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President and CEO

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The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

**RE: Calendar Year 2022 Physician Fee Schedule Proposed Rule, CMS-1751-P**

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico, including 59 facilities and 7,147 beds in Tennessee. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates the opportunity to comment on several proposals in the Centers for Medicare and Medicaid Services (CMS) proposed rule for calendar year 2022 Medicare Physician Fee Schedule (PFS). FAH's comments will include recommendations related to telehealth services, valuation for cardiac ablation services, appropriate use criteria for advanced diagnostic imaging, physician self-referral, and quality reporting.

## **II.D. Telehealth and Other Services Involving Communications Technology**

### **All temporary telehealth codes should be extended through the end of December 2023.**

The FAH supports extending the timeframe for the inclusion of Category 3 codes past the end of the COVID-19 public health emergency (PHE). Continuing these codes is critical to allow providers additional time to collect, analyze, and submit data regarding the services to support their consideration for permanent addition as telehealth services. Second, the extension will ensure that providers have enough time following the end of the PHE to phase out these telehealth services in a careful and deliberate manner that does not undermine patient care.

We also request that CMS extend the non-Category 3 codes that are temporarily available for telehealth during the PHE through the end of December 2023. The difference between Category 3 codes and non-Category 3 codes is primarily one of data: CMS has made an initial determination that there is likely to be clinical benefit from Category 3 codes when the services are furnished via telehealth, but has not yet been able to make that determination for the non-Category 3 codes. An extension for non-Category 3 codes would again give providers the time needed to collect data supporting a clinical benefit.

Extending the temporarily available telehealth codes also is important in relation to behavioral health services. First, behavioral health services are well-suited for delivery via telehealth, making it more likely that the data will demonstrate a clinical benefit supporting permanent inclusion on the telehealth list, if providers are given sufficient time to collect it. Second, and even more importantly, the United States suffers from a serious shortage of qualified behavioral health providers. This shortage restricts the ability of patients to get timely access to care, and sometimes requires patients to travel long distances for necessary services. The delays associated with provider scarcity have significant negative consequences on health. For example, individuals are likely to develop more acute mental illness when they do not receive needed and timely interventions, ultimately leading to increased suffering for the patient and their families, as well as higher burdens on the health care system. Telehealth offers an opportunity to interrupt a cascade of negative outcomes by ensuring that care is available promptly.

While the case for behavioral health services is overwhelming, other codes should be continued through the end of December 2023. Flexibility is needed to offer many types of services through telehealth, which is essential to ensure that patients have access to care in a reasonable timeframe. For all of the above reasons, the FAH strongly supports continuation of all the Category 3 codes through the end of December 2023, and additionally requests the continuation of the non-Category 3 codes on the same timeline.

### **The requirement in the Consolidated Appropriations Act of 2021 for an initial in-person visit within six months of telehealth services should be interpreted flexibly.**

The *Consolidated Appropriations Act of 2021* (CAA) expanded Medicare coverage of telehealth that is furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder by removing originating-site restrictions. However, the CAA limited its

expansion to circumstances when the physician or practitioner furnishing the telehealth services provides an item or service in person without the use of telehealth within the six-month period prior to the first telehealth service (the six-month requirement). While the FAH recognizes the statutory nature of the six-month requirement, we request that CMS exercise its discretion to implement it in a way that promotes access to care and a positive patient experience.

To that end, the FAH supports the proposal to consider other practitioners of the same specialty in the same practice to be the same person as the in-person treating practitioner for purposes of meeting the CAA's six-month requirement. Many practices offer excellent care from a team of providers who have access to the same electronic health record and consult with each other as needed about individual patient treatment decisions. It promotes flexibility – and ultimately access to care – when practitioners in the same specialty in the same group can cover for one another on a routine basis. Patients who wish to receive continuing care from such an integrated practice should not be precluded from scheduling a telehealth appointment with another practitioner in the same practice merely because the first in-person appointment took place with someone else in the group. As noted in the Proposed Rule, CMS has historically treated the billing practitioner and other practitioners of the same specialty or subspecialty in the same group as if they were the same individual in certain circumstances, such as when determining whether the patient qualifies as new or established. CMS should extend the same interpretation to the determination of whether the in-person visit requirement of the CAA has been met.

CMS also should exercise its interpretive discretion in other ways to promote patient access to care. For example, if a patient who comes to an emergency department is referred to a telehealth practitioner for follow-up mental health services, the initial ED visit should satisfy the CAA's six-month requirement so long as the treating practitioner at the ED is of the same specialty as the telehealth provider to whom the patient is referred. This interpretation can be harmonized with the language of the CAA because “such physician or practitioner” can be understood to mean a physician or practitioner of the same practice. By implementing the statutory requirement in this way, CMS would ensure that patients in crisis can receive continuing mental health care after an emergency visit even in the face of otherwise insurmountable barriers to access. To the extent that CMS wishes to impose guardrails on a more permissive interpretation of the CAA's six-month requirement, we request at a minimum that it allow a visit with another practitioner of the same specialty to satisfy the requirement when the patient faces barriers to in-person care, such as a lack of transportation, or when the patient cannot secure an in-person follow-up appointment in a reasonable timeframe. We believe these kinds of policies appropriately balance the need to promote patient access to care with concerns about program integrity.

***The frequency of follow-up in-person visits required by the CAA should be determined by the treating physician.***

In addition to the six-month requirement discussed above, the CAA mandates that the physician or practitioner furnishing telehealth services also furnish an item or service in-person without the use of telehealth “during subsequent periods in which such physician or practitioner furnishes such telehealth services to the eligible telehealth individual, at such times as the

Secretary determines appropriate.” (42 U.S.C. § 1395m(7)(B)(i)(II).) The Proposed Rule would implement this condition by requiring “an in-person, non-telehealth service” to be furnished at least once within six months before each subsequent telehealth service “furnished for the diagnosis, evaluation, or treatment of mental health disorders by the same practitioner, other than for treatment of a diagnosed SUD or co-occurring mental health disorder.” (86 Fed. Reg. 39146-47 (July 23, 2021).) The FAH opposes such a one-size-fits-all standard for the frequency of in-person follow-up visits. The treating physician or practitioner has the most information to assess the needs of the patient, along with the appropriate expertise to make a determination of when a follow-up in-person visit is necessary. We therefore propose that each treating practitioner or physician be allowed to develop an individualized plan of care for the patient that specifies the required frequency of in-person visits based on the unique needs of the patient.

**CMS should continue coverage of audio-only mental health services, should not impose new and overly burdensome documentation requirements, and should consider a more flexible set of guardrails to protect patient choice and quality of care.**

The FAH supports the proposal to make permanent the ability to furnish audio-only mental health services by amending the regulatory definition of “interactive telecommunications system.” We agree that paying for audio-only mental health care will increase access to care, particularly in geographic areas and populations without widespread access to broadband, and will help to alleviate the persistent shortage of mental health care professionals.

However, the FAH opposes conditioning coverage of audio-only mental health services on compliance with overly burdensome documentation requirements. The Proposed Rule requests comment on whether to mandate documentation in the patient’s chart that supports the clinical appropriateness of providing audio-only telehealth services to patients in their homes for mental health. We believe a requirement of this kind would be counter to the policy goals of expanded access and reduced barriers to care. We are particularly concerned that the implied threat of audits and claim denials – and the associated battle of experts over whether audio-only mental health services are “clinically appropriate” – would chill the provision of audio-only mental health services to patients who cannot otherwise secure access to care. Instead of imposing additional documentation expectations, CMS should establish a presumption that audio-only mental health services are clinically appropriate and instruct contractors that such services may not be denied solely on the basis of the telehealth technology used to deliver care.

