

Washington, D.C. Office

800 10th Street, N.W. Two CityCenter, Suite 400 Washington, DC 20001-4956 (202) 638-1100

September 6, 2022

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services 7500 Security Blvd Baltimore, MD 21244

Re: CMS-1770-P, Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts.

#### 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) 2023.

We appreciate CMS's proposals in this rule that support care delivery and patient outcomes, particularly those that take steps to improve the stability and flexibility of the Medicare Shared Savings Program (MSSP) to better allow participants to provide care to beneficiaries. In addition, we support CMS's proposal to delay implementation of its revised "split" or "shared" evaluation and management visit policy. Finally, the AHA also shares CMS's commitment to advancing health equity, and supports the agency's proposals to prioritize the use of health-equity-related measures in the Merit-based Incentive Payment System (MIPS), and implement a health equity adjustment for the MSSP.

However, we have strong concerns about CMS's proposed changes to the Medicare Economic Index (MEI) and urge the agency to pause its update of the index. In



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addition, we continue to have concerns about the feasibility of the MIPS Value Pathways (MVPs), and believe much work remains to be done to ensure they result in fair, equitable performance comparisons across MIPS clinicians and groups. Finally, while we appreciate CMS' proposals to improve access to behavioral health services, we question the utility and adequacy of the proposals related to family psychotherapy and chronic pain management.

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 Joanna Hiatt Kim, AHA's vice president of payment policy, at <a href="mailto:ikim@aha.org">ikim@aha.org</a>, regarding the payment provisions, or Akin Demehin, AHA's director of policy, at <a href="mailto:ademehin@aha.org">ademehin@aha.org</a>, pertaining to the quality provisions.

Sincerely,

/s/

Stacey Hughes Executive Vice President

**Enclosure** 

# American Hospital Association Detailed Comments

#### **Proposed Payment Changes**

<u>Conversion Factor</u>. The proposed payment update for CY 2023 reflects several different factors, some of which are unique to this year so as to account for policy changes implemented last year. Specifically, CMS proposes to cut the conversion factor to \$33.08 in CY 2023, as compared to \$34.61 in CY 2022. This update includes: the expiration of a 3% increase in the PFS conversion factor for CY 2022 *only*, which was provided by the Protecting Medicare and American Farmers From Sequester Cuts Act; a 0% update factor as required by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015; and a budget-neutrality adjustment.

This decrease would come just two years after CMS finalized a 10.2% cut to the conversion factor. Additionally, on July 1, additional cuts were made to physician payments as a result of the expiration of the moratorium on the Medicare 2% sequester reduction. And in the event Congress doesn't take action to waive the cuts, a sequester order would be issued two weeks after Congress adjourns, along with an additional 4% sequester reduction that would be imposed the following month due to statutory PAYGO. These cuts occur in an environment in which Medicare payments already have not kept pace with inflation. For example, the proposed CY 2023 conversion factor of \$33.08 is only \$0.175 more than the 1994 conversion factor of \$32.9050. In fact, this 1994 conversion factor is equivalent to \$66.69 in today's dollars – more than double the proposed conversion factor.¹ Finally, because many other payers tie their fee schedules to the Medicare physician fee schedule, providers' losses under Medicare's proposed policies would be compounded by losses from other payers. We are concerned that the conversion factor cut will have an extremely negative affect on patients' access to certain services.

Our concern is heightened by the fact that the conversion factor cut would come after over two years of unrelenting financial pressure on the health care system due to the ongoing COVID-19 public health emergency and inflationary environment. Indeed, historic inflation has continued and heightened the severe economic instability that the pandemic wrought on hospitals, health systems and their clinicians. Specifically, high inflation began to take hold in the second half of calendar year 2021, with the consumer price index (CPI), a measure of general inflation, ultimately hitting a 12-month high in June 2022 at 9.1%. Fannie Mae forecasts that inflation will remain elevated through at

<sup>&</sup>lt;sup>1</sup> U.S. Bureau of Labor Statistics. (June 13, 2022). Consumer Price Index Summary Results. https://www.bls.gov/news.release/cpi.nr0.htm; Statista. (June 27, 2022). Monthly 12-month Inflation Rate

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least the end of 2022, averaging 5.5% in the fourth quarter of the calendar year.<sup>2</sup> Because this high rate of inflation is not projected to abate in the near term, it is critical that it be accounted for when considering providers' financial stability in 2023 and beyond.

After fighting to care for patients at all costs, these cuts threaten the ability of hospitals and health systems, as well as 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 2023. 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.

Medicare Economic Index (MEI). 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. In this rule, CMS proposes to rebase and revise the MEI. However, it would delay application of the new MEI to the RVUs until the public has an opportunity to comment on the proposed methodology.

In the nearly 50 years since the initial establishment of the MEI, CMS has consistently used data collected by the American Medical Association (AMA) as its source of information about physicians' work and practice expenses. However, it now proposes the use of non-AMA data as its source for this information; this yields an MEI that, once fully applied, would dramatically shift RVUs and payments away from work to practice expenses, as shown in the table below.

**Table 1: RVU Allocation Over Time** 

	1975-1992	1993	Current	Proposed
Physician Work	60%	54.2%	50.9%	47.3%
Practice Expense	40%	41.0%	44.8%	51.3%

in the United States from June 2021 to June 2022. <a href="https://www.statista.com/statistics/273418/unadjusted-monthly-inflation-rate-in-the-us/">https://www.statista.com/statistics/273418/unadjusted-monthly-inflation-rate-in-the-us/</a>

<sup>&</sup>lt;sup>2</sup> Fannie Mae. April 19, 2022. Inflation Rate Signals Tighter Monetary Policy and Threatens 'Soft Landing'. <a href="https://www.fanniemae.com/research-and-insights/forecast/inflation-rate-signals-tighter-monetary-policy-and-threatens-soft-landing">https://www.fanniemae.com/research-and-insights/forecast/inflation-rate-signals-tighter-monetary-policy-and-threatens-soft-landing</a>

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Professional	(included with	4.8%	4.3%	1.4%
Liability Insurance	practice expense)			

The current MEI weights are based on data obtained from the AMA's Physician Practice Information (PPI) Survey. This survey was last conducted in 2007/2008 and collected 2006 data. We understand and agree that these data are outdated. However, the AMA is actively engaged in a process to update these data. It had anticipated that it would collect 2020 cost information in 2021, but understandably postponed that effort due to the COVID-19 public health emergency. It now anticipates collecting 2022 data in mid-2023. Given these efforts, and our substantial concerns about CMS's proposed alternative data sources and their redistributional effects (described below), we strongly urge the agency to pause updating the MEI until the AMA effort is complete.

