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Advancing Health in America

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September 11, 2023

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–1784–P Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

On behalf of 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) 2024.

We are deeply concerned with CMS' proposed payment update, which would *reduce* payments approximately 3.3% from their CY 2023 levels. This negative update would pose significant risks to patients' access to care and health systems' financial stability, particularly for providers serving historically marginalized communities. Our concern is heightened by the fact that this cut is coming in the wake of over three years of unrelenting financial pressures on the health care system due to COVID-19, along with rising inflation, increasing input costs, and persisting staffing shortages and supply chain disruptions.

At the same time, the AHA applauds CMS' proposals to extend through 2024 many of the COVID-19 telehealth flexibilities. In addition, the AHA continues to

encourage CMS to work with Congress on permanent adoption of waiver provisions such as eliminating the originating and geographic site restrictions for all telehealth services and expanding telehealth eligibility to certain practitioners. We also encourage CMS to leverage its existing statutory authority to make permanent other waivers as appropriate.

We are also pleased that CMS is proposing to delay implementation of its split/shared visit policy and revised Medicare Economic Index (MEI), both of which would have resulted in significant reductions and redistributions in physician revenue on top of this proposed rule's other cuts. In addition, we are encouraged by the agency's proposed reevaluation of the Appropriate Use Criteria for Advanced Diagnostic Imaging program. We have expressed longstanding concerns that the current program could result in inappropriate claims denials, increased administrative burden and ultimately unnecessary delays in patient care.

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, regarding the payment provisions, at jholloman@aha.org, or Akin Demehin, AHA's senior director of policy, pertaining to the quality provisions, at ademehin@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice
President

Enclosure

American Hospital Association
Detailed Comments on the Physician Fee Schedule Proposed Rules for Calendar Year 2024

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CONVERSION FACTOR UPDATE

The proposed payment update for CY 2024 reflects several different factors. Specifically, CMS proposes to cut the conversion factor to $32.75 in CY 2024, a 3.34% reduction from the CY 2023 rate of $33.89. This update includes: the expiration of a 2.5% increase in the PFS conversion factor for CY 2023 *only,* which was provided by the Consolidated Appropriations Act of 2023; a 1.25% increase in the PFS conversion factor for CY 2024 *only*, which was provided by the CAA, 2023; 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 considering the declines in physician reimbursement over the last few decades. Data from the Medicare Trustee's Report indicate that physician reimbursement has dropped over 20% over the last 20 years when accounting for inflation.[1] Indeed, as noted in a December 2022 MedPAC presentation, inflation (as measured by the MEI) is growing faster than increases in PFS rates.[2] This suggests that reimbursement is not keeping pace, and in fact, the delta between rates of inflation and reimbursement rates is getting worse.

Health care providers continue to struggle with persistently higher costs and additional downstream challenges because of the lasting and durable impacts of high inflation and the COVID-19 pandemic. 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.

Finally, because many other payers tie their fee schedules to the Medicare PFS, providers' losses under Medicare's proposed policies are compounded by losses from other payers. Uncertainty in year-to-year payment updates and program extensions have only exacerbated hospital financial instability. Adequately accounting for inflation and rising input costs is essential to supporting hospitals' and physicians' abilities to provide access to needed services for patients.

We are deeply concerned that the conversion factor cut will have an extremely negative affect on patients' access to certain services. For example, a recent Medical Group Management Association poll found that, in 2022, 90% of physician practices said that the payment cuts for 2023 would reduce access, direct impacts of

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[1] https://www.beckershospitalreview.com/hospital-physician-relationships/the-stark-reality-of-physician-reimbursement.html

[2] https://www.medpac.gov/wp-content/uploads/2021/10/Tab-E-Physician-Updates-8-Dec-2022.pdf

which would include reducing staff and considering office closures.[3] After hospitals' and health systems' unyielding efforts to ensure their ability to care for patients, this rule's proposed cuts threaten their ability, as well as that of their clinicians, to continue to offer essential services to the patients who need them.

Therefore, we strongly urge CMS to work with Congress to eliminate the budget neutrality cut to the conversion factor for CY 2024. 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 is simply not sustainable for providers.

REVISING THE MEDICARE ECONOMIC INDEX

The 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 prices 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 had been 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 that represent all types of physician practice ownership. However, the agency did not actually apply the new weights to its payment methodology in 2023. This was because while it anticipated that revised weights would not impact overall spending for PFS services, they would impact distribution of payments based on geography and specialty.

For CY 2024, CMS proposes to again delay 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 PHE.

We share CMS's 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

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[3] https://www.mgma.com/getmedia/00456f68-8a79-4d3e-bc8c-d54a33e4ded0/MGMA-Stat-2022-Year-in-Review-Final.pdf.aspx?ext=.pdf

would also occur. For example, a significant reduction in the weight of office rent would lead to reductions in payments 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 to the conversion factor that CMS has proposed in this year's rulemaking.

REQUEST FOR INFORMATION ON STRATEGIES FOR UPDATES TO PRACTICE EXPENSE DATA COLLECTION

Since 2007, the AMA Physician Practice Information Survey (PPIS) has supported identification of direct and indirect practice expenses (PEs). Integration of PPIS data was phased into CMS RVU calculations over the course of 2010-2014. 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. **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 (estimated in December of next year).

GEOGRAPHIC PRACTICE COST INDEX (GPCI)

The CAA, 2021 extended a 1.0 floor on the work GPCI through Dec. 31, 2023. With the expiration of this extension, CMS proposes that CY 2024 work GPCI will no longer reflect the 1.0 floor. **We urge CMS to work with Congress to implement a non-budget neutral work GPCI floor for CY 2024.**

A recent GAO report found that removal of the work GPCI floor may adversely impact rural providers, as the locations where the actual work GPCI are lower than the national average are expected to have $415.8 million in losses.[4] These areas already are challenged by inadequate reimbursement and provider shortages. Further cuts will continue to exacerbate inequities in access and provider coverage.

PAYMENT FOR DENTAL SERVICES

CMS proposes to cover certain dental services linked to certain covered medical services for immunocompromised beneficiaries, including:

- Chemotherapy when used in the treatment of cancer
- CAR-T therapy when used in the treatment of cancer

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[4] https://www.gao.gov/assets/gao-22-103876.pdf

- Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer

CMS proposes payment for dental exams performed in the inpatient or outpatient setting, medically necessary diagnostic and treatment services for infections, and ancillary services for dental services (e.g. x-rays, anesthesia, etc.) when they are linked to above services.

We support coverage for the above circumstances, however we urge CMS to provide coverage for *all* immunocompromised beneficiaries, not only those receiving the above services.

CHANGES TO PAYMENT FOR TELEHEALTH SERVICES

CMS proposes several changes to telehealth services that build on the numerous, critical telehealth flexibilities provided during the COVID-19 public health emergency (PHE), and the additional flexibilities that the agency finalized via rulemaking and sub-regulatory guidance, which have enabled our members to better serve their communities. **The AHA and our members continue to applaud the Administration's support of telehealth and ongoing study into creating a long-term structure for the efficient delivery of telehealth services.**

Among the fundamental changes that resulted from the COVID-19 PHE is the way patients consume health care. The significant uptake of telehealth and other virtual care services increased patients' access to physicians, therapists and other practitioners, helping ensure they receive the right care, at the right place, at the right time. A report from the Department of Health and Human Services found that in 2020, telehealth services increased by over 51 million encounters, representing a 63-fold increase from 2019.[5] Furthermore, there is a growing body of evidence to suggest that for the vast majority of specialties, telehealth services provided during the COVID-19 pandemic were not duplicative of in-person services. For example, most recently, a study of over 35 million records by Epic found that for most telehealth visits across 33 specialties, there was not a need for an in-person follow-up visit within 90 days of the telehealth visit.[6] In other words, telehealth served as an effective substitute for in-person care and did not result in duplicative care. Also, given some of the current health care challenges, such as major clinician shortages, telehealth holds tremendous potential to leverage geographically dispersed provider capacity to support patient demand.

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[5] https://www.cms.gov/newsroom/press-releases/new-hhs-study-shows-63-fold-increase-medicare-telehealth-utilization-during-pandemic
[6] https://epicresearch.org/articles/telehealth-visits-unlikely-to-require-in-person-follow-up-within-90-days

Changes to Medicare Telehealth Services List. To assess requests for adding or deleting services from the Medicare telehealth list of services under Section 1834(m) of the Social Security Act, CMS historically assigned the requests to one of two categories. Category 1 services are similar to services that are currently on the Medicare telehealth list, whereas Category 2 services are not similar to services on the list, and, as such, CMS requires supporting evidence of its clinical benefit to add said service to the list. In the CY 2021 PFS final rule, CMS added a third category of criteria for adding services to the Medicare telehealth list on a temporary basis. “Category 3” describes services added during the COVID-19 PHE for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the services as permanent additions under the Category 1 or Category 2 criteria. In this rule, CMS proposes to not include on a permanent basis but to include on a temporary basis through CY 2024 42 codes. These include:

- Cardiovascular and Pulmonary Rehabilitation (CPT codes 93797 and 94625)
- Deep Brain Simulation (CPT codes 95970, 95983, 95984)
- Therapy Services (CPT codes 90901, 97110, 97112, 97116, 97161-97164, 97530, 97550, 97663).
- Hospital Care and Emergency Department Care (99221-99236, 99238, 99239,
- 99281-99283)
- Health and Well-Being Coaching (0591T-0593T)

CMS also proposes permanent inclusion of a new HCPCS code for Social Determinants of Health Risk Assessment (GXXX5), pending adoption of CMS’ general proposal for addition of this code (see “Services Addressing Health Related Social Needs” Section).

