through which they can track a patient's health status and intervene early, often preventing emergency department visits and other complications. During the PHE, remote monitoring has been a critical tool allowing hospitals and health systems to conserve critical PPE and limit health worker exposure while collecting valuable data to inform care decisions.

*Proposal on Interactive Communication.* With respect to CPT Codes 99457 and 99458, CMS proposes that the minimum 20 minutes of interactive time with a patient in a billing period be "face-to-face time with the patient or patient's caregiver/medical decision-maker" and for services not typically furnished in person with the patient, it will interpret time to mean "the time spent in direct, real-time interactive communication with the patient." **The AHA urges CMS to reconsider this proposal as it fails to account for review of the data generated.** RPM is not a Medicare telehealth service and therefore accrual of time should not be dependent on synchronous interaction with a patient or caregiver. This runs counter to the very nature of remote monitoring.

*RPM Codes 99453 and 99454.* CMS proposes that, in scenarios where a single patient is using multiple medical devices, the CPT codes 99453 and 99454 may be billed only once per patient each 30-day period. The AHA is concerned that CMS' proposal fails to account for patients who may be monitored by multiple clinicians under separate care plans during the same 30-day period. **CMS should clarify that the limitation is on the number of times a provider can bill for these codes within a 30-day period rather than the number of providers who can bill during that period.** It is critical to ensure patients have access to RPM for multiple conditions where remote monitoring is appropriate to promote improved health outcomes.

*Requirements for Established Patients.* **The AHA urges CMS to reconsider its proposal to reinstate the requirement that RPM services be furnished only to established patients at the conclusion of the PHE.** The use of RPM for acute conditions has underscored the value of these services for patients without an established relationship and this flexibility should be made permanent.

- *Monitoring Period.* The AHA appreciates that CMS acknowledges there may be clinical scenarios that warrant a shorter monitoring period than 16 days in a 30 day period, suggesting a period of 8 days may be reasonable. **We agree with CMS that establishing an option for a shorter monitoring period would expand the applications of RPM to include post-surgical monitoring and other scenarios where remote monitoring would be beneficial.**

## **MEDICAID PROMOTING INTEROPERABILITY PROGRAM**

The AHA supports CMS's proposal to align eCQMs for Medicaid Eligible Professionals (EPs) with eCQMs on the final list of quality measures established for the Merit-Based Incentive Payment System's 2021 performance period. We further support the agency's proposal to continue the 2020 reporting requirements for 2021. These policies will promote stability and reduce clinician burden in the final year of the program.

## **UPDATES TO CERTIFIED EHR TECHNOLOGY**

The AHA appreciates that CMS in the proposed rule takes initial steps to harmonize updates to certified EHR technology (finalized in the ONC Cures Act final rule) with the agency's reporting programs that require use of certified EHR technology.

*Quality Payment Program and Promoting Interoperability Program.* The AHA supports CMS's proposal to harmonize requirements and provide flexibility to health care providers to use technology certified to either the current 2015 Edition certification criteria or the new 2015 Edition Cures Update during the transition period. This is critical due to the varying timelines on which these changes will be implemented by hospitals and health systems.

We are concerned, however, that the Aug. 2, 2022 deadline fails to account for any period of time between when IT developers are expected to have the newly certified technology available and when providers are required to have such technology fully implemented and in use for the QPP and Promoting Interoperability Programs. Once upgrades are deployed, a period of testing is required to identify and resolve issues with the software and provide necessary training to end users. These activities are critical to ensuring patient safety is not compromised.

**The AHA urges CMS to extend flexibility to use technology certified to either the current 2015 Edition certification criteria or the new 2015 Edition Cures Update for at least an additional six months to Feb. 2, 2023.** This will ensure adequate time for providers to fully implement the new version of certified EHR technology for use in CMS quality and reporting programs.