CMS proposes to use 2017 data from the Census Bureau's Service Annual Survey (SAS) to update the MEI weights in 2024. The agency itself acknowledges that using these data would cause significant redistribution among the RVU weights, which is why it does not propose to implement the new weights in 2023. If CMS's proposed MEI weights were adopted, cardiac surgery would see a payment cut of 9%, neurosurgery would see a payment cut of 8% and emergency medicine would see a payment cut of 7%. In addition to significant specialty redistribution, geographic redistribution would also occur. For example, a significant reduction in the weight of office rent (from 10.2% to 5.9%) 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. And, similar to the proposed conversion factor cuts, the new MEI would threaten the ability of hospitals and health systems, as well as their clinicians, to continue to offer all essential services to the patients who need them.

In addition, almost all of CMS's proposed changes are to the cost category weights – not their price proxies. Data for the weights are primarily derived from the Census Bureau's 2017 SAS for the "Offices of Physicians" industry. However, these data were not designed with the purpose of updating the MEI; as a result, there are key areas (physician work, nonphysician compensation and medical supplies) where CMS must supplement with data from other sources. Yet, both the SAS data and the supplemental data have substantial flaws. For example:

 The SAS for "Offices of Physicians" collects payroll and benefits for all staff combined, but the MEI has separate cost categories for physician and nonphysician compensation, with non-physician compensation further broken out by staff type. CMS proposes to use data from the Bureau of Labor Statistics (BLS) as a supplement in order to work around this issue, but these data have additional shortcomings, such as not including compensation for physicians owning the practice. The Honorable Chiquita Brooks-LaSure September 6, 2022 Page 6 of 28

- The SAS and BLS data that CMS proposes to use exclude physicians employed in hospitals. This results in an underrepresentation of physician work and professional liability insurance as compared to practice expenses.
- Seven percent of the revenue for "Offices of Physicians" on the 2017 SAS is from non-patient care sources (e.g., grants, investment income) and any expenses associated with these sources should not be excluded.

Cardiac Ablation Codes. Cardiac ablation procedures aim to eliminate atrial fibrillation, the most common of all cardiac arrhythmias, which occurs predominantly in the elderly. For 2022, the Current Procedural Terminology (CPT) codes for these procedures were revised and the Relative Value Update Committee (RUC) surveyed physicians on the revised codes in order to help determine their RVU values. However, the RUC believed that many of the respondents did not realize that the code descriptors had been substantially revised and/or may not have read the updated code descriptors thoroughly enough to understand that services that had been separately billed were now combined into the existing codes. Therefore, the RUC re-surveyed the ablation codes.

In last year's rulemaking, CMS considered only the original survey's values, which yielded cuts to payment for ablation codes. In this year's rulemaking, CMS is considering the re-surveyed values, which yield further cuts, and is also proposing additional payment cuts. The agency is basing this decision on a comparison of the ablation code values to those of lower limb revascularization – a procedure unrelated to cardiac ablation. As a result, payment for cardiac ablation services would see cuts of 40% over two years.

Cuts of this magnitude would greatly undervalue these services, especially when considering the significant cuts CMS had already finalized in previous years. Further, they simply do not reflect the reality of the provision of ablation services. For example, these codes include bundling of intraprocedural imaging services that require additional cognitive work not reflected accurately in the RVUs. In addition, our members report a marked increase in same-day discharge of ablation patients, which requires additional pre- and post-procedure planning not reflected in the codes and their RVUs. Finally, there are two additional years of training required to be able to perform these procedures – the physical wear-and-tear (due to wearing lead, for example) and radiation exposure constitute occupational hazards also unaccounted for in the codes. Therefore, in order to maintain patients' access to care and accurately reflect the value of these services, we urge CMS to set the payment rate for these codes at their values from 2021, which is prior to the code revisions.

<u>Audiology Codes</u>. Currently, Medicare beneficiaries must obtain a physician order to see an audiologist for coverage of diagnostic hearing and balance tests. However, in this rule, CMS proposes to allow beneficiaries to obtain certain audiology services directly, without a physician order. Specifically, it proposes to allow audiologists to bill for HCPCS code GAUDX for audiology services "furnished personally by an audiologist without a physician/NPP order for non-acute hearing assessment unrelated to

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disequilibrium, or hearing aids or examinations for the purpose of prescribing, fitting, or changing hearing aids once in a period of 12 months." However, this code blends 36 separate and distinct services, which would not allow tracking nor monitoring of services performed by the audiologist without a physician order. In addition, the proposed RVUs for the code were not established through the RUC process and do not consider the clinical input and expertise of the audiologists that furnish the service.

Therefore, we urge CMS to allow audiologists to bill for the specified services with the existing CPT codes, reimbursed at the current fee schedule payment rate and appended with a newly created modifier. The modifier would be used to identify services performed by audiologists via direct access to Medicare beneficiaries. We believe that this method will that allow beneficiary access to quality care, as well as streamline the process for providers, and reduce unnecessary administrative burden for CMS.

<u>Dental Services</u>. In the rule, CMS proposes to cover dental services for beneficiaries in certain circumstances. The agency provides several examples of services for which dental services (and associated ancillary services) may be covered:

- Organ transplant;
- · Cardiac valve replacement; or
- Valvuloplasty procedure.

In these circumstances, Medicare would cover dental services if the patient has an oral infection and success of the procedure could be compromised if the infection is not properly diagnosed and treated. However, we urge CMS to provide coverage for all immunocompromised beneficiaries, not only those that have an oral infection under the circumstances above. In addition, we urge the agency to clarify that all physicians, not only dentists, may bill for these services.

#### **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, and the flexibilities that the agency finalized in last year's PFS rule, 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.

As has been widely reported, the COVID-19 public health emergency fundamentally changed the way patients consume health care. The significant uptake of telehealth and other virtual care services has increased patients' access to physicians, therapists and other practitioners, helping ensure they receive the right care, at the right place, at

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the right time. It also greatly reduced patient travel time and missed appointments. In fact, one AHA member in California estimates that across the state, its 1.1 million video visits in 2020 translated into approximately 11.5 million miles saved for patients who would otherwise have had to commute to a site of care. According to the Centers for Disease Control and Prevention (CDC) Center for Preparedness and Response, telehealth prevents disease exposures, preserves personal protective equipment, reduces surge demand, improves surveillance, and promotes health equity. And, according to many of our members, patients are extremely satisfied with the telehealth services they have received.