The AHA supports the agency’s proposed additions to the eligible telehealth services list, which will add to the tools providers can use to care for patients. We also urge the agency to consider these on a permanent basis. In addition, for the therapy codes, we urge CMS to work with Congress to permanently expand eligible provider types to include physical therapists, occupational therapists, speech language pathologists and audiologists. We recognize this would be required in order to adopt therapy codes on a permanent basis.

Revisions to the Process for Considering Changes to the Medicare Telehealth Services List. As noted above, CMS currently has three categories for eligible telehealth services. For CY 2024, CMS proposes to replace the current three categories with a pair of categories: “permanent” or “provisional.” Services currently identified as Category 1 or Category 2 would be redesignated as “permanent” for CY 2024. Any codes that are listed as Category 3 or temporary would be assigned to “provisional” status. Provisional codes would be re-evaluated in future years to determine if they should be added on a permanent basis or removed from the fee schedule. CMS does not propose a timeline for re-evaluating provisional codes.

CMS also proposes to revise the process for adding services to the telehealth eligible list. The revised process would consist of the following steps:

1) identify if the service is separately payable under the PFS;
2) determine if the service is subject to provisions of section 1834(m) of the Social Security Act;
3) review elements of the service and determine if each can be completed via interactive telecommunications technology;
4) consider if the service elements map to service elements of other services that are already included as permanent; and
5) consider if the clinical benefit of telehealth service is analogous to clinical benefit of in person service.

We support CMS' proposed simplification of the process to add codes to the list of eligible telehealth services. We also support streamlining the telehealth categories into "permanent" and "provisional" designations. The historical presence of 3 categories as well as other temporary codes has led to confusion in the field on what is considered an eligible telehealth service. That said, we encourage CMS to develop similar processes to evaluate virtual services outside of the historical definition of telehealth. CMS has already adopted on a case-by-case basis non-face-to-face codes for Remote Physiological Monitoring, Remote Therapeutic Monitoring, Artificial Intelligence, and eVisits as well as Virtual Check-ins. This would also potentially enable evaluation of audio-only applications and services. As technology advances, applications of digital care delivery will become broader than audio-visual visits. Many of these services may be captured in the proposed "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.

Implementation of Provisions of the Consolidated Appropriations Act, 2023. CMS proposes to implement the telehealth provisions in the Consolidated Appropriations Act, 2023 (CAA, 2023). These provisions extend the following policies through Dec. 31, 2024:

- delaying the in-person visit requirements for mental health services furnished via telehealth;
- waiving the geographic and originating site rules to allow telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home;
- allowing certain services to be furnished via audio-only telecommunications systems;
- allowing physical therapists, occupational therapists, speech-language pathologists and audiologists to furnish telehealth services; and

- allowing continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established during the COVID-19 PHE.

We support this proposal. In addition, we urge the agency to work with Congress to make the above waivers permanent, in line with what we have recently communicated to Congress.[7] The COVID-19 PHE has made clear that telehealth is a key feature in providers' toolboxes and, thus, has a permanent place in the future of care delivery. Permanent extension of the above waivers would allow patients nationwide to receive telehealth services in their homes, residential facilities and other locations. Without this change, much of the progress that has been made since the COVID-19 pandemic first hit will disappear, since historically telehealth was limited to rural areas of the country and required patients to be at certain facilities to receive care. The COVID-19 PHE clearly demonstrated the need to access telehealth in non-rural areas and in the safety of patients' homes, and we urge CMS to partner with us to help ensure federal policy reflects the realities of today's health care environment.

Place of Service for Medicare Telehealth Services. 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 modifier "95" for telehealth claims for the duration of the COVID-19 PHE and report the Place of Service 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 in 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 Place of Service codes:

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

For 2024, CMS proposes that for claims billed with a POS "10," providers would be paid at the non-facility rate. The agency stated that since tele-mental health services to the patient's home are approved on a permanent basis, and costs for those services do not vary significantly between in-person and virtual for those services, then all at-home services should be reimbursed at the non-facility rate. For claims billed with a POS "02," CMS proposes that providers would be paid at the lower facility rate.

The AHA supports reimbursement at the non-facility rate for telehealth visits to the patients home. However, we request that the agency issue sub-regulatory guidance to operationalize this element for hospitals and hospital outpatient

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

departments administering services. In addition, we also request the agency issue clarifying guidance specifying that this policy would be applicable for *any* telehealth services to the patient's home, not only tele-mental health.

However, we disagree that telehealth provided to locations other than the patient's home should be reimbursed at the facility rate. In these instances, reimbursement should reflect a rate based on where the service would have occurred if it were in person, as was done during the PHE. Prior to the COVID-19 pandemic, CMS reimbursed providers administering telehealth at a facility rate regardless of if the provider were 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 virtually room patients or software licenses. This was a challenge for providers, who were providing the same level of work and quality of care as in-person visits, but receiving less reimbursement. During the COVID-19 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.

We note that this policy directly implemented requirements of Section 1834 of the Social Security Act, which states 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." This requirement was permanently adopted as part of the SSA, and was not tied to waivers. Therefore, it is still in effect.

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 if the encounter were in person or virtual. For example, malpractice expenses, which cover professional liability insurance premiums, are the same regardless of the method that care is delivered. In addition, for practice expense (which covers 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).

<u>Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facilities and Critical Care Consultations</u>. Historically, certain telehealth eligible services had frequency limitations. During the COVID-19 PHE, certain frequency limitations were lifted, and CMS indicated that it was exercising enforcement discretion through CY 2023.

For CY 2024, CMS proposes to 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)

This would align with other CAA, 2023 flexibilities and allow additional time for input on the provision of these services. **The AHA supports the proposed extension of flexibilities to waive frequency limitations for the telehealth inpatient, nursing facility, and critical care consultation services listed above.**

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). In the proposed rule, CMS proposes guidance in several areas:

New vs. Established 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 the proposed rule, CMS proposes to return 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 a critical capability to safely discharge patients with chronic conditions from the hospital, transition patients to better self-manage conditions 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 extend flexibilities to allow for both new and established patients to access RPM and RTM services.**

Data Collection Requirements. CMS proposes to revert to pre-COVID-19 pandemic rules where data collection must be for at least 16 days in a 30-day period in order to bill for services. Services can only be reported once per month (only one practitioner can bill for services regardless of the number of devices used). **However, we encourage CMS to evaluate alternative options for clinical use cases that may not require 16 days of monitoring in a 30 day period.**

Use of RPM and RTM in Conjunction with Other Services. In the proposed rule, CMS proposes that RPM and RTM cannot be billed at the same time, but either may be billed concurrently with Chronic Care Management (CCM)/Transitional Care Management (TCM)/Behavioral Health Integration (BHI), Principal Care Management (PCM), and Chronic Pain Management (CPM) services.

While we strongly support concurrent billing for RPM/RTM with CCM, TCM BHI, PCM and CPM services, however, we contend that concurrent billing for RPM and

RTM should also be allowed. There are instances where a patient may be treated for co-morbidities and therefore require both RPM and RTM services. For example, a patient may be diagnosed with Congestive Heart Failure and Chronic Obstructive Pulmonary Disease. As such they may require RPM of blood pressure, weight, blood oxygen levels and temperature. They may also require RTM for pulmonary function using spirometers. Being able to use both of these services concurrently would help ensure patients are receiving the right care at the right time.

Use of RPM and RTM in Conjunction with Global Period. In the rule, CMS proposes that when a beneficiary receives a procedure or surgery under a global period, RPM or RTM services can be administered and separately billed so long as they are unrelated to the diagnosis for the global procedure, and must address an episode of care that is separate and distinct from the global service.

We disagree that RPM and RTM services should need to address an episode of care that is separate and distinct from global service in order to be separately billed. Global services do not account for the time and work associated with technology set-up and monitoring; therefore, providers should be able to bill for RPM and RTM services regardless of their relation to the global service.

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. Prior to 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 2024. **The AHA strongly supports the proposed extension of virtual presence to satisfy direct supervision requirements by interactive telecommunications technology. We urge the agency to make this policy permanent and stand ready to assist in determining appropriate guardrails for its operationalization.**

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, flexibilities for virtual supervision were extended to include MSAs. CMS is exercising enforcement discretion through CY 2023.

In this rule, CMS proposes to extend virtual supervision flexibilities for all residency training locations through the end of CY 2024. **The AHA strongly 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 in both non-MSAs and MSAs during the COVID-19 PHE has enabled improved access for patients 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 essential in training 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. Extending virtual supervision flexibilities for residents falls within regulatory purview of CMS, and other independent accrediting organizations (such as ACGME) have updated competencies and guardrails to ensure patient safety during encounters that are virtually supervised.