*IQR Program.* The AHA supports CMS's proposal to allow hospitals' use of either technology certified to the 2015 Edition criteria (as previously finalized in the FY2019 IPPS final rule) OR technology certified to the 2015 Edition Cures Update, beginning with the CY2020 reporting period and for subsequent years. Should CMS choose to revisit this flexibility in future rulemaking, we urge the agency to consider our comments above regarding the importance of providers having adequate time to fully implement technology upgrades.

## **PROPOSAL TO REMOVE SELECTED NATIONAL COVERAGE DETERMINATIONS (NCDs)**

In this rule, CMS proposes to sunset nine NCDs on the basis that they no longer contain clinically pertinent and current information. While we support CMS's ability to update outdated coverage determinations, we urge the agency to do so in a way that does not contract coverage and access nationwide. Specifically, we urge CMS to think critically about which coverage determinations are most appropriately made at a national, centralized level, and which can be safely delegated to local entities. We also recommend CMS consider before sunsetting NCDs whether services covered by them should have a minimum level of coverage, and instruct Medicare Administrative Contractors (MACs) accordingly. We also suggest CMS consider whether sunsetting an NCD may result in inconsistent coverage determinations by MACs, which have historically provided different determinations for a single service, thereby creating a confusing array of benefits – or lack thereof – for patients. Finally, we are concerned that CMS's proposal to eliminate NCDs further increases variation in coverage of Medicare services across beneficiaries. Specifically, because Medicare Advantage (MA) plans may not adhere to all of the local coverage determinations (LCDs) in a given market, such as in instances when they opt to apply the LCDs of another MAC in the plan's region, beneficiaries in the same region may have differential coverage.

## **CLINICAL LABORATORY FEE SCHEDULE REPORTING REQUIREMENT CHANGES**

As required by provisions in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, CMS proposes to revise the clinical laboratory fee schedule (CLFS) so as to delay by one additional year the requirement that certain "applicable laboratories," including hospital outreach laboratories, report their private payer data. Additionally, the CARES Act limits the reduction in payment annually under the CLFS. **The AHA supports CMS's proposal to implement these CARES Act provisions by delaying the next CLFS data reporting period until 2022. Further, the AHA supports extending the phase-in of payment cuts for CLFS services through CY 2024, resulting in a zero-percent reduction for CY 2021, and a cap of 15% on payment reductions for CYs 2022 through 2024.**

## **MEDICARE PART B BENEFIT FOR OPIOID TREATMENT PROGRAMS (OTPs)**

OTPs are healthcare entities that focus on providing medication-assisted treatment (MAT) for people diagnosed with opioid use disorder (OUD). Enacted October 2018, Section 2005 of the Substance Use-disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) For Patients and Communities Act established a new Medicare Part B benefit category for OUD services furnished by an OTP beginning on or after Jan. 1, 2020. In this rule, CMS proposes several refinements to the OTP benefit and offers clarifications on program logistics in response to stakeholder questions; the agency also proposes to implement two other provisions of the SUPPORT Act.

**The AHA appreciates CMS' continued commitment to addressing the opioid crisis, and values how CMS has listened to providers and implemented additional flexibility and reimbursable services in the benefit.** We encourage the agency to continue to look for ways to improve this benefit and access to care for patients not only with OUD, but other substance use disorders as well.

*Payment for Naloxone Dispensing.* As with last year's drug pricing provisions, the AHA is concerned about the proposal to price take-home supplies of nasal and auto-injector naloxone using the average sales price or wholesale acquisition cost, respectively, without the standard six percent add-on. This add-on is used in pricing other Part B drugs to account for overhead costs or additional mark-ups accrued in traditional drug distribution channels. However, CMS states that it believes "many OTPs purchase the drugs from manufacturers," thus limiting these extra costs. **We again believe that the agency has a legal obligation to include a factor for overhead; CMS should also adequately justify using data any add-on less than the standard 6%. That obligation is not met by an unsupported assertion of belief.**

