American Hospital Association™
Advancing Health in America

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September 09, 2024

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

Submitted Electronically

RE: 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 Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations; 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) 2025.

The AHA applauds CMS' proposals to extend many telehealth regulatory flexibilities through 2025. There are, however, many statutory waivers that are also scheduled to expire at the end of the year. **As such, we urge CMS to work with Congress to extend these telehealth provisions.** Their expiration would result in a telehealth "cliff," risking reducing access to care for the millions of Americans who rely on virtual modalities to receive necessary services. As we have previously advocated, we cannot emphasize enough how essential waivers like removing geographic and originating site restrictions are to the provision of care and continued access to services.[1]

[1] https://www.aha.org/system/files/media/file/2023/01/aha-feedback-to-the-senate%20on-the-creating-opportunities-now-for-necessary-and-effective-care-technologies-connect-act-letter-1-30-23.pdf

We are also pleased that the agency proposes to exclude significant, anomalous and highly suspect (SAHS) from Medicare Shared Savings Program (MSSP) financial calculations. As we have previously commented, the inclusion of SAHS billing can have a significant impact on these calculations, in many cases resulting in a loss of shared savings.[2] We applaud the agency for taking quick action to develop proposals to address concerns raised by stakeholders.

However, we are deeply concerned with the proposed payment update, which would reduce payments by approximately 2.8% from their CY 2024 levels. This negative update comes after over two decades of conversion factor decrements and in the face of significant staffing shortages, rising inflation and unrelenting financial pressures. We are concerned that such a reduction in payment would pose significant risks to patients' access to care. Indeed, a recent Medicare Trustees report highlights the potential impact of continued payment decrements on disparities in care**. We urge CMS to work with Congress to provide a payment increase for 2025 and to develop a long-term plan for sustainable physician payment.**

Finally, we have concerns regarding CMS' proposed updates to Medicare Parts A and B overpayment policies. As we have previously commented, we continue to assert that CMS' reliance on *UnitedHealthcare Insurance Co. v. Azar* to remove "reasonable diligence" standards does not, in our view, hold what CMS understands it to hold.[3] **Additionally, while we appreciate that CMS acknowledges that additional time beyond 60 days is needed to complete investigations of overpayments, the proposed 180-day window to suspend reporting and repayment is insufficient. We urge CMS to provide sufficient exceptions when complex, multi-year or multi-site investigations necessitate additional time beyond 180 days.**

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 Jennifer Holloman, AHA's senior associate director of policy at jholloman@aha.org.

Sincerely,

/s/

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

Enclosure

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[2] https://www.aha.org/system/files/media/file/2024/07/Comment-Letter-on-CMS-Proposed-Rule-to-Mitigate-the-Impact-of-Significant-Anomalous-and-Highly-Suspect-Billing-Activity.pdf
[3] https://www.aha.org/system/files/media/file/2023/02/aha-comments-on-the-cms-proposed-rule-for-policy-and-technical-changes-to-the-medicare-advantage-program-in-cy-2024-letter-2-13-23.pdf

American Hospital Association
Detailed Comments on the Physician Fee Schedule Proposed Rules for Calendar Year 2025

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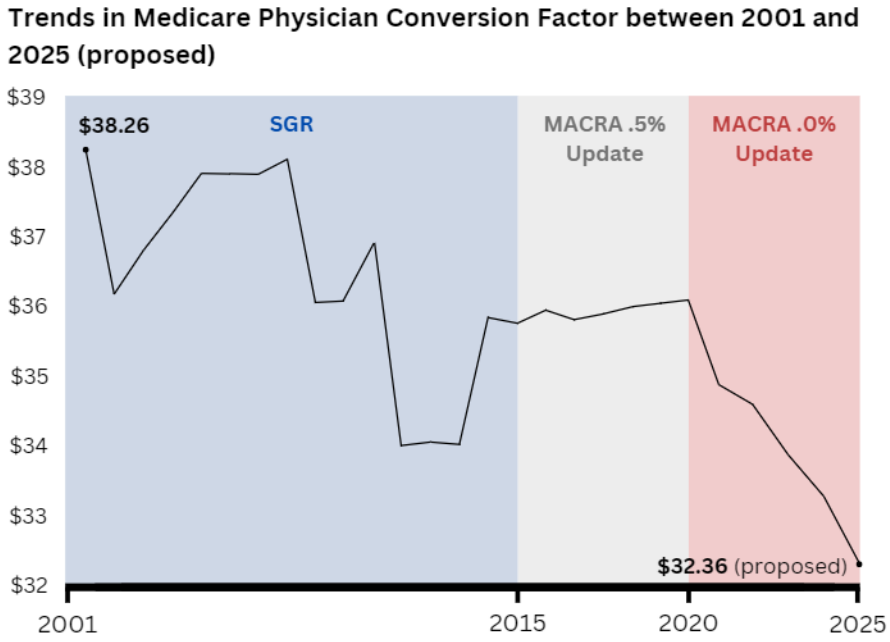
CONVERSION FACTOR UPDATE

CMS proposes to cut the conversion factor to $32.36 in CY 2025, a 2.8% reduction from the CY 2024 rate of $33.29. This update includes the expiration of a 2.93% increase in the PFS conversion factor for CY 2024 *only,* which was provided by the Consolidated Appropriations Act (CAA) of 2023 and 2024; a 0% update factor as required by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015; and a budget-neutrality adjustment.

The AHA considers the proposed conversion factor update woefully inadequate, especially considering the declines in physician reimbursement over the last few decades. Portions of MACRA were intended to fix legacy issues with the Sustainable Growth Rate (SGR) model, namely by replacing updates to the conversion factor, which had been tied to Gross Domestic Product increases, with updates that more accurately covered rising health care input costs (through the Medicare Economic Index or MEI). However, the conversion factor has continued to decline in real dollars. Specifically, as shown in Figure 1, it decreased by over 15% from 2001 through 2025.

Figure 1. Conversion Factor Trends 2001-2025 (proposed)



The conversion factor has declined even more when considering inflation. Specifically, data from the Medicare Trustee's report indicate that physician reimbursement has

dropped over 29% over the last 20 years when accounting for inflation.[4] The impacts of inflation and rising input costs continue to outpace the reimbursement for services covered by the PFS. Appropriately accounting for recent and future trends in inflationary pressures and cost increases in the payment updates is essential to ensure that Medicare payments for professional services more accurately reflect the cost of providing care. Proposed cuts to reimbursement stand in contrast to unprecedented increases in expenses from supply chain disruptions, workforce shortages, and labor and drug costs.

The latest Medicare Trustees report acknowledged the inadequacy of continued decrements to Medicare physician payments and the potential impact on quality of care. It states, "certain features of current law may result in some challenges for the Medicare program … the availability, particularly with respect to physician services, and quality of health care received by Medicare beneficiaries would, under current law, fall over time compared to that received by those with private health insurance."[5]

Finally, because many other payers tie their fee schedules to the Medicare PFS, providers' losses under Medicare are compounded by losses from other payers. Uncertainty in year-to-year payment updates and program extensions has only exacerbated hospital financial instability.

We are deeply concerned that the proposed conversion factor cut will have an extremely negative effect on patients' access to certain services. Hospitals and physicians alike cannot continue to absorb reductions in Medicare physician payments. This is especially true because these reimbursement shortfalls have come at a time of other headwinds. Hospitals and health systems are currently facing a national staffing emergency that could jeopardize access to high-quality, equitable care for patients and the communities they serve. Indeed, physician shortages are projected to exceed 86,000 physicians by 2036 according to the Association of American Medical Colleges. We have also seen how increased administrative burden contributes to physician burnout and clinicians leaving the field. The aging beneficiary population has increased demand for services, while the supply of clinicians continues to decline. More sustainable solutions are needed to ensure that updates to the PFS more accurately reflect the cost of delivering services.

Therefore, we urge CMS to work with Congress to provide a payment increase for 2025. Doing so would help protect patients' access to care and ensure Medicare maintains a robust network of providers of all specialties at a time when such access is critically important. **CMS also should work with Congress to develop a long-term plan for ensuring the adequacy of the conversion factor and associated payments to sustain all types of physicians and physician practices.** Years of enormous cuts

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[4] https://www.ama-assn.org/press-center/press-releases/medicare-trustees-warn-payment-issue-s-impact-access-care
[5] https://www.cms.gov/oact/tr/2024

are simply not sustainable. Additionally, we ask that CMS provide data showing the impacts of the reduced conversion factor across specialties.

REVISING THE MEDICARE ECONOMIC INDEX

The Medicare Economic Index (MEI) has long served as a measure of practice cost inflation and a mechanism to determine the proportion of relative value units (RVUs), and therefore payments, attributed to physician earnings (work) and practice expenses. It measures changes in the cost of resources used in medical practices including labor (both physician and non-physician), office space and medical supplies. These resources are grouped into cost categories and each cost category is assigned a weight and a price proxy. The MEI also includes an adjustment to account for improvements in the productivity of practices over time.

Historically, the MEI was based on 2006 data representing only self-employed physicians. In the CY 2023 PFS final rule, CMS rebased and revised the MEI to use publicly available data sources for 2017 input costs representing all types of physician practice ownership. However, the agency did not actually apply the new weights to its payment methodology in 2023 or 2024. This was because while it anticipated that revised weights would not impact overall spending for PFS services, they would impact the distribution of payments based on geography and specialty.