We request clarification that this does not only apply to virtual services where the resident, supervising physician and patient are in 3 separate locations at the time of the visit, and that it also includes other instances. For example instances where the resident and patient are in one location and the supervising physician is in another. For many hospitals and health systems, supervising physicians may be geographically dispersed or balancing supervisory functions with care delivery and administrative tasks. To maximize the benefit of virtual modalities (i.e. to connect geographically dispersed supply with demand), we would encourage flexibility. 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.

Payment for Medicare Telehealth Services Furnished Using Audio-only Communication Technology. Historically, section 1834(m) of the Social Security Act specifies that for Medicare payment, telehealth services must be furnished via a “telecommunications system.” In 42 CFR § 410.78(a)(3), 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.”

During the COVID-19 PHE, CMS established separate payment for telephone E/M services, including CPT codes 99441-99443 and 98966-98968. In accordance with the CAA, 2023, which extended audio-only services, CMS proposes to extend payment for telephone E/M services through CY 2024.

The AHA continues to enthusiastically support CMS’ ongoing efforts to reimburse audio-only services. This flexibility has enabled our 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 who otherwise were not able to participate in audio-visual encounters. Indeed, a recent report from ASPE reviewing Census Bureau data from 2021 found that there were 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, the majority of surveyed respondents 65 and older used audio-only visits (56.5%) compared to video visits, partly driven by the fact that over 26% of Medicare beneficiaries reported not having computer or smartphone access at home.[8] Continued coverage and reimbursement for audio-only services will ensure that patients without access to technology are still able to access care where clinically appropriate. Additionally, audio-only behavioral health services have become extremely popular with patients who are more comfortable without hour-long, face-to-face visits. Reverting audio-only telehealth to pre-COVID-19 PHE requirements would be a disservice to the most underserved Medicare beneficiaries. **Therefore, we urge CMS to do all that it can, including working with Congress, to enable permanent support for audio-only telehealth.**

Payment for Virtual Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy to Patients' Homes. During the COVID-19 PHE, CMS established the Hospital Without Walls policy, which enabled hospitals to classify patients' homes as temporary extension sites for the provision of services. This also enabled billing of virtual services furnished by HOPDs to include diabetes self-management training and medical nutrition therapy. In combination with other CAA telehealth flexibilities to enable expansion of eligible provider types, HOPDs were able to administer remote virtual occupational, physical and speech therapy services to patients' homes as well. Remote therapy services supported improved access for patients with mobility issues, transportation issues, and patients in underserved areas with a significant distance to travel for in person appointments. There is also growing evidence that these flexibilities also supported improved treatment adherence and increased patient satisfaction.

In this rule, CMS proposes to continue to allow institutional providers to provide remote outpatient physical therapy, occupational therapy, speech language pathology, diabetes self-management training, and medical nutrition therapy in patients' homes through CY 2024. CMS also seeks input on future rulemaking in terms of whether these services should be allowed permanently and whether they fall under statutory purview of CMS (as defined in section 1834(m) of the Social Security Act).

We support CMS' proposal to extend flexibilities through 2024 to allow 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 due to the impact this has on patient access and satisfaction. Many organizations continue to depend on remote therapy services for geographically dispersed patients, patients without reliable transportation, patients with lengthy drive times and those 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

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

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.[9] Survey respondents also reported benefits such as being able to get tailored feedback from providers on equipment that was set up in their home, more easily coordinating caregiver training for patient transitions back to their home since caregivers could be at the patient's home with the patient, and reduced drive times and added convenience.

While we support extension of these flexibilities, we would also ask CMS to provide clarifying implementation guidance on its proposed policy. Therapy services fall under the Physician Fee Schedule (per Chapter 6 of the Medicare Benefit Policy Manual). However, for many hospitals and health systems, physical therapists, occupational therapists, and speech language pathologists are employed by the hospital under outpatient hospital-based services. Therefore, they bill for these professional services on the UB-04 (not the CMS-1500 claims form).

For CY 2023, CMS indicated that it would exercise enforcement discretion and that providers should continue to bill for these services in the same way they did during the PHE.[10] As such, during the PHE, many organizations that had therapists aligned under a hospital outpatient department would bill on the facility UB-04 form with the appropriate telehealth modifiers. However, without a Place of Service code designation on the UB-04 form, as would be required in CY 2024, it is unclear how CMS would like for HOPDs to process claims forms moving forward. Therefore, we urge CMS to allow institutional providers to bill on the UB-04 using the current guidance and modifiers. There would be undue administrative burden, and in some cases untenable organizational realignment (i.e. different workflows, EHR modules, billing processes, accounting systems etc.), to migrate hospital-based therapists to CMS-1500 claims forms. Updates to the UB-04 could optimize billing for virtual services on the form in the future, but CMS should the current billing guidance until the UB-04 could be updated.

We also continue to urge CMS to work with Congress on necessary statutory updates to ensure these services can be administered permanently. On the statutory side, we support permanent expansion of eligible provider types to include physical therapists, occupational therapists, speech language pathologists and audiologists. (Registered dietitians and nutrition professionals are already included as eligible providers). Also on the statutory side, we encourage permanent elimination of the originating and geographic site restrictions to allow for provision of telehealth

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[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7526401/

[10] https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf

services to patients' homes. One lesson learned from the COVID-19 pandemic has been that patients across geographies and settings, including both rural and urban areas, have benefited from the increased access and improved convenience provided by telehealth services. For example, patients with chronic disease and mobility issues have experienced similar benefits in using telehealth for follow-up appointments regardless of their geography since they could receive care from their home. Data from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) showed that the majority of patients using telehealth in 2020 (92%) received telehealth from their home.[11]

On the regulatory side, we contest that so long as the above are adopted statutorily, CMS would have the authority per 1834(m) to extend these services permanently given that virtual therapy services fall under the Physician Fee Schedule not the Outpatient Prospective Payment System. As professional services that are substitutes for in person, face-to-face visits that can be delivered via real-time audio-visual technology, these services would fall under the current definition of telehealth services.

Provider Home Address. We were disappointed to see that the proposed rule did not include any changes to CMS' forthcoming requirement for providers administering telehealth from their home to report their home address. During the PHE, CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. CMS issued guidance in a Frequently Asked Questions document that the waiver will continue through Dec. 31, 2023.[12] However, beginning Jan. 1, 2024, these providers will be required to report their home address.

We are deeply concerned with this requirement, and the potential privacy issues it poses to providers, since home addresses may be publicly available on sites like Medicare Care Compare without their knowledge or consent. We urge CMS to permanently remove this requirement as soon as possible.

Given experience with COVID-19, many hospitals, health systems and providers have moved to hybrid schedules where some physicians and staff are working remotely. This fosters improved retention, especially in light of the significant staffing shortages nationwide. Requiring providers to list their personal home addresses on enrollment and claims forms, which patients or others in the public have access to, poses privacy and safety risks. **This is a particular concern to us given the increased incidence in violence against health care workers.** Recent studies indicate, for example, that 44% of nurses reported experiencing physical violence and 68% reported

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[11] https://aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf
[12] https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf

experiencing verbal abuse during the COVID-19 pandemic.[13] **At a minimum, CMS must implement a mechanism to automatically mask the home address from any public sites and directories.**

Additionally, there is not clear guidance on the appropriate reporting of the home address. For example, it is unclear if it is only required for providers doing 100% encounters from their home, or whether this would support 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.

SERVICES ADDRESSING HEALTH RELATED SOCIAL NEEDS

The proposed rule includes several coding and billing updates for Social Determinants of Health (SDOH) risk assessments, Principal Illness Navigation Services (PIN) and Community Health Integration (CHI). These are intended to account for resources and services supported by community health workers, care navigators and peer support specialists. **In general, we are very supportive of expanding reimbursement for health related social needs services provided by auxiliary staff such as community health workers and care navigators.**

However, we do have concerns regarding beneficiary cost sharing. For example, CHI services are intended to be provided to patients with health-related social needs that are limiting the ability to treat or diagnose a condition. Therefore, in many cases, cost-sharing may not be feasible or would be a deterrent to accessing services. **As such, we encourage CMS to work with Congress to waive cost-sharing requirements for the health-related social needs codes in the final rule.**

Additionally, we encourage CMS to align health related social needs requirements and provide sufficient reimbursement regardless of site of care. For example, although there are new health-related social needs screening measures in the Inpatient Quality Reporting (IQR) Program that are intended to encourage hospitals to conduct screening during inpatient stays, there is currently no additional reimbursement for screenings under the inpatient PPS. Yet, under this proposed rule, the same screening in a physician office would be reimbursed because it appropriately recognizes that these services warrant reimbursement due to the clinical time and effort required to perform. Ensuring sufficient reimbursement regardless of the site of care would also incentivize screening by the appropriate provider in the appropriate clinical setting (hospital, hospital outpatient department, or practice setting).

Specific feedback on the individual proposals are below.