In addition, we take issue with the callous language used to justify the frequency limit of naloxone dispensing. In the rule, CMS states "there are other services that OTPs should already be performing...that should limit the need for this emergency treatment" and thus providers should not need to bill for dispensing more than once every 30 days. We hope that the agency recognizes the complex nature of OUD, and even patients receiving the highest quality care are at risk for overdoses and other adverse effects associated with the illness of addiction. The rule notes that most Part D plans do not limit the amount of naloxone beneficiaries are able to receive in a given month, and even when they do, these beneficiaries use only two units within a 30-day period. Using this data, it is unclear why the agency sees the need to impose a frequency limit in order to discourage misuse, since its own data does not appear to indicate such a risk. **We believe CMS should reconsider its frequency limitation on naloxone dispensing and instead defer to prescribers' medical expertise for determining how much naloxone is appropriate to dispense to patients at risk for overdose.**

*Periodic Assessments.* We understand CMS' reasoning to price the code for these assessments on a crosswalk to a level 4 office/outpatient E/M visit due to the complexity of patients requiring periodic assessments. We also appreciate that CMS recognizes the need to allow these periodic assessments to be furnished via two-way, interactive audio-video communication technology; we recommend that CMS extend this allowance permanently, instead of solely for the duration of the COVID-19 PHE. This allowance would better extend the reach of the professionals who provide these assessments, thus increasing access to care for severely ill individuals.

*Electronic Prescribing of Controlled Substances (EPCS).* As noted in our [comments](#) on the CY 2021 Inpatient Prospective Payment System (IPPS) Proposed Rule, the AHA has significant concerns regarding EHR vendor capacity to deploy, and hospitals' and

health systems' capacity to implement, such a high volume of IT system changes on a short timeline; this is especially the case in light of the redirection of resources to support technology and data needs specific to the COVID-19 PHE. Because of this, we appreciate CMS' proposed delay of the requirement to conduct e-prescribing of Schedule II-V controlled substances using the NCPDP SCRIPT 2017071 standard to Jan. 1, 2022.

Indeed, a further delay might be necessary, as many providers – small hospitals in particular – struggle to implement IT upgrades due to the cost and logistical barriers to working with EHR vendors. Due to U.S. Drug Enforcement Agency requirements, the EPCS capability is often an add-on to existing EHR systems; this can result in added costs and workflow challenges. In addition, while many providers have experience using the required standard under the Part D program for certain e-prescriptions, newly Medicare-eligible OTPs (which commonly describe and dispense controlled substances for use in MAT) likely have not used this standard before. In fact, as CMS notes in its background on e-prescribing, there is a mismatch in EPCS capabilities nationwide. While 97% of U.S. pharmacies are capable of processing EPCS, only 49% of prescribers were capable of EPCS. Even if the EHR contains the EPCS capability, there has been a low uptake in physician practice; in other words, organizations will need to engage in staff training and implementation of workflow alterations. Even a one-year delay might not be sufficient, considering the myriad other pressures, IT-related and otherwise, facing providers.

To be clear, the AHA agrees that e-prescribing is appropriate for controlled substances due to the security and data advantages it provides. However, as we will note in our comments on the separate Request for Information on this requirement, **we recommend that CMS move forward with a gradual implementation timeline, along with a period of enforcement discretion and a lack of penalties due to the current strain on IT systems.**

*Screening for SUD in Physicals.* Section 2002 of the SUPPORT Act requires the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential substance use disorders and a review of any current opioid prescriptions. We agree with CMS that the elements proposed for addition to the IPPE and AWV to comply with the SUPPORT Act requirement are similar and in line with the existing elements of the exams, and thus will not add significant burden for providers.

## **QUALITY PAYMENT PROGRAM**

Mandated by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the QPP began on Jan. 1, 2017, and includes two tracks – the default MIPS, and a track for clinicians with a sufficient level of participation in certain advanced alternative payment models (APMs). Most of the rule's proposals affect the CY 2021 performance period, which would affect Medicare reimbursements in CY 2023.