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

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

As part of this effort, CMS also should consider which elements of the business of providing care will need to be adjusted to account for when services are delivered via virtual connection. For example, providers should be able to capture during telehealth visits those diagnoses that impact risk adjustment so as to avoid having to conduct the same patient visit twice – once via telehealth and once in-person – to record all of the patient's conditions. Similarly, CMS should create a mechanism by which providers can collect and document vital signs obtained as part of the Annual Wellness Visits (AWVs) "Measure" component. We commend CMS for permitting

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<sup>&</sup>lt;sup>3</sup> The Role of Telehealth in Expanding Access to Healthcare During the COVID 19 Pandemic: Considerations for Vaccine Uptake and Monitoring for Adverse Events Clinician Outreach and Communication Activity (COCA) Webinar.

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beneficiaries for the duration of the COVID-19 pandemic to self-report vital signs when clinically acceptable. We urge the agency to continue this policy after the COVID-19 public health emergency ends and to disseminate guidance on what providers can do in situations in which patients cannot self-report. We also recommend CMS consider how to account for missing diagnosis data that will certainly occur as a result of the dramatic decline in utilization this year.

We again thank the agency for its unprecedented efforts to expand telehealth access. Below are our comments on specific proposals in the rule.

Category 3 Services. "Category 3" includes telehealth services added during the COVID-19 public health emergency 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 to the telehealth list. Any service added under Category 3 will remain on the Medicare telehealth services list through the calendar year in which the COVID-19 public health emergency ends; it would then need to meet additional criteria to be added on a permanent basis. In this rule, CMS proposes to add numerous services, such as certain therapy and ophthalmology services, to the telehealth list on a Category 3 basis. CMS believes that including these as Category 3 services will provide additional time for the development of evidence for potential permanent inclusion on to the telehealth list.

The AHA supports the agency's proposed additions to Category 3, which will add to the tools providers can use to care for patients. In addition, we urge CMS to consider making Category 3 a permanent part of the Medicare telehealth list. Establishing Category 3 as a subregulatory means for temporarily adding services to the Medicare telehealth list would provide much-needed regulatory flexibility for the adoption of essential and innovative technologies in response to the emergence of new challenges.

<u>Statutory Telehealth Flexibilities</u>. CMS proposes to implement the telehealth provisions in the Consolidated Appropriations Act, 2022 (CAA, 2022) through program instructions or other subregulatory guidance. These provisions extend the following policies for 151 days after the COVID-19 public health emergency ends:

- 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

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

The CAA, 2022 requires that services that are temporarily included on the telehealth list, but not on a Category 1, 2, or 3 basis be maintained on the telehealth list for 151 days following the end of the COVID-19 public health emergency. Lastly, it delays the in-person visit requirements for mental health services furnished via telehealth until 152 days after the end of the COVID-19 public health emergency.

We support CMS's proposals to implement the telehealth provisions of the CAA, 2022. In addition, we further urge the agency to work with Congress to make the above waivers permanent. The COVID-19 public health emergency 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 pandemic first hit will disappear, since the status quo limits telehealth to rural areas of the country and requires patients to be at certain facilities to receive care. The COVID-19 public health emergency 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.

Expiration of COVID-19 Public Health Emergency Flexibilities for Direct Supervision Requirements. During the COVID-19 public health emergency, 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. In the CY 2021 PFS final rule, CMS finalized the continuation of this policy through the end of the calendar year in which the COVID-19 public health emergency ends *or* Dec. 31, 2021, whichever is later. In this rule, CMS continues to seek comment on whether it should make this flexibility permanent, including whether this should be allowed only for a subset of services. The AHA strongly supports the COVID-19 pandemic policy regarding direct supervision 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.

Payment for Medicare Telehealth Services Furnished Using Audio-only Communication Technology. Section 1834(m) 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

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distant site physician or practitioner." During the COVID-19 public health emergency, CMS has made several policy changes, including waiving requirements that telehealth services be delivered with video technology to allow the provision of certain behavioral health, counseling, and evaluation and management (E/M) services via audio-only communication.

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, or when a video connection fails. In those situations, if a provider and patient are connected via audio/video technology and their video connection fails, they can default to an audio-only visit and pick up where they left off. Additionally, audio-only behavioral health services have become extremely popular with patients who are more comfortable without hour-long, face-to-face visits. Reverting audio-only telehealth to pre-COVID-19 public health emergency 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.

Telehealth Services for Diagnosis, Evaluation, or Treatment of Mental Health Disorder. Section 1834(m) of the Social Security Act limits the provision of Medicare telehealth services to certain, largely rural, geographic areas and to certain originating sites in which a patient must be located to receive telehealth. For telehealth services furnished for the purpose of diagnosis, evaluation or treatment of a mental health disorder, the CAA waived these geographic restrictions and added the patient's home as a permissible originating site, effective for services furnished on or after the end of the COVID-19 public health emergency. The CAA also required that the provider furnishing a telehealth service must furnish an in-person service within six months prior to the telehealth service and thereafter, at such times the Secretary of Health and Human Services determines appropriate.

To implement this provision, CMS requires providers to conduct an in-person, non-telehealth service within six months prior to providing an initial mental health telehealth service, and at least once every twelve months thereafter. While we appreciate CMS's efforts to support mental health services via telehealth, we continue to have concerns about this policy. For a specialty that has been so successful via telehealth and for which no physical examination is required, the requirements simply would create a barrier to access, an insurmountable burden on patients and providers, and a deterrence from seeking mental health services. As such, we continue to oppose requiring that the billing practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the sixmonth period before the date of the telehealth service, and at least once every twelve months thereafter. Such a restriction is antithetical to use of remote care modalities and inconsistent with CMS' general approach to telehealth services.

# Payment for Evaluation & Management Visits

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 last year's rulemaking, CMS finalized a policy under which, for 2022, the "substantive portion" of non-critical care split (or shared) visits was defined as the performance of <a href="either">either</a>: one of the three key components of a visit (history, physical exam or medical decision-making), or more than half of the total time performing the visit. For 2023 and beyond, the agency would define the substantive portion of the visit only as more than half of the total time spent. However, CMS now proposes delaying implementation of this policy for one year, until Jan. 1, 2024. Thus, for 2023, the substantive portion would continue to be defined as <a href="either">either</a>: one of the three 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's 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.