CMS also requests comments regarding additional documentation requirements to support clinical appropriateness for providing audio-only telehealth services for mental health. Although the FAH is strongly opposed to burdensome documentation requirements, we agree that there is value in establishing guardrails to protect patient choice and promote quality of care. As discussed in the Proposed Rule, payment for audio-only services is appropriate when the patient is unable or does not wish to use two-way, audio/video technology. Additionally, we request that payment be allowed when furnishing services via audio-only technology is necessary in the physician or practitioner’s clinical judgment. Establishing a standard based on clinical judgment accounts for the wide range of potential circumstances when audio-only services are appropriate. If CMS takes the alternative path of imposing a rigid rule-based approach, it likely

would stifle innovation in care delivery and undermine telehealth’s potential to expand access to services in a specialty plagued by severe provider shortages.

***The flexibility to provide direct supervision through real-time audio/video technology should be made permanent.***

Current Medicare regulations permit supervising professionals to satisfy direct supervision requirements using real-time audio-visual technology through at least the end of the calendar year in which the public health emergency ends. (See 42 C.F.R. § 410.32(b)(3)(ii).) The FAH supports making this method of providing direct supervision permanent. In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic, or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to admit the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary.

When the current policy is made permanent, there should not be a requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology. Physicians and other supervising practitioners benefit from the flexibility to supervise in person, via telehealth, or through a combination of modalities depending on clinical need and circumstances. In some cases, services may even be supervised in part through an in-person presence and in part through a telehealth modality. Requiring practitioners to track whether and to what extent they supervised through telehealth would significantly increase administrative burdens associated with these flexibilities, undermining their ability to improve physician care delivery. Because there is no obvious benefit to collecting data on how supervision is facilitated, the burdens associated with a modifier requirement cannot be justified. Thus, the FAH requests that the definition of direct supervision be permanently amended to allow for telehealth supervision, without the requirement for a new modifier.

## **II.E. Valuation of Specific Codes: Cardiac Ablation Services Bundling**

Because of technologic innovations and changes in clinical practices associated with Cardiac Ablation Services (CPT codes 93653 – 93657), the specialty societies recommended referral of this code family to the CPT Editorial Panel to have the code descriptors for these services updated and bundle services commonly performed together. In October 2020, the CPT Editorial Panel revised CPT code 93653 to bundle with 3D mapping and to include “induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus” and revised CPT code 93656 to add 3D mapping and “left atrial pacing and recording from coronary sinus or left atrium” and “intracardiac echocardiography including imaging supervision and interpretation” to their descriptors. After receiving the survey data, the

specialty societies were concerned that the survey respondents were confused about the coding changes and requested the CPT panel to rescind the code changes for one year; this request was denied. These codes were re-surveyed and reviewed at the April 2021 RUC meeting. These recommendations were not considered for the calendar year 2020 PFS proposed rule. The RUC recommendations are included in its August 31, 2021 comment letter<sup>1</sup> submitted in response to this proposed rule.

**The FAH is concerned that CMS' proposed relative value units (RVUs) for cardiac ablation services will significantly impact the delivery of these important services and recommends that CMS implement the RUC recommendations for these services, as discussed in its August 31, 2021 comment letter, rather than implement the CMS proposed values.** Coding changes to reflect the evolving technology changes and changes in clinical practice are important but do not necessarily equate to reduction in work intensity and time. We are concerned that the significant coding changes were not initially appreciated by survey respondents who were more appropriately focused on treating vulnerable, critically ill patients with COVID-19. As the COVID-19 public health emergency continues and all health care providers are again challenged with increasing numbers of COVID-19 admissions, we do not support reducing reimbursement by approximately 30% for these procedures.

The COVID-19 pandemic has impacted every sector of the U.S. health care system in 2020, 2021, and potentially beyond. Hospitals and clinicians continue to be on the front line, and it is unknown when this pandemic will end. Our hospital members remain concerned about the impact proposed reimbursement changes will have on contracts with clinicians, physician staffing firms, and managed care organizations. Instead of reducing payment for individual services, CMS should be working to maintain reimbursement levels and work with Congress to eliminate the proposed reduction in the PFS conversion factor or otherwise mitigate the payment reductions for these cardiac services.

### **III.F. Appropriate Use Criteria for Advanced Diagnostic Imaging Services**

The Appropriate Use Criteria (AUC) are a set of individual criteria that present information linking a specific condition or presentation with one of more services and an assessment of the appropriateness of the services. The *Protecting Access to Medicare Act of 2014* (PAMA) requires CMS to establish a program that promotes AUC for advanced diagnostic imaging whereby a clinician would consult a clinical decision support mechanism (CDSM) prior to ordering advanced diagnostic imaging. PAMA requires payment to be made to the furnishing professional for an applicable advanced diagnostic imaging service *only if* the claim indicates that the ordering professional consulted with a CDSM as to whether the ordered service adheres to the applicable AUC.

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<sup>1</sup> CMS-2021-0119-14543

The “educational and operations” testing period of AUC began in 2020, where ordering professionals must consult specified applicable AUC through qualified CDSMs and furnishing professionals must report the AUC consultation information on Medicare claims, but CMS continued to pay claims even if the AUC information is incorrect. This more lenient period was extended through 2021 in order to account for the effects of the COVID-19 PHE.

**As the FAH stated in previous comments, our members generally support the use of AUC. However, we remain concerned about the ability of providers to implement the changes required under the current schedule, the continued complexity of AUC implementation, and its potential impact on patient care. The FAH greatly appreciates the proposal to further delay the payment penalty phase for at least one year to ensure successful implementation of the AUC program, as expressed in greater detail below.**

In order to maintain the focus of the program on the goal of helping clinicians with decision-making and increasing quality in patient care – rather than producing a “check-the-box” exercise – the FAH offers the below comments and recommendations.

**Delay the payment penalty through the end of the PHE**

**The FAH supports the proposed further delay of the payment penalty phase for the program until the later of January 1, 2023, or the first of the January that follows the end of the PHE.** Due to the unprecedented financial and operational strain placed on providers by the COVID-19 PHE, continued challenges in implementation, and the need for additional programmatic guidance, we greatly appreciate this delay. This much-needed additional time will enable hospitals and other providers to maintain their ongoing COVID-19 response efforts while still allowing time to undergo necessary education and operations training on conducting the AUC program.

Given the many complexities around the scope and application of the AUC program claims processing edits, it is necessary to delay the payment penalty phase so providers can continue to work on how to best implement the program. In the calendar year (CY) 2018 physician fee schedule final rule, CMS adopted a delayed start date of January 1, 2020 (which was then extended until January 1, 2022, as a result of the PHE for AUC consultation and reporting requirements. During this time, CMS expected AUC consultation information to be reported on claims, but claims would not be denied for failure to include proper AUC consultation information. The FAH appreciates the need to collect and report on the AUC data and reiterates the importance that there should not be an attached penalty given the complicated and sometimes unclear requirements of the program.