Since the program's inception, the AHA has urged CMS to implement MIPS in a way that is gradual and flexible; measures providers accurately and fairly; minimizes unnecessary data collection and reporting burden; focuses on high-priority quality issues; and fosters collaboration across the silos of the health care delivery system. A number of MIPS policies have aligned with these principles, including CMS's gradual increases to reporting periods, data standards and performance thresholds for receiving positive or negative payment adjustments. CMS has also implemented a facility-based measurement approach and removed some outmoded quality measures.

However, in last year's PFS final rule, CMS signaled a dramatically new direction for the MIPS program by adopting a framework for MIPS Value Pathways (MVPs) that the agency intended to implement beginning in 2021. The AHA raised numerous concerns about the design, feasibility and equitability of MVPs. **We are pleased that in this rule, the agency proposes to delay implementation of MVPs until CY 2022 at the earliest. At the same time, we strongly urge CMS to conduct further analysis and obtain additional stakeholder input before proceeding with MVPs.**

In this rule, CMS also proposes a new MIPS APM Performance Pathway (APP) that the agency believes would be a complementary to MVPs. The APP would replace the APM scoring standard and require all MIPS to report the same six measures. **The AHA has significant concerns about the design of the APP, and urges CMS not to finalize the proposal at this time.**

*MIPS Value Pathways.* As we understand it, MVPs are intended to align and reduce reporting requirements across the four MIPS performance categories. Built over time, the MVPs would organize the reporting requirements for each MIPS category around specific specialties (e.g., ophthalmology), treatments (e.g., major surgery) or other priorities (e.g., preventive health). CMS intended to propose specific MVPs in this rule to implement starting with the CY 2021 performance period. However, CMS notes it is deferring these proposals in light of the COVID-19 pandemic until at least the CY 2022 performance period. The agency also proposes a number of additional principles to guide the development of future MVPs.

**The AHA agrees that moving forward with MVPs in CY 2021 is too much, too soon, especially in light of the COVID-19 PHE. However, there remain a number of conceptual problems with MVPs, and we are not confident that the agency's goal of beginning to implement MVPs in CY 2022 is sufficient time to address them. For this reason, we again urge CMS not set any date certain to move forward with MVPs unless and until it can address several issues.**

**First, CMS would need to ensure there are enough measures available to create MVPs applicable to the more than 1 million eligible clinicians that currently participate in the MIPS program.** Given the wide range of specialty types participating in the MIPS, this is a daunting task. Furthermore, given CMS's correct focus on

implementing “Meaningful Measures” in its programs, it would seem misguided to add measures simply for the sake of having enough to create an MVP. However, if the agency’s concept is to assign clinicians to particular MVPs, it would need to ensure it has measures that meaningfully apply to their clinical practice. We suggest that CMS attempt to construct several more “prototype” MVPs, determine how many clinicians it could potentially assign to each, and obtain clinician input on whether the measures in those MVPs actually do align with their clinical practice.

**Second, CMS must ensure that using an MVP approach would provide a fair, equitable comparison of performance across clinician and group types and specialties.** If CMS’s ultimate intention is to assign clinicians to particular MVPs, then their goal should be that clinicians have comparable opportunities to perform well. Stated differently, CMS would need to ensure that some MVPs are not inherently “easier” to score well on than others. This, too, is a profoundly challenging issue to address. However, we suggest that CMS use the “prototype” MVP analysis articulated above to look at the performance distributions across MVP models to determine whether any specialty types or group types score any worse than others.

**Third, the AHA remains concerned about the feasibility and potential administrative burden of MVP approach for a multi-specialty group practices.** We have previously urged the agency to consider approaches that allow multi-specialty practices that operate under a single tax ID number (TIN) to identify sub-groupings within their practices; this could then be used to measure and report separately under the MIPS (i.e., “decomposing” the TIN). We believe such an approach would be necessary to implement MVPs. However, the key distinction between the current MIPS and the MVP approach is that decomposing a TIN may be compulsory rather than voluntary. As a result, multi-specialty groups may actually face an increase in their reporting burden, which would contradict CMS’s stated goal of reducing provider burden.

