American Hospital Association™
Advancing Health in America

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September 13, 2021

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

RE: CMS-1751-P, Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

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) 2022. **We appreciate CMS' proposals in this rule that support care delivery and patient outcomes by extending the timeline for certain programs and continuing others beyond the end of the COVID-19 public health emergency.** In particular, we support CMS' proposal to delay the payment penalty phase of the Appropriate Use Criteria (AUC) program and the compliance date for e-prescribing of controlled substances. We also appreciate CMS' proposals to extend temporary coverage of certain telehealth services and increase access to audio-only services for those who need them. Finally, the AHA also supports CMS' proposal to delay until 2023 the implementation of the Merit-based Incentive Program's Value Pathways (MVP) approach.

However, we continue to have concerns about the feasibility of the Merit-Based Incentive Payment System (MIPS) Value Pathways, and believe much work remains to be done to ensure they result in fair, equitable performance comparisons across MIPS clinicians and groups. **In addition, we urge CMS to reevaluate its proposals to require routine, in-person visits for the coverage and payment of telehealth**

mental health services. If these policies are finalized as proposed, access to these services would be greatly reduced for certain patients.

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

Sincerely,

/s/

Stacey Hughes
Executive Vice President

Enclosure

American Hospital Association
Detailed Comments

Proposed Payment Changes

Conversion Factor. The proposed payment update for CY 2022 reflects several different factors, some of which account for policy changes implemented last year. Specifically, the Consolidated Appropriations Act of 2021 (CAA) provided a 3.75% increase in the PFS conversion factor only for CY 2021. Because the CAA instructed CMS to ignore the 3.75% increase when determining PFS payment rates for subsequent years, the agency calculated the CY 2022 conversion factor as though the 3.75% increase never occurred. Thus, CMS proposes a slight 0.14% decrease in PFS payment rates in CY 2022. However, when factoring in the expiration of the 3.75% increase, the actual change that providers will feel is a decrease of $1.31, or 3.89%. This decrease comes just one year after CMS finalized a 10.2% cut to the conversion factor. Additionally, on Jan. 1, 2022, physician payments are set to see additional cuts from the expiration of the moratorium on the Medicare 2% sequester reduction. And in the event Congress doesn't take action to waive it, two weeks after Congress adjourns, there would be imposition of an additional 4% sequester reduction due to statutory PAYGO. These cuts occur in an environment in which Medicare payments already have not kept up with inflation. Specifically, the proposed CY 2022 conversion factor of $33.58 is *less* than the 1994 conversion factor, which would be equivalent to $61.45 in today's dollars ($32.9050 in 1994 dollars).[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 this cut is coming amidst nearly two years of unrelenting financial pressure on the health care system due to the ongoing COVID-19 PHE. Even taking into account federal Coronavirus Aid, Relief, and Economic Security (CARES) Act funding, hospitals will lose billions of dollars this year due to the pandemic, in addition to the approximately $323 billion they were projected to have lost last year.[2] Many of the specialties that would face drastic cuts due to the conversion factor cut and clinical labor pricing proposal (described below) are those practicing in the facility setting, exacerbating the already significant financial challenges our nation's providers are facing.

One example of the impact of the proposed conversion factor reduction and other proposed cuts in this rule can be seen in the potential payment reduction for

[1] Using the U.S. Bureau of Labor Statistics inflation calculator, the conversion factor in 1994, $32.9050, is worth approximately $61.45 today.
[2] AHA Report: Hospitals and Health Systems Continue to Face Unprecedented Financial Challenges due to COVID-19, June 2020.

electrophysiologists (EPs), who treat abnormal heart rhythms, or arrhythmias. Among other services, EPs perform invasive ablation procedures to eliminate atrial fibrillation. If the proposals in this rule are finalized, EPs face a 5% cut from the proposed conversion factor and other CY 2022 changes, on top of the significant cuts finalized in last year's PFS rule, and due to many of their services being bundled for the first time in CY 2022, for a net cut of 25%. This is especially concerning given that recent data has demonstrated that ablation procedures are particularly effective treatment for patients with atrial fibrillation. Cuts of this magnitude will greatly undervalue these services and threaten patient access to them.

After almost two years of 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 all of their essential services to the patients who need them. **Therefore, we strongly urge CMS work with Congress to maintain the 3.75% increase to the conversion factor for CY 2022 and 2023 or, alternatively, secure a waiver of budget neutrality for the PFS for CY 2022.** Doing so would allow CMS to protect patient access to care and help ensure Medicare maintains a robust network of providers of all specialties at a time when such access has never been more important. CMS also should work with Congress to develop a long-term plan for ensuring the conversion factor and associated payments are adequate to sustain all types of physicians and physician practices. Years of enormous cuts to the conversion factor is simply not sustainable for providers.

Clinical Labor Pricing. Another proposed payment change in this rule relates to clinical labor pricing. Specifically, CMS proposes to update clinical labor pricing for 2022 using data from the Bureau of Labor Statistics and other supplementary sources. CMS has not updated the clinical labor rates since 2002. Given this long delay, there is a disparity between CMS' clinical wage data and the market average for clinical labor. The agency explains that if it does not regularly update the data, clinical labor could become artificially undervalued over time.

Because the practice expense (PE) component of Relative Value Units (RVUs) used for calculating physician payment rates must maintain budget neutrality, an increase in clinical labor pricing carries a corresponding relative decrease for other PE components, such as supplies and equipment. However, while changes to the PE component of RVUs may be budget neutral for Medicare as a whole, they would not be budget neutral for individual providers depending on the degree to which they rely on clinical labor. For example, certain specialties that rely primarily on supply or equipment items, including vascular surgery, radiation oncology and oral/maxillofacial surgery will face significant cuts to their payments from the clinical labor pricing proposals. Moreover, CMS greatly underestimates the impact of these pricing cuts, as the agency does not factor in the impact of other proposed changes, including the nearly 4% reduction to the conversation factor mentioned above. For example, radiation oncologists stand to face an 8.75% cut in payments from the clinical labor pricing proposals and the proposed conversion factor reduction. This is a substantial cut, even before it is compounded by

the proposed discount factors in the Radiation Oncology (RO) model, in which many of these providers would be required to participate. This compounding effect with the RO model is described in our forthcoming comments to the CY 2022 Outpatient Prospective Payment System (OPPS) proposed rule. **These concerns underscore the importance of our request above for CMS to work with Congress to maintain the 3.75% increase to the conversion factor and/or work with Congress to secure a waiver of budget neutrality.**

Additionally, while we recognize the need to update data, we urge CMS to reduce the degree to which its proposals redistribute funds among providers. To that end, we strongly support the agency's proposed use of a four-year transition to implement the clinical labor pricing update. The AHA routinely supports phase-in policies in order to moderate substantial fluctuations in payment rates, thereby promoting predictability and reliability. Such an approach would also be consistent with previous actions taken by the agency when incorporating significant new data into the PFS. For example, CMS implemented a four-year transition period in the CY 2007 PFS final rule when changing to the "bottom-up" PE methodology, as well as a similar, four-year transition period in the CY 2019 PFS final rule when incorporating new supply and equipment values based on the StrategyGen survey.

Valuation of Specific Codes: (37) Remote Therapeutic Monitoring (RTM). The AHA strongly supports CMS' proposal to activate five new CPT codes for RTM (989X1, 989X2, 989X3, 989X4 and 989X5) and to require that devices used for these services must meet the Food & Drug Administration (FDA) definition of a medical device. While these RTM codes are specific to respiratory and musculoskeletal therapy, RTM more broadly has great potential to benefit patients in a range of ways with a variety of conditions.

We also appreciate that CMS solicits feedback on how to remedy certain issues identified with the code construction. Specifically, the RTM codes are "incident to" services and, therefore, cannot be billed independently by physical therapists and other practitioners who are not physicians or non-physician practitioners (NPPs). In addition, as "incident to" services, direct, as opposed to general, supervision requirements would apply. The AHA believes there are multiple steps CMS can take in order to resolve the technical issues identified and better support the intent of these codes, including:

- Designating CPT codes 989X4 and 989X5 for "treatment management services" as E/M codes, similar to Remote Physiologic Monitoring (RPM) Treatment Management Services. As E/M codes, 989X4 and 989X5 could be billable to physicians and other qualified healthcare professionals, including physician assistants, nurse practitioners, certified nurse specialists, and certified nurse midwives. This designation is necessary to ensure that a broader range of practitioners are able to participate in the provision of RTM services "incident to" and under general vs. direct supervision.

- Creating temporary HCPCS G-Codes that mirror 989X4 and 989X5 for treatment management services. This approach would be consistent with CMS' creation of the G2061, G2062, and G2063 codes for e-visits, allowing non-physician providers who cannot bill E/M to bill these codes directly.

