Charles N. Kahn III
President and CEO

October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: [CMS-1734-P] Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (August 3, 2020)

Dear Administrator Verma:

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 across settings in both urban and rural areas. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Notice of Proposed Rulemaking on the Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use

Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (proposed rule).

II.D. Telehealth and Other Services Involving Communications Technology

Proposed Permanent Coverage of Additional Category 1 Codes

Several conditions must be met for Medicare to make payments for telehealth services under the Physician Fee Schedule (PFS). One condition is that the service must be on the list of Medicare telehealth services. In calendar year (CY) 2003, CMS established a process for adding to and deleting from the list of Medicare telehealth services. Such maintenance of the telehealth services list is critical to ensuring that Medicare beneficiaries have access to a broad range of services that may be furnished safely and effectively via telehealth.

Category 1 services on the telehealth lists are for services that are similar to those specified by statute (office visits, office psychiatry services, consultations). In the 2021 PFS rule, CMS proposes to add nine codes that were temporarily covered during the COVID-19 public health emergency (PHE) to the telehealth services list on a permanent basis. ***The FAH supports the nine services proposed for addition to the Category 1 list of services.*** In addition, the FAH urges CMS to consider three additional codes, noted below, to be added to Category 1 for CY 2021.

- Inpatient hospital care services (99221-99223);
- Observation admission services (99218-99220); and
- Same day inpatient/observation admission and discharge services (99234-99236).

Creation of Category 3 Codes

CMS also proposes creating a new Category 3 list of telehealth services. Services on Category 3 may be provided via telehealth during a PHE through the end of the calendar year in which the PHE ends. ***The FAH supports, with modification, the creation of Category 3 codes as it allows for additional data and evidence to be gathered to demonstrate the appropriateness of furnishing these services via telehealth permanently.***

As noted above, for services added on a Category 3 basis, CMS proposes that they remain on the list of Medicare telehealth services until the end of the calendar year in which the PHE expires. If this policy is finalized and the PHE were to end toward the end of a calendar year, services added on a Category 3 basis would remain on the list of Medicare telehealth services only until December 31 of that year. Such an outcome would not fully achieve CMS's objective of allowing a sufficient period of time for evidence to be collected to support permanent addition to the telehealth services list. ***As such, we recommend that CMS consider a policy where services added to the Medicare telehealth services list on a Category 3 basis expire at the end of the calendar year that follows the year in which the PHE expires.*** This would afford additional

time for data collection that would allow for the study of the efficacy of these services during and after the expiration of the PHE.

The FAH supports CMS's proposal to add 13 services to the list of telehealth services on a Category 3 basis. As part of this proposal, the Agency would temporarily include lower level emergency department visits (99281-99283) on the telehealth services list. Equally important is the inclusion of the higher-level emergency department visits. CPT codes 99284 and 99285 are closely related to the lower level emergency department evaluation codes and should be included under the proposed Category 3. These services (99284-99285) differ from lower level codes only in the complexity of medical decision making required to evaluate a patient's history and medical examination. During a patient visit via telehealth or in person, the physician will not have any ability to have determined in advance if the patient requires a lower or higher level of care. Temporarily including codes 99284 and 99285 on the telehealth service list is consistent with the current proposed code set for inclusion on a Category 3 basis.

Audio Only Services

CMS has appropriately recognized the need for providers to perform evaluation and management (E/M) services remotely, including using telephones and cell phones for audio only services. This is particularly important in rural and underserved areas that do not have access to reliable broadband and for communities that may not have access to smartphones or other video-enabled technology. In these circumstances, telephone visits have been able to supplement care provided during the PHE. ***The FAH appreciates CMS' recognition of the role audio-only E/M services have played during the PHE as well as the Agency's openness to maintaining payment for such services. Moreover, until new audio-only codes are established and valued, we recommend CMS consider covering current audio-only E/M services on a Category 3 basis.***

Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings

The FAH supports CMS' proposal to revise the frequency limitation for nursing facilities and to permit subsequent nursing facility visits to be furnished via telehealth once every 3 days, eliminating the current 30-day frequency limitation. We agree with CMS that it should be left to the provider's discretion to determine the frequency of visits furnished as a Medicare telehealth service, rather than in person depending on the needs of specific patients.

Physical, Occupational, and Speech, Language Therapy (PT, OT, SLP) and Other Providers

During the PHE, CMS specifically allowed communication-based technology services (CBTS) to be billed by licensed clinical social workers (CSWs), clinical psychologists, PTs, OTs, and SLPs. In this proposed rule, CMS proposes to finalize this policy to allow those providers to bill CBTS services within their scope of practice. The FAH strongly supports this proposal. We also recommend that CMS clarify in final rulemaking that facility-based outpatient therapy providers, who have been identified as eligible to furnish and bill these CBTS during the PHE, also are recognized as eligible to furnish and bill these codes on a permanent basis. And finally, in addition to CSWs, we urge CMS to also recognize the important role of licensed professional counselors.