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[13] 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

CHI Services. CMS proposes to create two new G codes for CHI services performed by certified and trained auxiliary personnel incident to professional services under the general supervision of the billing practitioner. It is proposing that the creation of these new codes would identify and value these services for PFS payment and distinguish them from current care management services.

- GXXX1: Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit. This would include an assessment, care coordination, health education, building patient self-advocacy skills, health system navigation services, and social support services.
- GXXX2: Community health integration services, each additional 30 minutes per calendar month (List separately in addition to GXXX1)

While we support reimbursement of CHI services and inclusion of auxiliary staff, we do request clarifying guidance to ensure appropriate assignment of HCPCS codes and claims submissions. Specifically, the proposal indicates that auxiliary staff can be employed by a community-based organization so long as they are contracted with a Medicare enrolled provider. Certain specialties may have limitations on incident to billing for auxiliary staff not employed by the physician (like behavioral health), in which case we'd like to clarify ability to bill for services. **Also as mentioned above, we do have concerns about patient cost sharing and encourage CMS to work with Congress to waive cost sharing requirements for these services.**

SDOH Risk Assessment. CMS proposes a new stand-alone HCPCS G code for administration of a standardized, evidence-based SDOH risk assessment.

- GXXX5: Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every six months This would need to be administered on the same day as an E/M visit. The assessment would need to include a standardized SDOH risk assessment tool that includes housing, food insecurity, transportation needs and utility difficulties and SDOH needs would need to be documented in the medical record. There would also be a frequency limitation (billable once every six months).

We support reimbursement for the time and effort associated with SDOH screening. However, we request clarifying guidance on what constitutes a "standardized, evidence based screening assessment" to help facilitate the appropriate and consistent assignment of this new HCPCS code. Given that there is currently not a standardized screening tool requirement for other programs like IQR, many organizations have invested resources in developing their own tools to assess for health-related social needs. We request flexibility in the screening instruments can be

used to qualify for reimbursement so that hospitals and health systems can standardize screening tools and procedures within their organization. We also request consistency across programs in terms of standards for SDOH screening. This will support a more consistent patient experience across sites of care.

PIN Services. CMS proposes to create a parallel set of services focused on patients with serious, high-risk illness who may not necessarily have SDOH needs. These PIN services would have new G codes:

- GXXX3: Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month
- GXXX4: Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to GXXX3)

Similar to CHI services, we encourage CMS to issue additional HCPCS coding application and billing guidance. For example, we request clarification on appropriateness of billing the two new G codes versus Principal Care Management codes (CPT codes 99424 through 99427) for Clinical Patient Navigators. We also are similarly concerned about potential cost-sharing implications for these services and encourage CMS to work with Congress to waive cost sharing requirements for these services.

PAYMENT FOR EVALUATION AND MANAGEMENT SERVICES

Split (or Shared) E/M Visits. A “split” or “shared” E/M visit is one that is performed by both a physician and a non-physician practitioner (NPP) in the same group. Because Medicare provides higher PFS payment for services furnished by physicians than those furnished by NPPs, CMS has addressed when physicians can bill for split visits. Specifically, physicians in a facility setting may bill for an E/M visit when both the billing physician and an NPP in the same group each perform portions of the visit, but only if the physician performs a “substantive” portion of the visit. If the physician does not perform a substantive part of the split visit and the NPP bills for it, Medicare will pay only 85% of the fee schedule rate.

In CY 2022, CMS finalized a policy under which the agency would define the “substantive” portion of the visit as more than half of the total time spent. Last year, CMS delayed implementation of this policy for one year. In this year’s rulemaking, CMS proposes delaying implementation of this policy for at least an additional year, until Jan. 1, 2025. Thus, for 2024, the substantive portion would continue to be defined as either one of the three specified key components of a visit, or more than half of the total time.

We continue to have substantial concerns about this policy and thus support CMS’ proposal to delay its implementation. We urge the agency to use this delay to

re-examine this policy, including by working with stakeholders to develop an alternative proposal to billing split or shared visits.

Add-On Outpatient/Office (O/O) E/M Complexity Code. In the rule, CMS proposes implementation of a new add-on code (G2211) to account for intensity and clinical complexity. This is 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, 2021. With the expiration of the moratorium scheduled for the end of 2023, CMS proposes to change the payment status to "active" beginning Jan. 1, 2024.

While we directionally support adjustments to reimbursement to account for clinical complexity, we are concerned about the redistributive impact of this particular code and impact on the conversion factor in outyears. In the proposed rule, CMS updated projections to indicate that this would potentially impact 38% of E/M office visits, and ultimately over half of E/M office visits. It is unclear given this volume how this relates to current E/M levels and future resource allocation. In addition, there is general confusion about the definition application, and reporting of this code. Therefore we ask the agency to issue additional clarifying guidance on resources, typical patient, time, definition and reporting.

ADVANCING ACCESS FOR BEHAVIORAL HEALTH SERVICES

In this rule, CMS proposes policies to implement several provisions of the Consolidated Appropriations Act of 2023 (CAA) designed to enhance access to behavioral health services. The AHA appreciates the approach to behavioral health that CMS appears to be taking in this and other rules for CY 2024. It is clear that CMS has considered the feedback provided by stakeholders including the AHA and its thousands of members in developing its proposals, and we are hopeful that the agency will continue this work with the input of patients, providers and partners into the future.

Coverage of Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs). The CAA adds a new benefit category under Medicare Part B to include MFT and MHC services. CMS proposes to create new regulation sections to codify the coverage provisions, including the professionals and eligible services included in the coverage. CMS is proposing to implement the benefit according to provisions already outlined by the CAA; **the AHA supports this approach and appreciates that CMS is working to expand access to behavioral health services by allowing for qualified professionals to provide this vital care.** In particular, we appreciate that CMS proposes to allow addiction counselors who meet the same coverage criteria to enroll in Medicare as MHCs. These specialized professionals offer unique services for people with addictions, and this provision will improve access to care.

Mobile Crisis Code. To implement another provision of the CAA, CMS proposes to create two new G-codes describing psychotherapy for crisis services furnished in any

place of service at which the non-facility rate for psychotherapy for crisis services applies. The agency proposes that these would be billed when the services are furnished in any non-facility place of service other than the physician's office setting, including the patient's home, temporary lodging (such as hotels and homeless shelters), or even a short distance from the patient's exact home location. The codes would be paid at 150% of the current PFS non-facility RVUs for similar psychotherapy for crisis codes. **The AHA supports this provision and is pleased that CMS is working to implement the provisions of the CAA without delay.** We hope that the agency is open to improvement and refinement of these codes as we glean more information about their use after they become available.

Adjustments to Payment for Timed Behavioral Health Services. CMS acknowledges the growing need for access to behavioral health services and the underlying process limitations that have resulted in undervaluing of person-to-person time-based work (such as CPT codes describing 45 minutes of psychotherapy). The agency notes that it plans to work on a long-term solution to determining how to appropriately value these types of services, but in the meantime it would allow practitioners to apply the add-on code for office/outpatient E/M services that involve inherent complexity (G2211, as discussed above) to certain psychotherapy codes. CMS estimates that this would result in an approximate upward adjustment of 19.1% for work RVUs for nine existing psychotherapy codes as well as the two newly proposed codes for mobile psychotherapy.

The AHA greatly appreciates CMS' thoughtful analysis of the dynamics that have led to the systematic undervaluing of time-based behavioral health services. We, our members, and many other stakeholders in the behavioral health community have been arguing this point for years. We look forward to working with CMS to develop more permanent solutions to appropriately valuing behavioral health services, both timed and untimed.

Periodic Assessments via Audio-Only for OTPs. CMS proposes to allow OTPs to conduct periodic assessments via audio-only interactions through the end of CY 2024. **The AHA supports this provision and recommends that CMS consider allow for permanent flexibility in the use of audio-only for opioid treatment program services including periodic assessments.**

RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS

General Care Management Services in RHCs and FQHCs. In the rule, CMS proposes several changes to care management services. Specifically, it would include RPM and RTM services as well as new services for Health Related Social Needs (CHI and PIN) in the consolidated general care management HCPCS code (G0511) when furnished by RHCs and FQHCs. This code includes a variety of services including CCM, TCM, general behavioral health integration, and Chronic Pain Management. Adding these

services to the G0511 code would encompass 22 different services in this consolidated code.