We further encourage CMS to confirm that the new RTM codes are subject to the same clarifications governing RPM codes, including those related to consent, asynchronous/real-time audio conversation as part of "interactive communications" and the ability for RTM to be used for both acute and chronic diseases.

More broadly, we urge CMS to recognize in the final rule that Software as a Medical Device (SaMD) used for medical services such as RTM is not equivalent to general computer software and should not be categorized as an Indirect PE. SaMD meets the FDA definition of a device regardless of whether the software is incorporated into a medical device or runs on a general purpose platform. Therefore, it should be treated as a Direct PE.

Appropriate Use Criteria (AUC) Program

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. This policy applies when applicable imaging services paid under the physician payment schedule, hospital outpatient prospective payment system, or ambulatory surgical center payment system are provided in specific settings. These settings include: a physician's office, a hospital outpatient department, an ambulatory surgical center or an independent diagnostic testing facility.

The proposed rule reveals that, based on CMS' review of the ongoing "educational and operations testing" period, only 9-10% of all claims would be compliant, due to numerous and varied issues that providers encountered in submitting the requested information, meaning that 90-91% of CY 2020 AUC claims would not have been paid if the program had been in a payment penalty phase.

Delay Payment Penalty Phase. In light of the complexities of operationalizing the AUC program, as well as the ongoing COVID-19 public health emergency (PHE), CMS proposes to delay the payment penalty phase of the program to the later date of Jan. 1, 2023, or the Jan. 1 that follows the end of the PHE. **We appreciate and support a delay in the penalty phase.** Responding to the challenges of the PHE drastically

limited the ability of providers to make the technology and workflow adjustments necessary to implement the AUC program. For example, information technology resources were re-deployed to meet the need for expanded telehealth services. Additionally, revenue cycle staff was instead needed to support newly designed billing requirements to ensure COVID-19 patient care was efficiently delivered. These essential steps to respond to the PHE were often prioritized over other technology and billing projects, including preparations for implementing an AUC program.

Additionally, we support the rule's specification that if providers still are not able to comply upon the new start date for the payment penalty phase due to issues brought about by the pandemic, they may utilize the "extreme and uncontrollable circumstances" hardship exemption. Indeed, during the ongoing and potential future surges of COVID hospitalizations, hospital resources must continue to be allocated toward helping our nation get through this pandemic. As a result, many hospitals will not be able to adjust workflows and resources until after the PHE ends, at which time there may be a backlog of important work that was not completed during the pandemic. In such instances, CMS should recognize that technological investment, workflow adjustment and education necessary to comply with the AUC program may take significant time. **As a result, we encourage CMS to allow providers to utilize the "extreme and uncontrollable circumstances" exemption for at least one year following the start of the payment penalty phase.**

Modified Orders. When providing advanced imaging services, hospital imaging centers and other furnishing providers may need to modify or add additional imaging services while a patient is under their care. The rule proposes that when performing these modified orders, when permissible under the Medicare Benefits Policy Manual, furnishing providers need not consult CDSMs. **The AHA supports this provision, which would help ensure that Medicare beneficiaries can obtain timely and important imaging services**. However, we seek clarifications as to its applicability and documentation. Specifically, although recognizing that furnishing providers may need to modify an order, the proposal seemingly would apply only to additional tests provided after the ordered service is complete. We encourage CMS to enable a furnishing provider to modify an ordered service as deemed medically necessary. Additionally, we encourage CMS to provide guidance as to how furnishing providers should report these services on a claim in order to ensure that they are not denied for failure to consult a CDSM.

Modifiers. The rule proposes two sets of HCPCS modifiers to be utilized on furnishing provider claims, one to report CDSM information and the other to report instances in which a CDSM was not consulted. Additionally, CMS proposes discontinuing usage of modifiers created for the educational period, including the "MH" modifier for reporting that an ordering physician failed to provide CDSM information. **The AHA believes the new modifiers provide the appropriate framework for furnishing providers to utilize in claims submission processes. However, we urge CMS to reconsider the**

discontinuation of the MH modifier. The AUC program promotes medically appropriate ordering habits for physicians utilizing advanced imaging for their patients. If an ordering physician fails to consult a CDSM or exercise a permissible hardship, furnishing providers should be permitted to utilize the MH modifier to report this issue, which would enable CMS to address the situation directly with the orderer. Discontinuation of this code would require furnishing providers to serve as the regulatory enforcement body, as they would presumably be expected to refrain from performing imaging services for non-compliant physicians. Requiring furnishing providers not to provide imaging services for non-compliant clinicians could create a dangerous situation in which patients are unable to obtain medically necessary care. We believe the MH modifier appropriately enables a furnishing provider to identify ordering clinicians with non-compliant orders that can be addressed by CMS as they see fit.

Critical Access Hospitals (CAHs). The proposed rule considers the difficulties that CAHs may have in adhering to the AUC requirements, specifically detailing that furnishing physicians within CAHs need not report order information on their claims. **The AHA supports these efforts to reduce the resource burden on CAHs, and we urge CMS to extend this exemption to CAH physicians ordering imaging services**. CMS created the CAH designation to reduce the financial vulnerability of rural hospitals and improve access to essential services in rural communities. As the designation indicates, these rural hospitals provide care to their communities, while dealing with limited resources. Under the proposed AUC protocol, CAH clinicians who order diagnostic imaging services from applicable facilities (e.g. external labs) would be required to consult with a CDSM. In order to achieve compliance, CAHs would need to license and maintain a CDSM and spend valuable resources updating workflows and educating personnel. Just as requiring furnishing providers to achieve compliance would result in undesired resource usage, requiring ordering clinicians to achieve compliance would do the same and would otherwise would be impractical.

Reconsideration of Program Design. Each of the preceding recommendations are important steps to make the current AUC process more manageable and practical for hospitals and other providers. However, the fact remains that even if they are implemented, the process will still be burdensome and require significant manual reworking of ordering and claims submission processes. For example, there is not currently a simple method for transferring the NPI and CDSM information from a furnishing provider's incoming order system into their claims submission process. In order to include the necessary information, providers will need to manually transfer data from the order onto the claim. This not only creates administrative burden for practices, but also increases the potential for claims errors.

In the proposed rule, CMS requests comments as to whether improperly completed furnishing provider claims should be sent back for correction or formally denied and subject to standard appeals processes. **While we appreciate the desire to solicit**

provider preference on this issue, we believe CMS should instead work to ensure that the program as a whole does not result in a substantial number of claims submission issues for furnishing provider claims. The AUC program was designed to achieve more appropriate ordering of advanced diagnostic imaging services by *ordering* physicians. However, the program places a significant amount of burden on *furnishing* providers, who must navigate a complex and manual workflow to report AUC information in order to successfully receive payment for their treatment. **Thus, in order to simplify this process and reduce administrative burden and claims documentation issues, we encourage CMS to reconsider the program design and collect requisite information directly from ordering provider CDSMs.** This would enable regulators to analyze and correct problematic ordering patterns with significantly less systematic disruption.

Telehealth and Other Communications Technology-based Services (CTBS)

CMS proposes several changes to extend temporary coverage of some telehealth services and make permanent coverage and payment for other services. These changes build on the numerous, critical telehealth flexibilities that CMS provided during the PHE, 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 PHE 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 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.[3] And, according to many of our members, patients are extremely satisfied with the telehealth services they have received.

The 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. Therefore, we urge

[3] 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

CMS to work with Congress to eliminate the geographic and originating site restrictions in Section 1834(m) of the Social Security Act. This would allow patients nationwide to receive all 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 PHE clearly demonstrated the need to access telehealth in non-rural areas and in the safety of patients' homes, and we urge CMS to work with Congress to ensure federal policy reflects the realities of today's health care environment.

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 end-user devices.

As providers continue to explore the possibilities for improved patient care through telehealth and other virtual services, we urge CMS to do the same. This effort will best support providers' ability to deliver high quality care and achieve improved patient outcomes. **This work must include a thorough and complete accounting of the costs that go into providing virtual visits and how such expenses relate to the need to maintain capacity for in-person services.** Armed with this information, CMS should ensure providers receive adequate reimbursement for the substantial upfront and ongoing costs of establishing and maintaining their virtual infrastructure, including secure platforms, licenses, IT support, scheduling, patient education and clinician training. Without adequate reimbursement of these costs, providers will be forced to decrease their telehealth offerings, thus 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 beneficiaries for the duration of the COVID-19 pandemic to self-report vital signs when clinically acceptable. We urge the agency to continue this policy after the PHE ends and to disseminate guidance on what providers can do in situations in which patients cannot

self-report. We also recommend CMS consider how to account for missing diagnosis data that will certainly occur as a result of the dramatic decline in utilization this year.