Remote Patient Monitoring

CMS clarifies several requirements surrounding devices used in remote patient monitoring in the proposed rule. The FAH appreciates CMS' comments and clarity provided on remote patient monitoring as outlined in the proposed rule.

Hospitals' and Health Systems' Critical Role in Providing Services via Telehealth

The FAH applauds CMS' efforts to expand access to services delivered via telehealth (under section 1834(m) of the Act) and telemedicine (under other provisions of the Act either under normal or waived rules). During the PHE, CMS has appropriately waived provisions of the statute to allow telehealth to originate from any geographic area (not just rural areas) and patient homes (not just health care sites). In addition, CMS waivers allowing for audio only telehealth services have expanded access to health care services for Medicare beneficiaries by allowing cell phones and other communication technologies that are part of everyday use by many Americans. The agencies' decisive and swift action granted providers the flexibility needed to scale quickly and preserve much needed access to health care services for beneficiaries during this challenging time.

As noted above, CMS has made significant proposals in the 2021 PFS proposed rule that provide a degree of certainty regarding payment for telehealth services following the PHE and sets the stage for additional services to be added for payment under the Medicare telehealth benefit. Unfortunately the Agency makes no mention of either the provision of telehealth or telemedicine services in the CY 2021 hospital outpatient prospective payment system (OPPS) proposed rule, nor does it provide any indication of the glide path for providers or any degree of certainty regarding the provision of hospital-based services via telehealth beyond the PHE.

While the FAH understands that CMS' authority to pay hospitals for telehealth services under section 1834(m) of the Act is limited, we provide the following comments for CMS' consideration for how hospitals can continue to play a significant role in the provision of services beyond the PHE through interactive telecommunications where the patient is located remotely from the hospital. ***We urge the Agency to work with stakeholders on a meaningful transition plan to ensure that beneficiaries experience no disruption in care and hospitals and health systems have time to prepare, absent Congressional action.***

CMS has facilitated the provision of telehealth and telemedicine services through the "hospitals without walls" waivers to allow hospitals to furnish outpatient hospital services to patients in their homes. The hospitals without walls provisions allow a patient home to be provider-based to the hospital. The hospital can either be paid under the OPPS for a clinic -visit when furnishing an outpatient hospital service via an interactive telecommunications system to a patient in their home- or by payment of the telehealth facility fee. Hospitals and health systems quickly expanded their telehealth platforms and utilized various forms of communications technologies to provide these services. We appreciate CMS recognizing these significant and necessary capital costs to the provider furnishing the service by allowing for payment under the OPPS via waivers during the PHE. We believe this is an important principal that must be considered as we think about future payment policy for telehealth services.

Section 1834(m) of the Act does not allow hospitals to receive payment for providing support to physician and non-physician practitioners for furnishing services via the telehealth benefit. It also does not allow hospitals to receive payment via the telehealth benefit (as is occurring currently during the PHE) when services do not require participation of a physician or non-physician practitioner and can be provided solely by hospital staff. Currently, the law limits payment of telehealth services to physicians and non-physician practitioners.

In an interim final rule with comment (IFC) published on May 8, 2020 in the *Federal Register* (85 FR 27562), CMS modified its regulations during the PHE to allow two types of hospital outpatient services to be paid under the OPPS and furnished via an interactive telecommunications system at temporary expansion locations.

The first category of services includes partial hospitalization, therapy, education, and training services. Examples of these services include psychoanalysis, psychotherapy, diabetes self-management training, and medical nutrition therapy. CMS indicates in the IFC that facility staff can effectively furnish these services using telecommunications technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location for the service to be furnished. CMS provides a list of services that meet this description on its website: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers. ***The FAH fully supports adding these services to the telehealth list in the event that Congress adds hospitals to the list of eligible providers that may furnish services via the telehealth benefit.***

The other category of services that may be paid under the OPPS when furnished to a patient that is remote from the hospital includes hospital services accompanying a professional service furnished via telehealth. In these instances, practitioners furnish and bill separately for their professional services indicating the place of service as a Hospital Outpatient Department (HOPD), and the hospital bills separately to be paid for the clinical labor, equipment, overhead, and capital to support the delivery of that professional service.