<u>Chronic Pain Management (CPM) Bundles</u>. CMS proposes to create separate coding and payment for CPM services, as there is currently no existing CPT code that specifically describes this work or reflects all of the services and resources required to furnish comprehensive, chronic pain management. The monthly bundle would cover care for "persistent or recurrent pain lasting longer than three months."

The AHA appreciates that CMS is looking for ways to account for holistic pain management services, considering the complex nature of treating chronic pain and the variety of treatments available. We agree that existing codes, including E/M, Chronic Care Management, Complex Chronic Care Management, and Principal Care Management, do not reflect all of the services and resources required to furnish needed care to beneficiaries living with pain. However, we request clarification on a few aspects of CMS' proposal before we can assess the impact of this change on patients and providers.

First, CMS notes that "[t]here are various definitions for chronic pain" but decides in this rule to define it for the purposes of the CPM bundle as pain that persists longer than

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three months. Some practitioners define this condition as pain that persists beyond the usual recovery period, occurs along with a chronic health condition, or persists despite medication or treatment. Due to the variety of definitions used in the field, it is unclear whether the definition proposed by CMS would account for the appropriate patient population and their clinicians who would benefit from this bundle—for example, pain associated with cancer diagnoses, neuropathic pain, psychogenic pain, or headaches. We recommend that CMS consider broadening the definition of pain by studying the potential lives that would benefit from this bundle rather than basing their policy on the most operationally convenient definition.

Next, we suggest CMS provide clarity on the interaction between the proposed CPM codes and existing E/M codes prior to their implementation. We worry that providers will inadvertently misuse these codes in a way that will suggest payment integrity issues where none exist, and recommend that CMS consider whether creating a modifier to attach to a CPM code will better prevent double payments.

Finally, we question how CMS' proposal in this rule relates to the proposal in the CY 2023 OPPS proposed rule that would add the Facet Joint Interventions service category to the prior authorization list. In the OPPS rule, CMS reasons that these services demonstrated higher average annual increases in claim submissions, suggesting questionable utilization. Facet joint interventions are an important part of chronic pain management, so it seems incongruous for CMS to be encouraging chronic pain management services in one rule while discouraging them in another. We understand that these proposed provisions are applicable to different payment systems, but they will certainly interact.

New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs). CMS proposes to create a new "G" code describing general BHI performed by clinical psychologists (CPs) and clinical social workers (CSWs). These professionals are not eligible to report the initiating codes for BHI services, but sometimes serve as the primary practitioner that integrates medical care and psychiatric expertise. The AHA appreciates and supports CMS' proposal to allow CPs and CSWs to bill for covered care management services for behavioral health conditions under general supervision.

# "Incident To" Physician Services Regulation for Behavioral Health Services

To improve access to behavioral health care by making greater use of the services of licensed professional counselors and licensed marriage and family therapists, CMS proposes to allow these services to be furnished under the general supervision—as opposed to direct—of a physician or NPP. The AHA supports this change and appreciates the effort to make use of more practitioners in the continuum of behavioral health care. The health care workforce is stretched thin, and behavioral health experiences these shortages acutely. By allowing behavioral health providers of

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all types to practice at the top of their license, CMS is increasing the number of access points to care.

#### **Change in Procedure Status for Family Psychotherapy**

CMS proposes to remove the Restricted status indicator from the CPT codes that describe family psychotherapy and instead assign the codes an Active indicator. The AHA appreciates that CMS is looking for ways it can improve access to care by removing unnecessary administrative burdens. However, changing the status indicator on CPT codes 90846 and 90847 from an "R" to an "A" does not mean that these services will be automatically covered. There remain national coverage determinations carrying documentation requirements and guidelines that the Medicare Administrative Contractor (MAC) can consider and ultimately use to restrict coverage. This proposal may result in less automatic application of these restrictions, but overall this appears to be a negligible change. While acknowledging that the scope of this rule is limited to the proposed provisions therein, the AHA encourages CMS to look closely at other policies that pose larger barriers to access to behavioral health care, such as broadening the range of behavioral health professionals who are eligible to bill under the PFS.

#### **Payment for Vaccine Administrative Services**

CMS proposes to annually update the payment amount for the administration of Part B preventive vaccines (HCPCS codes G0008-G0010) based upon the increase in the MEI. CMS also proposes to adjust this payment amount geographically using the geographic adjustment factor (GAF). The agency also would update the \$35.30 add-on payment for vaccine administration in the same manner. In addition, CMS proposes to update the \$40 payment amount for COVID-19 vaccine administration using the MEI as long as the Emergency Use Authorization (EUA) declaration is still in place. **The AHA supports these proposals.** 

# Requiring Hospital Outpatient Departments (HOPDs) and Ambulatory Surgical Centers (ASCs) to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Currently, when a provider discards an unused portion of a drug from a single-dose container or single-use package, Medicare provides payment for the discarded amount as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier is used to report the amount of a drug that is discarded and eligible for payment. Beginning in 2017, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs, CMS began to require the uniform use of this JW modifier for all claims for separately payable drugs with discarded drug amounts from single use vials or single

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use packages payable under Part B. The policy does not apply to drugs that are not separately payable, such as drugs packaged under the OPPS.

The Infrastructure Investment and Jobs Act requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. CMS proposes to implement these provisions, including requiring physician offices, HOPDs and ASCs to report the JW modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the PFS, OPPS or ASC payment system. The agency also proposes that physician offices, HOPDs and ASCs use a separate new modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts. The proposed JZ modifier is intended to address purported inconsistent compliance with the use of the JW modifier.

The AHA opposes the new JZ modifier. It is repetitive to the JW modifier and will unnecessarily increase reporting burden for providers. Instead, the AHA recommends that CMS instead undertake an education campaign, directed to physician offices, hospital and ASC pharmacy and coding experts, to reinforce the requirements related to the use of the JW modifier, which has been in place since 2017.

Furthermore, the AHA also urges CMS to take steps to address some confusion around its existing policy regarding the appropriate use of the JW modifier. Specifically, a special edition MLN Matters article SE1316, issued Aug. 1, 2013, reminded providers that the billed amount for administered dosage plus waste "must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient." That is, some drugs are purchased in several different dose strengths, resulting in multiple national drug codes (NDCs) being in inventory for the same drug. Some drugs also come in different vial types (single-dose and multi-dose). Hospitals, ASCs and physician offices have had difficulty identifying what is the smallest dose (vial) available for purchase for which they are required to report wastage and have sought the help of CMS in the past. We are aware that CMS has directed providers to look to their MACs to interpret this matter. However, different MACs have responded to the same question with different answers. Therefore, the AHA urges CMS to clarify at a national level which vial size represents the smallest dose vial for each of the drugs for which reporting of wastage is required.