While we appreciate that CMS is seeking to reimburse for these services for FQHCs and RHCs outside the AIR, we are concerned about the level of reimbursement and impact on other general care management services. Specifically, CMS proposes to significantly reduce the rate for G0511 after adding these services. Not only is this counterintuitive, but also it would impact CCM and TCM reimbursement for organizations who may not actually provide RPM and RTM since CCM and TCM are already included in the code and organizations may only be able to bill for one service per patient per month. Even using a weighted average of services included in the code would reduce rates notably, from $77.94 to $72.98. Adding RPM, RTM, CHI or PIN services takes time and investment to build those capabilities. Meanwhile, under this reimbursement, organizations would face decremented reimbursement. Therefore, we **recommend that CMS carve RPM and RTM services, as well as Health Related Social Needs services out of the G0511 General Care Management Services code and reimburse them separately at the PFS rate for FQHCs and RHCs**. At a minimum, additional guidance would be required in terms of whether the G0511 could be billed more than once per month. **CMS should allow multiple G0511 services to be allowed per patient per month considering many of these services are allowed to be billed concurrently in the PFS.**

PROVIDER ENROLLMENT

<u>Timeframes for Reversing a Revocation</u>. Current regulations provide that if an enrollment revocation was due to adverse activity by a provider or supplier's owners, managing employee, authorized or delegated officials, or supervising physician, the revocation can be reversed if the provider or supplier terminates, and submits proof that it has terminated, its business relationship with that party within 30 days of the revocation notification. CMS has been concerned that this 30-day period is too long for Medicare payments to be made to providers and suppliers that have relationships with parties presenting program integrity risks. Therefore, CMS proposes to reduce this 30-day period to 15 days and seeks comments on whether 15 days is an appropriate timeframe.

The AHA recommends opposes this proposed policy change. Instead, we recommend that it continue the 30-day period. Fifteen days is simply too short a period to allow many providers, particularly larger hospitals or health systems with many structural layers and large numbers of employees and contractors, to conduct the due diligence necessary to consider and carry out a termination of a business relationship and submit proof of this termination to CMS. Moreover, we are not convinced that a 30-day period versus the proposed 15-day period to end a business relationship substantially increases the risk to the Medicare program.

Definition of "Pattern or Practice". CMS states that there are three existing reasons for Medicare enrollment revocation that are based on the provider or supplier engaging in a "pattern or practice" of certain conduct:

- The provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.
- The physician or eligible professional has a pattern or practice of prescribing Part B or D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements.
- The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

In response to stakeholder questions regarding what constitutes a pattern or practice under these provisions, the agency notes that it has always made these determinations on a case-by-case basis and does not propose changing this general procedure. However, in order provide additional clarity for stakeholders and to institute minimum regulatory parameters, CMS proposes to establish a definition of pattern or practice to mean that the provider or supplier engaged in the "pattern or practice" of conduct *in at least three instances*. CMS notes that this does not mean three non-compliant claims, orders, etc., would always trigger a revocation.

The AHA urges the agency not to finalize this definition of pattern or practice. Although the proposed rule provides certain cautionary language about three instances not automatically triggering a revocation, that language is not sufficiently clear or certain. In addition, three instances is not a sufficient "pattern or practice" to qualify under that term. That is, "pattern or practice" is a term of art in the law, and it is typically understood to require more than three instances. Indeed, it is our understanding that "pattern or practice" typically means activity done in a systematic way, typically by means of policies and procedures. Thus, we are concerned that the three-instance threshold sets too low a bar, deviates from the original understanding of pattern or practice, and gives the agency too much discretion to impose serious consequences without a sufficient factual basis.

False Claims Act (FCA) Civil Judgments. CMS proposes to revoke the enrollment of a provider or supplier if it, or any owner, managing employee or organization, officer, or director thereof, has had a civil judgment under the FCA imposed against them within the previous 10 years. CMS notes that a "civil judgment" would not include FCA settlement agreements, but a judgment against the provider or supplier.

CMS should not finalize this policy. While the agency appropriately does not include settlement agreements as a basis for revocation, this proposal improperly incentivizes entities to settle rather than dispute FCA claims. Faced with the serious consequence of revocation, parties would rationally conclude that they must settle, rather than challenge

weak claims all the way to judgment. This would provide too much leverage to FCA plaintiffs. It is particularly problematic because hospitals face a disproportionate amount of FCA litigation. The most recent Department of Justice statistics show that health care entities are defendants in roughly two-thirds of all FCA cases. Many of these cases, however, lack merit. Year after year, the number of FCA cases increases, but the Department of Justice continues to decline participation in the overwhelming majority of them – a clear indicator that these cases never should have been brought in the first place. But under the proposed rule, hospitals would have a strong incentive to settle, inflicting serious financial costs that would divert scarce resources from their core mission of providing patient care and improving the health of their communities.

If the agency nonetheless chooses to move forward with this misguided proposal, it should make clear that the 10-year window applies prospectively. As written, it is possible that the agency may be authorized to seek revocation for judgments that occurred in the 10-years prior to the final rule's effective date. Those hospitals would not have been able to make the calculus described above, *i.e*., should I settle in the face of a close case (despite its good faith arguments that it did not commit an FCA violation) and run the risk of revocation. As such, the only just approach would be to start the 10-year clock at the effective date, so that parties can make their settlement decisions with all of the relevant consequences in mind.

APPROPRIATE USE CRITERIA (AUC) PROGRAM

CMS proposes withdrawing all previous rulemaking and regulations on the Appropriate Use Criteria established under the Protecting Access to Medicare Act of 2014, citing significant concerns with burdens associated with reporting necessary information on imaging claims. **The AHA strongly supports CMS's recommendation to withdraw and reevaluate the AUC program, which would have added substantial administrative burdens for providers and potentially interfered with patient access to care.**

Established under the Protecting Access to Medicare Act (PAMA) of 2014, the AUC program seeks to prevent inappropriate or unnecessary ordering of advanced diagnostic imaging services. The statute requires an ordering professional to consult with a qualified clinical decision support mechanism (CDSM) to determine if the ordered service adheres to applicable AUC. Payment for the ordered service may only be made to the furnishing professional and facility if the claim includes the required AUC data elements, which are the ordering provider's National Provider Identifier (NPI), the CDSM queried, and the response on the adherence of the ordered service to the applicable AUC.

Since July 1, 2018, the AUC program has been in an "educational and operations testing," phase, during which CMS would pay claims regardless of whether they contained information on the required AUC consultation. This phase was designed to raise awareness about the program and enable ordering and rendering providers to

adjust workflows, train staff, and gain necessary experience with the program before it impacted claims payments.
However, based on information learned, CMS notes that the program's claims-based reporting processes cannot be automated in current systems. As a result, adhering to the program requirements could lead to inappropriate denials of valid claims and substantial administrative burden on both ordering and furnishing professionals to transmit necessary data and to know whether AUC requirements applied to the particular treatment at the time of care. CMS also questions the reliability and accuracy of reported data that would be used to identify outlier ordering clinicians. Furthermore, the agency cites concerns that the program could lead to delays in care access for Medicare beneficiaries if ordering professionals do not properly transmit AUC information with an order to furnishing professionals/facilities. As a result, CMS considers the AUC program impracticable.

The AHA shares CMS's concerns with provider administrative burden and patient access to care, as we expressed in the past. We commend the agency's proposal to withdraw all previous rulemaking and regulations, and its recommendation that the program paused for reevaluation. The AHA stands ready to help the agency determine alternate ways of achieving the program's intended goals of reducing unnecessary imaging for patients.

MEDICARE SHARED SAVINGS PROGRAM

Medicare Clinical Quality Measures (Medicare CQM) Reporting Option. In prior rulemaking, CMS adopted a policy sunsetting the MSSP's CMS web interface measures after the CY 2024 reporting year in favor of the CQMs used in the MIPS APM Performance Pathway (APP) measure set. Currently, ACOs reporting the APP measures must collect data on all patients meeting the measure definition regardless of payer. By contrast, ACOs using the web interface collect and report measure data on only the Medicare beneficiaries attributed to them. Many stakeholders, including the AHA, have expressed concern that not all ACOs are operationally ready to collect all-payer quality data. Furthermore, some believe all payer data collection does not align with the MSSP program's focus on the Medicare population.

In response, CMS proposes that, beginning with the CY 2024 reporting year, ACOs will have the option to report APP CQMs on only the Medicare beneficiaries in their ACO. CMS indicates that Medicare CQMs are a "transition collection type" that the agency believes would help ACOs build the infrastructure and expertise needed to report on all-payer data. CMS also states its belief that offering a Medicare-only APP CQM reporting option can help the agency advance its goal of moving to digital quality measures.
The AHA has previously expressed concerns that the APP measure set may not be the best suited to assessing ACO performance. We continue to encourage CMS to obtain multi-stakeholder feedback on the suitability of the measure set through its pre-rulemaking Measure Applications Partnership (MAP) process.

The AHA supports CMS' proposal to add a Medicare CQM reporting option, and appreciates CMS' responsiveness to stakeholder concerns. At the same time, we continue to have broader concerns about the transition to reporting the APP measure set. ACOs have expressed concern about the significant resources that would be required to switch data submission from the current CMS Web Interface reporting option to the other two collection types CMS will mandate starting in CY 2025 – MIPS clinical quality measures (MIPS CQMs) and electronic clinical quality measures (eCQMs). 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 and engage with ACOs to determine whether a longer transition time is necessary.