CMS indicates that when a physician or practitioner who ordinarily practices in the HOPD furnishes a telehealth service to a patient who is located at home, the hospital would provide administrative and clinical support for that service. While CMS did not originally pay under the OPPS for a service in this situation, it later indicated that a clinic visit (G0463) could be paid to the hospital for furnishing this support to the physician.[1]

While the situations described above are for temporary expansion of the hospital to include the patient's home, CMS' policy demonstrates the important role that hospitals play in the provision of services to patients via interactive telecommunications technology. For these reasons, the FAH will continue to advocate for legislative changes that will allow for hospitals and their related services to be considered in future telehealth policy.

As Congress considers legislation to advance telehealth payment policy, the FAH urges CMS to share data and information with policymakers regarding the important role and contribution of hospitals and health systems in delivery of telehealth services beyond those services already

[1] https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

permitted by Congress. Moreover, the FAH urges CMS to continue to allow hospitals to provide and bill for clinic visits (G0463), partial hospitalization services, and therapy, education, and training services for the duration of the PHE.

II.F. Refinements to Values for Certain Services to Reflect Revisions to Payment for Evaluation and Management (E/M) Visits

CMS proposes several significant changes to coding and payment for office/outpatient E/M visits with resulting impacts on payments throughout the Physician Fee Schedule starting January 1, 2021. The agency: 1) proposes changes to E/M coding and documentation policies; 2) proposes increases in payment for E/M visits and analogous services (and decreases in payment for non-E/M visits); and 3) solicits comments regarding the definition and utilization assumption of HCPCS add-on code GPC1X. To account for the increased E/M payments, CMS also proposes a -10.61 percent budget neutrality adjustment, resulting in significant redistributive effects for clinicians. For example, while endocrinology, rheumatology, and family practice would see significant payment increases, other specialties such as radiology, pathology, and physical/occupational therapy would see significant payment decreases.

While the FAH supports the agency's intent to increase payments for primary care providers and other providers who perform predominantly E/M services and/or analogous services, ***the FAH does not support the implementation of such dramatic, redistributive payment policies in 2021. For the reasons outlined below, the FAH urges CMS <u>not</u> to implement these coding and payment policies, including the use of the HCPCS add-on code, until at least CY 2022.*** Following this delay of at least one year, CMS could also consider a phase-in over a period of years, though this could create operational complications for hospitals and clinicians without a clearly defined path for that transition over each year.

In light of the COVID-19 pandemic and the financial and operational stress it has placed on hospitals and physician practices in 2020 and is widely expected to continue well into 2021, the FAH strongly believes that an additional year is needed to enable hospitals and clinicians to implement the coding and documentation changes and prepare for the coming payment changes. In addition, as CMS has done in the past for other policy changes that had large redistributive effects, the CMS could also consider whether a phase-in of the payment changes could limit the impact of the payment decreases in any given year. For instance, in the 2010 PFS final rule (74 FR 61751), CMS indicated "while we did not propose any changes to the methodology in the proposed rule, we are persuaded by commenters that the use of the new PPIS data [practicing physician information survey] has a sufficiently significant impact to warrant the use of such a transition. In light of the comments received and our past practice, we are finalizing a four-year transition (75/25, 50/ 50, 25/75, 0/100) from the current PE [practice expense] RVUs to the PE RVUs developed using the new PPIS data." Most recently, CMS provided a four-year PE transition period in the CY 2019 PFS final rule (83 FR 59474) when transitioning new PE values based on updated supply and equipment pricing from its market-based survey.

The COVID-19 pandemic has impacted every sector of the U.S. health care system and will continue to do so for the remainder of 2020, into 2021, and potentially beyond. Hospitals and clinicians have been on the front line and without emergency funds from Congress and the

Administration earlier this year, many faced closure or curtailment of services to patients. As we head into an uncertain fall and winter – and the confluence of COVID-19 and the annual flu season – now is simply not the time to undertake dramatic changes that place unnecessary burden on hospitals and clinicians, dramatically redistribute payments, and upend contracts between hospitals and their employed and/or contracted clinicians.

As noted above, FAH members believe that at least a year is needed to implement these proposed changes – not the mere 30 days CMS outlines in the proposed rule. These proposed changes result in significant financial and operational issues that require additional time for hospitals to incorporate into its financial systems and legal contracts. And while many of the E/M changes were finalized last year for implementation in 2021, the COVID-19 PHE has disrupted any planning that hospitals would have normally undertaken. Further, CMS has finalized policies in the past for implementation in a future year that is one or more year(s) away but then changed the effective date and/or the policy itself.

As this experience means hospitals can never be sure of planned implementation of a policy CMS adopts until it is actually finalized, hospitals need an additional year to: 1) work with electronic health record (EHR) vendors to update coding and billing software; 2) train clinicians on the new coding and documentation policies, as well as on the appropriate use of the HCPCS add-on code; 3) evaluate – and potentially renegotiate – contracts with clinicians, physician staffing firms, and managed care organizations; and 4) and work through the implications of the HCPCS add-on code on "fair market value" compensation under the Physician Self-Referral Law (Stark Law).