For CY 2025, CMS proposes to again delay the implementation of the rebased and revised MEI until future rulemaking. The agency cited a desire to continue to evaluate trends and impact on data following the COVID-19 public health emergency (PHE). **We share CMS' concerns about the redistributive effects of the new MEI and therefore support a further delay in its implementation.** Specifically, its adoption would cause significant cuts for cardiac surgery, neurosurgery and emergency medicine. In addition to significant specialty redistribution, geographic redistribution would also occur. For example, a significant reduction in the weight of office rent would lead to substantial reductions in payment for urban localities. These changes would, of course, come on top of the other substantial cuts physicians have seen in recent years, including the decrease in the conversion factor CMS has proposed in this year's rulemaking.

DETERMINING PRACTICE EXPENSE RELATIVE VALUE UNITS

Since 2007, the American Medical Association (AMA) Physician Practice Information Survey (PPIS) has supported the identification of direct and indirect practice expenses (PEs). Integration of PPIS data was phased into CMS RVU calculations between 2010 and 2014. The current rate setting is based on AMA PPIS data, supplemental data sources as required by Congress, and in certain circumstances, crosswalks in indirect PE allocation. In CY 2023, CMS requested feedback on strategies to update PE data collection and methodology. Stakeholders expressed concern regarding out-of-date data sources, inappropriate variation in reimbursement across places of service, and

inflexibility to changing practice/business models. CMS continues to solicit feedback on ways to update PE valuation methodologies. We are encouraged that CMS is evaluating strategies to improve PE data collection. We would request that CMS revisit this issue once updated PPIS data are available.

CHANGES TO PAYMENT FOR TELEHEALTH SERVICES

The AHA and our members continue to applaud the Administration's support of telehealth and ongoing efforts to develop a long-term structure for the efficient delivery of telehealth services. **We appreciate CMS' proposals to extend several telehealth flexibilities through 2025. However, we cannot emphasize enough the need for permanent extensions of both statutory and regulatory waivers.**

The telehealth flexibilities granted because of the COVID-19 PHE resulted in significant benefits to patient care; their continuance is needed now, more than ever, to ensure patients' continued access to high-quality care. The expansion of telehealth services has transformed care delivery, expanded access for millions of Americans and increased convenience in caring for patients, especially those with transportation or mobility limitations. Given current health care challenges, including major clinician shortages nationwide, telehealth holds tremendous potential to leverage geographically dispersed provider capacity to support patient demand.

However, there is currently a patchwork of temporary waivers for telehealth services that, barring further action, will expire at the end of 2024. If this occurs, we risk a telehealth "cliff" that would negatively impact patient access in all communities. **Recognizing both the immediate and potential long-term benefits of telehealth, we urge CMS to work with Congress to ensure that statutory waivers are extended including:**

- Permanently eliminating originating- and geographic-site restrictions, which would allow telehealth visits to occur at any site where the patient is located, including urban areas and the patient's home.
- Permanently eliminating in-person visit requirements for tele-behavioral health, which would ensure that patients do not need an in-person visit before initiating virtual treatment.
- Permanently removing distant site restrictions on federally qualified health centers and rural health clinics, which would ensure that they can continue to provide telehealth services.
- Permanently allowing payment and coverage for audio-only telehealth services.
- Permanently expanding eligible telehealth provider types to include physical therapists, occupational therapists, speech-language pathologists and audiologists.

While the temporary extensions have been much appreciated, they have also created uncertainty for patients, caregivers and providers. Operationally, many providers are scheduling appointments several months out (especially in provider shortage areas), and the lack of stability has left both providers and patients concerned about the ability to continue vital services.

Our feedback on CMS' specific PFS telehealth proposals is as follows.

Changes to Medicare Telehealth Services List. In this rule, CMS proposes 13 services for addition to the Medicare Telehealth Services List for CY 2025:

- Home International Normalized Ratio Monitoring on a provisional basis (CPT code G0248)
- Caregiver training codes on a provisional basis (CPT codes 97550-97552; 96902-96903; GCTD1-GCTD3; GCTB1-GCTB2)
- Preexposure Prophylaxis of HIV permanently (CPT codes G0011 and G0013)

The AHA supports the agency's proposed additions to the telehealth services list, which will add to the tools providers can use to care for patients.

CMS did receive other requests to add services to the telehealth list but did not propose to do so, stating that they did not meet the definition of telehealth services per 1834(m) of the Social Security Act. While we recognize that certain services may not meet the statutory definition of telehealth, evaluation of virtual services outside the definition is still worthwhile. Indeed, CMS has already adopted, on a case-by-case basis, certain non-face-to-face codes for remote physiological monitoring, remote therapeutic monitoring, artificial intelligence and e-visits, and virtual check-ins. As technology advances, applications of digital care delivery will become broader than audio-visual visits. Many of these services could be captured in the "provisional" telehealth category, where services do not have a direct in-person equivalent. **To support innovative applications, we would encourage CMS to define a parallel process to review proposals in virtual services that may not meet the statutory definition of telehealth services.**

Finally, CMS proposes to complete an analysis of all provisional codes before determining whether individual provisional codes should be made permanent. **We request that CMS complete this evaluation in a comprehensive, timely and transparent manner.**

Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facilities and Critical Care Consultations. Historically, certain telehealth-eligible services had frequency limitations. During the COVID-19 PHE, some were lifted, and CMS extended certain frequency limitation waivers through 2023 and 2024.

For CY 2025, CMS proposes to temporarily remove telehealth frequency limitations for:

- Subsequent inpatient visits (CPT code 99231, 99232,99233)
- Subsequent nursing facility visits (CPT code 99307, 99308, 99309, 99310)
- Critical Care Consultation services (HCPCS G0508, G0509)

The AHA supports the proposed temporary waiver of frequency limitations for the services listed above. We urge CMS to consider permanent removal of frequency limitations, as when and how patients receive care should be left to clinical judgment so long as the standard of care is met.

Audio-only Services. Statute specifies that for Medicare payment, telehealth services must be furnished via a "telecommunications system." CMS defines "telecommunications system" to mean an "interactive telecommunications system," which the agency further defines as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner."

In CY 2022, CMS revised the definition of "interactive telecommunications system" to include audio-only communications for tele-behavioral health services furnished to beneficiaries in their homes for circumstances when the patient is incapable or does not consent to video technology. The agency is now proposing to revise it again to include audio-only communications for other services furnished to beneficiaries in their homes for circumstances when the patient is incapable or does not consent to video technology. CMS notes that, statutorily, many waiver flexibilities, including recognizing the patient's home as an eligible originating site, are scheduled to expire at the end of 2024 barring congressional action.

The AHA enthusiastically supports CMS' proposal to expand the definition of interactive telecommunications systems to include audio-only communications. This flexibility has enabled our hospital members to maintain access to care for numerous patients who do not have access to broadband or video conferencing technology, lack data plans or devices, are diverted when a video connection fails, and otherwise cannot participate in audio-visual encounters. Indeed, a recent report from the Assistant Secretary for Planning and Evaluation (ASPE) reviewing Census Bureau data from 2021 found differences in utilization of audio-visual versus audio-only visits across different demographic subgroups like age, income level, race, insurance coverage and education level. For example, most surveyed respondents 65 and older used audio-only visits (56.5%) compared to video visits, partly because over 26% of Medicare beneficiaries reported not having computer or smartphone access at home.[6] Reverting audio-only telehealth to pre-COVID-19 PHE requirements would be a

[6] https://aspe.hhs.gov/sites/default/files/documents/4e1853c0b4885112b2994680a58af9ed/telehealth-hps-ib.pdf

disservice to Medicare beneficiaries, especially those who are underserved. **We encourage CMS to not limit the telecommunications technology definition expansion to include audio-only strictly for instances where the patient is incapable or does not consent to audio-video. Instead, CMS should expand the definition to include audio-only without exceptions.** For example, some patients may prefer to receive care via audio-only technology, even if audio-video is possible. Patients and providers should be the ones to jointly determine the modality most appropriate for receiving care.

However, the ability to provide these services to patients in their homes is still predicated on statutory waiver extensions to originating- and geographic-sites restrictions. **While we appreciate CMS' effort to expand the regulatory definition, if the waivers expire, the expanded definition of interactive communications technology to include audio-only would only apply to mental health, substance use disorder and end-stage renal disease services. Therefore, we urge CMS to do all it can, including working with Congress, to enable permanent support for audio-only telehealth by extending the waivers.**

Provider Home Address. During the PHE, CMS allowed practitioners to render telehealth services from their homes without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. For CY 2025, CMS proposes extending these flexibilities as it reviews proposals to address provider safety concerns. **We support CMS' efforts to allow providers to continue billing from their currently enrolled practice location instead of their home address when providing services from their home. Indeed, we urge CMS to expeditiously remove this requirement permanently.**

We are deeply concerned with this requirement, and the potential privacy issues it poses to providers if it were to go into effect, since home addresses may be publicly available on sites like Medicare Care Compare without providers' knowledge or consent. Given the experience with COVID-19, many hospitals, health systems and providers have moved to hybrid schedules where some physicians and staff are working remotely. This flexibility fosters improved retention, especially in light of the significant staffing shortages nationwide. Requiring providers to list their home addresses on enrollment and claims forms, which patients or others in the public can access, poses privacy and safety risks. This is a particular concern given the increased incidence of violence against health care workers. Recent studies indicate, for example, that 44% of nurses reported experiencing physical violence and 68% reported experiencing verbal abuse during the COVID-19 pandemic.[7] **At a minimum, CMS must implement a mechanism to automatically mask the home address from all public sites and directories.**

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[7] https://www.aha.org/system/files/media/file/2022/09/Fact-Sheet-Workplace-Violence-and-Intimidation-and-the-Need-for-a-Federal-Legislative-Response.pdf

Additionally, there is unclear guidance on the appropriate reporting of the home address if this requirement were to take effect. For example, it is unclear if it is only required for providers doing 100% encounters from their homes, or whether this policy would result in audits and inspections of providers' homes. There is also concern about the operational and administrative burden of tracking and reporting changes in providers' home addresses if and when they move.