#### **Quality Payment Program (QPP)**

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).

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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 a number 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. CMS has indicated that MVPs are intended to align and reduce reporting requirements across the four MIPS performance categories. Built over time, the MVPs would organize the reporting requirements for each MIPS category around specific specialties, treatments or other priorities. In prior comment letters, the AHA has expressed our concern about setting a date certain for transitioning to mandatory MVP participation. We appreciate that CMS again proposes to keep participation in MVPs voluntary. The AHA believes that unless and until CMS can address several conceptual issues with MVPs described below, CMS should not set a date certain for transitioning to mandatory MVP participation.

First, CMS would need to ensure there are enough measures available to create MVPs applicable to the more than 1 million eligible clinicians that currently participate in the MIPS program. Given the wide range of specialty types participating in the MIPS, this will be exceptionally difficult to achieve. The measures currently available in the MIPS program have enabled CMS to propose a modest expansion of the number of available MVPs. Specifically, starting with the CY 2023 reporting period, CMS would add five new MVPs related to cancer care, kidney health, episodic neurological conditions, neurodegenerative conditions and promoting wellness. While the AHA supports this proposal, it is not clear how many more MVPs CMS can add to the program without significantly adding to the program's measure count. 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.

That is why we also continue to urge CMS to construct several more "prototype" MVPs, determine how many clinicians it could potentially assign to each, and obtain clinician input on whether the measures in those MVPs would align with their clinical practice. CMS's proposed process for getting feedback on MVPs under development could be to inform the development of these prototypes.

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CMS must also ensure that using an MVP approach would provide a fair, equitable comparison of performance across clinician and group types and specialties. If CMS's ultimate intention is to 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. We suggest that CMS use the "prototype" MVP analysis we suggested above to look at the performance distributions across MVP models to determine whether any specialty types or group types score any worse than others.

Lastly, the AHA remains concerned about the feasibility and potential administrative burden of the MVP approach for multi-specialty group practices. We supported the policy that CMS adopted in the CY 2022 PFS final rule to allow multi-specialty practices to form "subgroups" within a single tax ID number (TIN), thereby allowing various parts of the group to report different MVPs, the MIPS APM Performance Pathway and other MIPS measures. We believe subgroups are an essential option for implementing MVPs. However, the key distinction between the current MIPS and the MVP subgroup CMS has adopted is that subgroups will be mandatory for multi-specialty practices that wish to participate in MVPs starting with the CY 2026 reporting year. As a result, multi-specialty groups may actually face an increase in their reporting burden, which would contradict CMS's stated goal of reducing provider burden. The AHA urges CMS to reconsider its policy of mandating subgroup formation for multi-specialty practices participating in MVPs.

MIPS Quality Category. For CY 2023 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 adopts several notable changes to reporting requirements and category scoring.

High Priority Measures. The AHA supports CMS's proposal to expand its definition of high priority measures to include health equity-related measures. We also support the addition of a new health-related social needs screening measure that would be available beginning with the CY 2023 reporting period. Under the traditional MIPS program, clinicians and groups are required to report a total of six quality measures, of which at least one must be an outcome or other high priority measure. Consistent with hospitals and health system's commitment to advancing health equity, we believe that CMS categorizing health equity measures as "high priority" in the MIPS program will provide an important incentive for clinicians to engage in this vital work.

Data Completeness Threshold. The AHA does not support CMS's proposal to increase the MIPS data completeness threshold from 70% to 75%, beginning in CY 2023. We agree that the reporting of complete data on quality measures is important to ensuring the data are an accurate representation of clinician performance. We

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appreciate that CMS has generally adopted gradual increases to this threshold over the duration of the MIPS program. However, as CMS itself has acknowledged, the impact of the COVID-19 public health emergency on physician practices, hospitals and others in the health care system has been profound. Raising the bar on data completeness may have been entirely appropriate policy in the absence of the pandemic. However, the full restoration of "normal" operations in physician practices could take time.

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 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.

CAHPS for MIPS. The AHA supports CMS's proposal to broaden the language adjustor in the Consumer Assessment of Healthcare Providers and Systems (CAHPHS) for MIPS measure to include any language other than English spoken at home. The CAHPS for MIPS includes adjustment for patient characteristics that could affect how patients respond to surveys. Under current MIPS policy, the case mix adjustment for the measure includes the following variables: age; education; self-reported health status; self-reported mental status; Medicaid dual-eligibility; proxy response; eligibility for Medicare's low-income subsidy; and Asian language survey completion. We agree with CMS that broadening the language adjustor to include any language other than English will more broadly capture the experiences and response patterns of patients that may have similar experiences interacting with the health care system (i.e., not speaking English as their primary language at home).

MIPS Cost Category. CMS proposes no new measures for the MIPS cost category, and minimal changes to the category's requirements. However, to conform to statutory requirements, CMS proposes to establish a cost improvement score of up to one percentage point starting with the CY 2022 performance period. While the AHA supports this proposal, we continue 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 National Quality Forum (NQF) endorsement of all cost measures, re-examining the attribution methodologies, and incorporating risk adjustment for social risk factors where necessary and appropriate.

MIPS Promoting Interoperability Category. In the proposed rule, CMS proposes changes to this category aligned with changes it proposed for hospitals in the fiscal year (FY) 2023 inpatient prospective payment system (IPPS) proposed rule. Taken together,

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the proposed changes signal the agency's approach to advancing the communication and secure sharing of relevant patient information among providers.

AHA urges CMS to allow flexibility for clinicians in areas where the prescription drug monitoring programs (PDMPs) have not yet improved. The proposed rule would expand the requirement to query the PDMPs to include schedule II, III and IV drugs. Yet, over the past few years, we have heard many reports from our members that accessing their state PDMPs is time consuming for clinicians, often requiring that they exit the hospital's medical record and then spend several minutes trying to connect with and query the PDMP because the state's technology is outdated. This was highly frustrating at any time for busy clinicians, and is especially now as we see the increased stress clinicians have experienced during the pandemic and continue to experience with the ongoing shortage of doctors, nurses and other clinicians. We urge CMS to recognize that this is not the time to put more burden on clinicians, even for the important task of consulting the PDMPs, and provide for enforcement discretion or a waiver until the state has improved its technology to enable easy inquiries.