We also urge CMS to conduct further analysis to ensure that permitting multiple data collection types in the MSSP program does not affect the comparability of data. As we understand it, through CY 2024, MSSP participants may submit data through the CMS Web Interface, electronic clinical quality measure (eCQM) specification, MIPS clinical quality measure (MIPS CQMs). Presuming CMS's proposal to include a Medicare CQM reporting option is adopted, it would add yet another data reporting mode to the MSSP program. There often are subtle differences in the measure specifications among each of these reporting types that can make it possible to receive slightly different scores. Yet, CMS has not indicated whether it has assessed ACO data for any potential differences in scores stemming from reporting method, and if it has, how it might reconcile these differences in determining quality performance scores. We encourage CMS to conduct such an analysis using the data submitted from the 2022 and 2023 performance periods.

<u>Health Equity Adjustment</u>. In last year's PFS final rule, CMS adopted a health equity adjustment that adds up to 10 bonus points to an ACO's quality performance score based on a combination of their quality performance and the extent to which they care for underserved patients. CMS proposes three modifications to its implementation of this adjustment. First, it proposes to make ACOs reporting Medicare-only CQMs eligible for the adjustment. Second, starting with the CY 2023 performance period, CMS proposes to remove beneficiaries without a national Area Deprivation Index (ADI) rank from the calculation of the underserved multiplier out of concern that its previous policy of imputing the 50th percentile for those beneficiaries may skew calculations. Lastly, starting with the CY 2024 performance year, CMS proposes to modify the calculation of the underserved multiplier to capture Medicare partial year enrollees in the Medicare Part D Low Income Subsidy (LIS), and beneficiaries that are dually eligible for Medicare and Medicare for a part of the year.

The AHA supports these proposals, and again thanks CMS for recognizing the complex interplay between health-related social needs and quality performance. We share the agency's goal of ensuring that all ACOs are incentivized to deliver high quality, equitable care to all Medicare beneficiaries, and especially to those beneficiaries in communities facing sustained hardship. While the AHA believes CMS should continue explore a full range of approaches to accounting for social needs in

quality measurement – including direct risk adjustment where appropriate – we believe the proposed health equity adjustment approach is an important step forward that could have applicability in other Medicare measurement programs.

However, we again urge CMS to consider applying the proposed health equity adjustment to ACOs that report data through the CMS web interface. Given the challenges with transitioning to eCQMs/MIPS CQM reporting, we anticipate that many ACOs will continue to report data through the web interface through CY 2024. Yet, CMS's proposal would make the health equity adjustment available to only those ACOs reporting eCQMs/MIPS CQMs. The need to account for the influence of health related social needs and incentivize caring for structurally marginalized communities does not and should not depend on the data reporting mechanism an ACO selects. By including all ACOs in the health equity adjustment, CMS can ensure that all ACOs and the beneficiaries they serve benefit from this important new policy.

Alignment of MSSP Certified EHR Technology Requirements with Merit-based Incentive Payment System (MIPS) Requirements. To date, the MSSP program has used its own set of requirements with respect to the adoption and use of EHR technology meeting certification requirements from the Office of the National Coordinator for Health Information Technology (ONC). Specifically, ACOs participating in the MSSP BASIC track levels A through D are required 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 must meet a higher threshold of 75% of eligible clinicians using certified EHR technology.

However, beginning with the CY 2024 reporting period, CMS proposes to align ACO certified EHR technology adoption and use requirements to align with the MIPS Promoting Interoperability category's requirements. That is, all eligible clinicians, regardless of MSSP track, would be required to report the MIPS Promoting Interoperability category's measures and requirements, and to earn a MIPS promoting interoperability category score. **The AHA urges CMS not to finalize this policy at this time, and instead focus on advancing policy approaches that can more broadly support wider adoption of EHRs by participants in ACOs.** CMS has proposed a similar policy for the QPP's Advanced APM track, and we refer the agency to our comments in the QPP section of this letter.

Quality Performance Standard – Use of Historical Benchmarks. Beginning with the CY 2024 performance period, CMS proposes to use historical data to calculate the 40th percentile MIPS quality performance score that ACOs would need to meet to achieve the quality performance standard. CMS would use a rolling three-year average with a lag of one performance year, and make quality performance standard score available prior to the start of the performance year. For example, for performance year 2024, CMS would set the 40th percentile performance standard based on data from 2020, 2021 and 2022, releasing the score publicly on the MSSP website in December 2023.

CMS believe using historical data responds to stakeholder input suggesting that the quality performance score that ACOs must achieve should be known to them prior to the start of the performance period. **The AHA supports this proposal.**

Scoring Policy for APP Measure Exclusions. In the proposed rule, CMS expresses its belief that ACOs should not be adversely impacted by events outside their control, such as the exclusion of an APP measure in a given performance year. As CMS notes, ACOs cannot select alternative measures to report under the APP. For this reason, CMS proposes that in the event an APP measure is excluded for a performance year, the agency would use the higher of the ACO's health equity-adjusted quality performance score or the equivalent of the 40th percentile MIPS quality performance category score. The ACO would still be expected to meet all other requirements for non-excluded APP measures. **The AHA supports this proposal.**

Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey. ACOs currently are required to administer and report the CAHPS for MIPS survey using a CMS-approved vendor. Beginning with the CY 2024 period, CMS proposes to require ACOs to contract with vendors that administer the official Spanish language version of the survey to those beneficiaries that prefer it. CMS has proposed a similar change to non-ACO participants in the MIPS program. **The AHA supports this proposal.**

Beneficiary Assignment. CMS has used a 2-step process, based on beneficiaries' use of primary care services, to determine beneficiary assignment for ACOs. As a "pre-step," CMS identifies beneficiaries who have had at least one primary care service from an ACO primary care or primary specialty professional. Under the first step, beneficiaries are assigned to an ACO if allowed charges for primary care services during the assignment window are greater than the allowed charges for primary care services from all other ACOs or non-ACO primary care professionals.

In the second step, beneficiaries who did not receive services from a primary care provider are assigned to an ACO if allowed charges for primary care services furnished by a specialty provider from an ACO are greater than allowed charges for primary care services furnished by another specialty provider. ACOs can use either a retrospective assignment approach (based on 12-months preceding the CY) or a prospective assignment approach with retrospective reconciliation. The rule proposes several changes to this assignment process.

Expanded Window for Assignment. CMS proposes to add a third step to the methodology. This would provide an extended 24-month assignment period to include current the 12-month assignment window and also the 12 months previous to that. For beneficiaries who do not meet pre-step requirements, but do have at least one primary care service during the proposed expanded assignment window, the beneficiary would be assigned to the ACO if allowed charges for primary care services furnished by primary care professionals in the ACO during the expanded window are greater than

allowed charges for primary care services furnished by primary care professionals not assigned to the ACO. This proposal would be implemented in CY 2025.

While we are generally supportive of expanding the window for beneficiary assignment, we encourage CMS to conduct additional analysis on impact. The simulations presented in the proposed rule indicate that this would expand the number of beneficiaries assigned and also would expand the number potentially assigned from underserved populations. Beneficiaries in the simulated assignable cohort had higher rates of disability, higher average ADI rankings, and higher proportions with at least one month of LIS. It would be useful to have detailed data to be able to analyze the distribution of assignable beneficiaries and help determine what updates are required for risk adjustments.

Updates to definition of Primary Care Services. CMS also proposes to update definitions of primary care services for performance year (PY) 2024 to include smoking and tobacco cessation counseling services, RPM, cervical or vaginal care screening services, office-based opioid use disorder services, complex E/M service add-on code, CHI services, PIN services, SDOH risk assessment, caregiver behavior management training, and caregiver training.

Given that many of the proposed codes for addition would be brand new codes to the PFS in CY 2024 (like CHI services, PIN services and SDOH risk assessment screening), it is unclear what redistributive impact this may have on assignment. **We encourage CMS to perform additional analysis on potential impact of this policy.**

Proposed Changes to Advance Investment Payment (AIP) Policies. In the CY 2023 PFS final rule, CMS finalized policies for AIPs to certain ACOs to begin in CY 2024. In the CY 2024 proposed rule, CMS proposes modifications to refine AIP policies in preparation for implementation.

Modification to AIP Eligibility Requirements to Allow ACOs to Advance to Performance Based Risk During the Five-year Agreement Period. CMS proposes to allow ACOs receiving AIPs to transition to 2-sided risk (i.e. transitioning from Level A or B to C, D, or E of the BASIC track) beginning in PY 3 of the organization's five year performance period. Also, if organizations become experienced with performance-based risk or transition to a high-revenue ACO during the first two PYs, CMS proposes to cease AIPs.

Modification to AIP Recoupment and Recovery Policies. For ACOs that voluntarily terminate participation agreements at the end of PY 2 in order to transition to higher levels of risk, CMS proposes to not seek AIP recoupment. Rather, it would carry forward any balance of AIPs owed to the new agreement period.

We are supportive of these policy proposals as they will enable further flexibility for organizations to transition to higher levels of risk. However, we continue to

urge CMS to eliminate its designation of ACOs as either low- or high-revenue and to remove eligibility requirements that specify only low-revenue ACOs are eligible for AIPs. The agency has used this label as a proxy measure to determine if an organization is supporting underserved populations and/or if the organization is physician led in order to qualify for AIPs. Yet, there is no valid reason to conclude that this delineation, which measures an ACO's amount of "captured" revenue, is an accurate or appropriate predictor of whether it treats an underserved region. In fact, analysis suggests that critical access hospitals, federally qualified health centers and rural health centers 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.