Direct Supervision. During the COVID-19 PHE, CMS allowed providers to satisfy direct supervision requirements for diagnostic tests, physicians' services and some hospital outpatient services through virtual presence using real-time audio-video technology. Before the COVID-19 PHE, supervision required the immediate in-person availability of the supervising practitioner. In the proposed rule, CMS would continue allowing virtual presence to satisfy direct supervision requirements through the end of CY 2025. **The AHA strongly supports the proposed extension of virtual presence to satisfy direct supervision requirements by interactive telecommunications technology.** This critical flexibility has supported improved access to care for patients in underserved areas.

We also appreciate that CMS has taken the step to *permanently* allow for the use of virtual presence to satisfy direct supervision requirements for specific services, including where the underlying Healthcare Common Procedure Coding System (HCPCS) code has been assigned a professional component/technical component (PC/TC) indicator of "5" and for CPT code 99211. The agency states that it will continue to take an incremental approach to adopt this policy for additional services that are inherently lower risk. We appreciate that CMS is prioritizing patient safety and quality. However, we would point out there is no evidence to suggest that the allowance of virtual presence to satisfy direct supervision has resulted in safety or quality of care differences during the PHE. **We would appreciate additional clarity on the process to identify additional services that would qualify permanently for virtual supervision.**

Supervising Residents in Teaching Settings. In CY 2021, CMS established that after the COVID-19 PHE, teaching physicians could meet requirements for key or critical portions of services through virtual presence (real-time audio-visual communications technology), but only for services furnished in residency training sites in non-Metropolitan Service Areas (MSAs). During the COVID-19 PHE and then through CY 2024, flexibilities for virtual supervision were extended to include MSAs.

In this rule, CMS proposes extending again virtual supervision flexibilities for all residency training locations through the end of CY 2025. **The AHA supports the proposed extension of virtual supervision flexibilities for both MSAs and non-MSAs. We urge the agency to make this policy permanent.** Flexibilities to enable virtual supervision of residents across geographic settings enabled improved patient access and maximized limited teaching physician capacity given prevalent staffing shortages. It has also provided real-world telehealth experience for residents across

geographies, with physicians able to supervise the appointment safely and effectively virtually. This will be an essential real-world experience to train the next generation of clinicians. In addition, health care provider shortage areas and staffing challenges are not limited to non-MSAs, particularly in areas like behavioral health.

The proposed rule specified that the proposal would only apply in clinical instances when the service was furnished completely virtually, with no in-person component. However, for many hospitals and health systems, supervising physicians may be geographically dispersed or balancing supervisory functions with care delivery and administrative tasks. We encourage flexibility to maximize the benefit of virtual modalities (i.e., to connect geographically dispersed supply with demand). For example, there may be instances where the resident is physically with the patient and the supervising physician is at a different location. The resident should be able to "dial in" the supervising physician in these instances. **As such, we urge CMS to extend flexibilities for instances where the resident and patient may be in the same location and the supervising physician is remote.**

Request for Information (RFI): Teaching Physician Services Furnished under the Primary Care Exception. The primary care exception allows teaching physicians to bill for certain services performed by residents in certain training settings when the physician is not present with the resident so long as certain conditions are met. CMS requests information about how best to expand the services provided under the primary care exception, specifically preventive services, and whether the currently required six months of training in an approved program is sufficient.

We directionally support expanding the list of eligible services under the primary care exception. The provision of teaching services in teaching settings where the physician is not physically present is becoming more important to maintain access to services, especially considering existing physician shortages. In addition to providing additional capacity, expanding the list of eligible services will also train residents on these services so that they can continue practicing preventive care beyond their residency. This will be important in shaping the future of care delivery, as residents will gain experience in upstream activities.

CMS also requests additional information about including higher-level evaluation and management (E/M) services in the exception and whether this would impede physicians' ability to be immediately available. However, it appears that the primary care exception expansion to include higher levels of E/M services only would support increased access to those services. This would free up more time for physicians to perform supervisory (including being immediately available) and other duties while enabling residents to practice to the fullest extent of their skills and training. There are also guardrails and standards to ensure residents are prepared. Specifically, the Accreditation Council for Graduate Medical Education (ACGME) has standards for residency programs, including competency assessments. The guardrails established by ACGME ensure that residents have the appropriate levels of supervision aligned with

their training, ability and patient complexity. **We support expanding services under the primary care exception, to include at a minimum level four E/M services, which will support improved access and continuity of care.**

Telehealth E/M Services. In February 2023, the CPT Editorial Panel added 17 E/M codes for reporting telemedicine E/M services. However, CMS states that there is no programmatic need to recognize the 17 new telemedicine E/M codes for payment under Medicare. That is because there are existing E/M codes on the Medicare telehealth services list. Therefore, CMS proposes adding a status indicator of "I" to the new telehealth E/M codes to denote that there is a more specific code that should be used for Medicare purposes. CMS also seeks comment from interested parties on the applicability of section 1834(m) of the Act to the new telemedicine E/M codes, and how CMS might mitigate negative impacts from the expiring telehealth flexibilities, preserve access and assess the magnitude of potential reductions in access and utilization.

Section 1834(m) of the Social Security Act specifies that "the Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system." **We agree existing services approved on the telehealth list should be paid equal to what would have been paid in person, as is required by statute. This includes telehealth E/M services already on the telehealth services list under existing E/M codes.**

As mentioned above in the Changes to Medicare Telehealth Services List, we also encourage CMS to adopt review processes to account for broader digital health codes that may not meet the statutory definition of telehealth services but warrant further review for adoption by Medicare.

Federally Qualified Health Center (FQHC)- and Rural Health Center (RHC)-specific Provisions. CMS proposes temporarily extending payment to FQHCs and RHCs for nonbehavioral health telehealth services (including audio only). RHCs and FQHCs would continue to bill these services using the G2025 HCPCS code. CMS also proposes to delay in-person visit requirements for behavioral health services at FQHCs and RHCs until Jan. 1, 2026. **We support continued telehealth services payment at FQHCs and RHCs and delayed in-person visit requirements for behavioral health services in these settings. We encourage CMS to adopt these provisions permanently.**

Place of Service for Medicare Telehealth Services and Reimbursement. In CY 2020, CMS finalized policies for telehealth modifiers and place of service codes on an interim basis. Specifically, CMS finalized that providers should use the modifier "95" for telehealth claims for the duration of the COVID-19 PHE and report the place of service (POS) based on where the service would have occurred if it were in person. This

ensured payment at the same rate that would have been paid if the services were furnished in person (facility rate or non-facility rate).

In CY 2023, CMS finalized that by the end of the calendar year in which the COVID-19 PHE ends, telehealth claims would no longer use the "95" modifier and would instead report the following POS codes:

- "02" (Telehealth provided to a location other than the patient's home)
- "10" (Telehealth provided to a patient's home)

For 2024, CMS finalized that for claims billed with a POS 10, providers would be paid at the non-facility rate, but for claims billed with a POS 02, they would be paid at the lower facility rate. CMS did not address this issue in the CY 2025 proposed rule.

For CY 2025, the AHA urges CMS to reimburse providers at the non-facility rate for all telehealth visits, including those with POS 10. Prior to the COVID-19 pandemic, CMS reimbursed providers administering telehealth at the facility rate regardless if the provider was performing the visit from a facility or non-facility setting. However, such reimbursement did not account for practice-related expenses, such as support staff to assist patients in connecting with physicians or following up if connections failed. This was a challenge for providers who delivered the same level of work and quality of care as in-person visits but received less reimbursement. As noted above, during the PHE, CMS updated guidance to reimburse providers at the rate they would normally receive if the patient were seen in person, which provided much more adequate reimbursement and therefore facilitated patient access to care.

In addition, as a matter of course, physician reimbursement should compensate for work expenses, malpractice expenses and practice expense-related costs; these expenses are generally the same regardless of whether the encounter was in person or virtual. For example, malpractice expenses, which cover professional liability insurance premiums, are the same regardless of the method by which care is delivered. In addition, for practice expenses (which cover staffing, supplies and equipment), virtual encounters may reduce supply expenses (like exam gloves or paper for exam tables), but increase technology expenses (like software licenses and hardware). This is all not to mention that per statute, CMS must pay physicians for telehealth at an "amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system."

Remote Outpatient Therapy, Diabetes Self-Management Training and Medical Nutrition Therapy. **As mentioned in our comments on the CY 2025 outpatient prospective payment system proposed rule, we urge CMS to work with Congress to extend waivers in support of virtual therapy services, preferably permanently.** During the COVID-19 PHE, CMS established the Hospital Without Walls policy, which enabled hospitals to reclassify patients' homes as temporary extension sites during the state of emergency. This also enabled billing of virtual services furnished by hospital outpatient

departments. For CY 2024, CMS allowed institutional providers to continue to provide remote outpatient physical therapy, occupational therapy, speech-language pathology, diabetes self-management training, and medical nutrition therapy in patients' homes via telehealth.