Further, AHA urges CMS to coordinate its revisions to the scoring of the Public Health and Clinical Information Data Exchange objective with CDC's efforts to ensure the public health agencies are capable of receiving the data. In the proposed rule, CMS plans to change from three different levels of active engagement to just two levels of engagement in exchanging data with public health entities. This is one of the four scored objectives of interoperability, which are electronic prescribing, health information exchange, provider to patient exchange of information, and public health and clinical data exchange beginning with the CY 2023 EHR reporting. Interoperability is truly an activity that requires two or more willing and capable partners. The Coronavirus Aid, Relief, and Economic Security (CARES) Act provided funding to CDC to disseminate to public health agencies to improve their technology systems' ability to receive significant public health data from hospitals and other providers of care. We believe CDC is in the process of disseminating that bolus of funds to state and local public health departments to update their critical information systems and become capable of receiving hospitals' information, but it will take time. We urge CMS to consult with CDC around this funding and the anticipated implementation schedule, and to delay updating categories of scoring until clinicians have the opportunity to work with a public health agency that is able to receive their data.

Advanced APMs. The MACRA provides incentives for physicians who participate in advanced APMs. These include a lump-sum bonus payment of 5% of payments for professional services in 2019 through 2024; exemption from MIPS reporting requirements and payment adjustments; and higher base payment updates, beginning in 2026.

The AHA supports CMS's proposal to make permanent its 8% generally applicable nominal financial risk standard for Advanced APMs. The standard had been set to expire after CY 2024, but in prior rulemaking, CMS indicated it would

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reevaluate the standard to ensure the amount of financial risk remained sufficiently high. CMS believes the standard remains appropriate for advanced APM participants.

The AHA also supports CMS's proposal to revise the advanced APM medical home clinician limit. However, we remained concerned that the limit severely constrains the ability for hospital or health system-affiliated clinicians and groups to benefit from medical home participation. Per the MACRA statute, participants can qualify as advanced APMs if they participate in certain qualifying medical homes. CMS adopted a relaxed nominal financial risk standard for medical homes in prior rulemaking, but limited its availability to APM entities owned and operated by organizations with 50 or fewer clinicians. We agree that applying the limit to the "parent organization" was arbitrary, and it is more appropriate to apply it at the APM entity level. However, we continue to urge CMS to explore ways of enabling more hospital and health system affiliated clinicians to use medical home participation to enter the advanced APM track.

Lastly, we urge CMS to work with Congress to extend the availability of advanced APM bonuses beyond the CY 2024 payment period. The MACRA statute indicates that advanced APM bonuses should end after the CY 2024 payment period. However, participation in the advanced APM track has fallen far short of initial projections. In 2015, CMS's Office of the Actuary estimated that 60% of QPP-eligible clinicians would participate in the advanced APM track. Yet, actual participation in each year of the QPP has come nowhere close to that expectation. Indeed, in the 2021 payment year, only about 17% of eligible clinicians participated in the advanced APM track. As a result, spending on advanced APM bonuses has fallen well short of the amount projected when the MACRA was originally scored by the Congressional Budget Office (CBO). We encourage CMS to engage with Congress to determine whether this spending shortfall could be re-purposed for modest APM bonuses in future years. Maintaining bonus payments for advanced APM participation will only serve to accelerate our shared goal of accelerating APM adoption.

### Medicare Shared Savings Program (MSSP)

Our members remain enthusiastic about the MSSP as one pathway to advance their ongoing efforts to transform care delivery through improved care coordination and financial accountability. The AHA appreciates that, as a whole, CMS's proposed changes to the program seek to address policies that the AHA and other stakeholders have raised with the agency over the years. While we outline suggestions that we believe could improve the program even more, taken together, we believe that CMS's proposals will help improve the stability and flexibility of the MSSP and expand participants' ability to provide care to beneficiaries.

That said, most proposals apply only to agreement periods beginning on or after Jan. 1, 2024. The vast majority of existing ACOs will not have access to these improved policies for several years without going through the onerous process of early renewing.

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Therefore, we urge CMS to allow existing ACOs to immediately opt-in to the new financial methodology approaches.

Advance Investment Payments (AIPs) for Certain ACOs. CMS states that ACOs treating underserved populations have indicated that to be successful in the model they need upfront capital in order to make necessary investments. Therefore, the agency proposes to make advance shared savings payments (referred to as AIPs) to certain ACOs participating in the MSSP. Specifically, it proposes that ACOs meeting all of the following criteria would be eligible:

- not a renewing ACO or re-entering ACO;
- has applied to participate in the MSSP under any level of the BASIC track glide path (because this participation option is indicative of an ACO's inexperience with performance-based risk, in which ACOs are typically less experienced with risk and are more likely to benefit from up-front funding or ongoing financial assistance);
- eligible to participate in the MSSP;
- inexperienced with performance-based risk Medicare ACO initiatives; and
- designated a low-revenue ACO (defined as the ACO's Medicare Parts A and B FFS revenue equaling less than 35% of the Medicare Parts A and B FFS expenditures for its assigned beneficiaries).

Qualifying ACOs may receive a one-time fixed payment of \$250,000, as well as quarterly payments for the first two years of the five-year agreement period. AIPs would be recouped once the ACO begins to achieve shared savings.

The AHA supports this proposal, but urges CMS to expand eligibility for AIPs to include all ACOs working to combat health inequities. Historically, beneficiaries in underserved communities have not had adequate access to health care; this significant unmet need has led to financial benchmarks that do not accurately reflect the cost of addressing the complex needs of these beneficiaries. We share CMS's commitment to advancing health equity and ensuring access to high-quality, high-value care. By providing adequate funding for all ACOs to address health related social needs and reduce disparities, we can advance our shared goal of achieving equitable health outcomes for all.

We particularly urge CMS to eliminate the criterion that qualifying ACOs be designated as low-revenue. CMS states that the goal of AIPs is to improve health equity outcomes by increasing MSSP participation in underserved regions, as well as improve the success of ACOs in achieving shared savings and meeting quality metrics. However, there is no valid reason to conclude that an ACO's amount of "captured" revenue is an accurate or appropriate predictor of whether it treats an underserved region. In contrast, whether or not an ACO treats underserved populations cannot be determined simply by dividing the world into high- and low-revenue. As an example, analysis suggest critical access hospitals, federally qualified health centers and rural

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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.