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

Category 3 Services. In the CY 2021 PFS final rule, CMS created a new Category 3 for adding services to the Medicare telehealth list on a temporary basis. This "Category 3" describes services added during the PHE for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the services as permanent additions under Category 1 or Category 2 criteria. In this rule, CMS proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. **The AHA strongly supports CMS' proposal to retain Category 3 services on the Medicare telehealth list for an additional two years.** Doing so will contribute greatly to the tools providers can use to care for patients and will mitigate the uncertainty of when the PHE will end, as well as the impact that will have on Category 3 services. **However, we urge CMS to clarify the requirements for the provision of Category 3 services after the end of the PHE.** Absent an act of Congress, we urge the agency to allow providers to continue to be able to furnish Category 3 services to patients in their homes. Otherwise, we will find ourselves in a counter-productive "one step forward, two steps back" arrangement, in which patients would have access to newly covered telehealth services, but only if they return to office- or facility-based visits.

We further urge CMS to consider making Category 3 a permanent part of the Medicare telehealth list. Establishing Category 3 as a subregulatory way to temporarily add 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.

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 geographic areas largely representing rural parts of the country and to the listed originating sites in which a patient must be located to receive telehealth. The CAA waived these geographic restrictions and added the patient's home as a permissible originating site for telehealth services furnished for the purpose of diagnosis, evaluation or treatment of a mental health disorder, effective for services furnished on or after the end of the COVID-19 PHE. 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 proposes to require 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 six months thereafter.

The AHA opposes CMS' proposal to require subsequent in-person visits every six months for the continued coverage of and reimbursement for telehealth mental health services. Additionally, as the industry continues to monitor the use of telehealth for mental health and other services, we urge CMS to work with stakeholders and Congress to revisit the required initial in-person visit within six months before telehealth services begin, and perhaps consider limiting it to services that may particularly benefit from in-person contact, such as psychiatric medication management. As the agency is well aware, the nation is currently suffering from extreme access challenges in the behavioral health field. More than one-third of Americans live in an area without sufficient behavioral health providers. Specifically, 56% of counties in the U.S. are without a psychiatrist, 64% of counties have a shortage of mental health providers and 70% of counties lack a child psychiatrist.[4] CMS should be implementing policies that reduce this access crisis, not policies — such as in-person requirements — that exacerbate it. Under such a policy, scores of beneficiaries who could benefit from telehealth mental health services would not have access to them because they are too far away from or are unable to travel to a mental health provider. 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.

Notably, CMS does not propose a corresponding in-person requirement for virtual mental health services provided by rural health clinics (RHCs) and federally qualified health centers (FQHCs). Rather than proposing an in-person visit requirement for RHCs and FQHCs that corresponds to the proposed in-person requirements for acute care hospitals, CMS seeks comment on whether it should require in-person visits or whether such a requirement could be especially burdensome for beneficiaries that receive treatment at RHCs and FQHCs. This request — rather than a proposal — demonstrates clearly that CMS does not view in-person visits to be clinically necessary for the provision of safe, effective virtual mental health services. If CMS did hold this belief, it would have no choice but to propose these in-person requirements for all beneficiaries receiving mental health telehealth services. That the agency declines to do so indicates it does not find in-person visits absolutely necessary. And, as described above, the access burden the agency fears in-person requirements could exacerbate for patients of RHCs and FQHCs is actually widespread across patients and providers nationwide.

While we continue to oppose in-person requirements for mental health telehealth services, if CMS chooses to move forward with this policy, we urge the agency to do so in the least burdensome way possible. Specifically, allowing any physician or

[4] Coe, Erica. A Holistic Approach For The U.S. Behavioral Health Crisis During the COVID-19 Pandemic, McKinsey & Company, August 2020. https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/a-holistic-approach-to-addressing-the-us-behavioral-health-crisis-in-the-face-of-the-global-covid-19-pandemic.

practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service to furnish the in-person service would help ameliorate the administrative burden of the requirement.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). CMS proposes to use its authority to extend the CAA provisions relating to mental health telehealth services to RHCs and FQHCs. Specifically, CMS proposes to allow RHCs and FQHCs to conduct mental health visits through interactive, real-time telecommunications technology for the purposes of diagnosing, evaluating, or treating a mental health disorder. CMS also proposes to allow RHCs and FQHCs to furnish mental health visits using audio-only communication in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. These changes would allow RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

We strongly support these proposals. However, in response to CMS' request for comment on whether it should impose a requirement similar to that specified by the CAA that there be an in-person service within six months prior to the furnishing of the telehealth service and every six months thereafter, for the reasons described above, we do not believe the agency should establish in-person requirements. **We further urge CMS to extend these proposals to CAHs to enable these providers, which are essential to rural health care, to also conduct mental health visits through interactive telecommunications technology and bill and be paid for these services as if they are provided in-person.**

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 distant site physician or practitioner." During the PHE, CMS waived the requirement 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.

In this rule, CMS proposes to amend its regulations to define "interactive telecommunications system" to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. CMS proposes to limit payment for audio-only mental health services to physicians or practitioners who have the capacity to furnish two-way, audio/video

telehealth services but are providing the mental health services via audio-only communication technology in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. The agency also proposes to allow RHCs and FQHCs to deliver virtual mental health services via audio-only connection, subject to the same restrictions described here.

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.

Therefore, we strongly support the agency's proposals in this rule to permanently enable providers to deliver certain mental health services via audio-only connection. We believe this is particularly important to ensure equitable access to mental health services for individuals in low broadband areas and for those whose jobs (e.g., low wage, hourly) prevent them from having a private space to conduct a video visit. Audio-only care ensures that these and other individuals remain connected to their providers and are able to maintain their health despite the daily challenges they face. To that end, we urge CMS to consider other services that can safely and appropriately be delivered via audio-only connection, especially for patients who do not have access to audio-visual technology.

Rural Emergency Hospitals (REHs). As required by law, CMS proposes to amend its regulations to add REHs, a new provider type created by the CAA, to the list of approved telehealth originating sites. **We support this proposal. Rural health care can benefit profoundly from robust telehealth services due to the longstanding challenges rural communities face in provider recruitment/retention, low patient volume and geographic isolation.** As detailed above, to maximize the potential for positive patient outcomes, we urge CMS to work with Congress to remove certain 1834(m) restrictions to allow REHs to also serve as distant sites for telehealth delivery to patients in their homes and other residential locations. These changes would allow patients to remain connected to their REH providers if they are unable to leave their homes or if it is unsafe to do so.

Direct Supervision by Interactive Telecommunications Technology. During the 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 communications technology. In the CY 2021 PFS final rule, CMS finalized the continuation of this policy through the later of the end of the calendar year in which the PHE ends or Dec. 31, 2021. In this rule, and in the CY 2022 OPPS

proposed rule, CMS seeks comment on whether it should make this flexibility permanent or if it should temporarily continue it beyond the current timeframe. **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.**

Proposal to Establish Values for Remote Retinal Imaging and Comment Solicitations. The AHA appreciates that CMS is considering how to better account for innovative technology, such as software algorithms and Artificial Intelligence (AI) within its existing PE methodology. Specific to diabetic retinopathy, we support CMS' proposal to crosswalk CPT code 92229 to CPT code 92325 as an interim means of accounting for total resource costs. We encourage CMS to continue to evolve its approach to reimbursement of this code in order to ensure it ultimately reflects an appropriate value.

The AHA also appreciates that CMS is gathering stakeholder input to assist with developing a better understanding of the resource costs for services involving software algorithms and AI. The request for information (RFI) addresses a number of complex issues, including changes in cost structures in the physician office setting, the impact on beneficiary access to Medicare-covered services, risks of overutilization, fraud, waste or abuse, and associations with improvements in quality or health equity. Given the critical importance of the future of innovative technologies in health care, the AHA encourages CMS to issue a separate, stand-alone RFI that looks holistically at this issue rather than in the context of a specific payment rule or structure. This will help to ensure a broader range of stakeholder views are represented.

Payment for Evaluation & Management Visits

Over the course of several years of PFS rules, CMS has engaged in an ongoing review of payment for office/outpatient E/M visit code sets. In this rule, CMS makes various proposals to refine some aspects of other E/M visit code sets, including: 1) "split" or shared E/M visits; 2) critical care services; and 3) teaching physician 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. 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 a portion of the visit, but only if the physician performs a substantive portion. 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. Due to changes to Medicare Claims Policy Manual sections that covered split visits, along with recent revisions to E/M visit coding and payment, CMS addresses specifications around billing split visits through rulemaking this year. Specifically, among other proposals, CMS proposes to define the "substantive portion" of the split (or shared) visit as more than half of the total time spent by the physician and non-physician practitioner

performing the visit. **The AHA urges CMS not to finalize this policy.** Doing so would result in a significant reduction in physician revenue on top of the other cuts proposed in this rule.