This was predicated on statutory waivers, including eligibility for physical therapists, occupational therapists and speech-language pathologists to serve as distant site providers and eligibility of the patient's home as a designated originating site for telehealth services. These statutory waivers were extended as part of the CAA of 2023, however, without congressional action these are scheduled to expire at the end of 2024.

Without the extension of these flexibilities, we risk a telehealth "cliff" which will negatively impact access across communities. Many organizations continue to depend on remote therapy services for patients who are geographically dispersed, without reliable transportation, with lengthy drive times and with mobility issues. For example, some organizations have cited the critical role that virtual swallowing therapy has had for patients with head and neck cancer and Parkinson's patients who may have challenges with mobility and transportation. This has prevented hospital admissions for aspiration pneumonia.

Also, recent studies from Harvard Medical School and Spaulding Rehabilitation Hospital found high levels of patient satisfaction across age, gender and these specialties of physical therapy, occupational therapy and speech-language pathology.[8] Survey respondents also reported benefits such as being able to get tailored feedback from providers on equipment that was set up in their home, and more easily coordinating caregiver training for patient transitions back to their homes since caregivers could be at the patient's home with the patient, and reduced drive times and added convenience.

Clarification for Remote Monitoring Services. In prior rulemaking, CMS established a set of codes for Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring Services (RTM).

New vs. Established Patients. While not included in the CY 2025 PFS proposed rule, we would like to reinforce our previous comments regarding the applicability of RPM for new patients. In CY 2021, CMS established that following the end of the COVID-19 PHE, RPM services may only be furnished to established patients. As such, in CY 2024, CMS returned to the CY 2021 guidance and pre-COVID-19 pandemic rules to require that RPM and RTM services only be administered to established patients.

We disagree that RPM and RTM services should be limited to established patients. RPM and RTM have been critical capabilities to safely discharge patients with chronic conditions from the hospital, transition patients to better self-manage conditions

[8] Outpatient Physical, Occupational, and Speech Therapy Synchronous Telemedicine: A Survey Study of Patient Satisfaction with Virtual Visits During the COVID-19 Pandemic - PMC (nih.gov)

and reduce readmissions. During the COVID-19 pandemic, the flexibility to provide these services to both new and established patients meant that patients were able to start monitoring services earlier (in many cases enrolling prior to discharge), which provided critical support in the immediate timeframe after discharge. There is concern that requiring an established relationship will create a barrier for patients to access services in a timely manner. Furthermore, there is precedent within E/M coding structure for new vs. established relationships (E/M codes are separated based on new vs. established). **As such, we urge CMS to reinstate flexibilities to allow for both new and established patients to access RPM and RTM services.**

PAYMENT FOR E/M SERVICES

Add-On Outpatient/Office (O/O) E/M Complexity Code. In CY 2024, CMS implemented a new E/M add-on code (G2211) to account for intensity and clinical complexity. This was intended to account for additional costs in treating a patient's single, serious or complex condition. The add-on code was originally scheduled for implementation in CY 2021, however, there was a statutory moratorium established in the CAA of 2021 that expired at the end of 2023. CMS implemented the code in CY 2024 but determined that it would not be payable when reported with the "25" modifier which prevented billing on the same day as annual wellness visits and other preventive services.

For CY 2025, CMS proposes to refine guidance regarding the complexity add-on code. Specifically, it would allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported by the same practitioner on the same day as an annual wellness visit, vaccine administration or any Medicare Part B preventive service furnished in the office or outpatient setting.

We directionally support reimbursement adjustments to account for clinical complexity and the application of preventive services. However, there is still confusion in the field about the definition, application and reporting of this code. Therefore, we ask the agency to issue additional clarifying guidance on resources, typical patients, time, definition and reporting.

Add-on Hospital Inpatient or Observation (I/O) E/M Infectious Disease Code. Stakeholders continue to provide recommendations to CMS on how to recognize the increased work associated with diagnosis, management and treatment of infectious diseases that may not be adequately accounted for in current hospital inpatient or observation E/M codes. As such for CY 2025, CMS proposes establishing a new HCPCS code (GIDXX) to describe the intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease performed by a physician with specialized training in infectious diseases. **We appreciate the recognition of the clinical complexity and intensity associated with infectious disease management. As such we support the implementation of the new add-on code.**

RFI: SERVICES ADDRESSING HEALTH-RELATED SOCIAL NEEDS

In the CY 2024 PFS final rule, CMS finalized G-codes to reflect new coding and payment for community health integration (CHI), principal illness navigation (PIN) and social determinants of health (SDOH) risk assessment. As expressed in our CY 2024 PFS comment letter, we support the expansion of reimbursement for health-related social needs (HRSNs) services provided by auxiliary staff such as community health workers and care navigators. For CY 2025, CMS seeks feedback on these newly implemented codes.

We provided feedback in last year's comment letter on ways to support the provision of these services. We encouraged CMS to explore options to alleviate beneficiary cost sharing and align incentives in other care settings (like inpatient and hospital outpatient settings).

Our members report that utilization of these codes has been low. However, given that the codes were just implemented in CY 2024, this is to be expected as providers update workflows, electronic health records (EHRs), and billing software, and develop partnerships with community-based organizations. **We encourage CMS to issue this RFI in next year's rules and provide additional time for organizations to implement processes and provide feedback.**

With respect to capturing Z-codes on claims associated with billing these codes, we support initiatives to encourage the collection, access, sharing and use of SDOH data to enhance clinical decision-making and increase referrals to address social needs. The U.S. Department of Health and Human Services (HHS) defines SDOH as "the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks." We acknowledge that as part of its Healthy People 2030 campaign, HHS has identified SDOH as a critical factor in addressing health equity. SDOH Z codes were introduced with the ICD, Tenth Revision (ICD-10) coding architecture in October 2015. HCPCS codes for CHI and PIN services were introduced in January 2024. The ICD-10-CM SDOH Z-codes and HCPCS codes for CHI and PIN services represent a way to standardize documentation and reporting of SDOH information. Having standardized data would be useful in efforts to better understand health disparities, promote improvement of health outcomes and help support quality measurement initiatives.

We also support CMS' collaboration with stakeholders to address barriers and promote a regulatory pathway to increase the use of Z-codes. Specifically, we encourage CMS to investigate expanding the number of diagnosis code fields on both the professional and institutional claim forms to better enable providers to report SDOH Z-codes. That is, there is a limit of 12 diagnosis codes on the professional claim and 25 diagnosis codes on the institutional claim form; these are often used for medical codes, leaving no available data fields for SDOH codes.

In addition, we recommend that CMS collaborate with applicable sources to ensure standard, nationally accepted definitions that could promote more consistent application and data capture of the SDOH Z-codes and the HCPCS CHI and PIN services. We encourage CMS to create and/or continue to enhance current educational resources that will inform health care providers and organizations about the benefits of capturing this SDOH information through the application of ICD-10-CM Z and HCPCS CPT codes. Health care providers' understanding of the value to health care organizations in collecting and using SDOH information is essential. Educational resources that include strategies on how best to discuss SDOH screening with patients would benefit health care providers.

We applaud CMS' work to increase the collection and use of SDOH data to improve community and individual health outcomes while considering the need to keep the added administrative burden at a minimum. The AHA welcomes the opportunity to work with CMS on these initiatives.

ENHANCED CARE MANAGEMENT AND ADVANCED PRIMARY CARE

Advanced Primary Care Management Services. In recent years, CMS has updated many of its payment policies around advanced primary care services. However, stakeholders continue to offer feedback on ways to improve payment, as some have expressed concerns that the current billing structure does not adequately support the spectrum of advanced primary care services required. In addition, the Center for Medicare and Medicaid Innovation (CMMI) has initiated many advanced primary care models including Comprehensive Primary Care (CPC), Comprehensive Primary Care Plus (CPC+) and Primary Care First (PCF), which have generated lessons learned.

As such, CMS proposes three new bundled codes to support Advanced Primary Care Management (APCM) services:

- GPCM1: APCM services provided by clinical staff and directed by a physician or other qualified health professional responsible for all primary care and serve as the continuing focal point for all needed health care services, per calendar month.
- GPCM2: APCM services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months; or until the death of the patient, which places the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month.
- GPCM3: APCM services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months; or until the death of the patient, which places the patient at significant risk of death, acute exacerbation/decompensation, or functional decline,

> provided by clinical staff and directed by a physician or other qualified health professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month.

While we appreciate that CMS is attempting to better describe advanced primary care services through the APCM proposal, we are concerned that the proposed bundles include too many disparate codes and that the valuation does not fully capture the cost of services. Specifically, they include a large variety of virtual and care management services. Additionally, this topic has previously been reviewed at the resource-based relative value scale update committee (RUC), and recommendations were made to stratify codes based instead on infrastructure capability. **We encourage CMS to continue to gather stakeholder input on the appropriate services and valuation of these codes.**

Advanced Primary Care RFI. CMS also seeks input on updating payment and policies to support advanced primary care activities. Specifically, CMS seeks input on potential hybrid primary care payment models including feedback on streamlined value-based care opportunities, billing requirements, person-centered care, health equity and quality improvement.

We appreciate policymakers are seeking innovative ways to improve physician reimbursement for advanced primary care and enhanced care management. Our members support the U.S. health care system moving toward the provision of more outcomes-based, coordinated care and are continuing to redesign delivery systems to increase value and better serve patients. Indeed, over the last 14 years, many of our hospital and health system members have participated in a variety of alternative payment models (APMs), including primary care APMs and accountable care organizations (ACOs). While the movement to value holds tremendous promise, the transition has been slower than anticipated and more needs to be done to drive long-term system transformations.