**Lastly, the AHA believes two of the proposed new implementation principles for MVPs are misguided and urges CMS to reconsider them.** First, we question whether the proposed principle that calls for all MVPs to report “the entire set” of Promoting Interoperability measures is appropriate or feasible. Yet, we do not know what future iterations of the Promoting Interoperability category will look like, and whether future requirements would be appropriate for all clinicians. Furthermore, it is not clear how one could ask those clinicians and groups who currently receive the hospital-based clinician exclusion from Promoting Interoperability to meet this requirement.

Second, we disagree with CMS’s proposed principle to include a hospital-wide readmissions measure in all MVPs. While this measure could be relevant to some specialties, we seriously question whether it would be equally applicable to the wide range of specialties that participate in the MIPS. For example, it is not clear how one might hold a group of dermatologists accountable for performance on hospital-wide

readmissions when many of the types of services they offer are so inherently ambulatory in nature.

*MIPS APM Performance Pathway.* Under current MIPS policy, MIPS-eligible clinicians and groups participating in certain APMs – including the Medicare Shared Savings Program (MSSP) – receive special scoring under the MIPS APM scoring standard. For CY 2021, CMS proposes to sunset the MIPS APM scoring standard, and replace it with the APP. While the APP is similar to the APM scoring standard in several ways, it would significantly diverge from it by requiring clinicians and groups to report and be scored on a common set of six quality measures. These measures reflect diabetes control, depression screening/follow up, blood pressure control, patient experience, hospital-wide readmissions and admissions for multiple chronic conditions. This requirement would apply to APP participants regardless of the APM model in which they participate.

**The AHA believes that requiring all MIPS APMs to report on the same six quality measures would be a misguided, “one size fits all” policy that fails to improve upon current policy. We urge CMS not to adopt it, and instead to retain the existing requirement that MIPS APMs report the measures already required under their models.** In the first place, we do not understand how the six proposed measures could be equally relevant to all 12 of the APMs that currently meet MIPS APM requirements. The design and goals of these programs all differ significantly, and each program’s quality measurement requirements are supposed to align with and help advance those programmatic goals. That is why in designing the APM Scoring standard, CMS allowed the models to fulfill the quality measurement requirement by reporting the measures required under each model.

At best, the measures CMS has proposed for all MIPS APMs would be a forced fit for some of the models. For example, for clinicians participating in the Bundled Payment for Care Improvement Advanced (BPCI A) model, it is not clear how depression screening and follow up are relevant to those models that are focused on procedural inpatient care. At worst, asking all of the models to report on these measures would simply add to clinicians’ and group’s administrative burden by asking them to attempt to report measures that have little to do with the care they provide. This would seem to contradict the stated goals of CMS’s Meaningful Measures initiative.

*MIPS Quality Category.* For CY 2021 quality reporting, CMS would mostly carry over CY 2020 reporting requirements and scoring approaches. However, CMS proposes three notable changes – the removal of the web interface reporting option, the incorporation of telehealth into Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey questions and sampling methodology, and a revised benchmarking approach specific to the CY 2021 performance period.

**The AHA opposes CMS’s proposal to eliminate the web interface reporting option from the MIPS program. We also oppose its removal from the Medicare Shared**

**Savings Program (MSSP).** We refer the agency to the MSSP section of this letter for additional details.

**The AHA supports CMS's proposals to incorporate telehealth into CAHPS for MIPS survey-and-sampling methodology.** Specifically, CMS would include a telehealth survey item that will ask patients to report whether they used telehealth (e.g., phone or video visit) during the CY 2021 performance year, and revise the survey cover page to include reference to care received in telehealth settings. In addition, CMS would codify the CPT and HCPCS codes added in the March 31, 2020, interim final rule expanding covered telehealth services in its definition of primary care services for the CAHPS assignment methodology. Given the uptick in the use of telehealth services during the COVID-19 pandemic, it is sensible to ensure the CAHPS survey reflects these changes in delivery.