In addition, CMS states that low-revenue ACOs tend to be small, physician-only ACOs that are less well capitalized organizations. However, the low- and high-revenue designations were flawed from the start; we continue to have concerns that their creation was based on incomplete and misguided data that suggested that "physician-led" ACOs outperform "hospital-led" ACOs, as well as a flawed assumption that high-revenue ACOs were likely to include hospitals, health systems, and/or other institutional providers. In the MSSP, CMS defines an ACO as "hospital-led" only if it includes an inpatient taxpayer identification number (TIN) on the participant list it submits to CMS. This definition misrepresents the wide range of hospitals' involvement in ACOs, including:

- jointly initiating and leading an ACO with a physician group;
- participating in the ACO contract without a leadership role;
- contracting with a physician group for health system services and resources without appearing on the physician group ACO's participant list; or
- participating in another manner.

For example, an academic medical center might have an ACO that is run through its faculty practice; CMS would call this ACO "physician-led" despite the obviously critical role the academic medical center would play in providing care to the ACO's patients. As another example, a "physician-led" ACO may be truly led by an investor, which would not be reflected in the ACO's participant list. Indeed, CMS itself recognized this fallacy of relying on participant lists when it indicated that to move from being a high- to low-revenue ACO, an ACO could simply remove a hospital from its participant list but make no other changes to its care delivery.

As such, CMS should not base any policies within the MSSP on the low- and high-revenue distinctions. We urge the agency to allow ACOs of all revenues to be eligible for AIPs.

<u>Transition to Performance-based Risk.</u> In response to feedback from AHA and other stakeholders that the MSSP requires too much risk too soon, CMS is proposing moregradual transitions for certain ACOs. Specifically, the agency proposes:

- Modifying the definition of "experience with performance-based risk Medicare ACO initiatives" to only include Levels C through E of the BASIC track
- Allowing ACOs in the BASIC Track Level A or B, and those that begin a Track A
  or B agreement period on Jan. 1, 2023, to elect to remain there for the
  remainder of their agreement period
- Allowing ACO that begin agreement periods on Jan. 1, 2024 to participate in Level A, for all five years of the agreement period if certain requirements are

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- met, and have a second, full agreement period in the BASIC track
- Allowing ACOs inexperienced with performance-based risk Medicare ACO initiatives, but not otherwise eligible to enter the BASIC track, to enter either the BASIC track Level E for all PYs of the agreement period, or the ENHANCED track
- For agreement periods beginning on Jan. 1, 2024, and after, allowing ACOs to remain in Level E of the BASIC track indefinitely; participation in the ENHANCED track would be optional for all ACOs

The AHA strongly supports these proposals. They would help create a more gradual glide path to risk, which will, in turn, help increase participation, experience, and shared savings under the program by empowering ACOs to maximize their contribution to patient care. However, as stated above, the low- and high-revenue designations were flawed from the start, and CMS should not base any policies within the MSSP on this distinction. Therefore, we urge the agency to eliminate the low- and high-revenue designations, including as part of the existing performance-based risk transition framework.

Finally, we ask CMS to clarify, however, that ACOs electing to remain in Level A or B have a clear path to obtain the necessary downside risk policy mechanisms (e.g., the repayment mechanism and skilled-nursing facility three-day stay waiver) in a timely manner should this proposal not be finalized, which would necessitate their advancement to Level C.

<u>Modifications to ACO Benchmarks</u>. CMS makes numerous proposals designed to improve the calculation of ACO benchmarks. It states that they are designed to help ensure that high performing ACOs have incentives to remain in the program for the long-term, including by helping to ensure that an ACO does not have to compete against its own best performance.

Trend Factor. To establish an ACO's historical benchmark for an agreement period, CMS uses historical expenditures for beneficiaries that would have been assigned to that ACO in the three most-recent years prior to the start of the agreement period. In this rule, CMS proposes to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to in the proposed rule as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each PY in the ACO's agreement period.

The agency believes that this proposal would help insulate a portion of the annual update from any savings occurring as a result of the ACO actions and address the impact of increasing market penetration by ACOs in a region. However, it does acknowledge that it could yield mixed effects – meaning that it could disadvantage certain ACOs as compared to the current two-way blend of national and regional growth rates. Therefore, it also proposes to recalculate the ACO's updated benchmark using

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the existing national-regional blended factor (two-way blend). If the ACO generates savings using the two-way blend (but not in the three-way blend), the ACO would neither be responsible for shared losses nor eligible for shared savings for the applicable performance year.

The AHA supports CMS's proposal to use the three-way blend to update ACO benchmarks. However, we also urge it to continue using the two-way blend and set ACOs' historic benchmark at the higher of the proposed three-way trend adjustment or the current two-way trend adjustment. Allowing an ACO to use the two-way blend, but then negating the shared savings it achieves under that factor, defeats the point of providing flexibility to account for different ACOs' circumstances.

Adjusting Benchmarks to Account for Prior Savings. CMS proposes to incorporate an adjustment for prior savings that would apply when establishing benchmarks for renewing ACOs and re-entering ACOs that were reconciled for one or more PYs in the three years preceding the start of their agreement period. Specifically, for ACOs with spending lower than the region, CMS would apply the higher of either the positive regional adjustment or a prior savings adjustment equal to the lesser of 50% of its prior savings or 5% of national FFS spending for assignable beneficiaries

We support this proposal. That said, in order to create more incentive for those taking the greatest risk, we urge CMS to allow ACOs in the ENHANCED Track to use their maximum shared savings rate from their prior agreement period to pro-rate the positive average per capita savings. Specifically, if an ACO was in the Enhanced Track in the prior agreement, then CMS should pro-rate the prior savings adjustment by 75%.

Negative Regional Adjustment. CMS proposes two policy changes designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high cost beneficiaries. Specifically, it proposes to reduce the cap on negative regional adjustments from negative 5% to negative 1.5% of national per capita expenditures for Parts A and B services under the original Medicare FFS program in the third benchmark year. It also proposes, after the cap is applied to the regional adjustment, to gradually decrease the negative regional adjustment amount as an ACO's proportion of dual eligible Medicare and Medicaid beneficiaries increases, or its weighted average prospective risk can reduce barrier to entry for ACOs whose spending is higher than their region.

We support this proposal, which should reduce the barriers to entry for future ACOs who have spending higher than their region. This includes ACOs who serve high-cost and medically complex populations.