We understand that hybrid payment models intend to support the transition to value-based care. However, we are concerned that this could confuse providers already participating in ACOs. Additionally, data from CPC and PFC have indicated that these models work best within a total cost-of-care framework. **Instead, we encourage CMS to focus on solutions to foster growth in certain existing APMs. For example, we urge CMS to remove the high-/low-revenue thresholds which have excluded many hospitals and health systems from advanced investment payments and even participation in full-risk models like ACO Primary Care (PC) Flex.**

Additionally, we urge CMS to work with Congress to extend APM incentive payments. The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 provided incentive payments (5%) for providers participating in advanced APMs through 2024. These payments were designed to assist with the provision of non-fee-for-service programs like meal delivery programs, transportation services, digital tools and care

coordinators which promote population health, among other services. Congress has acted to extend these payments through single-year CAA provisions.

We continue to urge CMS to consider our common principles that we believe should guide value-based payment model design which are also relevant to approaching hybrid payment models.[9]

CARDIOVASCULAR RISK ASSESSMENT AND RISK MANAGEMENT

CMMI's Million Hearts® Cardiovascular Disease Model was intended to reduce first-time incidence of heart attacks and strokes among medium- and high-risk beneficiaries and reduce spending on cardiovascular events. Million Hearts® included screening assessments and subsequent lifestyle recommendations. Overall, the model resulted in decreased mortality rates and risk of mortality from cardiovascular events.

Based on findings from Million Hearts®, CMS proposes incorporating a separate billing code for administering a standardized, evidence-based Atherosclerotic Cardiovascular Disease Risk Assessment (GCDRA). **We support the incorporation of this billing code, as this will further incentivize proactive, evidence-based screening for cardiovascular risk.**

SUPERVISION OF OUTPATIENT THERAPY SERVICES

Supervision of Outpatient Therapy Services in Private Practice. To the extent permitted under state law, CMS proposes to allow for general supervision of occupational and physical therapy assistants by occupational and physical therapists in private practice instead of requiring direct supervision. **The AHA supports the allowance of general supervision instead of direct supervision, which would no longer require physical and occupational therapists to be physically onsite where services performed by assistants are administered.** Given the significant national shortages, this flexibility would make better use of limited provider capacity. Additionally, this will align supervision standards of physical and occupational therapy assistants across settings (since other settings already allow for general supervision of these provider types).

Certification of Therapy Plans of Care with a Physician or NPP Order. Over the last two years, the agency has received requests to reduce the administrative burden associated with physician/non-physician practitioner (NPP) sign-off on treatment plans. Current regulations require a physician or NPP's sign-off on treatment plans at least every 90 days, with documentation reflecting a continued need for therapy services. There is no time limit for physicians/NPPs to modify treatment plans.

CMS proposes to amend requirements for cases when a patient has a signed and dated referral or order for therapy services from a physician or NPP. This would be treated as

[9] https://www.aha.org/testimony/2024-06-26-aha-house-statement-improving-value-based-care-patients-and-providers

equivalent to a signature on the therapy plan. CMS proposes to establish an exception to the plan of care signature requirement for initial certification in instances when there is a signed and dated order or referral on file from a physician or NPP and the therapist has evidence that the plan of treatment has been delivered to the provider within 30 days of completion of the initial evaluation. CMS is not proposing exceptions for recertification of plans of care. **We believe this is a step in the right direction to reduce the administrative burden for the referring physician and therapist. The AHA supports exceptions for the signature requirement for the initial plan of care in instances where there is a signed and dated referral or order for therapy services.**

CMS requests additional input for modifications to timelines for changes to treatment plans. Given that there currently are no time limits for physicians and NPPs to modify treatment plans, we would be concerned with establishing restrictive time limits. Therefore, we recommend that CMS maintain its current policy until additional input can be gathered from stakeholders.

ADVANCING ACCESS TO BEHAVIORAL HEALTH SERVICES

In this rule, CMS proposes several provisions to expand payable services and practitioners to enhance access to behavioral health care. The AHA appreciates the agency's continued focus on behavioral health, particularly as it works to widen reimbursement to cover vital services that have otherwise gone under (or un-) paid.

<u>New Payments for Services Delivered to Patients at High Risk for Suicide or Overdose.</u> CMS proposes creating separate coding and payment for services furnished in the emergency department (ED) or other crisis settings for patients with suicidality or at risk of intentional suicide by overdose. These payments would be covered by newly established G-codes: one for safety planning interventions (SPI) to be billed along with E/M or psychotherapy codes and one for monthly Follow-up Contacts Intervention (FCI).

The AHA supports the establishment of payment for these evidence-based protocols, but we recommend the agency modify its proposals to remove barriers to these services being furnished when indicated. Specifically, the new SPI code would be an add-on equivalent to 20 minutes of psychotherapy for crisis. **We suggest CMS permit SPI as a stand-alone service as opposed to an add-on service; we also suggest it explicitly permits additional types of staffing for these services.** As an add-on code, SPI would only be able to be furnished by the same practitioner who furnishes the E/M or psychotherapy visit to which the SPI services are being added. This would be a barrier to access in the ED, in particular, where E/M visits are typically furnished by an emergency physician, who may not be the most appropriate practitioner to furnish this care. Similar issues would arise in primary care as there might not be clinical overlap in the E/M services provided by a primary care physician and SPI services. In other words, the care a patient receives that is covered by the E/M code may be clinically different than what is involved in SPI; thus, we urge CMS to allow different clinicians or licensed

practitioners to furnish SPI services by adopting it as a standalone code. **In addition, we recommend that CMS allow multiple instances of the SPI code to be billed based on the actual duration of the service rather than limiting it to 20 minutes.** Our members have noted that 20 minutes is generally the minimum time needed to furnish evidence-based SPI; patients with more complex needs may require additional care.

CMS proposes to allow monthly billing of the FCI code, which describes post-discharge telephone contacts between a provider and a patient. Under this proposal, the code would cover up to four calls in a month, each lasting between 10 and 20 minutes. **We suggest that CMS allow billing per call, up to four units in one month, rather than a single payment that covers up to four calls**. We think this method would more accurately account for time spent and ensure practitioners are paid for services rendered even if they cannot reach the patient four times in a month to qualify for the bundle.

Payment for Digital Mental Health Treatment. CMS proposes to create a new code to describe digital mental health treatment (DMHT) furnished incident to professional behavioral health services. It would define DMHT as software devices cleared by the Food and Drug Administration (FDA) and intended to treat or alleviate a mental health condition in conjunction with ongoing behavioral health care treatment. **The AHA directionally supports this proposal. We would like clarification on what is meant by FDA clearance and whether this includes low-risk devices and those exempt from 510(k) approval.**

Payment for Interprofessional Consultation. CMS proposes to create new coding describing interprofessional consultations performed via communications technology by clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors. **The AHA supports this proposal and recommends that CMS work with professional societies to provide technical assistance to practitioners in billing for this work.**

Opioid Treatment Programs. CMS proposes several modifications to the policies governing Medicare coverage and payment for opioid use disorder treatment services furnished by Opioid Treatment Programs (OTPs). These include allowing periodic assessments to be furnished via audio-only telecommunications permanently; allowing the use of audio-visual telecommunications for initial treatment with methadone; and payment for new FDA-approved opioid agonist and antagonist medications. The AHA supports these proposals and appreciates that CMS continues to refine the OTP program to ensure appropriate payment and access to care.

The agency also proposes establishing payment for new requirements for OTPs to include services addressing HRSNs. Specifically, CMS proposes adding value to the payment rate for intake activities to also cover OTP-performed risk assessments for social drivers of health. **The AHA appreciates that CMS recognizes the additional**

resources needed for programs to identify and work to address the HRSNs of their patients and supports this proposal. We encourage the agency to revisit the methodology to establish payment once additional information is collected about how OTPs are extending access to services not included in the Medicare OTP benefit.

DENTAL SERVICES

CMS proposes covering dental services performed as part of a comprehensive workup in an inpatient or outpatient setting before dialysis administration for end-stage renal disease patients, as well as medically necessary diagnostic and treatment services to address oral infections for these patients. The agency does not propose to add dental coverage for hemophilia or sickle cell disease, diabetes or autoimmune diseases but states it will continue to evaluate the impact of dental services on these conditions. Finally, CMS proposes to require the use of the KX modifier to identify dental services inextricably linked to covered medical services beginning on Jan. 1, 2025.

We support coverage for the above circumstances. We also urge CMS to provide coverage for *all* immunocompromised beneficiaries, not only those receiving the above services. We also request clarification on whether billing guidelines also apply to institutional claims.

MEDICARE PRESCRIPTION DRUG INFLATION REBATE PROGRAM

The AHA recognizes CMS' statutory obligations under the Inflation Reduction Act (IRA) to exclude all Part B and Part D drug units purchased under the 340B Drug Pricing Program from the calculation of the Medicare inflationary rebates. We support the agency's approach to use the existing "TB" claims modifier to identify and exclude Part B drug units purchased under the 340B program. We know that 340B providers already have the systems in place to append this modifier, as the agency has required a modifier to identify 340B claims since 2018. However, it is important to note that the process of appending a claims modifier for 340B drugs is both operationally and financially burdensome.