The education and operations testing year was, and continues to be, necessary in order to raise awareness about the program and enable providers to adjust workflows, train staff, and gain the necessary experience before impacting claims payments of this extensive program. However, the PHE severely impacted providers ability to engage in these preparatory steps, which is why the payment penalty phase delay is necessary to provide time for successful implementation of the AUC program under the new timeline.

### **Maintain use of HCPCS Modifier MH**

The modifier MH was created for use during the educational and operations testing phase to identify claims for which AUC consultation information was not provided to the furnishing professional and furnishing facility. **CMS is proposing to end the current use of modifier MH at the end of the educational and operations testing period, and the FAH urges CMS to withdraw this proposal.**<sup>2</sup>

Through the educational and operations testing period, the modifier MH has been extremely helpful to hospitals when implementing the AUC program – and the current system works well. For example, when a patient walks into a hospital from a community clinic and there is no AUC modifier on an imaging order, the hospital can use the modifier MH to continue treating this patient without unnecessary delay. Unnecessary delay would occur because hospitals do not have the opportunity to complete AUC after the fact and the patient is presenting without AUC criteria from the ordering physician. *With the modifier MH in its current form, there is no delay in the triage and treatment decisions of patients* as hospitals can continue to treat patients if they come in without AUC from an outside clinic or provider. Hospitals are put in a very precarious situation without the use of the modifier MH if the hospital is not the ordering institution because there is nothing to report in the absence of this modifier, which could affect patient access to timely care. Patient care should not suffer due to non-compliant ordering physicians, which is why the modifier MH continues to be necessary to mitigate these circumstances. **Thus, the FAH urges CMS to allow continued use of modifier MH in its current form in order to promote patient access to timely and quality care.**

### **Provide Greater Clarity or Guidelines on Use of Modifier MA**

CMS created the modifier MA to identify claims for patients with a suspected or confirmed emergency medical condition, which would create an exemption from use of AUC. **The FAH urges CMS to provide more information around the use of the modifier MA, including specific guidelines for accurate and appropriate use of the modifier.** In the absence of more specific guidance, modifier MA has the potential for overuse. The challenge of this modifier is knowing when to apply it and whether it applies to EMTALA patients generally or only to patients with certain conditions, (e.g., a trauma patient). FAH members support the quality implications of the AUC program, and more specific guidelines regarding implementation and appropriate utilization of modifier MA would advance this goal.

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<sup>2</sup> Beginning for services furnished on and after the effective date of the AUC program claims processing edits, CMS proposes to redefine modifier MH to describe situations where the ordering professional is not required to consult AUC and the claim is not required to report the AUC consultation. CMS notes this could be repurposed for Critical Access Hospitals (CAH) and other circumstances that fall outside the scope of the AUC program requirements. We believe this proposal is too narrow and does not cover instances where the ordering physician does not include AUC on the order.



### ***Allow Providers to Resubmit Denied Claims That Fail AUC Claims Processing Edits and Pay Non-AUC Services***

CMS is seeking comments on the process of denying claims when the claims fail the AUC claims processing edit. Given the complexity of the program, we believe professionals and facilities should have the opportunity to correct and resubmit claims that do not initially pass the AUC processing edits. This process will be helpful as providers are learning the intricacies of this complex program. Should CMS adopt a denial policy, the FAH urges CMS to implement line-item denial if AUC info is not present and get paid on the rest of the claim – that CMS should not deny the entire claim. Not getting paid for an entire claim, instead of just the one that is AUC-noncompliant, would be an excessive penalty.

### **III.P. Updates to the Physician Self-Referral Regulations**

#### ***Indirect Compensation Arrangements (§ 411.354(c)(2))***

The FAH understands that CMS has undertaken efforts to provide additional clarification to the physician self-referral law (Stark law) via the proposals included in this proposed rule related to the extensive updates and revisions put in place via the *Modernizing and Clarifying the Physician Self-Referral Regulations* (“MCR Final Rule”) published on December 2, 2020. The industry has been working to understand and implement the revisions and clarifications to the Stark law included in the MCR Final Rule, including the changes to the definition of an indirect compensation arrangement at §411.354(c)(2). **With the additional revisions to the Stark law contained in the proposed rule, our members seek additional understanding of whether the proposed revisions to the indirect compensation arrangement revisions are necessary and, if so, whether the proposals will have the intended result if finalized.**

#### ***Definition of “Indirect Compensation Arrangement”***

The MCR finalized revisions to the definition of indirect compensation arrangement for Stark Law purposes by adding a second condition when reviewing compensation to determine whether the compensation implicates the Stark Law and would then need to satisfy an applicable exception. CMS acknowledged in the MCR that the revised definition will “reduce the number of unbroken chains of financial relationships that fall within the ambit of the physician self-referral law as indirect compensation arrangements (although they may still implicate the anti-kickback statute, depending on the facts and circumstances)” and that as a result, “many unbroken chains of financial relationships will no longer be required to satisfy the writing requirement.” In this proposed rule, CMS seeks to further revise the definition of an indirect compensation arrangement due to CMS inadvertently omitting language in the MCR revised definition that would have ensured that additional arrangements continued to qualify as indirect compensation arrangements for which an exception must be met. Specifically, CMS included in this PFS proposed rule revisions focused on certain arrangements involving unit of service-based payment for the rental of office space or equipment that would qualify as indirect compensation arrangements for which an exception must be met.

In the proposed rule, CMS notes that the language excluded in the current streamlined definition of ‘indirect compensation arrangement’ removed a subset of unbroken chains including compensation arrangements that CMS has long identified as presenting significant program integrity concerns. i.e., certain arrangements involving unit of service-based payment for the rental of office space or equipment. (86 FR 39322). The proposed revisions to §411.354(c)(2)(ii) would require a two-step analysis of 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 (or immediate family member), including arrangements for the rental of office space or equipment.

As a result of this proposed revision, if there is an unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member) is an arrangement for the rental of office space or equipment, an indirect compensation arrangement will be determined to exist if all other conditions of 42 C.F.R. §411.354(c)(2)(i)-(iii) are met. The impact of this revision is that compensation for the rental of office space or equipment may not be determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessee to the lessor in order for the indirect compensation arrangement to qualify for the indirect compensation arrangement exception at 42 C.F.R. § 411.357(p).

The definition of “indirect compensation arrangement” as it currently exists in the regulations has limited the number of arrangements that meet the definition and therefore must satisfy an exception. The FAH is concerned that the additional proposed changes would necessitate additional review and consideration of arrangements to determine the criteria that applies to the arrangement – and that some of these arrangements may not be those that CMS is intending to capture with the proposed changes. There also may be additional confusion for those arrangements that did not qualify as indirect compensation between the effective dates of the changes.

**The FAH asks that CMS clarify the criteria applicable for arrangements in place under the changing definition of “indirect compensation arrangement.” Alternatively, as CMS has targeted its concerns regarding the indirect compensation arrangement definition on per-click or per unit of service leases, the FAH recommends that CMS consider a simpler revision. Specifically, CMS could instead simply reference these specific per-click or per unit arrangements in the definition.** This approach would address the specific arrangements at the root of the proposed rule while providing clarity of the impact and intent and limiting the potential questions that may result in applying the revisions as proposed.