**The AHA also supports CMS's proposed quality measure benchmarking policy for CY 2021.** Current MIPS policy requires CMS to, where possible, use historical data to set measure score benchmarks. However, in light of the COVID-19 public health emergency, CMS made data reporting for the CY 2019 reporting period optional. We agree with CMS that it may not have a representative sample of data to use from CY 2019 to set benchmarks, and that using data from CY 2021 itself may be more appropriate.

*MIPS Cost Category.* CMS does not propose changes to the current set of MIPS cost measures, but does propose to increase the weight of the cost category to 20% for CY 2021 reporting (CY 2023 payment), and to the statutorily required 30% by for CY 2022 reporting (CY 2024 payment). **While the AHA understands that CMS is implementing statutory requirements, we remain very concerned about the reliability, accuracy and meaningfulness of the measures included in the cost category. We strongly urge CMS to take the steps we outlined in our [comment letter](#) on the PFS CY 2020 proposed rule to improve the cost measures, including pursuing NQF endorsement of all cost measures, re-examining the attribution methodologies, and incorporating risk adjustment for social risk factors where necessary and appropriate.**

*MIPS Promoting Interoperability Category.*

Reporting Period. The AHA appreciates that CMS proposes to continue certain policies that offer stability to the program and reduce burden for clinicians, particularly in light of the ongoing COVID-19 PHE. **AHA consistently has advocated for an EHR reporting period of any continuous 90-day period and strongly supports CMS's proposal to continue this policy for CY 2022 and future years.**

Query of PDMP Measure. As noted in previous comments, PDMP integration with certified EHRs continues to pose a number of challenges for clinicians. **The AHA supports the agency's proposal to retain the query of prescription drug**

**monitoring program (PDMP) measure under the electronic prescribing objective as optional and increase the bonus points from five to ten.** We further support mitigating burden on clinicians by continuing to require only a “yes/no” attestation versus a numerator/denominator for this measure. This appropriately recognizes that technical capabilities to count PDMP queries vary across EHRs and can be impacted by state laws prohibiting integration and storage of PDMP data.

We concur with CMS’s lengthy review and description of considerations that supports additional time to address challenges including EHR-PDMP integration, variation in implementation of PDMP queries into health IT and clinical workflows, and lack of robust certification specifications and standards. Key federal and private sector efforts are currently underway aimed at improving technical approaches to EHR-PDMP integration, addressing stakeholder concerns around readiness, implementing key PDMP-related provisions of the SUPPORT for Patients and Communities Act (P.L. 115-271) and assessing alternative measure approaches.

Health Information Exchange Objective. CMS proposes to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to better reflect the measure’s intent. The new proposed name would be Support Electronic Referral Loops by Receiving and *Reconciling* Health Information. **The AHA supports this change and concurs with CMS that including the concept of “reconciling” versus “incorporating” health information will reduce confusion among clinicians.**

Health Information Exchange Bi-Directional Exchange Measure. CMS proposes to add a new measure for the 2021 performance period: Health Information Exchange (HIE) Bi-Directional Exchange. CMS uses “bi-directional exchange” to indicate a clinician’s EHR can support sending, receiving and incorporating information for every patient via an HIE.

**The AHA supports the addition of this optional measure as an alternative to the two existing HIE measures – Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Incorporating Health Information.** We further support that this measure would be reported via attestation.

We appreciate that CMS acknowledges the variation that exists in the availability and capabilities of HIEs across the country. The AHA concurs that gaps exist impacting clinician engagement with HIEs. We agree that HIEs are an important component of the health data exchange ecosystem and share CMS’s belief that the COVID-19 PHE has underscored the importance of bi-directional exchange.