Our hospital members are particularly concerned about the impacts the E/M changes will have on contracts with clinicians, physician staffing firms, and managed care organizations. As you know, most employed and contracted physicians are not guaranteed a base salary, but rather are compensated based on an incentive model – most commonly a specific dollar amount per work relative value unit (wRVU) performed. As such, the significant changes to the wRVUs in the proposed rule will dramatically impact payment to clinicians – in the form of increases for some physicians and large reductions for others – under these contracts. For employed physicians, hospitals need time to correctly model these changes and adjust or amend contracts, if needed. For contracted physicians, hospitals are already being asked by physician staffing firms to fill the expected gap in revenues resulting from these proposed payment changes and will need time to negotiate new and/or updated contracts with these entities. A contract negotiation usually takes months, and hospitals will need to undertake these for a significant number of clinicians and contracted firms. Such an effort is simply impossible between now and the end of 2020, and FAH members anticipate it will take all of 2021. In addition, hospitals need time to evaluate how these proposed changes will impact their managed care contracts, particularly those that are tied to Medicare rates, and undertake the appropriate contract negotiations.

FAH members note that, while hospitals and clinicians rely on EHR software to assist clinicians with appropriate documentation and coding, they are aware of no EHR vendor at this time that has the documentation and coding functionality needed to implement the proposed changes, particularly with regard to the HCPCS add-on code. Without the ability to use the EHR, complying with these documentation and coding changes will need to be done manually,

resulting in additional clinician burden – clearly inconsistent with CMS' original goal motivating these changes to reduce burden associated with selecting an E/M code. As such, additional time is needed for EHR vendors to build the requisite functionality and for hospitals to deploy the software and train clinicians on these new documentation and coding policies.

EHR vendors will also need to update the functionality for the use of the HCPCS add-on code, and hospitals will need to train clinicians on the use of the new code. There is currently significant confusion among hospitals and clinicians and they, as well as EHR vendors, need guidance from CMS regarding the proper use of the code. Such guidance is necessary not only to ensure the requisite software updates and training and avoid potential post-payment reviews, but also to provide hospitals with the ability to model when and how frequently this code will be used. The frequency with which this HCPCS add-on code is billed could have dramatic implications for a clinician's compensation. As such, modeling is vital for hospitals as they look at anticipated payments to their employed and contracted physicians and work through the HCPCS add-on code's implication for "fair market value" compensation under the Stark Law.

The FAH urges CMS not to implement the HCPCS GPC1X add-on code until 2022. As noted above, there are significant concerns about how this code would be billed and the documentation required to support its use. Moving the implementation date to 2022 provides CMS with more time to develop detailed coding and billing guidance and also would significantly cushion the potential decrease to the Medicare PFS conversion factor. The FAH has concerns about the projected utilization CMS has assumed and its implications on a permanent reduction to the Medicare PFS conversion factor. We believe that CMS' assumption that this code would be used for every E/M visit for certain specialties is not sufficiently precise given its significant budgetary implications for 2021 and future years. Providing an additional year before implementation would give CMS more time to develop better projections for this code that considers better coding and billing guidance. The current lack of CMS clarity and transparency in the proposed rule about the implications the HCPCS GPC1X add-on code has on the Medicare PFS conversion factor has made it difficult to appropriately comment on this code.

The FAH notes that if utilization is less than anticipated, CMS will be making a reduction in the conversion factor that will permanently reduce Medicare physician payments. In the past, CMS has significantly overestimated utilization of the transitional care management (TCM) and chronic care management (CCM). In the 2013 PFS final rule (77 FR 68991-68993), CMS applied a budget neutrality adjustment based on 5.7 million claims for TCM with utilization at 75 percent for 99495 and 25 percent for 99496. According to CMS' 2013 utilization crosswalk used to set 2015 PFS rates, TCM had a total utilization of 160,291 or under three percent of CMS' forecast volume.[2] In the 2015 PFS final rule (79 FR 67442), CMS indicates it made a budget neutrality adjustment of -0.06 percent. The utilization crosswalk used for the 2015 PFS indicates that CMS assumed utilization of 4.7 million claims for CCM (CPT 99490). However, actual utilization was only 790,274,[3] or just under 17 percent of CMS' forecast. The FAH urges CMS to be conservative in its estimates of utilization of the add-on code to avoid repeating the same

[2] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1612-FC

[3] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1654-F

experience it has had with TCM and CCM.