### **Personally Performed**

In addition to the revisions to what constitutes an indirect compensation arrangement, CMS also proposes a definition of “services that are personally performed” to accompany the other changes. Under the proposed rule, 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) are not considered to be personally performed by the physician. The FAH seeks clarification from CMS on how this definition impacts an analysis of services provided “incident to” a physician’s personally performed services. Because these services are often performed by an employee of the physician as “incident to” services, does CMS consider these services within the definition of “services that are personally performed”? **The FAH asks that CMS clarify whether indirect compensation arrangements that include “incident to” services are more problematic, or whether these services will qualify as “personally performed” and not trigger an indirect compensation analysis under that criteria of the definition.** We note that if CMS were to address the specific arrangements at the root of the proposed rule (e.g., per click or per unit), in lieu of the “personally performed” approach in the proposed rule, as we recommend above, the “incident to” question we raise here would not come into play and thus would be resolved.

#### **Definition of “Unit” for Purposes of Applying § 411.354(c)(ii)(A)**

The proposed rule also includes a proposal to define the word “unit” included in the definition of indirect compensation arrangement that was finalized in the MCR effective January 2021. Because commenters have expressed confusion as to what constitutes a “unit” under this definition, CMS proposed that an individual time “unit” would be defined as (1) time, where the compensation paid to the physician (or immediate family member) is based solely on the period of time during which the services are provided; (2) service, where the compensation paid to the physician (or immediate family member) is based solely on the service provided; or (3) time, where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided. CMS clarifies that in instances where both services and time are used in the physician's compensation formula, then the controlling unit to be considered is time. CMS also proposed that if an arrangement includes more than one unit of the same type, then each unit must be analyzed separately.

The FAH agrees that identifying the appropriate “unit” of compensation did introduce some confusion following implementation of the new indirect compensation arrangement definition of the MCR, as most compensation is based on a particular unit whether it be per service, hourly, monthly, annually, etc. **We appreciate the clarification from CMS and believe that identification of the applicable unit for analysis under the Stark law will result in clearer and more accurate analysis of whether an arrangement constitutes indirect compensation based upon this clarification.**

#### **Exception for Preventive Screening Tests, Immunizations, and Vaccines (§ 411.355(h))**

Vaccines are generally considered designated health services (DHS) as they are included in the definition of outpatient prescription drugs. At this time, Medicare does not pay for COVID-19 vaccines, therefore they are not included in the definition of DHS. CMS noted that when the federal government stops purchasing COVID-19 vaccines, the COVID-19 vaccines would be considered DHS if they are then paid for under the Medicare program. Unless an applicable exception to the Stark law is satisfied, the prohibitions under § 411.353(a) and (b) would apply to the referral and billing of COVID–19 vaccines.

Section 411.355(h) provides an exception for preventive screening tests, immunizations, and vaccines. In the calendar year (CY) 2021 PFS Final Rule, CMS added COVID-19 vaccines to the list of immunization and vaccine codes under this exception. However, one of the conditions for this exception is compliance with frequency limits established in statute or by CMS. Because frequency limits for COVID-19 vaccines have not yet been set, CMS proposes to waive the frequency limit condition for COVID-19 vaccines until such time as any such limits are established. The FAH agrees with CMS that making the exception at § 411.355(h) available for COVID-19 vaccines to which no CMS-mandated frequency limits apply would not pose a risk of program or patient abuse. **We believe that limiting the applicability of this provision only during the PHE for COVID-19 might be too restrictive, and instead support the proposal that this exception apply until such time as CMS-mandated frequency limits apply for COVID-19 vaccines.**

**List of CPT/HCPCS Codes (§ 411.351)**

In order to provide a precise definition of DHS that implicate the Stark law, CMS identifies certain DHS by publishing specific lists of CPT and HCPCS codes that physicians and providers most commonly associate with a given designated health service (the Code List). Currently the Code List is updated annually to account for both changes in the most recent CPT and HCPCS publications as well as changes in Medicare coverage policy and payment status.

CMS notes that coding changes have become more frequent since the first Code List was published in the Physician Fee Schedule and posted to the CMS website. In order to make the most recent updates available in a timelier manner, CMS proposes to update the Code List each calendar quarter and provide public notification in advance of Code List updates. CMS proposes that this advance notification would be posted on the CMS website on March 1, June 1, September 1, and December 1 of each year, with corresponding Code List updates effective on April 1, July 1, October 1, and January 1, respectively. These quarterly updates would also provide for a 30-day public comment period following the posting of the advanced notification.

**The FAH does not believe that more frequent updates to the DHS Code List will be beneficial to the industry. Although decisions related to services that are DHS and should therefore be included in the Code List occur throughout the year at CMS, quarterly adjustments to the Code List will likely add confusion and another level of administrative burden to Stark law compliance efforts.** With a more frequent change of DHS codes, it is possible that certain compensation arrangements with physicians could fall out of compliance with the Stark law inadvertently. Due to the strict liability nature of the Stark law, this could result in additional opportunities for technical noncompliance for financial arrangements with physicians. The FAH encourages CMS to reconsider this proposal and maintain an annual update to the DHS Code List to ensure clearer application of the Stark law to financial arrangements with physicians.

## IV. Quality Payment Program

### Merit-based Incentive Payment System Value Pathways (MVPs)

#### *MVP Implementation Timeline*

CMS makes proposals that would begin to operationalize MVPs, describe registration, reporting and scoring requirements, and MVP development and maintenance. **The FAH appreciates CMS’ proposal to begin the MVP implementation no sooner than performance year 2023 but we urge CMS to opt for an even slower pace related to changes to the Quality Payment Program (QPP).** Regrettably, the COVID-19 PHE is not resolved, and the entire health care industry continues to face incredible challenges with little potential for resolution by the end of the year. Our members remain significantly impacted by the PHE and any changes such as the introduction of MVPs adds burden to those organizations that do not have the current capacity or resources to implement these changes.

The FAH supports MVPs starting with an optional and limited set of specialties and permitting reporting through traditional MIPS until sufficient infrastructure can be developed to support the wide variety of clinicians currently required to participate in MIPS. We would recommend not retiring the MIPS program until more clinicians have a detailed reporting pathway in which to prepare.

The FAH continues to question CMS’ reassurances that the introduction of MVPs will reduce clinician burden and rather believes that the proposed reporting and registration requirements add further complexity and unnecessary work to an already overly complex and burdensome program. While we appreciate that participation in MVPs will remain voluntary for several years, much work is still needed to determine whether MVPs will serve as the “glidepath” toward alternative payment models and demonstrate value as envisioned. For example, CMS must still:

- Move beyond the current conceptual model and validate how MVPs will be scored and how those differences may or may not impact an eligible clinician or practice’s ability to achieve the performance threshold.
- Model using existing data how the resulting scores from quality, cost and the population health measures in the foundational layer represent value-based care.
- Determine what the additional reporting burdens will be with the addition of subgroup reporting and for multi-specialty practices or health systems if CMS requires one group to report multiple MVPs.
- Explore how it can minimize any negative unintended consequences such as a practice earning a penalty based on MVP reporting when the same group would have earned an incentive through traditional MIPS; and
- Balance MVP implementation with other competing priorities such as the shift to digital quality measures by 2025.