***MIPS Complex Patient Bonus.* The AHA supports CMS’s proposal for a one-time doubling of its complex patient bonus for the CY 2020 performance period, and**

**thanks the agency for considering the impact of the COVID-19 PHE in determining MIPS performance.** Since the CY 2018 performance period, CMS has calculated a “complex patient bonus” to better account for clinical and sociodemographic differences across patient populations. This bonus awards up to five points to the MIPS final scores of clinicians and groups based on their hierarchical condition category (HCC) scores, and their ratio of patients dually eligible for Medicare and Medicaid. For the CY 2020 reporting period, CMS would double the complex patient bonus such that clinicians would receive up to 10 points.

We agree with CMS that the COVID-19 public health emergency has significantly affected patient complexity. Emerging evidence suggests that needed care for some patients has been deferred or delayed because of the COVID-19 pandemic. As a result, by the time patients receive care, their health issues may have taken on greater complexity. In addition, COVID-19 patients themselves can have long, intensive and often complex care trajectories that can span many months after they might receive hospital services. Therefore, it is appropriate to recognize this impact by increasing the complex patient bonus.

***MIPS Performance Threshold Score.* The AHA supports CMS’s proposal to lower the MIPS performance threshold score for the CY 2021 performance/CY 2023 payment year from 60 points to 50 points in recognition of the impact of the COVID-19 PHE.** The performance threshold score is the score above which positive payment adjustments apply and below which negative adjustments apply. Given the profound impact of the COVID-19 pandemic on the health care field, lowering the performance threshold certainly is appropriate.

## **QUALITY PAYMENT PROGRAM – ADVANCED ALTERNATIVE PAYMENT MODELS**

The Medicare Access and CHIP Reauthorization Act (MACRA) provides incentives for physicians who participate in advanced APMs. These include a lump-sum bonus payment of 5% of payments for professional services in 2019 through 2024; exemption from MIPS reporting requirements and payment adjustments; and higher base payment updates beginning in 2026. For the most part, advanced APM criteria and processes carry over from prior rulemaking, and CMS proposes few changes.

**The AHA supports CMS’s proposed revision to calculating Qualifying Participant (QP) threshold scores.** As the agency correctly notes, some advanced APMs use prospective beneficiary attribution. Yet, under current policy, those prospectively-attributed beneficiaries could be included in the denominators of other APMs that do NOT use prospective attribution. This makes it more challenging for those other APMs to meet the QP threshold needed to qualify for the advanced APM track. Therefore, it is appropriate to exclude prospectively-attributed beneficiaries from the QP score denominators of those APMs that do not use prospective attribution.

**The AHA also supports CMS's proposal to establish a limited targeted review process for the advanced APM track.** The MIPS program has long provided a process that allows clinicians and groups to review and help correct potential errors in how CMS has calculated performance, but the advanced APM track does not have such a policy. The targeted review policy would allow APM entities to ensure their eligible clinician lists are correct, and therefore, that their QP and other scores are calculated appropriately.

## **MEDICARE SHARED SAVINGS PROGRAM (MSSP)**

CMS proposes significant changes to the MSSP quality measurement approach beginning with the 2021 performance year. The agency suggests the changes are intended to bring the MSSP quality measurement approach into closer alignment with the MIPS quality category. CMS also proposes updates to the MSSP's attribution methodology.

*Quality Measure Set.* **While the AHA supports the concept of streamlining and focusing quality measure sets, we are not confident that the measure set CMS has proposed for the MSSP is best suited to advancing the program's goals. We urge CMS to obtain further stakeholder input before finalizing these changes.** CMS's proposed policy would require MSSP ACO participants to report on the same six measures that are proposed for the new MIPS APP. We acknowledge that versions of these six measures already are used in the MSSP program. However, as we note below, CMS has proposed a significant change to how the data would be reported by eliminating the web interface reporting option, which would significantly affect how ACO performance is benchmarked in the coming years. As a result, MSSP participants do not know how they would fare using this specific configuration of measures, which is especially alarming given that CMS also proposes to eliminate any pay-for-reporting years (also discussed below).