Request for Comment on Incorporating a Risk Track Higher than ENHANCED. In the proposed rule, CMS requests feedback on whether to pursue even higher risk tracks within the MSSP program**. AHA supports the creation of a voluntary higher risk track within MSSP.** Although there are currently 6 tracks within MSSP, the highest risk track (ENHANCED) offers 75% shared savings. Adding an even 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.

340B Remedy and Impact on ACO Benchmarking. Following last year's unanimous U.S. Supreme Court decision in favor of the AHA and others, the Department of Health and Human Services issued its proposed remedy for the unlawful payment cuts to certain hospitals that participate in the 340B Drug Pricing Program. As relevant here, the AHA strongly supports many features of the proposed remedy, including a onetime lump sum repayment to hospitals for underpayments for outpatient drugs purchased under the 340B Drug Pricing Program between calendar years (CYs) 2018 and 2022 (based on the difference between ASP -22.5% and ASP +6%).[14] As detailed in our comment letter, the AHA opposes HHS's proposal to claw back $7.8 billion that hospitals have already spent, including during the COVID-19 pandemic, on patient care.

For purposes of this rule, we are concerned about potential impacts of the proposed remedy on ACO benchmarks. Specifically, benchmarks would include historical data from the 2018-2022 timeframe when payment for 340B drugs was set at ASP -22.5%. However, moving forward (starting in CY 2023), performance periods would include payments at ASP + 6%. This would make 340B expenditures appear artificially higher when compared to benchmarks even if there was no change in drug utilization, leading to an inappropriate negative impact on affected hospitals. Indeed, some contractors have actually already reprocessed CY 2022 payments at the ASP + 6% rate, which may

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[14] https://www.aha.org/lettercomment/2023-08-07-aha-letter-cms-remedy-340b-acquired-drug-payment-policy-calendar-years-2018-2022

impact reconciliation for PY 2022. **Hospitals should not be penalized for court-mandated changes to payment levels. To address this concern, we urge CMS to update the ACO benchmarking methodology in a way that is fair and appropriate.** Specifically, we recommend CMS either carve out 340B payments from reconciliation altogether or adjust the methodology to ensure consistency when comparing periods containing differing 340B payment levels.

QUALITY PAYMENT PROGRAM

Mandated by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the QPP began on Jan. 1, 2017, and includes two tracks – the default MIPS, and a track for clinicians with a sufficient level of participation in certain advanced alternative payment models (APMs).

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's MIPS policies have aligned with these principles, including CMS's gradual increases to reporting periods, data standards and performance thresholds for receiving positive or negative payment adjustments. CMS has also implemented a facility-based measurement approach and removed some outmoded quality measures.

However, the AHA remains concerned about the direction of the MIPS Value Pathways (MVPs) that CMS intends as an eventual replacement for the current approach to MIPS. We also have concerns about several of CMS's proposed changes to MIPS reporting requirements and scoring approaches.

MIPS Value Pathways. **The AHA supports CMS' proposal to add five new MVPs that would be available for voluntary participation beginning with the CY 2024 performance period.** Specifically, CMS would add MVPs focused on ear, nose and throat disorders; prevention and treatment of infectious disorders; mental health and substance use disorders; and rehabilitative support for musculoskeletal care. The AHA also appreciates that participation in MVPs remains voluntary, and that CMS has yet to set a date certain for transitioning to mandatory MVP participation.

Indeed, the AHA believes there remain several conceptual and practical barriers to mandating MVP participation. As we have advised in prior comment letters,[15] if CMS is intent on mandating MVP participation in the future, we urge the agency to take the following steps:

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[15] 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 1 million eligible clinicians that currently participate in the MIPS program.* Given the wide range of specialty types participating in the MIPS, this will be exceptionally difficult to achieve. Presuming CMS finalizes its proposal to add five new MVPs for CY 2024 reporting, the program would include only 16 MVPs total. 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's 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's 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 burden on multi-specialty practices.* We appreciate CMS's desire to allow multi-specialty practices to use MVPs to participate in the MIPS. However, the AHA remains concerned that CMS's policy of requiring multis-specialty practices to report subgroups starting with the CY 2026 reporting year will lead to excessive administrative and reporting burden. We urge CMS to reconsider this policy.

MIPS Quality Category. For CY 2024 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 several notable changes to reporting requirements and category scoring.

Data Completeness Threshold. **The AHA recommends that CMS retain its current data completeness threshold of 75% while using experience from CY 2024 and CY 2025 reporting to inform whether and when to adopt further increases.** CMS proposes to increase the data completeness threshold for MIPS quality data from 75% to 80% of denominator-eligible counters for each quality measure starting with the CY 2027 reporting period. As a general principle, the AHA agrees that the reporting of complete data is critical to ensuring the data are an accurate representation of clinician performance.

However, CMS also just adopted an increase in the data completeness threshold to 75% for CY 2024 reporting. While an even higher threshold may be appropriate, CMS and clinicians have had limited experience with the CY 2024 threshold, and it is not entirely clear whether the higher threshold is realistic at this time. This is especially true on the heels of a public health emergency that profoundly impacted physician practices hospitals and others in the health care system.

Furthermore, we note that in the MSSP, CMS will require the reporting of MIPS quality measures and the use of many MIPS quality category reporting requirements – including data completeness – starting with the CY 2025 reporting period. As noted in the MSSP section of this letter, we continue to question the readiness of ACOs to collect the all-payer data on electronic clinical quality measures (eCQMs) that the MIPS quality category would require of them. Adopting an even higher data completeness threshold could serve to make the transition for ACOs to all payer data collection even more problematic. Thus, we recommend that CMS revisit increases to the data completeness threshold after the CY 2025 reporting period, and use the experience of both ACOs and MIPS eligible clinicians to determine when increases to the threshold would be feasible.

Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS. **The AHA supports CMS' proposal to require MIPS participants that report the CAHPS for MIPS survey to contract with vendors that administer the official Spanish language version of the survey to those patients that prefer it.** Clinicians and hospitals are working steadfastly to advance health equity, and are working to ensure that language does not hinder the quality or experience of care. Given that many clinicians serve significant numbers of Spanish speakers, the administration of the CAHPS in Spanish would help enable the capture of their insights into their care.

MIPS Cost Category. **The AHA does not support CMS' proposal to adopt five new episode-based cost measures for the CY 2024 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 pursing 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.[16]

The AHA supports CMS' proposed update to CMS' methodology of calculating cost category improvement points starting in CY 2025. Specifically, CMS would calculate improvement points at the category level by calculating the percentage change in cost category score from the previous performance period. While we believe

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

a measure-level score would be more robust, we also agree that the approach is complex and potentially infeasible.

MIPS PROMOTING INTEROPERABILITY CATEGORY

Performance Period. **The AHA opposes CMS' proposal to lengthen the reporting period for the Promoting Interoperability category from 90 to 180 continuous days beginning with the CY 2024 reporting period.** CMS previously established a reporting period of any continuous 90 days during a reporting year in recognition that EHRs are far from static tools. EHRs are continually undergoing software upgrades, system downtime, expansions to other sites with a system, and a variety of other improvement and maintenance activities. When CMS makes changes to the requirements of the Promoting Interoperability program, these changes affect *all* of the more than 1 million clinicians expected to participate in the program.

Yet, to make the changes and upgrades needed to comply with Promoting Interoperability category requirements, clinicians draw on the same EHR vendors simultaneously, and the capacity of those vendors is finite. That is why clinicians and groups have frequently chosen reporting periods later in the year. In some cases, their vendors are simply not available to perform the needed work because they are working with multiple other facilities and groups. Clinicians also need sufficient time for testing and implementation, which is necessary to identify and resolve problems with the software and provide essential training to end users. Ultimately, these activities are crucial to ensuring EHRs do not inadvertently compromise the safe delivery of care.

In addition, the COVID-19 pandemic has left the health care field facing profound financial, workforce and operational challenges, all of which have implications for the resources they are able to dedicate to meeting new Promoting Interoperability requirements. Many critical health IT projects were appropriately delayed at the height of the COVID-19 pandemic in order to free up resources to meet other vital needs in helping clinicians respond. **As the health care field continues its recovery from a once-in-a-century pandemic, we urge CMS to use a measured approach to considering and adding any new promoting interoperability category requirements, including lengthened reporting periods.**

Query of Prescription Drug Monitoring Program Measure. In the CY 2023 PFS final rule, CMS adopted a requirement for MIPS eligible clinicians and groups to report the Electronic Prescribing objective's Prescription Drug Monitoring Program (PDMP) measure. The measure has an exclusion for any MIPS eligible clinician that writes fewer than 100 permissible prescriptions during the performance period. However, in the proposed rule, CMS indicates this exclusion may be problematic because it does not address situations in which MIPS eligible clinicians cannot electronically prescribe Schedule II opioids or Schedule III and IV drugs due to applicable laws, but may write more than 100 prescriptions during the performance period. As a result, CMS proposes a modification to make the exception available to those clinicians that do not

electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period. **The AHA supports this proposal.**

SAFER Guides. In prior rulemaking, CMS added the SAFER Guide measure to the Protect Patient Health Information objective of the Promoting Interoperability program. Developed by ONC, the SAFER assessment includes nine guides to assess the safety and effectiveness of their EHR implementation, proactively identify potential vulnerabilities and adopt a "culture of safety" with respect to the use of EHRs in their organizations. Currently, MIPS eligible clinicians and groups are required to attest "yes/no" to whether they conducted an annual assessment using the SAFER guides. However, given CMS's stated interest in EHR safety, CMS proposes that beginning with CY 2024 reporting / CY 2026 payment year, MIPS eligible clinicians would be required to conduct the annual SAFER Guides self-assessments on the High Priority Practices guide, and attest "yes."