### *MVP Requirements: Maintenance Process and Future Health Equity Measures*

In addition, the FAH supports an annual MVP development, maintenance and selection process that is open, transparent, and allows input from multiple specialties and providers on a rolling basis. The process must also emphasize measures that are electronically generated at the point of care to enable clinicians and groups to actively engage in quality improvement using these MVPs. We support the development of a process that emphasizes health equity and encourage CMS to work with clinicians, specialties, and providers to determine whether a broadly applicable MVP on health equity, targeted MVPs, or stratification of quality and cost results using existing measures will better address inequities and drive improvements at the point of care.

### *Health Equity Measures in MVPs*

The FAH emphasizes its commitment to working with CMS, HHS, and others on a continuous and sustained effort to ensure health care equity nationwide. We commend CMS for undertaking and sharing its strategic thinking of the opportunity to develop a broad group of health equity measures for various specialties and subspecialties. We believe a good first step would be to identify measures that are suitable for reporting stratified by race and ethnicity. Ideally, this can set the stage for thoughtful expansion over time to developing new health equity measures that are tested and found to be important to measure, able to perform as designed and feasible to collect. The FAH also believes that practical work can begin on improving data collection, particularly data element definition, a complete environmental scan of existing measures and efforts, and exploration of strategies for safeguarding privacy at every step.

### *MVP Reporting Requirements*

The FAH encourages CMS to revisit the inclusion of the population health measures within the foundational layer of MVPs as we do not believe that any of the current and proposed measures are appropriately attributed or yield reliable and valid results and the performance scores are not actionable by clinicians or practices.

We also do not support the inclusion of the *Acute Unplanned Cardiovascular Related Admission Rates for Patients with Heart Failure* for MIPS as a potential measure in this foundational layer due to our concerns detailed later in this letter. The FAH questions whether the proposed definition for population health measures sufficiently distinguishes the current set of administrative claims-based measures from the other quality measures in the program – many of which have a broad population health focus.

The FAH urges CMS to be conservative in the number of changes proposed for MIPS during the current PHE and postpone implementation of MVPs at this time given all of the unanswered questions and concerns.

### **APM Performance Pathway (APP)**

CMS proposes to extend the CMS Web Interface as a reporting option for clinical quality measures under the APM Performance Pathway (APP) for use by clinicians of Shared Savings Program ACOs for performance years 2022 and 2023. The FAH appreciates that CMS acknowledges the challenges that accountable care organization (ACOs) are encountering with the shift to the APP and specifically the move to reporting of MIPS clinical quality measures or electronic clinical quality measures (eCQMs). The FAH supports the proposed extension of the CMS Web Interface for an additional two performance years but also encourages CMS to continue to assess whether ACOs have had sufficient time to integrate these measures into their electronic health record systems (EHRs), determine how to best accomplish some of the new requirements such as patient de-duplication, and validate the resulting data.

In addition, the FAH continues to believe that CMS must reconsider the measures that are included within the APP. Specifically, we do not support CMS' one-size-fits-all approach to the APP. While the FAH continues to support reducing the number of measures on which MSSP APMs must report, we recommend more flexibility in the measure selection. More specifically, the FAH urges CMS to develop a "specialty-set approach" that applies a reduced set of measures to each MIPS-eligible APM based on the unique characteristics of the APM and these sets should be aligned with the measures used in Center for Medicare and Medicaid Innovation (CMMI)-developed APMs. For instance, primary care-focused models could report on one, smaller established measure set, while cardiology models could report on a different, smaller specialty set relevant to that model. This approach would advance the goal of focusing on population health while appreciating the nuances inherent in different APMs to ensure that the measures selected are relevant and have a meaningful impact on quality. The FAH also urges CMS to make the use of the APP standard voluntary for MIPS APMs.

### **MIPS Performance Category Measures and Activities**

#### *Quality Performance Category*

- Data Completeness Criteria

CMS proposes to retain the current threshold of at least 70 percent through performance year 2022 and to raise the threshold to at least 80 percent beginning with performance year 2023. The FAH supports retaining the current threshold of 70 percent in performance year 2022 and urges CMS to postpone any increase in the data completeness requirements until CMS addresses what impact the additional requirement might have on individual clinicians and practices as this question remains unanswered.

The FAH is concerned that it may be difficult, if not impossible, for some practices to report higher numbers of patients due to challenges with data collection and aggregation across sites, particularly if the EHR systems are not interoperable. In addition, there may be challenges if a clinician or practice participates with a specific registry for MIPS reporting but one of the sites of service at which they provide care is not a participant of that same registry. Lastly, providers and practices continue to face environmental and financial challenges that require mid-

year EHR transitions and other impacts to their ability to meet the increased data completeness threshold.

The FAH also encourages CMS to explore other alternatives to establish adequate sample sizes, such as minimum sample sizes for each measure, to ensure that the performance scores produce reliable and valid results, particularly for small or rural providers.

- Measure Change Proposals

*Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PRO-PM)*

The FAH supports the development and implementation of PRO-PMs, but we also believe that additional questions and work remain before their widespread use, such as:

- the degree to which multiple PRO-PMs could lead to survey fatigue for patients,
- the potential impact additional PRO-PMs may have on the reporting of well-established measures such as CG-CAHPs, and
- what level of data collection burden for an individual PRO-PM is acceptable for a hospital or other healthcare providers.

While the reporting of this measure will be voluntary in MIPS, the FAH believes that additional research and guidance are needed on how PRO-PMs should be integrated into existing programs while minimizing any unintended consequences.

*Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System*

While the FAH agrees that measuring the frequency of admissions for patients with heart failure enables clinicians to understand where quality improvement efforts may be needed, we do not support the inclusion of this measure in MIPS at this time. The FAH does not believe that it is appropriate to attribute these admissions to clinician groups since MIPS participants do not know which patients were assigned to them until well after the reporting period ends (i.e., retrospectively), making it impossible for clinicians and practices to implement near real-time interventions. This measure should not be implemented until MIPS clinicians can actively engage in activities that minimize and prevent those hospitalizations that could be avoided, and the FAH encourages CMS to explore avenues by which attribution of patients could be done prospectively to allow for such engagement. A practice's improvement in avoiding unplanned admissions must be based on its ability to leverage one or more structures or processes of care.

The FAH is also concerned that while the median reliability score was 0.60 for practices with at least 21 patients, the range was from 0.401 to 0.995. The FAH believes that the minimum sample size must be increased to a higher number to produce a minimum reliability threshold of sufficient magnitude (e.g., 0.7 or higher). Ensuring that the resulting performance scores produce information that would not misrepresent the quality of care provided by a group is imperative and while an increase in the sample size would result in a decrease in the number of groups to



which the measure would apply, we believe that it would still be a considerable number of patients with heart failure that would continue to be factored into the measure.

The FAH appreciates the inclusion of social risk factors within the risk adjustment model and strongly advocates that dual eligibility also be included since it was a strong predictor of whether a patient would be admitted. If the desire is to develop measures that can be used in other programs that may not include an adjustment for complex patients, then it becomes imperative that all variables that are determined to be predictors that are outside of the control of a group be included.

*Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions*

The FAH continues to have the same concerns with this measure as what was outlined in our proposed rule comments from last year. Specifically, these concerns include the insufficient evidence to support attribution to individuals or groups, particularly with the attribution assigned retrospectively; the minimum sample size and reliability threshold remain too low; and additional information on the validity of the measure when applied at these levels is needed.