II.G. Scope of Practice and Related Issues

The FAH appreciates CMS' proposals regarding Medicare regulations with more restrictive supervision requirements than existing state scope of practice laws or that limit health care professionals from practicing to the full extent of their licenses. More specifically, CMS is proposing policies to provide greater flexibility for supervision and other requirements under its regulations to address the issue. We note that the proposed policies are still subject to state- and facility-specific policies that limit the ability of professionals to perform certain services.

The proposed policies have been in effect during the COVID-19 PHE, and CMS is considering making them permanent after the PHE ends. For example, CMS proposes to permit on a permanent basis: supervision of residents in teaching settings through audio/video real-time communications technology, including when the resident furnishes telehealth services; an expanded primary care exception, including services furnished by residents via telehealth; NPs, CNSs, PAs, and CNMs to supervise diagnostic tests consistent with state law and scope of practice requirements; pharmacists to provide services incident to services (such as medication management services) under the appropriate level of supervision of the billing physician or NPP, consistent with state scope of practice and applicable state law. The FAH commends CMS for its flexibility and supports making these policies permanent. This flexibility would promote patient access to care, especially regarding practitioners in certain communities, as well as provide additional safety for patients who might be compromised by receiving services in a health care facility setting regardless of the COVID-19 PHE.

CMS notes, however, its concern that not all of the policies should become permanent, and the FAH agrees that the proposal to permit resident moonlighting in the inpatient setting should be discontinued (under a glide path, and not a hard stop) after the end of the PHE. We do not believe these services will be necessary at that time for purposes of continued access to care or patient safety.

Finally, the FAH has long supported CMS' flexibility in establishing that any individual authorized to furnish and bill for their professional services may review and verify (sign and date) the medical record for the services they bill; they are not required to re-document notes in the medical record made by other care team members. We further support CMS' clarification in the propose rule that this principle also applies to therapists who bill for therapy services.

II.I. Modifications Related to Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

In the CY 2021 proposed rule, CMS proposes modifications and refinements to the bundled episodes of opioid use disorder (OUD) care furnished by opioid treatment programs (OTPs). CMS is proposing to add overdose education to a beneficiary and/or their family or partner as well as to add opioid antagonist medications such as naloxone and others to be included either in the weekly bundled payments for episodes of care or as add-on payments.

Opioid overdose rates have been shown to decrease in communities where nasal naloxone and overdose education were provided to people at risk for overdose and to nearby bystanders such as friends and family members.[4] ***The FAH supports the proposal to extend the definition of OUD treatment services to include both overdose education and opioid antagonist medications such as naloxone and others approved by the FDA for emergency treatment of known or suspected opioid overdose.*** However, appropriate frequency limits need to be applied to ensure optimal flexibility, thus increasing the odds of positive outcomes. The nature of OUD treatment services is complex, and patients may experience relapses. As such, limiting OTP providers to one add-on code for naloxone every 30 days can be a barrier to adequate treatment. In addition, supporting negative perceptions on the use of agonist medications by setting arbitrarily low frequency limits will additionally serve as a barrier to successful treatment.[5] ***We urge CMS to evaluate the frequency of use of naloxone associated with positive outcomes in order to determine a more flexible frequency limit that will enable positive outcomes.***

The FAH applauds CMS' inclusion of nasal naloxone and auto-injector naloxone as favorable formulations to make available to facilitate layperson use. The use of injectable naloxone has been associated with positive patient outcomes, particularly for patients who relapse and non-compliant patients.[6] ***The FAH supports the inclusion of injectable naloxone in addition to the nasal and auto-injector formulations to provide flexibility of use to providers.***

CMS proposes to use average sales price (ASP)+0 to price the add-on payment for nasal naloxone with respect to acquisition by OPTs**.** ***The FAH disagrees with CMS's continued assertion that the standard (ASP)+6 percent is not necessary for inclusion as part of the weekly bundle due to assumptions regarding how hospitals obtain the drugs from manufacturers.*** The Part B six percent add-on accounts for variability in hospital acquisition costs related to overhead for storing, handling, and administration overhead, which need to be factored into the reimbursement. CMS must recognize and include a factor for overhead and administration of the drug and update the bundle to include the (ASP)+6 percent to reflect hospital costs as CMS has provided no evidence that this drug should be treated differently than other Part B drugs.

CMS also proposes to continue to allow OTPs to furnish periodic assessments using audio-only telephone calls provided all other applicable requirements are met. The use of audio-only telehealth encounters for buprenorphine induction without requiring in-person evaluations or video interface has enabled innovations to meet the needs of this vulnerable population.[7] ***The FAH supports the continued use of and payment for audio-only codes, in particular as applied to behavioral health and substance abuse disorders without the need for an in-person examination***.