For any patient visit, there are several tasks that are essential components of clinical care, but which do not require physician time, such as securing pre-authorization, explaining test results to patients and families, completing preliminary documentation, and arranging for durable medical equipment, for example. On the flip side, while physician medical decision-making often drives the patient assessment and care plan, high-complexity medical decision making (MDM) doesn't necessarily take more time than moderate or low MDM. Thus, given the general health system move toward team-based care and support for top-of-license care, both of which the AHA strongly supports, the tasks for which a physician is not necessary will almost always make up the bulk of the *time* of a patient visit. This does not mean these tasks make up most of the complex analysis key to the visit. In fact, these policies could create an incentive for physicians to spend time performing tasks that NPPs at the top of their licenses are qualified to perform. This result would undermine the use of NPPs to provide complete patient care and to keep costs down. The physician payment rate is meant to compensate for the years of training, experience, and expertise of the physician and should not be available only in the rare situation when the physician spends *more* time with the patient (greater than 50%) than the NPP.

The AHA recognizes that CMS needs some way to measure a physician's contribution to the visit and that time is an expedient way to do so. We also recognize that if a physician does not substantively contribute to a visit, however that is defined, the payment rate should reflect that. **Therefore, to capture physicians' contribution to medical decision making, we recommend CMS set the threshold for the "substantive portion" of the visit at 25%.** This would ensure appropriate compensation for physicians when they make a substantive contribution to team-based care for a patient and entitle them to bill for their role as the party ultimately responsible for a patient's care. Conversely, when physicians decide that a case is straightforward and does not necessitate their involvement to a substantive degree, they can leave the care and billing to the NPP and turn their attention to other cases.

Critical Care Services. CMS makes several proposals in this rule related to critical care visits, including a proposal to bundle critical care visits with procedure codes that have a global surgical period. Under this proposal, practitioners would be prohibited from reporting critical care visits during the same time-period as a procedure with a global surgical period. **The AHA urges CMS to reconsider this policy.** It is a near universal practice for physicians to be paid at least partly based on their productivity. The physicians that perform critical care services are different from the physicians that perform the surgery in a global surgical period. Thus, bundling critical care visits, as proposed, would result in a significant revenue reduction for critical care physicians. This is because without the ability to get paid separately for their services, it may

artificially appear for some critical care physicians that they have zero visit volume and no productivity. This will essentially slash the portion of their compensation that is based on productivity to zero. As discussed throughout this letter, these types of proposals would institute cuts that only build upon the already-large proposed cuts to the conversation factor change and the clinical labor pricing changes. Yet, critical care physicians have been on the front lines fighting COVID-19 for nearly two years — now is not the time to cut their payments.

Payment for Therapy Services

As it has done in prior rulemakings, CMS in this rule implements sections of the Bipartisan Budget Act (BBA) of 2018, which required outpatient physical and occupational therapy services furnished in whole or in part by a therapy assistant on or after Jan. 1, 2022 must be paid at 85% of the PFS amount. In the CY 2019 PFS rulemaking, CMS finalized a definition of "in whole or in part" as visits during which more than 10% of the therapy service is furnished by a therapy assistant. This is known as the "*de minimis* standard." In the CY 2020 PFS final rule, CMS finalized the *de minimis* standard to apply only to the minutes that the therapy assistant spends independent of the therapist.

In March 2021, CMS posted guidance on how to assign the modifiers in different billing scenarios. In this rule, CMS notes that it received feedback indicating the guidance created confusion, especially regarding how the *de minimis* standard applies to a final unit of a multiple-unit timed service. Thus, CMS makes several proposals in this rule in an attempt to address that confusion.

However, CMS' clarifications on the use of the *de minimis* standard remain complex and confusing. **We urge CMS to clarify in the final rule when the *de minimis* standard applies to the use of the modifiers. Alternatively, we urge CMS to simplify this policy by requiring the modifiers only when therapy assistants furnish a visit "in whole," without services furnished by a therapist.** This approach would avoid penalizing providers for providing two sets of professionals when they are needed to ensure patient safety and effective outcomes.

Laboratory Specimen Collection and Travel Allowance under the Clinical Laboratory Fee Schedule (CLFS)

The clinical laboratory fee schedule provides a nominal fee, generally between $3 and $5, for specimen collection from homebound patients and nonhospital inpatients. In March 2020, CMS established two additional specimen-collection level II HCPCS codes related to COVID-19: G2023 (specimen collection for COVID-19, any specimen source) and code G2024 (specimen collection for COVID-19 from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, any specimen source) for independent laboratories to use for the duration of the COVID-19 PHE. CMS

established a payment amount of between $23 and $25 for these specimen collection codes to reflect the increased resource costs and the need for trained personnel in collecting specimens for COVID-19 testing during the PHE. Although CMS states that it expects the increased specimen collection fees for COVID-19 laboratory tests will end at the termination of the PHE, it is seeking comment on these policies for consideration in future rulemaking. In particular, the agency is requesting comment regarding what additional resources might be needed for specimen collection for COVID-19 laboratory tests and other tests after the PHE ends.

The AHA recommends that CMS continue to maintain, beyond the end of the PHE, the current increase in the fees provided to hospital and independent laboratories that collect specimens for COVID-19 laboratory testing from homebound patients and nonhospital inpatients. The novel coronavirus is expected to become endemic and remain even after the PHE ends. While outbreaks will likely be rarer and smaller, they will still occur, particularly as immunity wanes among the vaccinated and recovered individuals and as immunologically naive babies are born. Additionally, new variants may evolve that can escape our current immune defenses. This means that it will still be necessary to continue to use higher level, and more costly, personal protective equipment (PPE) and continue other training and protocols necessary for the protection of those health care personnel who obtain these laboratory specimens.

In fact, the use of these enhanced protective measures is recommended by CDC and mandated by the Occupational Safety and Health Administration (OSHA). CDC's Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing state, "For healthcare providers collecting specimens or working within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control and use recommended PPE, which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown." Furthermore, for initial diagnostic testing for current SARS-CoV-2 infections, CDC recommends collecting and testing an upper respiratory specimen using sterile swabs by a trained health care provider only. This is important both to ensure patient safety and preserve specimen integrity.

Moreover, OSHA's recently issued COVID-19 Health Care Emergency Temporary Standard (ETS), which is expected to become a permanent standard by the end of 2021. The ETS requires that health care employers must provide a respirator to each employee who has exposure to a person with suspected or confirmed COVID-19 and ensure that it is provided and used in accordance with OSHA's Respiratory Protection Standard. Employers must also provide each of these employees with gloves, an isolation gown or protective clothing, and eye protection, as well as ensure that the PPE is used in accordance with OSHA's PPE requirements.

In fact, the AHA recommends that CMS also increase the nominal fees for collection of non-COVID-19 specimens from homebound patients and

nonhospital inpatients for purposes of other infectious disease laboratory testing. Hospital and independent laboratories are finding that the safety practices and protocols put into place for COVID-19, such as using more and higher level PPE and increased training of personnel, improve safety for their laboratory personnel and patients, even if the specimens collected are intended to test for other infectious diseases, such as influenza. Respiratory infections are among the top 10 causes of death in the U.S., and it is clear that they can be reduced through infection control measures, such as those employed for reducing the burden of COVID-19. There is evidence that such enhanced safety measures work extraordinarily well; last year the rate of infection and death from influenza dropped precipitously, primarily due to the social distancing and masking mandates put into place for the COVID-19 pandemic. CMS should support the effort to reduce morbidity and mortality from influenza and other infectious diseases by increasing the nominal fee provided for specimen collection.

Medicare Part B Benefit for Opioid Treatment Programs (OTPs)

OTPs are healthcare entities that focus on providing medication-assisted treatment (MAT) for people diagnosed with opioid use disorder (OUD). Enacted October 2018, Section 2005 of the Substance Use-disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) For Patients and Communities Act established a new Medicare Part B benefit category for OUD services furnished by an OTP beginning on or after Jan. 1, 2020. In this rule, CMS proposes adjustments to the payment rate of the previously finalized service of naloxone dispensing. In addition, the agency proposes to allow audio-only counseling and therapy services beyond the end of the PHE for COVID-19.

The AHA appreciates CMS' continued commitment to addressing the opioid crisis, and values that CMS has listened to providers and stakeholders by allowing additional flexibility to offer the most effective and accessible care possible. We encourage the agency to continue to look for ways to improve this benefit and access to care for patients not only with OUD, but other substance use disorders as well.