The FAH applauds CMS for including social risk factors within the risk adjustment model and strongly advocates that dual eligibility also be included since it was a strong predictor of whether a patient would be admitted. However, even with the addition of these variables in the risk model, the FAH does not believe that it is appropriate to attribute these admissions to clinicians. On review of the methodology report released for public comment in May 2019 and materials submitted to the National Quality Forum (NQF) during the endorsement review, CMS did not provide sufficient data and empirical evidence to demonstrate that individual clinicians or groups can meaningfully influence unplanned admissions in this population. The supportive evidence demonstrated that improvements in unplanned admissions could be made when coordinated programs or payment offsets were also in place, but much of these efforts in those studies required involvement of larger entities such as health plans or ACOs.

In addition, MIPS participants do not know which patients were assigned to them until well after the reporting period ends (i.e., retrospectively), making it impossible for clinicians and practices to implement near real-time interventions. This measure should not be implemented until MIPS clinicians can actively engage in activities that minimize and prevent those hospitalizations that could be avoided, and the FAH encourages CMS to explore avenues by which attribution of patients could be done prospectively to allow for such engagement.

CMS must ensure that the data produced yields scores that more accurately and consistently represent the quality of care. As outlined in the NQF submission, while the median reliability score was 0.873 for practices with at least 15 clinicians and 18 patients with multiple chronic conditions, reliability ranged from 0.413 to 0.999. The FAH believes that the developer must increase the minimum sample size to a higher number to produce a minimum reliability threshold of sufficient magnitude (e.g., 0.7 or higher).

In addition, only the results from face validity testing were provided during the NQF review. The FAH does not believe that face validity is sufficient to demonstrate that the measure as attributed provides appropriate and evidence-based representations of the care provided by these clinicians. We strongly encourage CMS to validate these measures through additional testing, such as predictive and construct validity, to ensure that application of the measure to each of the accountable units is appropriate and yields scores that are valid and useful prior to its implementation in MIPS.

- Definition of Substantive Changes to a Measure

CMS proposes a list of factors for consideration in determining substantive measure changes that would need to be proposed and identified through notice-and-comment rulemaking. The FAH supports the proposed list of factors that would be used to determine whether a substantive change was made to a measure. We also encourage CMS to consider a substantive change to be any modification to a measure that impacts performance scores that may likely be due to the changes in the measure construct or coding and not actual performance.

**RFI: COVID-19 Vaccination by Clinicians Measure**

CMS requests public comment on a draft measure *SARS-CoV-2 Vaccination by Clinicians* that would assess the percentage of patients aged 18 and over seen for a visit during the measurement period who have ever completed, or reported having completed, a COVID-19 vaccination series.

While the FAH supports the intent of this measure and appreciates the revisions that CMS made in response to the NQF Measures Application Partnership (MAP) review, we urge CMS to consider postponing its inclusion in MIPS until the measure specifications have been finalized and tested and the COVID-19 vaccines have been given full FDA approval, not just for Emergency Use Authorization. The underlying evidence for this measure is still emerging, additional vaccines are in development, methods for addressing measure collection challenges related to anticipated “booster” shots may be required, full approval by the NQF has not yet occurred, and feedback from the field is needed to ensure that this measure reflects the most current knowledge and evidence and can be easily collected and reported.

Additionally, because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions, nor should it be publicly reported until the underlying evidence is stable and feasibility reporting of the measure has occurred for several years. Adopting this measure would require all EHRs to certify this additional clinical quality measure or require clinicians who use eCQMs to add an additional reporting method to meet this requirement. Ultimately, the FAH generally believes that measures that increase the reporting burden and leverage specifications that are not aligned with other measures should be avoided.

### **Changes to CAHPS for MIPS Measure**

CMS previously finalized the replacement of CAHPS for ACOs with CAHPS for MIPS as a required measure for reporting via the APP. While implementing this change, CMS has identified several CAHPS for ACOs survey administration policies as potential additions to CAHPS for MIPS, and requests input on those additions for performance period 2022. The FAH supports the proposed changes to the sampling specifications, inclusion of an Asian language survey as a case-mix adjustor, and the resumption of benchmarking and scoring of the *Access to Specialists* survey summary measure.

### **Cost Performance Category**

#### *New Episode-Based Measures for CY 2022 and Future Performance Periods*

CMS proposes five new episode-based measures for addition to the Cost category measure inventory beginning in performance year 2022. The FAH appreciated CMS' attempts to respond to the MAP conditions on these measures but believes that additional work is still needed to address some of the concerns. For example, none of the measures have yet been endorsed NQF and CMS must begin to further explore the correlations of quality and cost beyond just the overall assessments (e.g., correlations of outliers such as eligible clinicians with high or low cost or quality scores).

CMS also did not adequately answer the MAP's concerns over the actionability of the diabetes and asthma/chronic obstructive pulmonary disease measures and concerns with the potential for overdiagnosis and subsequent gaming of the sepsis measure. For example, we would have anticipated data analyses examining what connections there may or may not be between upstream clinical interventions and downstream costs. Statements on what opportunities are believed to be available for clinicians to act are insufficient. These concerns must be further addressed prior to their implementation in MIPS.

In addition, while CMS has not yet publicly released information on the variation on costs for these measures, data that are available for existing cost measures in MIPS demonstrate that not every measure has significant variation and determinations on costs may be made based on small differences in spending. The FAH reiterates our previous recommendations for CMS to reevaluate the current benchmarking approach for the cost measures where higher cost is associated with lower deciles and points. Lower cost should not automatically achieve higher scores, and we believe that these assumptions are inherently flawed and should not be viewed in isolation, as it could lead to negative unintended consequences, such as misleading clinicians and the public on what constitutes reasonable costs, as well as lead to stinting of care. The FAH recommends that CMS explore alternative ways to analyze costs, such as identification of outliers, and ensure that the costs for these proposed new measures are sufficiently distributed across the deciles used for benchmarking.

### *Reliability and Case Minimum*

The FAH encourages CMS to reexamine the current average reliability threshold of 0.4 it has set for cost measures. CMS must ensure that the data produced yields scores that more accurately and consistently represent the quality of care provided by an individual clinician and practice. As such, the FAH recommends that CMS increase the minimum sample size to a higher number to produce a minimum reliability threshold of sufficient magnitude (e.g., 0.7 or higher). Several of the measures had mean reliability rates at the lowest episode minimums well below a reliability rate of 0.7 at one or both reporting levels (i.e., clinician, practice).

- Identifying Factors for Use in Determining Whether a Cost Measure Change is Substantive

CMS proposes a list of factors for consideration in determining substantive cost measure changes that would need to be proposed and identified through notice-and-comment rulemaking. Similar to our comments on the factors for a substantive change to a quality measure, the FAH supports the list of factors that would be used to determine whether a substantive change was made to a cost measure. We encourage CMS to consider another factor, specifically that a substantive change could be any modification to a measure that impacts performance scores that may likely be due to the changes in the measure construct or coding and not actual performance.

### **Improvement Activities Category**

The FAH supports the changes CMS proposed to the Improvement Activities (IA) category for the 2022 performance period and future years, including revising group reporting requirements for the 50 percent threshold in order to address subgroups, revising the timeframe for IAs nominated during a PHE, revising the required criteria for IA nominations received through the Annual Call for Activities; suspending IAs outside of the rulemaking process when an activity raises possible safety concerns or becomes obsolete; and updating the IA inventory.