We appreciate that CMS acknowledges that a similar modifier approach is not feasible to identify Part D drugs purchased under the 340B program, since it is not possible for the dispensing entity, CMS or the Part D plan sponsor to know the 340B status of the drug at the point of sale. Therefore, we support the agency's proposed methodology to estimate the number of 340B drug units purchased under Part D. We believe this proposal comports with the agency's longstanding policy to minimize provider burden. However, we advise CMS to validate its calculations carefully, as overestimating the number of Part D drug units purchased under the 340B program could have negative downstream impacts. Specifically, overestimating the number for a given drug could artificially decrease the inflation rebate amount for that drug. A lower inflation rebate results in a higher acquisition price which, over time, can artificially increase the 340B

price for that drug. CMS should be mindful of these and other unintended consequences that could manifest as a result of their estimation methodology.

The agency also asked stakeholders to provide feedback on alternative approaches it could pursue in future rulemaking to identify and exclude Part D drug units purchased under the 340B program, including the use of a claims modifier or the submission of data to a claims repository. First and foremost, we reiterate our objection to using a claims modifier to identify Part D drug units purchased under the 340B program; it is practically infeasible as CMS itself has outlined in the proposed rule. Even if the agency could develop some sort of methodology to append a claims modifier for Part D drugs, such a process would undoubtedly be extremely complex, operationally burdensome, and require significant financial investment on the part of 340B providers.

On the other hand, the AHA would be supportive of the creation of a Part D claims repository depending on how CMS chose to operationalize such a process. If the agency decides to pursue this approach instead of the estimation methodology in future rulemaking, we encourage the agency to model its approach after a similar model successfully used by Oregon Medicaid.[10] In addition, any process that requires 340B providers to submit claims information to CMS or its delegated third party should ensure sufficient safeguards against potential cyber threats, especially in light of recent cyberattacks on third parties. Further, the data required for submission to the claims repository should be limited only to the data elements required for the agency to identify and exclude 340B drug units from the Medicare inflation rebate calculation. We agree that the only data elements required for the agency to identify 340B drug units are the four data elements that the agency has outlined in the rule reported on a quarterly basis. CMS should also ensure that claims data submitted by providers is not shared with drug manufacturers or other entities that can use this data for their own financial benefit. Finally, CMS should employ a similar repository approach for effectuating the IRA's maximum fair price (MFP) provisions as it is considering here for the inflation rebate provisions. This would not only make it easier for the agency to meet its statutory obligations under both the MFP and inflation rebate provisions but also would be significantly less burdensome for 340B providers than what the agency proposed in its draft guidance issued earlier this year.

RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS

RHCs and FQHCs Conditions for Certification or Coverage (CfC) Proposals. RHCs are required to be primarily engaged in providing primary care services, and CMS has enforced this standard by considering the total hours of an RHC's operation and whether a majority (i.e., more than 50%) of hours involve the provision of RHC services. Stakeholders have questioned this interpretation in relation to the ability for RHCs to provide specialized services. As such, CMS is proposing that RHCs and FQHCs would

[10] https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20State%20Policy.doc

continue to be required to provide primary care services to their patient populations, but CMS would no longer determine or enforce the standard of RHCs "being primarily engaged in furnishing primary care services" and would no longer consider the total hours of an RHC's operation and whether a majority of those hours involve primary care services through the survey process. **We support this proposal.**

Additionally, RHCs are currently required to provide six specific diagnostic laboratory tests directly (i.e., at the RHC by RHC personnel). However, CMS is proposing to remove hemoglobin and hematocrit from the list given the financial and physical burdens associated with maintaining labor and equipment for this test, which is ordered infrequently and often sent to the nearest hospital with a full-service laboratory. The proposal does not prevent RHCs from providing tests not listed in regulations. **We support this proposal.**

MEDICARE PARTS A AND B OVERPAYMENT PROVISIONS OF THE AFFORDABLE CARE ACT

In 2022, CMS proposed rules regarding standards for "identified overpayment" under Medicare Parts A, B, C and D. The agency has not yet finalized proposals on overpayments under Parts A and B, however after reviewing comments, it is proposing to retain proposals for Parts A and B in that rule and makes additional proposals regarding the deadline for reporting and returning overpayments in this proposed rule.

The Affordable Care Act requires overpayments to be reported and returned either 60 days after the overpayment was identified or the date any corresponding cost report is due (whichever is later). Overpayments retained after the deadline for reporting and returning are considered an obligation under the False Claims Act (FCA).

The principal decision upon which CMS relies, *UnitedHealthcare Insurance Co. v. Azar,* does not, in our view, stand for the proposition that CMS cites it to support. But based on its reading of that decision, CMS moved to replace "reasonable diligence" with "knowing" and "knowingly" with the thresholds being "has actual knowledge," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information."

In addition, CMS proposes circumstances to suspend the deadline for reporting and returning overpayments to allow time for providers to investigate and calculate overpayments. This may occur if a person is on notice of a potential overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment; and if the person conducts a timely, good-faith investigation to determine whether related overpayments exist. In such cases, deadlines would be suspended until the investigation is concluded and overpayments are calculated or 180 days after the date where the initial overpayment was identified (whichever is earlier).

The AHA previously commented on this issue in the CY 2024 Medicare Advantage proposed rule[11] and raised concerns about CMS' interpretation of *United Healthcare Ins. Co*. requirements and the unrealistic timelines the agency proposed to identify overpayments. **While we appreciate that CMS has attempted to define a window for providers to perform timely, good-faith investigations in the CY 2025 PFS, we remain concerned that the interpretation of *United Healthcare Ins. Co*. is not accurate and the 180-day window proposed still may not provide adequate time for providers to complete the investigations in certain cases.**

First, the proposed rule proposes to adopt the CY 2024 Medicare Advantage proposed rule standard for an "identified" overpayment under 42 U.S.C. § 1320a-7k(d)(2)(A) to the "knowing" and "knowingly" standard in the False Claims Act. In so doing, the proposed rule via the CY 2024 Medicare Advantage rule relies on a single federal district court decision, *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140). It explains that UnitedHealthcare Ins. found that a "knowing" and "knowingly" standard "would be consistent with" both the False Claims Act and the Affordable Care Act (ACA), and so the proposed rule appears to adopt that conclusion without independent analysis. In reality, UnitedHealthcare Ins. did not definitively interpret the term "identified." Specifically, it explained that the ACA "did not define at what point [an overpaid entity] might be said to have 'identified' an overpayment, thus triggering the 60-day clock." As such, any implication that one district court's reading of the state in *UnitedHealthcare Ins. Co.* requires HHS to amend its standard for when an overpayment is "identified" is incorrect.

The better reading of the statute is that the term "identified" has a different meaning than "knowing" and "knowingly." Starting with the plain text, the language on which the proposed rule relies provides that "[i]n this subsection … [t]he terms 'knowing' and 'knowingly' have the meaning given those terms in section 3729(b) of title 31, United States Code." 42 U.S.C. § 1320a-7k(d)(2)(A) (emphasis added). But the relevant statutory term in the relevant subsection is "identified" — not "knowing" or "knowingly." (In fact, the terms "knowing" and "knowingly" appear nowhere in the subsection, which is likely the consequence of the statute's legislative history. See infra at 19 & n. 7.) Thus, the statute's adoption of any extrinsic definition of "knowing" or "knowingly" applies to those words. It does not apply to the word "identified."

What's more, under "ordinary principles of statutory construction[,] … where Congress includes particular language in one section of a statute but omits it in another section of the same Act, we generally take the choice to be deliberate." *Badgerow v. Walters*, 142 S.Ct. 1310, 1317-1318 (2022) (internal quotation marks omitted). Here, Congress chose to use a different word "identified" in the same subsection as where it defined the terms

[11] https://www.aha.org/system/files/media/file/2023/02/aha-comments-on-the-cms-proposed-rule-for-policy-and-technical-changes-to-the-medicare-advantage-program-in-cy-2024-letter-2-13-23.pdf

"knowing" and "knowingly." HHS therefore must conclude that Congress did so intentionally. See *Russello v. United States*, 464 U.S. 16, 23 (1983) see also *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 671 (2008) Put simply, then, the agency should read the term "identified" has having a different meaning than "knowing" and "knowingly" — exactly the opposite approach than it takes in this proposed rule.

If all of this were not enough, the ACA's legislative history supports this conclusion. The initial bill introduced by the House of Representatives in 2009 included a provision that was similar to the "report and return" provision ultimately enacted in the ACA but which stated that "known," rather than "identified," overpayments had to be reported and returned within 60 days. See H.R. 3200, 111th Cong. § 1641 (as introduced by the House, July 14, 2009). But that was not the bill Congress ultimately enacted. Instead, Congress adopted the Senate's version of the bill, which included the current 60-day deadline, using the word "identified" instead of "known." See Public L. 111–148 § 6402(a) enacting H.R. 3590, 111th Cong.7 This change matters. Here, both the text and history of Section 1320a-7k(d)(2)(A) clearly point in the same direction: The term "identified" must be read differently than "knowing" or "knowingly."