Payment for Take-home Supply of Naloxone. As with the previous years' drug pricing provisions, the AHA is concerned about the proposal to price the higher dose naloxone product using the average sales price without the standard 6% add-on. This add-on is used in pricing other Part B drugs to account for overhead costs or additional mark-ups accrued in traditional drug distribution channels. Although CMS *believes* that many OTPs purchase the drugs directly from manufacturers, which would limit these extra costs, the agency provides little evidence to support this assertion. **Thus, we again recommend that CMS include a factor for overhead in its drug pricing methodology.**

In addition, we again urge CMS to reconsider the frequency limitation of once every 30 days, except when a further take-home supply is medically reasonable and necessary. CMS' rationale behind this limitation is unclear. Previous US Surgeon General Jerome Adams stated in his 2018 advisory that "increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths," so it is incongruous that CMS would apply limitations on the distribution of this safe, live-saving drug to those patients who meet the criteria for opioid overdose listed in the Surgeon General's advisory.

Payment for Audio-Only Counseling and Therapy Services. Near the beginning of the PHE for COVID-19, CMS temporarily allowed OTPs to provide counseling and therapy services via audio-only telephone call rather than requiring that these services be provided in-person or via two-way interactive audio/video communication technology when the latter is not available to the beneficiary. While the original waiver of existing regulations would only last until the end of the PHE, CMS proposes in this rule to extend this allowance after the PHE ends. **The AHA supports this proposal and strongly supports the allowance of audio-only telehealth services to improve access to care.** While digital modalities and virtual care have been increasingly available as a result of the PHE for COVID-19, many citizens are unable to use these tools due to lack of broadband internet, personal computing equipment, or experience and comfort using the technology. By including audio-only telephone calls as another way to get in touch with one's clinician, CMS is offering an important lifeline for those otherwise on the wrong side of the "digital divide."

In addition, CMS proposes to require OTP providers to document in the beneficiary's medical record why counseling and therapy services were delivered via audio-only telephone call instead of in-person or via two-way, audio/video technology. It is unclear what type and level of detail of documentation the agency expects. In the proposed rule, CMS defines "not available to the beneficiary" as circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction. Would providers be expected to merely note that the beneficiary is not capable of or has not consented to the use of these devices, or would they be required to include details as to *why* the beneficiary is not capable (e.g., "lacks broadband internet access," or "unable to locate smart phone")? Would CMS require a separate or different informed consent process for audio-only services that providers would have to demonstrate in the medical record? The billing codes themselves do not require any such documentation. **Therefore, we urge CMS to ensure that providers have the information they need to appropriately bill for these services, before the requirements begin.**

Electronic Prescribing of Controlled Substances (EPCS)

In the CY 2021 OPPS/ASC final rule and the FY 2021 IPPS/LTCH final rule, CMS delayed the requirement to conduct e-prescribing of Schedule II-V controlled

substances using the NCPDP SCRIPT 2017071 standard to Jan. 1, 2022. We supported this delay due to our concerns regarding electronic health record (EHR) vendor capacity to deploy — and hospitals' and health systems' capacity to implement — such a high volume of IT system changes on a short timeline, especially in light of the redirection of resources to support technology and data needs specific to the COVID-19 PHE.

In fact, we recommended that CMS implement an even further delay. Many providers — small hospitals in particular — struggle to implement IT upgrades due to cost and logistical barriers, and even if an EHR contains the EPCS capability, organizations would need to train staff and implement workflow alterations, which is a lot to take on in one year. **Thus, we appreciate and support CMS' proposal to further delay the compliance date for EPCS until Jan. 1, 2023. We also are grateful that CMS recognizes the disparities in EPCS capabilities for long-term care providers, and support the even later compliance date of Jan. 1, 2025 for these providers.** In particular, we appreciate that CMS has looked outside of its own regulatory structure to determine how the work of other agencies and gaps in IT resources and infrastructure would affect providers' ability to comply with its rules, such as the Department of Justice's work on requirements for multifactor authentication that will make EPCS easier and the lack of LTC-specific guidance on using the NCPDP SCRIPT and broadband internet access in rural communities.

We also understand and agree with CMS' rationale behind the other provisions regarding EPCS. According to the agency's analysis, providers are able to conduct EPCS for at least 70% of their Part D controlled substance prescriptions, and thus will be required to meet that threshold beginning with the compliance date. If the agency had not delayed this date, we would have recommended a phased-in approach (for example, requiring just 50% of Part D controlled substance prescriptions to be done electronically for the first year before ramping up to 70%), but because of the additional year the agency proposes to grant, we find this requirement to be reasonable. We also agree with the exceptions — and lack of exceptions — proposed in the rule. We agree that EPCS provides for additional security and can improve access to necessary controlled substances, and the agency proposes providing exceptions when implementing EPCS would result in opportunities for diversion or would be unnecessarily burdensome.

Finally, we support CMS' proposal for compliance actions. As we noted in our reply to CMS' 2020 RFI on EPCS, enforcement actions must be remedial rather than punitive, at least in the beginning stages of compliance. While many providers have experience using the required standard, significant barriers remain to universal adoption, and there has been a low uptake of the process in physician practice. Thus CMS' proposal to send letters informing providers of noncompliance and furnishing resources on how to come into compliance is helpful and appropriate.

Physician Self-Referral Updates

In this proposed rule, CMS further clarifies the definition of "indirect compensation arrangements" that are subject to the prohibition on self-referrals. The December 2020 final rule, "Modernizing and Clarifying the Physician Self-Referral Regulations," which significantly narrowed the definition, thereby narrowing the universe of arrangements subject to regulation, inadvertently also excluded certain rentals of office space or equipment arrangements between providers and physicians from regulatory oversight. The proposed change would clarify that the two-step analysis of such arrangements that were finalized in 2020 will apply to any unbroken chain of financial relationships in which the compensation paid under the arrangement closest to the physician (or immediate family member) is for anything *other than* services personally performed by the physician; this includes arrangements under which unit-based payments are made for leasing (or purchasing) office space or equipment.

To further clarify that office space and equipment arrangements are subject to heightened scrutiny, CMS poses a definition to draw lines around what "personally performed" services means. CMS proposes to define personally performed services to "not include services that are performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member)."

AHA appreciates the need to modify the definition of "indirect compensation arrangement" to address the unintended deregulation of certain equipment and space leases between physician-owned entities and DHS entities. **We are concerned, however, that the proposed modification would effectively prohibit some common and benign arrangements, while creating new ambiguities regarding what is a "personally performed" physician service. As an alternative, we urge CMS to avoid these issues by simply carving out equipment and space leases from application of the "unit test."** The resulting regulation would not affect previously acceptable service arrangements such as mobile lithotripsy arrangements, but would restore the prior regulatory scheme for space and equipment leases.

Regardless of whether CMS adopts our proposed solution to the space and equipment lease issue, we urge the agency to clarify its commentary in the rule regarding when a service is personally performed. We are concerned that CMS' proposed definition of "personally performed," if read literally, would mean physicians could not get full work RVU credit for services that CMS has long recognized as personally performed for reimbursement purposes. The physician fee schedule has long recognized that certain procedures or services might include some aspect of the service performed by others in conjunction with the physician and that the work RVUs for the physician service include such personally performed supervision.

For instance, CMS has long recognized that the practice expenses for evaluation and management visits include clinical labor costs for office staff who help to perform parts of those services, such as taking parts of the history or vital signs before the physician sees the patient. Further, in a hospital setting, surgeons routinely work with and oversee teams of hospital staff to perform various tasks during complex surgical procedures. This includes, for example, suturing the incision at the conclusion of the procedure. As long as a physician's role in that team setting meets criteria set in reimbursement policy, CMS pays the physician for performing the service albeit in a team setting. We see no reason to apply different rules to assess whether a service is personally performed in a compensation context than CMS applies in a reimbursement context (which is effectively what the rule would do if finalized and read literally).

It is important to ensure that hospitals have the guidance needed to inform their compliance programs and avoid the diversion of resources to defend against unwarranted False Claims Act allegations.

Quality Payment Program – Merit-based Incentive Payment System (MIPS)

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 a number of CMS' MIPS policies have aligned with these principles, including CMS' 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 a replacement for the current approach to the MIPS. We also have concerns about several of CMS' proposed changes to MIPS reporting requirements and scoring approaches.

MIPS Value Pathways. As we understand it, MVPs are intended to align and reduce reporting requirements across the four MIPS performance categories. Built over time, the MVPs would organize the reporting requirements for each MIPS category around specific specialties, treatments or other priorities. While CMS had intended to begin MVP implementation in the CY 2022 performance year, CMS proposes seven MVPs in this rule that would be available for voluntary participation beginning in CY 2023 —

rheumatology, stroke care and prevention, heart disease, chronic disease management, lower extremity joint repair (e.g., knee replacement), emergency medicine, and anesthesia. MIPS participants would be required to register for MVPs if they wish to report them. However, CMS also indicates in the rule that it intends to sunset "traditional MIPS" and require all MIPS participants to participate in MVPs starting after the CY 2027 performance year.