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[4] Walley, AY, Xuan Z, Hackman H, et al. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. BMJ 2013.
[5] Howell J, Sheridan D, Bruacht G. Supporting individuals using medications for opioid use disorder in recovery residences: challenges and opportunities for addressing the opioid epidemic. The American Journal of Drug and Alcohol Abuse; 2020 feb;46(3):266-272.
[6] Alteraris L, Edmond MB, Roman PM. Adoption of injectable naltrexone in U.S substance use disorder treatment programs. J Stud Alcohol Drugs. 2015 Jan;76(1):143-51.
[7] Yang, YT, Weintraub, E., Haffajee, RL, Telemedicine's Role in Addressing the Opioid Epidemic. Mayo Clinic Proc. 2018 Sep.

III.A. Clinical Laboratory Fee Schedule (CLFS): Revised Data Reporting Period and Phase-in of Payment Reductions; Comment Solicitation on Payment for Specimen Collection for Covid-19 Tests

Conforming CLFS Regulations to Statutory Changes

The FAH supports CMS' proposal to make conforming regulatory changes that implement the provisions of the Further Consolidated Appropriations Act (FCAA) of 2020 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act that effectively delays reporting of private payor prices and volumes to CMS by applicable labs through March 31, 2022.

Since 2019, CMS has been requiring hospitals to report private payer prices for "non-patient" laboratory services or when the hospital laboratory is acting as a referral laboratory and only performing a laboratory test for a patient that has neither been admitted to the hospital for inpatient services or been registered as a hospital outpatient. Under current law and regulations, hospitals are required to collect private payer prices and volumes for non-patient services (generally those clinical laboratory services billed on a 14x type of bill) for the period January 1, 2019 through June 30, 2019. The FAH reiterates its long-held position that Congress intended to exclude hospital laboratories as applicable laboratories, which was apparent from the statutory language, in particular, the majority of Medicare revenues threshold criterion in section 1834A(a)(2) of the Act, as discussed in the CY 2018 Medicare Physician Fee Schedule proposed rule.

While we appreciate Congress delaying the reporting time frames, we urge CMS to reconsider its position regarding the definition of an applicable laboratory. As outlined in previous comments and consistent with previous CMS impact analyses, we do not believe that reporting by hospital outreach labs will have a material impact on payment rates and remain concerned by the increased personal and administrative costs borne by hospitals. ***During this unprecedented time of economic uncertainty for hospitals, we believe it is critically important for CMS to reexamine this policy and consider that the costs associated with this reporting requirement would be better redirected toward direct patient care. While we appreciate the additional reporting time provided by Congress, we urge CMS to exempt hospital outreach labs from this administratively burdensome reporting requirement.***

Comment Solicitation on Payment for Specimen Collection for COVID-19 Clinical Diagnostic Tests

The FAH supports the additional increased payment for specimen collection of homebound and non-hospital inpatients as we believe it will continue to support labs in their outreach to ensure that as many beneficiaries are tested as possible. Medicare must continue to utilize every tool to ensure that testing remains widespread and support all providers in their outreach. Homebound patients are particularly difficult to reach and while they may be at a lower risk for contracting COVID-19, the risks remain.

III.G. Medicare Shared Savings Program (MSSP)

Quality Performance Standard

The current quality performance standard requires accountable care organizations (ACOs) to meet minimum attainment (defined as 30 percent or the 30th percentile of the performance benchmark for pay-for-performance (P4P) measures) on at least one measure in each domain to be eligible to share in any savings generated. In the CY 2021 proposed rule, CMS proposes that ACOs must achieve a quality performance score "equivalent to the 40th percentile or above across all Merit-Based Incentive Payment System (MIPS) Quality performance category scores." The language used to describe this proposal is so different from the previous standard that the proposal has sparked debate among our members as to its application and makes it difficult to meaningfully comment. Is the achievement of a quality performance score "across all MIPS Quality Performance scores" meant to apply across all domains in the aggregate, or across each individual domain at the 40th percentile? As ACOs prepare for the upcoming year, the FAH urges CMS to clarify its intent.

Pay-for-Reporting

As CMS discussed in the proposed rule, the quality performance standard is based on an ACO's experience in the program rather than its financial track. The quality performance standard is currently defined at the level of full and complete reporting (pay-for-reporting (P4R)) for the first performance year of an ACO's first agreement period under the MSSP. The P4R period in the first year is important to new ACOs entering the MSSP. ***The FAH urges CMS to maintain this P4R year to support fledgling ACOs as they adapt to the program.*** These new ACOs should have the same benefit existing ACOs were provided when they first began.