### **Promoting Interoperability Performance Category**

#### *Future Query PDMP Measure Direction: Request for Comments*

The FAH supports the proposal to add the Query PDMP measure to the MIPS Promoting Interoperability (PI) category in the future. Regarding the agency's question as to when state PDMPs will be ready to effectively exchange data with provider systems using Health Level 7's Fast Healthcare Interoperability Resources standards (HL7® FHIR®), we offer information shared with us by our membership. The barriers to readiness remain primarily those of interoperability and ease of information exchange across systems and jurisdictions. They have suggested that information exchanges and/or data aggregators may have the capabilities to partially overcome the described barriers, but aggregators are unevenly distributed geographically, and their services are costly, making this strategy infeasible for many providers, especially those that are smaller or in rural locations. We further note that easy and inexpensive access to aggregators potentially could obviate the adoption of FHIR standards as a prerequisite to usable PDMP information exchange. Requiring EHR vendors to build into their products all of

the elements to support Query of PDMP and its interoperability also seems to be a viable strategy. Additionally, MIPS eligible clinicians may be unable to routinely query PDMPs due to varying state requirements and to be unable to integrate PDMPs into their clinical workflows due to PDMP configurations that are not easily accessed by all EHR products.

*Health Information Exchange Objective: Changes to the Provide Patients Electronic Access to Their Health Information Measure*

CMS is proposing to modify this measure to require reporting by MIPS eligible clinicians to ensure that patient health information remains available to the patient indefinitely, using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the hospital's certified electronic health record technology (CEHRT). The requirement would apply beginning with the CY 2022 EHR reporting period and would include all patient health information from encounters on or after January 1, 2016.

The FAH fully supports the principle that patients should have prompt access to their electronic health information with minimal effort. We are concerned, however, about the breadth and depth of this proposed requirement, including the implications of the term "indefinitely" and the retrospective time-period. We disagree with requiring providers to support patient records indefinitely for PEA given that does not match the legal requirement to retain patient records.

For example, the ever-growing volume of information for which each clinician is responsible will likewise require ever-growing resource investments for storage capacity and ongoing essential maintenance by hospital health IT personnel. Further, we note that a similar requirement for other entities (e.g., MA organizations, CHIP managed care entities, Medicaid FFS programs) became effective January 1, 2021, although CMS has announced enforcement discretion for that requirement until July 1, 2021. Therefore, we are quite concerned that CMS, having had little or no hands-on experience with administering this type of patient electronic health information access requirement, now proposes its very broad expansion to clinicians over a very short timeline. The FAH is also troubled by other confounders. For example, the types and amount of stored and potentially retrievable patient data has grown each year. Will clinicians be required to try to backfill what are considered information gaps by current standards for years going back through January 1, 2016? Additionally, states have varying timeframes on which certain information must be maintained and stored, and it is not clear from the rule how CMS will align the state and federal policies in time for the proposed CY 2022 requirement implementation date.

Considering these challenges, the FAH does not support proceeding with the proposed modifications to the *Provide Patients Electronic Access to Their Health Information* measure at this time. We recommend that CMS defer adoption of the modified measure until at least two years of experience has been gained with the analogous MA/Medicaid/CHIP requirement. We also urge CMS to structure the measure initially to allow clinicians to become compliant using an application of the clinician's choice before being required to support any API a patient might choose. Should CMS proceed with modifying this measure, we recommend starting the data availability lookback period on or after January 1, 2019 and providing exceptions for situations

in which clinicians cannot access the historical data (e.g., EHR conversions, ransomware). In addition, the FAH continues to urge CMS to work with other agencies and the private sector to develop a privacy and security framework to ensure patient information is accessed and used in accordance with their expectations by non-HIPAA-covered third-party applications.

### *Revised Information Blocking Attestation*

Starting the CY 2022 EHR reporting period, CMS proposes to streamline the attestation statements associated with the prevention of information blocking, decreasing them from three items to a single item (the current statement 1). The FAH fully supports this change as proposed.

### **Requests for Information (RFIs)**

#### *Request for Information on Additional Objectives Adopting FHIR®- Based API Standards*

CMS states that APIs based on the FHIR® standard could substantively improve health data exchange by consistently providing all users with security, performance, scalability, and structure. For example, the 2015 Edition Cures Update standards-based API criterion could support connections to an HIE that would allow clinicians to satisfy the current rule's proposed PI measure for engagement in bi-directional exchange through an HIE.

Through this RFI, CMS seeks comments about how the measures of the HIE and Public Health and Clinical Data Exchange Objectives of the PIP could be integrated with HL7® FHIR® standard-based API functionality. The FAH commends CMS for its efforts to explore and adopt advances in health IT into the PIP. The ultimate promise of universal interoperability as a lever to move health care delivery and quality forward is unassailable.

The substantial variability in public health reporting requirements across states will not be solved by FHIR-based APIs, nor will the equally variable levels of readiness for state and regional agencies to digest the data hospitals are being mandated to provide. Similarly, lack of alignment between federal, state, tribal, and other public health entities does not have a technical solution. The finite resources available to providers to attempt to meet requirements of CMS, other payers, and governmental entities are already stretched, and how providers can fund the purchases of new hardware, software, and connectivity purchases remains unclear.

In addition, reliable high-speed connectivity remains absent for many rural providers and smaller communities. The FAH recommends that CMS focus time and energy on assessing and improving its own IT profile before requiring providers to embrace additional expensive IT solutions. The IT capabilities of CMS are challenged by current programmatic demands, and the agency must make sure it can meet its obligations to providers in areas such as data submission, measure scoring, and prompt patient-level feedback. We support the agency's pursuit of FHIR®-based APIs that can make CMS IT more reliable, nimble, and user-friendly. While CMS does so, the many health IT-related initiatives underway in the private sector may produce affordable solutions applicable to hospitals and other providers and time should be allotted for such development.

### *Patient Access Outcomes Measure*

The FAH concurs with CMS that better understanding of the patient’s role as an active end-user of EHRs could lead to health information exchange that is more useful to patients in health care decision-making and that is more likely to result in patient activation. The FAH members report that patients continue to use online portals more often than APIs to access their EHRs, perhaps being more trusting about sharing sensitive information with known partners than of third-party API vendors. Patient choice of access method seems likely to be driven by factors such as availability, ease-of-use, patient demographics (e.g., age), health literacy level, and computer/smart phone usage proficiency.

The FAH has previously commented on the tradeoff between patient privacy and broader access to information, particularly by non-HIPAA-covered third-party applications, and continues to urge CMS to work with other agencies and the private sector to develop a privacy and security framework to ensure patient information is accessed and used in accordance with patients’ expectations. Superficial population-wide measures should largely be avoided, such as login frequency or number of messages sent, both of which would be higher for patients with active diseases or conditions and thereby less likely to be meaningful measures of access by younger and healthier patients.

The FAH opposes the concept of requiring providers to track the third-party applications used by patients as burdensome and of unclear value. We recommend that CMS consider settings of care in designing patient electronic access outcome measures; for example, outpatient test results are more likely to be sought electronically by patients whereas inpatients are more likely to expect to hear those results from their clinicians during their inpatient care. Care must be taken to avoid unintended consequences, such as incenting patients to retrieve results from tests that require nuanced interpretations and explanations by clinicians. Finally, we recommend that any PIP measure and/or scoring changes be deferred until patient access choice is more fully explored and understood.