The AHA appreciates that CMS has proposed to delay the implementation of MVPs by an additional year (i.e., until CY 2023), and that MVP participation would remain voluntary at this time. **However, 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. Furthermore, given CMS' correct focus on implementing "Meaningful Measures" in its programs, it would seem misguided to add measures just for the sake of having enough of them to create an MVP. However, if the agency's concept is to assign clinicians to particular MVPs, it would need to ensure it has measures that meaningfully apply to their clinical practice. We again 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 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' 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 MVP approach for multi-specialty group practices. In this rule, as we have encouraged in prior comment letters, CMS proposes a process that allows 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 would be an essential option for implementing MVPs. However, the key distinction between the current MIPS and the proposed MVP subgroup approach is that subgroups would be

compulsory for multi-specialty practices that wish to participate in MVPs starting with the CY 2025 reporting year. As a result, multi-specialty groups may actually face an increase in their reporting burden, which would contradict CMS' stated goal of reducing provider burden. **The AHA urges CMS not to mandate subgroup formation for multi-specialty practices participating in MVPs at this time.**

MIPS APM Performance Pathway (APP). **The AHA supports CMS' proposal to allow MIPS-eligible clinicians to report the APP as a subgroup.** Beginning with the CY 2021 performance period, CMS sunset the MIPS APM scoring standard, and replaced it with the APP. The APP is similar to the former MIPS APM scoring standard, but requires clinicians and groups to report on a common set of six quality measures. Notwithstanding our conceptual concerns with mandating MVP participation (described above), the AHA has supported giving multi-specialty practices the option of forming subgroups to participate in the MIPS, and believes CMS proposal increases the flexibility available to practices.

MIPS Quality Category. For CY 2022 quality reporting, CMS would mostly carry over CY 2021 reporting requirements and scoring approaches. However, CMS proposes three notable changes — an updated measure benchmarking approach, a higher data completeness threshold and the removal of bonus points for end-to-end electronic reporting and high priority measure.

The AHA supports CMS' proposed quality measure benchmarking policy for CY 2022. Current MIPS policy requires CMS to, where possible, use historical data to set measure score benchmarks. For performance year 2022, the benchmark period ordinarily would be CY 2020. However, in light of the COVID-19 PHE, CMS is not sure whether it will have sufficiently representative data to establish benchmarks. We believe it would be appropriate for CMS to data from either the CY 2022 performance period itself, or other historical data from an earlier year (e.g., 2019) to establish benchmarks.

The AHA supports the concept of increasing the MIPS data completeness threshold from 70 percent to 80 percent beginning in CY 2023. However, in light of the continued impact of the COVID-19 PHE on MIPS-eligible clinicians, we urge CMS to monitor reporting from the CY 2021 performance period before adopting this increase. The reporting of complete data on quality measure is important to ensuring the data are an accurate representation of clinician performance. We 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 PHE 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. Having data on the level of completeness of data reported in CY 2021 could give CMS insights into whether practices are truly ready for the higher data completeness threshold.

The AHA asks CMS to delay the removal of high-priority measures and end-to-end electronic reporting bonus points by at least one year (until the CY 2023 performance period). Current MIPS policy awards clinicians and practices 2 bonus points for reporting measures high-priority measures beyond the one required outcome/high-priority measure that CMS requires. CMS also awards one bonus point for each measure reported using end-to-end electronic reporting. We appreciate that these bonus points stem from early versions of the MIPS program that sought to maximize rewards for those clinicians who choose to participate in the program. At the same time, CMS has also proposed to raise substantially the MIPS performance threshold that clinicians must meet to achieve neutral or positive payment adjustments. To ensure a less disruptive transition to this higher performance threshold, we believe CMS should retain the availability of these bonus points for at least one more year.

MIPS Cost Category. CMS proposes to add five episode-based cost measures to the list of measures on which eligible clinicians and groups could be scored. **The AHA continues to have substantial concerns with the measures used in the MIPS cost category, and at a minimum, we ask CMS not to finalize these new measures at this time.** We also 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 NQF endorsement of all cost measures, re-examining the attribution methodologies, and incorporating risk adjustment for social risk factors where necessary and appropriate.

MIPS Improvement Activity Category. As it does each year, CMS proposes updates to the improvement activity inventory by proposing seven new improvement activities, three of which are focused on promoting health equity. **The AHA applauds CMS' focus on health equity, and believes using the improvement activity category is an effective mechanism to encourage the adoption of practices that can advance health equity.**

CMS also proposes a process to suspend and remove improvement activities that the agency believes raise patient safety concerns or are obsolete. CMS would use subregulatory processes (e.g., listservs, the QPP webpage) to suspend any affected improvement activities, and then use notice and comment rulemaking to formally propose the removal of the improvement activity. **The AHA supports this proposal.**

MIPS Promoting Interoperability Category.

Reporting Period. The AHA consistently has advocated for an EHR reporting period of any continuous 90-day period to promote program stability and reduce clinician burden. We strongly support CMS' decision, finalized in last year's PFS rule, to make the 90-day reporting period an ongoing policy for the Promoting Interoperability Category.

Electronic Prescribing Objective: Query of PDMP Measure. As noted in previous comments, prescription drug monitoring program (PDMP) integration with certified EHRs continues to pose a number of challenges for eligible clinicians. **The AHA supports CMS' proposal to retain the query of PDMP measure under the electronic prescribing objective as optional and worth 10 bonus points.** We further support mitigating burden on clinicians by continuing to require only a "yes/no" attestation vs. a numerator/denominator for this measure. This appropriately recognizes that technical capabilities vary across EHRs, the reality that PDMPs do not exist in every state, and, where they do exist, can be impacted by state laws prohibiting integration and storage of PDMP data.

Key federal and private sector efforts are currently underway aimed at improving technical approaches to EHR-PDMP integration, addressing stakeholder concerns around readiness and continued implementation of key PDMP-related provisions of the SUPPORT for Patients and Communities Act (P.L. 115-271). We believe additional time for this work to mature, as well as continued assessment of the PDMP landscape, is needed prior to CMS proposing to modify the agency's current optional, attestation-based approach to this measure.

Provider to Patient Exchange Objective. CMS proposes modifying the Provide Patients Electronic Access to their Health Information measure to require eligible clinicians to ensure that patient health information remains available indefinitely and using any application of the patient's choice that is configured to meet the technical specifications of the application programming interface (API) in the certified EHR. This would include all patient health information from encounters on or after Jan. 1, 2016.

The AHA strongly supports patients having access to their health information. We are concerned, however, that CMS' proposed changes to the measure do not accurately reflect the realities of the EHR technology environment. This is particularly true with regard to the proposed requirement that all patient health information remain available indefinitely with a lookback to Jan. 1, 2016. It is unclear how CMS would define "indefinite," what data would be included in "all patient health information," and how potential conflicts with state laws would be reconciled.

We appreciate that, citing many of the concerns outlined above, CMS did not finalize these proposed changes for the 2022 Hospital Promoting Interoperability Program. We urge the agency to continue its approach of aligning policies across eligible hospitals and eligible clinicians by similarly not finalizing these proposed changes for the 2022 MIPS Promoting Interoperability Category.

With respect to third-party applications, we urge prioritization of patient privacy protections and cybersecurity considerations as their use becomes more prevalent in health care. These applications both present opportunities to allow patients to access

their health information in new and innovative ways but also present significant risks as data increasingly flows outside of the HIPAA-protected EHR environment.

Public Health and Clinical Data Exchange Objective. The ongoing PHE highlights the critical importance of the ability to collect, exchange and analyze public data. Clinicians have successfully implemented reporting capabilities for key public health data over the past several years. Yet, throughout the pandemic, and in the years leading up to, it became clear that our public health agencies' (PHA) data systems are, in many cases, antiquated and often unable to receive these data electronically. Similar to the state of PDMPs discussed above, public health data systems capabilities vary widely by state and jurisdiction.

Clinicians are eager to engage in standards-based exchange of data with PHAs. We are encouraged that Congress recognized the need for investment in public health data systems and provided funding for modernization efforts in multiple COVID relief bills. While this work is underway, and at a nascent stage, expansion of this objective should be considered in the context of the current public health data reporting landscape.

The AHA is concerned that a prescriptive vs. staged approach to this measure for eligible clinicians, as proposed by CMS, does not accurately reflect the current state of PHA capabilities in many areas of the country. We are further concerned that this approach will drive reliance on exceptions rather than incentivize expanded public health reporting by eligible clinicians. **Therefore, the AHA recommends that CMS maintain the flexibility for clinicians to report on any two of the current public health and clinical data exchange measures and provide five bonus points to clinicians who voluntarily attest to a 3rd measure.** We would support an annual review of this approach based on progress of PHA data modernization efforts.