Beneficiary Assignment – Telehealth

CMS, in response to feedback from ACOs as well as a review of the HCPCS and CPT codes currently recognized for payment under the PFS, proposes to amend the definition of primary care services used in the MSSP assignment methodology. This proposal would include certain additional codes and make other technical changes to the definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. The codes CMS proposes to add include Online Digital Evaluation and Management Services (CPT codes 99421, 99422, and 99423).

The FAH supports this update in light of the COVID-19 pandemic and the resulting changes in care delivery. The use of telehealth has surged in the past year and is likely to remain a much larger part of health care than it was prior to the PHE. ***The FAH commends CMS for expanding primary care services in this way for performance year 2020 and any subsequent performance year that starts during the COVID-19 PHE.***

Quality Scoring – Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs Survey

Under the current MSSP quality scoring methodology, the CAHPS for ACOs survey is counted as ten separate measures. Under the newly proposed Alternative Payment Model (APM) Performance Pathway (APP), the CAHPS for MIPS survey would be counted as one. CMS is proposing that ACOs use the CAHPS for MIPS survey under the APP, beginning in 2021, combining the CAHPS survey into a single measure out of six for quality scoring purposes from the current composition of ten out of 23 quality measures. CMS does not explicitly propose any changes to the methodology of the survey.

The FAH notes that the methodology of the two surveys differ, with the CAHPS for MIPS survey having minimum survey size requirements as a function of the Taxpayer Identification Number (TIN) and the CAHPS for ACOs survey having minimum survey size requirements as a function of the ACO. The FAH requests that CMS be explicit if they intend to make any changes in the survey methodology with this proposal. Shifting the survey size requirement to be based on TINs rather than ACOs will result in substantial financial burden to ACOs.

Quality Measures

Multiple Chronic Condition (MCC) Admissions

The FAH does not support inclusion of the MCC Admissions measure in MSSP due to limited information on how the measure performs and the lack of endorsement by the National Quality Forum (NQF). CMS must ensure that the data produced yields scores that more accurately and consistently represent the quality of care provided by an ACO. As such, the FAH recommends that CMS increase the minimum sample size to produce a minimum reliability threshold of sufficient magnitude (e.g., 0.7 or higher) in light of the reliability range from 0.12 to 1.00 using data from the 2018 performance year. 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 ACOs is appropriate and yields scores that are valid and useful. We also ask that the measure be reviewed and endorsed by the NQF prior to its finalization for MSSP.

Days at Home

The FAH cautions CMS on the development and potential implementation of a measure that examines the rate of days at home for Medicare beneficiaries. This type of measure could be considered the inverse of many of the measures currently included within MSSP, such as the Hospital-Wide, 30-day, All- Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups and the proposed Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs. Because this new measure would present the opposite viewpoint of the time spent in health care facilities, it could be viewed as a form of double

counting. As such, the FAH encourages CMS to reassess the set of measures used for MSSP if and when this measure is ever proposed.

The FAH believes that the recent work by the Medicare Payment Advisory Commission (MedPAC) and the Harvard School of Public health to explore the usefulness of a Healthy Days at Home measure underscores several of the challenges associated with this potential measure.[8] For example, the time that individuals aged 65 years of age and older spent at home ranged from 343.1 to 353.9 days during a 12-month period. While the days at home were slightly lower for those with two or more chronic conditions (minimum: 334.0 and maximum: 348.7) and those with three or more chronic conditions (minimum: 327.5 and maximum: 344.5), these ranges demonstrate minimal variation across 306 markets. The analysis of the number of markets that performed better or worse than the national mean is also useful in understanding the degree to which differences in performance across ACOs could be meaningfully distinguished. Across all Medicare beneficiaries in the sample, their time at home was just under six days, and the best was 5 days greater than the national mean. Those beneficiaries with more complex health needs (3 or more chronic conditions) receiving care in the worst performing market spent 9 days less at home and just under 8 days more in the best performing markets. The researchers also found that there were several socioeconomic factors that would be significantly associated with healthy days at home including but not limited to, median income, percentage below the poverty line, physician and primary care physician density, and acute care hospital beds per 1,000 residents. These findings indicate that this type of measure may not provide sufficient variation to enable assessments of which ACOs are better or worse performers and will likely require inclusion of social risk factors within any risk adjustment.

The FAH encourages CMS to carefully consider whether the measure produces results that are reliable and valid and enables groups to distinguish differences in performance in a meaningful way. The measure must also be first reviewed and endorsed by the NQF prior to its proposal in rulemaking.