The AHA urges CMS not to finalize its proposal to require eligible clinicians to attest "yes" to completing the SAFER Guides annually. We remain concerned that the SAFER guidelines have not undergone a comprehensive review and update since 2016. The health IT landscape has shifted dramatically since then, calling into question whether the contents of the SAFER guide remain relevant and effective in ensuring the safe implementation of EHRs. Furthermore, we note the considerable length of the guides, and the level of administrative effort required to complete them, especially for CAHs and other hospitals with fewer resources.

The AHA also believes the concept of requiring clinicians to attest "yes" on this or any other Promoting Interoperability measure is a fundamental misuse of the program's design. When CMS adopted a performance-based scoring approach for the category, the agency's goal was to provide differential rewards in order to incentivize the adoption of certain EHR practices and functionalities. Performance-based scoring was never intended to create an across-the-board requirement for all eligible clinicians and groups; yet, this is precisely what CMS's proposal would do.

At the same time, we appreciate CMS's focus on ensuring the safety of the implementation and use of EHR technology. We believe these efforts can most effectively advanced through the dissemination of more modernized approaches and guidelines to EHR safety, and not necessarily through the use of a measure in a promoting interoperability program.

That said, if CMS is intent on adopting a measure, we encourage the agency to consider a more focused approach that that addresses more specific gap areas in EHR safety, rather than a broad-based assessment like the SAFER guides. If CMS is intent on mandating the use of the SAFER guides, then we urge the agency to work with ONC on an update of the guides, informed by stakeholder input, and undertake an education and awareness campaign to disseminate information to the field, including information tailored to small and medium-sized health care organizations.

Elimination of Health IT Vendors as a Third-Party Intermediary. Under current MIPS policy, health IT vendors are an approved category of intermediaries that may submit data on behalf of MIPS eligible clinicians. However, in the proposed rule, CMS suggests that there have been instances in which health IT vendors have submitted inaccurate or unusable data. Furthermore, CMS notes that health IT vendors do not have the same data validation requirements as other authorized third party intermediaries such as Qualified Clinical Data Registries (QCDRs) and qualified registries. As a result, CMS proposes that, beginning with the CY 2025 reporting period, health IT vendors would no longer be a distinct type of third party intermediary. In order to submit MIPS data on clinicians'' and groups behalf, health IT vendors would need to self-nominate to become qualified registries or QCDRs.

The AHA urges CMS to consider a less sweeping policy change that ensures health IT vendors fulfill their obligation to submit accurate data while minimizing undue administrative burdens to participating clinicians and groups. The AHA shares CMS's interest in ensuring that any submitted MIPS data are accurate and complete. At the same time, the AHA is concerned by potential disruptions resulting from eliminating the ability for health IT vendors to serve as third party intermediaries. Some clinician groups use their EHR vendors in an "end-to-end" fashion to both help set up the data feeds needed to collect data, and to ensure those data are submitted to CMS. If their health IT vendor chooses not to self-nominate as a qualified registry or QCDR, the group would then incur additional expense to identify another entity that could perform this function.

Rather than removing health IT vendors as a third-party, we believe CMS should consider further corrective action steps targeted at those vendors that repeatedly submit inaccurate data. For example, CMS could require health IT vendors found to submit inaccurate data to submit a corrective action plan, and if they are found to submit inaccurate data again, they should be prohibited from serving as a third-party intermediary for several performance periods. CMS also could consider establishing more stringent data validation requirements for health IT vendors that are consistent with those for QCDRs and qualified registries. No matter what process CMS chooses, it is vital that any clinician or group be held harmless when their health IT vendor fails to perform their duty to support the submission of accurate and complete data.

ADVANCED APMS

Qualifying Participant (QP) Determinations. The Advanced APM track's QP determination process helps CMS determine whether clinicians and APM entities meet the threshold percentages of patients or payments needed to qualify for the track. Beginning with the CY 2024 performance period, QP determinations will be made at the eligible clinician level only. CMS indicates it has heard concern from stakeholders that conducting QP determinations at the APM entity level may lead to the exclusion of some specialty clinicians who furnish proportionately fewer services that could help the

entity qualify for the advanced APM track. Conversely, CMS also believes that some clinicians who see relatively few patients through an APM entity may still accrue disproportionate benefit by still qualifying for advanced APM payments through their APM entity. For these reasons, CMS believes conducting QP determinations at the clinician level would be fairest.

The AHA opposes CMS' proposal to conduct QP determinations at the clinician level only. We believe the proposal would run counter to CMS's stated goal of getting wider range of specialty types engaged in and eligible for the Advanced APM track. Generally speaking, a policy in which QP determinations are made at the individual clinician level could make it far more difficult for specialists to be included in APM models, as APM entities may face incentives to exclude them in order to ensure they clear the participation threshold. In addition, given that QP determinations have been done at the APM entity level since the program's inception, we are concerned by the level of administrative burden that may be incurred by switching to a clinician-level determination process.

If CMS is intent on a more granular QP determination process, then we would encourage CMS to instead conduct QP determinations at both the APM entity and clinician level, awarding QP status on the higher of these scores. Over the long term, we continue to encourage CMS to explore further mechanisms of ensuring specialists have an opportunity to participate in the advanced APM track. This could include examining attribution and benchmarking approaches.

Certified EHR Technology Requirements. Current advanced APM track policy requires that 75% of eligible clinicians in each APM entity must use certified EHR technology to document and communicate clinical care to patients or other health providers. However, beginning with the CY 2024 performance period, CMS proposes to remove this threshold, and instead require that APMs use certified EHR technology that meets both the 2015 Edition base EHR definition or any subsequent base EHR definition promulgated by ONC, and any such health IT certification criteria that are determined to be applicable for the APM for the year. CMS believes the elimination of the threshold will ensure broad adoption of EHRs, while its two other criteria would allow the more effective tailoring of EHR-related requirements to the needs of APMs.

The AHA continues to believe that widespread adoption of certified EHR technology is an important enabler to innovative care approaches. However, we are 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 benefit from the advanced APM track. **For these reasons, the AHA urges CMS not to finalize this policy at this time, and instead focus on advancing policy approaches that can more broadly support wider adoption of EHRs by clinicians.**

For example, the AHA recently recommended to CMS that 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.

Revising the definitions of CEHRT for the Medicare Promoting Interoperability Program and for the Quality Payment Program. CMS proposes to directly link the definition and minimum capabilities of certified electronic health record technology (CEHRT) to ONC's definition of these systems.

After 2015, the ONC stopped publishing yearly "editions" of EHR or Heath IT Certification Criteria, and began making only incremental updates, with periodic notice of changes. Since 2015, however, the current editions have still been referred to with the year 2015 in the title, so the current editions are "2015 Edition Base EHR and 2015 Edition Health IT Certification Criteria," respectively. If the proposed rule changes in the ONC's Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency and Information Sharing (HTI-1) are accepted, the year gets dropped, so 2015 Edition Base EHR, becomes just "Base EHR" and 2015 Edition Health IT Certification Criteria becomes "ONC Certification Criteria for Health IT", effective Jan. 1, 2025.

Even though the HTI-1 changes have not yet been finalized, based on AHA's review of published comments, these sections of HTI-1, referenced in III.R, are likely to be adopted this year, with an expected effective date of January 2025 for these changes; however, CMS states "we do not believe that ONC must finalize their proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT. These changes would not impact EHR requirements in the CY 2024 EHR reporting period or the CY 2024 performance period, and therefore we predict that it would have no impact on clinicians (1389)."

AHA applauds this proposal to permanently reference the ONC definitions of EHR technology and health IT certification criteria. Adoption of this recommendation supports regulatory harmonization across agencies by ensuring that any ongoing changes to this ONC definition will not require any additional regulatory action by CMS.

Extension of Advanced APM Bonus Payments for CY 2025. CMS proposes to offer APM Incentive Payments in CY 2025 to those clinicians that qualify. This one-year extension of the bonus payments (at a reduced rate of 3.5%) was required by CAA, 2023. CMS would calculate the payment based on the estimated aggregate payments for covered professional services during the incentive payment base period. In this case, the base period is CY 2024.

The AHA strongly supports extension of bonus payments. We encourage CMS to work with Congress to continue their extension beyond CY 2025 and to revert back to the 5% payment level (versus the reduced 3.5% payment).