Protect Patient Health Information Objective. While we agree that implementing safety practices for planned or unplanned EHR downtime is important, we believe the proposed Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure is out of scope for the Promoting Interoperability Category that was established to incentivize eligible professionals to "adopt, implement, upgrade and demonstrate meaningful use of certified EHR technology." Further, the SAFER Guides have not gone through a comprehensive review and update process since 2016, calling into question whether their content remains relevant.

Additionally, requiring this type of annual assessment of the High Priority Practices Guide would place burden on clinicians, particularly those with limited resources. CMS should work with ONC to engage in an update of the guides, informed by stakeholder input, and undertake an education and awareness campaign to disseminate information to the field.

Given these considerations, the AHA cannot support CMS' proposal to require eligible clinicians to attest to having completed an annual assessment of the High Priority Practices Guide. Should CMS choose to finalize this measure, we urge the agency to provide clarification, as it did in the FY 2022 IPPS final rule for the hospital Promoting Interoperability Program, that a "no" response is acceptable and will not result in a penalty.

Prevention of Information Blocking Attestation Requirement. **The AHA supports CMS' proposal to remove attestation statements B and C from the prevention of information blocking attestation requirement.** We agree that the similarities between practices described in statements B and C and the practices that could constitute information blocking under ONC's information blocking regulations could create confusion for eligible clinicians. We further believe that streamlining this attestation to require only statement A more accurately reflects the statutory provision in the Medicare Access and CHIP Reauthorization Act (MACRA) law.

MIPS Complex Patient Bonus. **The AHA supports CMS' proposal to extend into the CY 2021 performance period its COVID-19 PHE policy of doubling the complex patient bonus. We thank CMS for thoughtfully considering the impact of the COVID-19 PHE in determining MIPS performance.** Since the CY 2018 performance period, CMS has calculated a "complex patient bonus" to better account for medical and social risk differences across patient populations. This bonus awards up to five points to the MIPS final scores of clinicians and groups based on their hierarchical condition category (HCC) scores, and their ratio of patients dually eligible for Medicare and Medicaid. For the CY 2021 reporting period, CMS would double the complex patient bonus such that clinicians would receive up to 10 points. We agree with CMS that the COVID-19 PHE has significantly affected patient complexity. Emerging evidence suggests that needed care for some patients has been deferred or delayed because of the COVID-19 pandemic. As a result, by the time patients receive care, their health issues may have taken on greater complexity. Additionally, COVID-19 patients themselves can have long, intensive and often complex care trajectories that can span many months after they might receive hospital services. Therefore, it is appropriate to recognize this impact by increasing the complex patient bonus.

Beginning with the CY 2022 performance period, CMS proposes significant updates to the calculation methodology of the complex patient bonus that the agency believes would more effectively target the bonus to those practices serving the largest proportions of patients with medical or social risks. First, the agency would standardize the calculation of medical and social risk scores so they are placed on a common scale. **The AHA supports the revised formulas for calculating complex patient bonus scores, and agrees that standardizing the scores is methodologically appropriate.**

CMS also proposes to limit the availability of the complex patient bonus to those eligible clinicians and groups that have least one complex patient risk (i.e., HCC score or dual

proportion) score at or above the median. CMS believes this is appropriate because their analysis found that clinicians with a higher share of complex patients had lower MIPS final score on average than other clinicians. Said differently, the practices with lower medical and social risk scores already tended to have higher MIPS scores, and as a result, their eligibility for complex patient bonus points may inadvertently magnify the disparities in scores between lower and higher complexity practices.

The AHA supports the concept of more effectively targeting the complex patient bonus, and agrees that the goal of the bonus should be to narrow — rather than expand — disparities in performance stemming from differences in clinical and social risk. At the same time, we caution that the selection of the median as a cutoff for receiving any complex patient bonus may be arbitrary. We fear it may introduce a "cliff" problem in which practices with small differences in risk factor scores could experience very different complex patient bonus scores. For example, a practice whose duals proportion is in the 48th percentile may be very similar to that with a duals proportion in the 51st percentile. Yet, only the latter practice would qualify for a bonus. We understand that targeting bonus points means that CMS has to have some quantitative mechanism for creating differential scores among practices. We would encourage CMS to carefully monitor the distribution of medical and social risk factor scores over time to determine to what extent scores may be clustering around particular values. The agency should take care to ensure threshold for the complex patient bonus is set in a way that minimizes the "cliff" issue.

MIPS Performance Threshold Score. CMS proposes increasing the performance threshold for the CY 2022 performance/CY 2024 payment year from 60 to 75 points. As required by law, beginning with the CY 2022 performance period, CMS must set the performance threshold at the either the mean or median MIPS performance score from a prior payment adjustment year. In this case, CMS chose the CY 2019 payment year because it would result in a more gradual increase than the alternatives.

The AHA understands CMS' statutory obligation to set the MIPS performance threshold at either the mean or median score of a prior year. At the same time, we are concerned that the magnitude of the increase could be challenging for the field in light of the COVID-19 PHE. That is why we have asked CMS to reconsider its proposals to remove bonus points in the quality category for reporting priority measures and performing end-to-end electronic reporting. It is also why we believe CMS should consider delaying the increase in the quality data completeness threshold. As the health care field continues to fight the COVID-19 pandemic and recovers from it, we encourage CMS to retain flexibility and reasonable opportunities for clinicians to benefit from MIPS participation.

Request for Information – Health Equity

The AHA applauds CMS' commitment to advancing health equity, and we are pleased the agency seeks input on a range of potential policy actions intended to accelerate the

nation's progress on this vital topic. Hospitals and health systems and the clinician practices with whom they partner are working hard to identify and address health disparities and to close remaining gaps in quality performance across patient populations. The AHA and CMS share the same goal: to ensure that all patients feel valued and recognized, and that the care they receive does not vary due to race, ethnicity, gender, sexual orientation or other demographic or social risk characteristics.

General Considerations. Most of the policy ideas shared in the RFI focus on the collection, analysis and use of health equity-related data within the context of CMS' existing framework of quality measurement and value programs. We certainly understand this focus, given both the visibility and importance of CMS' quality measurement programs, and the vital need to have reliable, accurate and actionable data to both identify disparities and track progress over time. As CMS continues to work with the health care field to advance equity and considers advancing its use of equity data, our members have asked that CMS:

- *Work to foster alignment and standardization of approaches to collecting, analyzing and exchanging demographic and social risk data.* This includes a consistent approach across CMS itself, and across other federal agencies and programs. Given the breadth of health equity issues, and the wide range of stakeholders affected by it, CMS can help ensure that all stakeholders use consistent definitions and standards. Furthermore, such standards should be thoroughly field tested before broader implementation.

- *Ensure that equity data use and collection efforts are aligned with CMS' broader goals and strategy related to health equity.* In other words, the collection, use and analysis of data should not be done in isolation and should be linked to achieving specific goals in CMS' strategy.

- *Identify and share more broadly data to which CMS itself may have access.* For example, to the extent CMS is collecting demographic and social risk data during the time of Medicare enrollment, the agency should explore ways of determining whether this information could be linked to quality data. These steps could help provide additional data for CMS' efforts to identify disparities in performance and outcomes.

- *Be judicious in requests for new data and ensure any efforts to collect equity data achieve an appropriate balance of value to advancing health equity and administrative burden*. As CMS notes in the proposed rule, "the development of consistent and sustainable programs to collect data on social determinants of health can be considerable undertakings." Indeed, data reporting often involves investments in systems and personnel as well as redesigns of workflows to ensure data can be captured. However, certain types of data (e.g., living situation, sexual orientation and gender identity) also may sensitive for patients

to disclose. We encourage CMS to engage patients and providers extensively as it explores additional data collection.

Measure Stratification and Indirect Estimation. The AHA would support providing clinicians and group practices with confidential reports that stratify their performance on MIPS measures by race, ethnicity, dual eligible status, and other demographic and social risk factors of interest. To identify disparities, clinicians and their hospital partners need good data to know whether they exist for particular measures or for particular dimensions of health equity. Stratified reports are one helpful tool for illuminating disparities in care.

As we understand it, one of the methods CMS is considering for creating these stratified reports is indirect estimation. Given the gaps in available demographic data for Medicare beneficiaries, CMS is considering using data from existing sources like the U.S. Census and Medicare administrative data (e.g., first and last names, and the racial and ethnic composition of the patient's neighborhood) to "impute" (i.e., infer) the demographic composition of the patient populations of clinician practices.