Additionally, the proposed changes to the measure set come on the heels of significant changes to the structure of the MSSP program as CMS implemented its New Pathways approach. The implementation of drastic changes to measurement as ACOs continue to adapt to the new program structure is enormously disruptive to ACOs, especially as they, too, grapple with the significant impacts of the COVID-19 PHE. Instead of finalizing the changes now, we encourage CMS to work with stakeholders to review the entirety of the current ACO measure set, and use their input to help identify which measures are the best candidates for elimination. The agency could consider using input from the Measure Applications Partnership (MAP) as a part of its upcoming cycle to obtain multi-stakeholder input on these changes. Again, the AHA strongly supports the concept of streamlining measure sets; however, we fear the potential for significant unintended consequences if the MSSP measure sets are adopted too precipitously.

*Removal of Web Interface Reporting.* **The AHA does not support the removal of the web interface reporting option for ACOs at this time.** The web interface has been used by ACOs since the MSSP's inception to report data on non-claims based measures used in the program. The web interface collects data on Medicare beneficiaries participating in the MSSP, and has a set of data collection and attribution approaches associated with it. However, CMS proposes to eliminate it because its use outside of the MSSP program is limited, and the agency is seeking to bring the MSSP quality measurement approach into closer alignment with the MIPS.

While we appreciate the potential benefits of greater alignment between programs, there are profound differences between how data are submitted in the "regular" MIPS program and how they are reported by ACOs using the web interface. In the first place, the data collection types that would now be available to ACOs – EHRs, qualified registries and qualified clinical data registries – all require data to be collected on an all-payer basis, and not simply on Medicare beneficiaries. For a program that is called the *Medicare Shared Savings Program*, and is intended to improve the care for Medicare beneficiaries, we question the appropriateness of including all-payer data.

Furthermore, allowing the use of multiple different reporting options in the MSSP could have significant impacts on measure benchmarks. There are differences in the measure specifications among each of these reporting mechanisms; it is possible, even when reporting on the same measure title, to receive different scores. For that reason, when CMS calculates performance benchmarks in the MIPS program, it creates separate benchmarks for each data collection type. Yet, CMS does not address in this rule how it intends to reconcile any potential performance differences among ACOs that may stem from differences in data collection types.

Unless and until CMS can address the two issues above, it is not appropriate to remove the web interface reporting option. At a minimum, we urge the agency to delay removal of the reporting mechanism until CY 2022 at the very earliest.

*Increase to Quality Performance Standard.* **The AHA does not support CMS's proposal to increase the quality performance standard for ACOs at this time.** We certainly appreciate CMS's intent to "raise the bar" on ACO performance. However, CMS proposes to require ACOs to achieve the 40th percentile of performance as compared to all MIPS quality category scores, as opposed to only ACO scores. As noted in the previous sections of this letter, there are numerous unresolved questions about whether it is appropriate to include non-Medicare patients in ACO quality performance assessment, and whether the inclusion of multiple data collection types would maintain equitable performance comparisons across all ACOs. Until those issues are resolved, it would be inappropriate to raise the performance threshold.

*Elimination of Pay-for-Reporting.* **The AHA opposes CMS's proposal to eliminate pay-for-reporting for first year of MSSP participation, as well as pay-for-reporting**



**for newly added or significantly revised measures.** For first-time participants in the MSSP, it takes significant resources to learn measure specifications, assess baseline performance and implement workflow changes – IT and otherwise – necessary for accurately capturing and improving quality performance. Furthermore, when CMS makes significant changes to existing measure specifications, providers must make several of these same adaptations. Given that CMS now scores MSSP ACOs on improvement over time, it is essential for CMS to establish an accurate performance baseline. Pay-for-reporting periods give ACOs the opportunity to ramp up their measurement and improvement capabilities in a sustainable fashion before their shared savings or losses are tied to quality performance.