Second, we remain concerned that the arbitrary 180-day time frame is still insufficient to complete investigations in certain cases, particularly for complex reviews that may span across multiple years or facilities. Once a hospital or health system is on notice of the existence of an overpayment, it must conduct extensive and rigorous audits to identify exactly how much money must be returned. This requires identifying every claim that may have been overpaid by claim number, dates of service, and amount billed and paid. It also may involve complex statistical sampling followed by quality checks, including, in some cases, reviews by busy caregivers. For multi-year lookbacks, some providers may have to manage archived records or reviews in legacy EHRs. And, in some cases, identifying refunds involves applying different legal standards to different years of claims because Medicare rules change over time, complicating the analysis and identification. For larger health systems, all of this may require analysis across a number of hospitals in the system; for smaller hospitals, they may not have the resources to complete this work in 180 days or fewer. Such a requirement would create unnecessary administrative burdens on the health care workforce who are caring for patients and divert critical resources needed for hospital operations. Further, an unfeasibly short timeline runs the serious risk of creating "false positives," where what at first may appear to be an overpayment (or underpayment), turns out, upon further review, to be appropriate. Adequate time is needed to determine whether there was an overpayment, underpayment or other software error, and this arbitrary timeline imposes added challenges.

Consistent with the law, CMS should continue to afford providers sufficient time to conduct their good faith investigations into potential overpayments to identify their precise size, scope and nature, so long as that recipient demonstrates good faith while working to quantify the exact amount it must return to the secretary. Because of

the challenges of completing a careful, prudent and accurate accounting of overpayments in only 180 days, a more balanced approach to the 180-day clock is both legally permissible and sound policy. CMS should adopt a definition of "identified" that does not impose impractical deadlines on hospitals and health systems before exposing them to False Claims Act liability. **To that end, CMS should establish sufficient exceptions to the 180-day window to ensure that providers who may need additional time to complete investigations can so long as good faith steps are being taken to identify and return overpayments.**

MEDICARE SHARED SAVINGS PROGRAM

Eligibility and Application. CMS proposes changes to MSSP eligibility and application procedures for performance years beginning on or after Jan. 1, 2025. Specifically, the agency proposes to sunset the requirement for CMS to terminate an ACO's participation or eligibility for shared savings if the assigned population drops below 5,000 by the end of a performance year. The 5,000-beneficiary threshold would still be required to enter a new agreement.

We generally support CMS' proposal to sunset the requirement to terminate ACO participation or eligibility for shared savings if the assigned population drops below 5,000 at the end of a performance year. However, we do encourage it to provide additional details on the process allowing providers to continue participation if the population does fall below 5,000 beneficiaries. We encourage the agency to evaluate such occurrences on a case-by-case basis and consider factors such as if the provider is in a rural area, how long the provider has had fewer beneficiaries, etc.

Beneficiary Assignment Methodology. CMS proposes revising the list of primary care services used for assignment to include SPIs, post-discharge telephonic follow-up contacts intervention, virtual check-in services, APCM services, cardiovascular risk assessment and risk management services, interprofessional consultation services, direct caregiver training services, and behavioral management/modification caregiver training services. **We support CMS' proposal to expand eligible codes for beneficiary assignment.**

MSSP Measure Set and Scoring Changes. Last year, CMS announced the establishment of a "Universal Foundation" measure set that it intended to use across as many relevant CMS programs as it could. To further align the MSSP measure set with the Universal Foundation, CMS proposes to add six new measures to the MSSP measure set. Titled the "Alternative Payment Model Performance Pathway Plus" (APP Plus), CMS would add the measures incrementally between the CY 2025 and CY 2028 reporting years.

Beginning in CY 2025, CMS also proposes to streamline reporting types for MSSP quality measures to just two — the Medicare clinical quality measure (Medicare CQM) which includes only Medicare patients, and electronic CQM (eCQM) which would

include all-payer data. ACOs could choose one or a combination of these reporting options. However, to incentivize using eCQM reporting, CMS proposes extending its scoring incentive to report eCQMs beginning in CY 2025 reporting year and beyond, applying slightly relaxed thresholds for meeting the minimum quality performance standard.

The AHA urges CMS not to finalize the addition of new measures to the MSSP measure set at this time. We also urge CMS not to finalize its proposal to restrict reporting to Medicare CQMs and eCQMs and urge CMS to retain the web interface reporting option that it would otherwise sunset after CY 2024. While the AHA appreciates CMS' interest in pursuing further measure alignment across its programs, CMS' approach to quality measurement in the MSSP program has been fraught with instability and uncertainty. Over the past several rulemaking cycles, CMS has changed the MSSP measure set, added the new Medicare CQM reported option, proposed the elimination of the long-standing web interface reporting option that has been available to ACOs since the program's inception, and changed the minimum quality performance standard. These are far-reaching and complex changes that fundamentally alter how ACOs collect and report their data and how their performance is evaluated. Adding more measures at this critical juncture could prove to be not only disruptive but untenable for ACOs.

Instead, the AHA recommends CMS work with the ACO stakeholder community to develop a more sustainable path forward for ACO quality measure reporting. This includes carefully assessing the timeline for transitioning measure data reporting options and when to add new quality measures. ACOs have expressed concern about the significant resources required to switch data submission from the CMS Web Interface reporting option to Medicare CQMs and eCQMs. That is why in 2022, only 37 ACOs out of 457 total reported their quality data using anything other than the web interface reporting option. The Medicare CQM reporting option was added to the program only last year, and CMS has indicated that the reporting option is only temporary, with the agency intending to eventually mandate all-payer eCQM reporting. This has made ACOs and the vendors they work with wary of investing resources to move to Medicare CQM reporting. At a time when the health care workforce is stretched thin, and health care providers face unprecedented financial pressures, we urge CMS to remain flexible.

<u>Rethinking Promoting Interoperability Requirements for MSSP.</u> While not specifically addressed in this rule, part of ensuring CMS' approach to MSSP performance assessment remains sustainable is the agency's requirements for Promoting Interoperability. Prior MSSP policy required ACOs participating in the MSSP BASIC track levels A through D to certify annually that at least half of their eligible clinicians use certified EHR technology to document and communicate clinical care to patients or other health providers. ACOs participating in the BASIC track level E or the ENHANCED track were required to meet a higher threshold of 75% of eligible clinicians using certified EHR technology. However, in last year's PFS final rule, CMS adopted a

policy requiring all clinicians in an ACO to use certified EHR technology that meets both the 2015 Edition base EHR definition or any subsequent base EHR definition promulgated by ONC.

The AHA continues to believe that widespread adoption of certified EHR technology is an important enabler to innovative care approaches. However, we remain deeply concerned that eliminating the percentage threshold for the number of clinicians meeting certified EHR requirements may inadvertently disqualify too many clinicians from the ability to participate in ACOs. The AHA urges CMS to revert to its prior policy and focus on advancing policy approaches that can more broadly support the wider clinician adoption of EHRs. For example, the AHA has recommended to CMS it consider expanding Safe Harbor protections (i.e., Stark and Anti-Kickback) for hospitals and health systems to extend access to their EHRs out to others — including clinicians — who also fill patient care needs in an episode-based payment model.

Mitigating the Impact of SAHS Billing Activity. Stakeholders have raised concerns regarding potential SAHS activity on catheter supplies billed in 2023. SAHS billing activity can represent significant claims increases (either in volume or dollars) with either a national or regional impact. If not addressed, SAHS can result in inaccurate and inequitable ACO payments, but current regulations do not provide a basis to adjust financial calculations in such instances. Given concerns about the impact of SAHS billing for 2024 and future years, CMS proposes to exclude such payment amounts from ACO expenditure and revenue calculations for the relevant CY. It would also exclude these amounts from historical benchmarks used to reconcile the ACO for a performance year. Finally, CMS proposes to clarify its discretion in determining whether to reopen payment determinations.

We applaud CMS for taking quick action to develop proposals to address concerns raised by the AHA and other stakeholders regarding the potential impact of SAHS billing. As the CY 2023 fraudulent catheter billing demonstrated, SAHS has the potential to significantly impact ACO financial calculations. Indeed, the recent catheter billing issue increased some ACOs' total spending by as much as 2%. As such, in many cases, the inclusion of this spending would actually lead to a loss of shared savings. **As such, we support CMS' proposal to exclude SAHS billing from future ACO financial calculations and historical benchmarks.** That said, this proposed rule would apply only to the MSSP. We encourage the agency to also evaluate impact and pursue similar policies for other APMs outside of MSSP. For example, the ACO Realizing Equity, Access, and Community Health (REACH) model appears similar to anomalous catheter billing, as has bundled payments for care improvement (BPCI) and comprehensive care for joint replacement (CJR). **Therefore, we would encourage CMS to adopt similar policies across APMs.**

To identify future instances of SAHS billing, we encourage CMS to create an outlier policy. For example, CMS could remove services from ACO financial

calculations if spending for those services surpasses some pre-determined threshold (e.g., two standard deviations from the mean) for individual billing codes.

Revised ENHANCED Track RFI. Currently, the ENHANCED track is a two-sided risk track under MSSP that has the highest level of risk/reward (at 75%). However, as described in the CY 2024 PFS proposed rule, CMS has considered higher-risk tracks within the MSSP program (somewhere between 80% and 100% at risk). For CY 2025, it seeks feedback on potential features of a revised ENHANCED Track, including benchmark discount rates, tapered sharing arrangements, medical-loss ratios (MLR) and caps on regional adjustment weights.

While we support the creation of additional tracks to support higher levels of risk, we oppose the revision or replacement of the existing ENHANCED track to require a higher level of risk. We have consistently advocated for common principles to guide value-based model design, including appropriate glide paths to assume higher levels of risk and voluntary participation.[12] Replacing the existing ENHANCED track with a higher level of risk would undermine CMS' existing glide paths. This would expose some providers to additional risks they are not equipped to assume and essentially create a "bait and switch" for providers already participating in the ENHANCED track (since terms would change amid implementation).