While the AHA appreciates that CMS is trying to make the highest use of the data it has, we are concerned about the potential for indirect estimation to lead to measurement bias. As CMS notes, the "gold standard" for race, ethnicity and other demographic data is patient self-reported information. Furthermore, the quality of the indirect estimation model would be only as good as the data that go into it. To the extent CMS draws on data from the census, we expect the data could lag the actual demographic composition of a hospital's patient population by several years. This would limit the usefulness of analyses based on indirect estimation. At a minimum, we urge CMS not to use indirect estimation in any public-facing analysis of equity performance.

Request for Information – Digital Quality Measurement

The proposed rule includes a request for comment on CMS' plans to advance the use of digital quality measures (dQMs) and expand the agency's use of Fast Healthcare Interoperability (FHIR) standards and Application Programming Interfaces (APIs) for both current eCQMs and future quality measures. CMS states that its goal is "to move fully to digital quality measurement" by 2025 and to enhance the interoperability of quality measure data.

The AHA agrees that a digital and interoperable quality measurement enterprise is a laudable long-term goal that could have positive and far-reaching impacts to quality of care and the provider experience. The AHA also sees significant potential in expanding the use of FHIR, as this standard is easier to implement and more fluid than many other available frameworks. At the same time, transitioning to only dQMs in CMS quality measurement programs will prove a staggeringly complex task. In this rule, CMS offers a working definition of dQMs and a long list of laudable attributes for dQMs. The agency

also correctly identifies the need to work with multiple stakeholders. While all of these things are helpful and necessary, they are not by themselves enough to ensure a successful transition to dQMs. This also is why it is difficult for AHA to judge whether CMS' stated goal of transitioning to fully dQMs by 2025 is achievable; given the complexity of the task, we are skeptical.

For these reasons, we urge CMS to propose a clearer overarching plan and goals for its proposed transition to dQMs. CMS should specify what steps it expects for hospitals and other stakeholders to take, the sequencing and timing of those steps, and identify any interdependent steps and policies across CMS, ONC and any other relevant federal agencies. We also believe that any new standards or processes that emerge from this plan would need to be adequately vetted and field-tested before they are made into regulatory requirements. The AHA and our members would be pleased to engage CMS in such a planning process.

Below we offer comments on several specific issues included in the RFI and provide additional recommendations to the agency.

dQM Definition. CMS' proposed definition of dQMs is very broad and lists a range of data sources, including administrative systems, clinical assessment data, case management systems, EHRs, instruments (e.g., wearable medical devices), patient portals, health information exchanges (HIEs), registries and "other sources." Hospitals do not manage some of these sources themselves; yet, their performance on a dQM could be linked to such data. We are concerned that the accuracy and reliability of dQMs could be compromised by poor data quality from outside sources. For these reasons, CMS, ONC and other stakeholders may need to consider the development of source system verification and/or certification criteria.

dQMs as Self-Contained Tools. In the RFI, CMS offers a lengthy list of attributes and functionalities that dQMs could have. This ranges from simple tasks like the ability to generate measure score reports, to considerably more complex tasks like being "compatible with any data source" and "having the ability to adopt to emerging advanced analytic approaches like natural language processing." The AHA encourages CMS to work across stakeholders to determine whether these attributes can be sequenced and scaled. We are skeptical that all of the attributes on CMS' proposed list would be achievable for even a single dQM by 2025, whereas certain attributes may be achievable by that point.

Public-Private Sector Collaboration. The AHA is pleased that CMS is considering the development of a "common portfolio" of dQMs that could be used across federal program and agencies, and with private sector quality measurement programs. Hospitals and their affiliated clinical practices have long aspired to an approach to quality measurement that enables them to report data only once and have it used for multiple purposes. Unfortunately, they continue to face discordant reporting

requirements among federal, state and private sector quality reporting and value programs. Even when the measure topics are the same, often there are differences in measure design across programs that result in the need for duplicative data collection, excess costs and confusion. As CMS advances a plan for dQMs, we encourage the agency to prioritize the development of dQMs that are usable across the public and private sector.

Medicare Shared Savings Program (MSSP)

In this rule, CMS includes proposals related to the MSSP quality measurement approach and other programmatic features of the MSSP.

Quality Measurement Proposals. In last year's PFS final rule, CMS adopted a policy in which it reduced the MSSP quality measure set to the same to the same six measures used in the MIPS APP, eliminated the web interface reporting option and its associated measure set, and increase the quality performance standard ACOs would have to achieve to qualify for shared savings or avoid owning maximum losses.

In response to concerns from AHA and other stakeholders about the proposal, CMS proposes a longer phase-in of the requirement to report the APP performance measure and a delay to the increase of the minimum quality standard. For the CY 2022 MSSP performance year, ACOs would be permitted to report either the current MSSP measure set via the CMS web interface, or the MIPS APP measure set. In CY 2023, those ACOs that choose the report the web interface measure set also would be required to report at least one measure from the APP measure set. CMS also proposes to delay the increase of the minimum quality standard from the 30th to the 40th percentile until the CY 2024 performance year. **The AHA supports these proposals, and thanks CMS for responding to stakeholder concerns about the pace of implementing the APP measure set.**

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

We also encourage CMS to use the time afforded by the longer phase-in to explore potential challenges with the new APP measure set. The AHA has expressed concerns that the APP measure set may not be the best suited to assessing ACO performance, and we encourage CMS to obtain multi-stakeholder feedback on the suitability of the measure set. We were disappointed the APP measure set was not reviewed as a whole by the Measure Applications Partnership (MAP) before it was adopted for MSSP, and we again encourage CMS to seek the MAP's input.

Revisions to the Definition of Primary Care Services Used in MSSP Beneficiary Assignment. Over the course of the MSSP, CMS has periodically updated the list of primary care services adopted for the purpose of beneficiary assignment. In this rule, CMS proposes adding several additional codes to the definition of primary care services for Performance Year 2022, including codes describing chronic care management, prolonged office or other E/M services, prolonged audio-only virtual check-in (if finalized in this rule). CMS also proposes to allow telephone E/M codes (CPT codes 99441 through 99443) to continue to be used for beneficiary assignment until they are determined to no longer be payable under Medicare FFS telehealth policies. **The AHA strongly supports these proposals and urges CMS to finalize them.**

Risk Adjustment of ACOs' Historical Benchmark. In this rule, CMS requests comment on issues related to its risk adjustment methodology. The current risk adjustment methodology that CMS uses to adjust ACOs' historical benchmarks for changes in severity and case mix is subject to a cap of positive 3% for the entire agreement period. This means that that any risk score growth between Benchmark Year 3 and any performance year in the agreement period cannot be larger than 3%. CMS mentions in the rule that stakeholders have expressed concern that this may not allow the agency to fully account for risk score growth in the ACO's regional service area, thereby penalizing them. **The AHA agrees that the positive 3% cap imposes artificial penalties on ACOs and will be especially problematic in light of the COVID-19 pandemic.**

As described in our comments to the Pathways to Success rule, the AHA believes a 3% cap on risk scores is too low and the five-year period over which it is spread is too long. For example, the 3% cap on risk scores is too low to capture the significant turnover and changes in health status that ACO beneficiaries experience. This is especially true as the burden of illness in the Medicare population increases over time. It is also complicated by COVID-19, during which there were significant decreases in patient encounter volume. As a result of these decreases, ACOs were unable to capture large swaths of beneficiaries' hierarchical condition categories (HCCs), upon which MSSP risk adjustment is based. Thus, most ACOs risk scores for 2021 will be extremely low. If in-person patient volume resumes in 2021, 2022 and beyond, and ACOs are once again able to capture their beneficiaries' risk scores, ACOs will likely have a significant increase in risk scores simply because patients returned to the office. Capping the risk score growth at 3% will artificially penalize ACOs for patients' need to stay in the safety of their homes during the pandemic.

Suppressing the payment of ACOs that were largely successful in navigating the pandemic and saved Medicare $1.9 billion in 2020 is inappropriate and counterproductive. At the least, we urge CMS to raise the cap to at least 5%, as included in the Value in Health Care Act of 2021(H.R. 4587) that the AHA and several other organizations support.

We also recommend that CMS apply the risk score cap on an annual basis, allowing risk scores to change by +/-5% year-over-year throughout the agreement period. This is especially important for ACOs in high churn areas; the patients with which these ACOs begin a year look very different from the patients they serve the following year. Freezing risk scores over five years could create a constant struggle against an outdated risk score under which ACOs are at risk for a population whose risk score was calculated several years prior. Such a situation could create a level of risk some ACOs cannot bear, deterring them from entering or remaining in the MSSP. CMS has already recognized the necessity of shorter-term caps on risk and price adjustments; the agency capped trend factor variation in the Bundled Payments for Care Improvement program on a quarter-over-quarter basis and risk scores in the Next Generation ACO program at 3% over two years.