Risk Adjustment. Currently, CMS uses prospective hierarchical condition category (HCC) risk scores to adjust ACOs' benchmarks and account for changes in severity and case mix. However, the adjustment is subject to a cap of positive 3% for the agreement period. Stakeholders, including the AHA, have raised concerns that this cap unfairly

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penalizes certain ACOs that may, for example, see higher volatility due to smaller sample sizes, or serve larger proportions of high-severity beneficiaries. Therefore, CMS is proposing to modify the cap, such that an ACO's aggregate prospective HCC risk score would be subject to a cap equal to the ACO's aggregate growth in *demographic* risk scores between the last benchmark year and the performance year plus three percentage points.

The AHA appreciates this proposal, which would help make the cap more equitable across ACOs. However, we continue to urge CMS to use a 5% threshold rather than a 3% threshold. We also ask CMS to expand its proposal to remove the cap on diagnosis risk scores, as well as demographic risk scores. Maintaining the cap on diagnosis risk scores does not allow ACOs to capture the significant turnover and changes in health status that their beneficiaries experience. This is particularly true as the burden of illness in the Medicare population increases over time. It is also particularly problematic in light of the COVID-19 pandemic. During the COVID-19 public health emergency, there were significant decreases in patient encounter volume; as a result, ACOs were unable to capture large swaths of beneficiaries' HCCs. Thus, most ACO risk scores for 2021 are extremely low. Subsequently, they will likely have a significant increase in scores simply because patients returned to the office, as well as they fact that that many patients delayed care during the COVID-10 pandemic and may now have a higher severity of illness. As such, applying the existing cap policy to diagnosis risk scores artificially penalizes them for patients' need to stay in the safety of their homes during the pandemic. This is particularly true for ACOs that have 2021 as their third, and most heavily weighted, benchmark year.

Low-revenue ACO Shared Savings. CMS proposes to provide more flexibility in how certain ACOs can qualify for shared savings. This change would apply to qualifying ACOs entering an agreement period in the BASIC track beginning on or after Jan. 1, 2024, including new, renewing and reentering ACOs. Specifically, ACOs in the BASIC track that *do not* meet the minimum savings rate (MSR) requirement but *do* meet the quality performance standard would qualify for a shared savings payment if:

- The ACO has average per-capita Medicare Parts A and B fee-for-service expenditures below the updated benchmark;
- The ACO is a low-revenue ACO at the time of financial reconciliation for the relevant performance year; and
- The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

Eligible ACOs that meet the quality performance standard to share in savings at the maximum sharing rate, but do not meet the MSR, would instead receive half of the maximum shared rate (20% instead of 40% under Levels A and B, and 25% instead of 50% under Levels C, D, and E). For eligible ACOs that do not meet the quality performance standard required to share in savings at the maximum sharing rate, but

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meet the proposed alternative quality performance standard, the sharing rate would be further adjusted using a sliding scale approach.

The AHA supports this proposal. However, as stated above, the low- and high-revenue designations were flawed from the start and CMS should not base any policies within the MSSP on this distinction. We urge the agency to allow ACOs of all revenues to be eligible for the proposed flexibility in shared savings.

Quality Performance Standard. The AHA supports CMS's proposal to determine eligibility for shared savings using a sliding scale rather than the current "all or nothing" approach. Beginning in CY 2023, ACOs that do not meet the minimum quality performance standard could still be eligible for shared savings (or owe shared losses) at a lower rate if they score at the 10th percentile or above on at least one of the four APM Performance Pathway (APP) outcomes measures used in the MSSP. The lower rates of shared savings/losses would be calculated on a sliding scale tied to the ACO's quality performance score. We agree with CMS that the current policy creates a "cliff" in which small differences in quality scores can eliminate any possibility of sharing savings, or result in owing large amounts of shared losses. The revised approach maintains a focus on achieving quality, while ensuring that ACOs that have opportunities for improvement are not deprived of the financial resources to do so.

APP Reporting Incentive. The AHA supports CMS's proposal to extend its incentives to report measures from the APP measure set through the CY 2024 performance period. However, we continue to have concerns about the transition to the APP measure set and urge CMS to undertake further work to ensure the APP measure set is truly ready for use in the MSSP. 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.

In addition, we continue to question the appropriateness of collecting all-payer data in the MSSP program. For a program that is called the *Medicare* Shared Savings Program, and that is intended to improve the care for and value delivered Medicare beneficiaries, it seems incongruous to base the judgment of quality performance on all payer data. Furthermore, 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.

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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) specifications, or MIPS clinical quality measure (MIPS CQMs). 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.

Health Equity Adjustment. Beginning in CY 2023, CMS proposes to add 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 indicates that the health equity adjustment would better support those ACOs caring for large portions of underserved patients while incentivizing high quality care for all populations an ACO serves. The bonus would be available to only those ACOs that opt to report the six measures in the APP measure set. The equity adjustment would be the product of two factors: a "measure performance scaler" and "an underserved multiplier." The measure performance scaler would assign ACOs points on each APP measure based on whether they score in the top, middle or bottom third of performance on each APP measure. The underserved multiplier would be based on the higher of: the ACO's Area Deprivation Index (ADI) score *or* its proportion of beneficiaries dually eligible for Medicare and Medicaid.

The AHA supports CMS's proposed health equity adjustment, and thanks CMS for recognizing the complex interplay between outcome measures and health-related social needs. 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 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

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all ACOs in the health equity adjustment, CMS can ensure that all ACOs and the beneficiaries they serve benefit from this important new policy.

RFI on CAHPS. In the proposed rule, CMS solicits comment on adding survey questions to the CAHPS for MIPS survey related to health disparities and price transparency. The items are as follows:

- Health Disparities: In the last six months, did anyone from a clinic, emergency room or doctor's office where you got care treat you in an unfair or insensitive way because of any of the following things about you?
  - Health condition, disability, age, culture, sex (including sexual orientation and gender identify) and income.
- *Price Transparency:* In the last six months, did you and anyone on your health care team talk about how much your prescription medicines cost?

Talking with patients about cost is an important part of the care experience, and something the AHA is very seriously considering how best to accomplish. We also believe patient perspectives are vital to informing the important work of addressing health equity. While we do not believe the CAHPS survey is well-suited to advancing these efforts, we look forward to further opportunities to engage with the agency on inclusive, culturally sensitive ways to ensure patients have the information they need to make informed decisions about and to plan for their care.