### **MIPS Final Score Methodology**

#### *Quality Measure Benchmarks*

CMS proposes to use actual 2022 performance period data to set 2022 quality measure benchmarks rather than the default historical baseline period, which in this case would be performance year 2020. For future use, CMS also proposes to expand the definition of baseline period by creating a sequence of options to be used for establishing a baseline period.

The FAH continues to encourage CMS to proactively consider the degree to which changes in care delivery as a result of the ongoing PHE directly impact the reliability and validity of much of the data used for the quality measures in MIPS. As a result, The FAH appreciates CMS’ response to the COVID-19 pandemic regarding quality benchmarking for the 2022 performance period and supports the proposed use of actual 2022 performance period data rather than using data from performance year 2020.

We caution CMS on expanding the definitions of baseline periods to 3 years as the FAH does not believe that it adequately addresses the concerns. For example, if a 3-year timeline was used to set benchmarks for performance year 2023, quality benchmarks would then be determined using data from performance year 2020 – the year during which significant disruptions to care occurred and data quality was negatively impacted.

We also remain disappointed that the proposed rule does not address the impact that the pandemic has had on the data used for other measures such as the cost measures and the risk-adjustment lookbacks for the population health administrative claims-based and cost measures, Disruptions to care delivery, transitions to telehealth services, and revisions to the data submission process all potentially compromise the reliability and validity of the data used for these measures and risk adjustment models.

We strongly urge CMS to consider every phase of performance under MIPS that has been, is currently, and will continue to be, impacted by the COVID-19 pandemic to apply consistent standards, and evaluate whether any of the impacted measures should be used for any purpose beyond pay for reporting.

#### *Achievement Point Scoring*

CMS proposes to remove the 3-point floor beginning with performance year 2022, and to award 1 to 10 points for each measure that can be scored reliably. CMS proposes modifications of current scoring policies for measures that cannot be scored reliably. CMS also proposes to add a new scoring category, Class 4 measures, for which it sets a 5-point floor. These are measures in their first two performance periods in the MIPS program and meet the data completeness requirement.

The FAH does not support the proposed removal of the 3-point floor beginning with performance year 2022 or the proposed modifications for measures that cannot be scored reliably. We support the 5-point floor for new measures as it may address one of the current challenges in MIPS participation – incentivizing reporting of measures for which no quality benchmarks are available.

As we mentioned previously, clinicians and groups who participate in MIPS continue to be impacted adversely by the COVID-19 PHE. They are being asked to continue to deliver high quality care during the PHE while also preparing for the proposed implementation of MVPs beginning in performance year 2023 and upcoming shift to digital quality measures by 2025. CMS should not make significant changes to the scoring policies that could negatively affect MIPS participants at this time.

#### *Achievement Points for Topped Out Measures*

CMS proposes an exception for the 2022 performance period for measures with benchmarks that are identified as topped out for 2 or more consecutive years: a measure would be considered topped out were it to be identified as such in the historical baseline-based



benchmarks for the 2021 MIPS performance period and in the performance period-based benchmarks proposed for use in the 2022 performance period.

The FAH supports this proposed exception as it will minimize the risk of MIPS participants being negatively impacted based on data derived during the PHE.

#### *Minimum Case Threshold Requirements*

CMS proposes a policy revision to accommodate measures that require different case minimums to ensure reliable performance scores and therefore the minimum case requirement will exceed 20 cases.

The FAH appreciates CMS's recognition that not all measures can achieve adequate reliability scores using the current minimum requirement of 20 cases. We encourage CMS to reexamine whether this revision should be applied to all quality measures in MIPS; whereby, each measure must be tested, and case minimums are set based on the number of cases needed to achieve the desirable minimum reliability score. Specifically, we believe that the current average reliability threshold of 0.4 is too low and CMS should increase the minimum sample size to a higher number to produce a minimum reliability threshold of sufficient magnitude (e.g., 0.7 or higher). CMS must ensure that the data produced yields scores that more accurately and consistently represent the quality of care provided by an individual clinician and practice and it is not clear that most of the measures have been adequately tested to ensure that they produce acceptable reliability thresholds using the current minimum requirement of 20 cases.

#### **Incentives to Report High Priority Measures**

##### *Incentives to Use CEHRT for Quality Measure Submission*

CMS proposes to discontinue awarding bonus achievement points for reporting more than one high priority quality measure and end-to-end electronic quality measure reporting through CEHRT, beginning with performance year 2022. The FAH opposes the removal of these bonus achievement points considering the COVID-19 PHE, MVP reporting beginning in performance year 2023, and move to digital quality measurement by 2025.

##### *Cost Performance Category*

CMS discusses the challenges encountered in assessing clinician performance on Cost category measures for performance year 2020 due to impacts of the COVID-19 PHE that resulted in the proposed reweighting of the Cost category to zero percent for performance year 2020 (payment year 2022). CMS proposes an addition to deal with similar circumstances. The

FAH strongly supports this policy, that if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score.

### *Promoting Interoperability Performance Category*

FAH also supports the proposal to revise the language to reflect that optional measures are worth 5 or 10 bonus points, as specified by CMS.

### **Final Score Category Weights**

#### *Reweighting the Cost Performance Category*

The FAH strongly agrees that CMS should continue to examine whether external factors should inform your decisions on whether to reweight the cost performance category. Factors such as, the delay between the time CMS can observe trends in claims and when you can test for potential impact on cost measures, the inability to ensure that the data included reflect final claims for all services in episodes, and the limited control providers have over costs, make it unlikely that CMS will be able to adequately capture and reflect the performance of clinicians.

#### *Category Weight Redistribution Policies for Performance Year 2023*

This redistribution of the category weights continues to raise concerns for clinicians, and the FAH does not believe that the proposed 30 percent weight to the cost performance category – particularly for the 2025 payment year – is appropriate. Providers continue to have difficulty understanding what truly comprises their cost category score, fueled by an inadequate and lagging data resulting in feedback that is delayed and makes it impossible to improve performance during the actual performance period. CMS' increases to the cost category weight do not appropriately account for barriers to improvement – from delayed data to limited provider control over costs. Without the ability to review and understand the data, not to mention the need to understand CMS' newly proposed MVPs, clinicians are not equipped to make any changes or adjustments that would improve their score in future years.

The FAH urges CMS to decrease the cost performance category weight – particularly for the 2025 payment year – while CMS works to develop more efficient pathways to communicate cost data so that clinicians can digest and act upon that information in a timely fashion, particularly as it relates to MVPs.

#### *Application for Reweighting for Performance Year 2021*

Given the challenges that continue to plague the health care system, the FAH agrees that MIPS eligible clinicians should be able to apply for category reweighting for performance year 2021 under the Extreme and Uncontrollable Circumstances policy using the hardship applications.

#### *Facility-based Clinician Scoring*

CMS has identified scenarios under which facility-based scoring could result in a lower score for a facility-based clinician or group than other scoring pathways for which the clinician

or group also is eligible. CMS proposes a new facility-based MIPS final scoring policy, beginning with the 2022 MIPS performance year.

The FAH agrees with the approach to allow MIPS quality and cost performance category scores to be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission.

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The FAH appreciates the opportunity to provide comments on CMS' proposed physician fee schedule rule. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