Instead, we recommend CMS create a new voluntary risk track that would allow providers currently participating in the ENHANCED track to assume more risk while enabling providers that wish to remain in the current ENHANCED track an opportunity to do so. Adding a new voluntary higher-risk track would provide an opportunity for the approximately 33% of ACOs participating in the ENHANCED track to assume higher levels of risk, continue to further innovate care pathways, and ultimately serve as a bridge to other capitated models like ACO REACH, *should they so wish*. The argument that creating a separate track would lead to self-selection issues, where only the highest-performing ACOs would participate, does not hold water. Indeed, this same argument could be made for any other risk tracks in the MSSP program. We would welcome the opportunity to provide additional feedback on design elements like benchmark discount rates, tapered sharing arrangements and regional adjustment weights for this voluntary new track if it were to be proposed.

We also would like to continue to reiterate the removal of problematic policies that prevent hospitals, in particular, from assuming higher levels of risk. For example, the agency has used a high-/low-revenue designation label as a proxy measure to determine if an organization is supporting underserved populations and/or is physician-led to qualify for advance investment payments. Yet, there is no valid reason to conclude that this delineation, which measures an ACO amount of "captured" revenue, is an accurate or appropriate predictor of whether it treats an underserved region. In

[12] https://www.aha.org/testimony/2024-06-26-aha-house-statement-improving-value-based-care-patients-and-providers

fact, analysis suggests that critical access hospitals, FQHCs and RHCs are predominantly classified as high revenue. Further, both low- and high-revenue ACOs are working to address health equity as part of their care transformation work; assistance investing in these efforts would help across the board. **We urge the removal of problematic high-/low-revenue thresholds that preclude rural and critical access hospitals from obtaining necessary resources for infrastructure investment and prevent other hospitals from participating in full-risk models.**

CHANGES TO THE QUALITY PAYMENT PROGRAM

Mandated by MACRA, the QPP began on Jan. 1, 2017, and includes two tracks — the default MIPS and clinicians with a sufficient level of participation in certain APMs.

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

However, the AHA remains concerned about the direction of the MIPS Value Pathways (MVPs) which CMS intends as an eventual replacement for the current approach to MIPS and CMS' approach to MIPS cost measurements. AHA offers comments below on several proposed QPP policy changes and RFIs that CMS included in the proposed rule.

MIPS Value Pathways. In the proposed rule, CMS proposes several new MVPs and solicits input on transitioning to mandatory MVP participation beginning with the CY 2029 reporting period. **The AHA supports CMS' proposal to add six new MVPs available for voluntary participation beginning with the CY 2025 performance period.** Specifically, CMS would add MVPs focused on ophthalmology, dermatology, gastroenterology, pulmonology, urology and surgical care.

However, the AHA believes it remains premature to set any date certain for mandating participation in MVPs for all MIPS-eligible clinicians and groups. We strongly urge CMS to keep MVP participation voluntary at this time. Indeed, the AHA believes there remain several conceptual and practical barriers to mandating MVP participation. As we have advised in prior comment letters if CMS is intent on mandating MVP participation in the future, we urge the agency to take the following steps:[13]

[13] https://www.aha.org/system/files/media/file/2019/09/aha-comments-on-cms-proposed-physician-fee-schedule-cy-2020-9-25-19.pdf

- Ensure there are enough measures available to create MVPs applicable to the more than one million eligible clinicians currently participating in the MIPS program. Given the wide range of specialty types participating in the MIPS, this will be exceptionally difficult to achieve. It is not clear how many more MVPs CMS can add to the program without significantly adding to the program's count of measures and improvement activities. Given CMS' correct focus on implementing "Meaningful Measures" in its programs, it would seem misguided to add measures just for the sake of having enough of them to create an MVP.

- Ensure MVPs provide fair and equitable performance comparisons across clinicians, groups and specialties. If CMS' ultimate intention is to either assign or require clinicians to select 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 daunting issue to address, but one that is essential for the MVPs to have credibility with participating clinicians and the public. To provide insights on this question, we urge CMS to continue constructing "prototype" MVPs and examine the performance distributions across MVPs to determine whether any specialty types or group types score any worse than others.

- Avoid imposing excessive administrative burdens on multi-specialty practices. We appreciate CMS' desire to allow multi-specialty practices to use MVPs to participate in the MIPS. However, the AHA remains concerned that CMS' policy of requiring multi-specialty practices to report subgroups starting with the CY 2026 reporting year will lead to excessive administrative and reporting burdens. We urge CMS to reconsider this policy.

MIPS Quality Category. For CY 2025 quality reporting, CMS is carrying over most previously adopted requirements and scoring approaches. However, in addition to updating the inventory of available quality measures, CMS proposes to establish a complex organization adjustment beginning with the CY 2025 performance / CY 2027 payment years for virtual groups and APM entities participating in the MIPS that opt to report eCQMs. CMS would award organizations one measure achievement point for each successfully submitted eCQM that meets data completeness and case minimum requirements. The adjustment would be capped at 10% of the available measure achievement points in the quality category.

The AHA supports this proposal. We agree with CMS that virtual groups and APM entities face unique challenges in aggregating and submitting eCQM data. The adjustment would both incentivize eCQM reporting and recognize the unique efforts of virtual groups and APM entities to report eCQMs.

RFI: Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS. The CAHPS for MIPS survey currently uses a "mixed mode" survey administration protocol in which the survey is first sent in the mail, with follow-up

phone calls to non-respondents. However, in the proposed rule, CMS expresses its interest in changing the survey protocol to first administer the survey electronically via the web, followed by mail and then by phone. CMS' initial mode testing suggests this "web first" survey approach increased response rates by 13%.

The AHA is pleased that CMS is working to establish a web-based survey mode for the CAHPS for the MIPS program. Indeed, at a time when fewer and fewer individuals respond to surveys sent via conventional mail, and when response rates to all types of surveys regardless of administration mode have declined, it is critical that CMS use all modern and effective approaches to collect the patient perspective. That is why the AHA and other stakeholders have long urged CMS to permit the use of web-based surveys for the CAHPS surveys used in CMS programs. We supported CMS' recently adopted policy of permitting web-based surveys for the Hospital CAHPS survey and likely would support it for the CAHPS for the MIPS program as well.

MIPS Cost Category. **The AHA does not support CMS' proposal to adopt six new episode-based cost measures for the CY 2025 reporting year.** The AHA continues to have substantial concerns with the measures used in the MIPS cost category. We 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 consensus-based entity endorsement of all cost measures, re-examining the attribution methodologies, and incorporating risk adjustment for social risk factors where necessary and appropriate.[14]

The AHA supports CMS' proposed updated criteria for removing cost measures from the MIPS program. We appreciate that CMS would consider measure feasibility, implementation costs, concordance with available clinical evidence and overlapping measures in considering whether to remove a cost measure from the MIPS program.

MIPS Improvement Activity Category. **The AHA supports CMS' proposals to simplify the scoring of the MIPS Improvement Activity category and to streamline the number of activities to which attestations apply.** Specifically, CMS would remove activity weightings, ensuring each activity receives an equal weight. CMS also would reduce the number of activities to which clinicians would be expected to attest. While our members appreciate that the MIPS program includes recognition for participation in activities linked to better care, they have expressed concern that CMS' existing participation requirements were excessive and that the scoring approach was confusing. We believe CMS' proposed changes would reduce administrative burden and better enable eligible clinicians and groups to select the improvement activities that are most relevant and meaningful to them.

[14] https://www.aha.org/news/headline/2019-09-25-aha-comments-physician-fee-schedule-proposed-rule-cy-2020

MIPS Category Reweighting. For clinicians that delegate data submission to a third-party intermediary, CMS proposes to allow clinicians to request reweighting of MIPS categories where data may be inaccessible and unable to be submitted for reasons outside the clinician's control. In determining whether to grant the reweighting request, CMS would consider whether the clinician knew or had reason to know of the issue with its third-party intermediary's submission of their data and whether the clinician made reasonable efforts to correct the issue. CMS also would consider whether the issue between the clinician and their third-party intermediary caused no data to be submitted.

The AHA supports this proposal and appreciates CMS' recognition of circumstances beyond the control of MIPS participants that can unexpectedly hinder their ability to submit data. At the same time, we encourage CMS to develop guidance that provides some examples of what "reasonable efforts to correct" data submission issues might look like. By necessity, policies like category reweighting and extraordinary circumstances exceptions require an assessment of the totality of circumstances that may hinder a participating clinician or group's ability to submit data or be assessed fairly on the MIPS. However, there is a risk that "reasonable efforts" could be interpreted subjectively by CMS and its QPP contractors that support category reweighting determinations. By providing illustrative examples and making clear that the examples are not intended to be exhaustive, CMS can ensure that participating clinicians and groups are given every fair opportunity to demonstrate how their ability to comply with data submission requirements may have been hindered by the inability of their third-party vendors to support them.

ADVANCED APMS

The 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. In 2016, CMS finalized the criteria by which clinicians will be determined to be qualified APM participants to receive these incentives. Last year, CMS extended the APM bonus payments into 2025, consistent with the requirements of the CAA of 2023.

Beginning with the CY 2025 performance period, CMS proposes an update to one of its attribution criteria for calculating the patient threshold score. CMS would use claims for all covered professional services to identify attribution-eligible beneficiaries for all advanced APMs. **The AHA supports this proposal.** We agree with CMS that this proposal should enable a more robust and accurate assessment of whether clinicians and groups meet the thresholds to participate in the advanced APM track.