III.I. Modifications to Quality Reporting Requirements on the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

The intent of the extreme and uncontrollable circumstances policy is to mitigate any negative impact of such a circumstance on an accountable care organization's (ACO's) quality performance or ability to report quality data to CMS and the resultant effect on financial reconciliation due to emergency circumstances outside of the ACO's control. In recognition of the many ACOs that find themselves operating under extreme and uncontrollable circumstances due to the COVID-19 pandemic, CMS is proposing a change to this policy to encourage quality reporting for performance year 2020.

Rather than assigning the higher of an ACO's own 2020 quality score or the 2020 mean ACO performance score under the current extreme and uncontrollable circumstances policy, CMS proposes an alternative that would apply the higher of an ACO's 2020 quality performance score or its 2019 quality performance score for ACOs that completely report quality data for 2020.

[8] Burke, Laura & Orav, E. & Zheng, Jie & Jha, Ashish. (2019). Healthy Days at home: A novel population-based outcome measure. Healthcare. 8. 100378. 10.1016/j.hjdsi.2019.100378.

ACOs that do not completely and accurately report for performance year 2020 would receive the 2020 ACO mean quality performance score.

The FAH supports encouraging ACOs to report quality data to the extent they are able. However, those who are not able to fully report should not be penalized. As acknowledged by CMS, the COVID-19 pandemic has raised novel issues for patients and providers. While providing an alternative modification for those who are able to submit the data is appreciated, those who are unable to report for reasons beyond their control should receive the benefit of the extreme and uncontrollable circumstances policy.

III.J. Proposal to Remove Selected National Coverage Determinations

In 2013, CMS established procedures for requesting a National Coverage Determination (NCD) or reconsideration of an existing NCD (78 FR 48164). CMS also established an expedited administrative process, using specific criteria, to remove NCDs older than 10 years. Because of the Supreme Court's decision in *Azar v. Allina Health Services*, CMS has decided to use the notice and comment rulemaking procedures described in section 1871(a)(2) of the Act to remove outdated or unnecessary NCDs. The FAH supports CMS using the notice and rulemaking process for consideration of removal of outdated National Coverage Determinations (NCDs).

III.K. Requirement for Electronic Prescribing for a Controlled Substance for a Covered Part D Drug Under a Prescription Drug Plan of an MA-PD Plan

CMS proposes to delay the implementation date for the electronic prescribing of Schedule II, III, IV, or V controlled substances under Medicare Part D from January 1, 2021 to January 1, 2022. While some hospitals and clinicians will be ready to meet the original 2021 implementation date, the FAH recognizes that other prescribers need additional time to undertake the necessary systems upgrades and associated training. As such, the FAH supports CMS' proposal to give prescribers an additional year for implementation, particularly in light of the technological and operational challenges associated with the COVID-19 pandemic.

III.M. Updates to the Certified Electronic Health Record Technology Due to the 21st Century Cures Act Final Rule

CMS proposes to update the certified electronic health record technology (CEHRT) requirements for the Promoting Interoperability Program (PIP) and the QPP to align with the Office of the National Coordinator (ONC) 21st Century Cures Act final rule and subsequent announcement of enforcement discretion. The ONC final rule requires electronic health record (EHR) vendors to meet the new certification requirements by May 2, 2022, and the enforcement discretion announcement pushed that compliance date back three months – to August 2, 2022. In the PFS proposed rule, CMS proposes that, until August 2, 2022, providers may use technology certified to either the 2015 Edition or the 2015 Edition Cures Update; after August 2, 2022, providers must use technology certified to the 2015 Cures Update.

While the FAH appreciates CMS' desire to align the PIP and QPP program timelines with those in the ONC final rule and subsequent enforcement discretion announcement, the proposal does not provide sufficient time for providers to implement the updated technology. For example, if an EHR vendor achieves ONC certification on that last possible day (August 2, 2022), the health care providers using that technology would have a zero-day implementation period. On August 3, 2022, those providers would be out of compliance with CMS requirements through no fault of their own.

The FAH urges CMS to give health care providers one year after the date by which vendors must meet the new certification requirements to begin using the updated technology (e.g., vendor compliance date of August 2, 2022; provider compliance date of August 2, 2023). This one-year period will allow time for health care providers to undertake the significant task of rolling out the updated technology, including staff and clinician training.

IV. Updates to the Quality Payment Program

General Comments

The FAH appreciates CMS' work to build upon the lessons learned during the initial years of the Quality Payment Program (QPP). These efforts are meant to support the continued transition to value based care and participation in the MIPS and Advanced Alternative Payment Models (Advanced APMs). However, the FAH feels strongly that the annual changes, and timing of these changes, continue to challenge individuals and entities working to participate meaningfully in these programs. Each year health care providers cannot truly begin to prepare, or to course correct, for the next performance year until the final regulations are issued. With the final rule being published just months before the changes are implemented – and this year a mere month before – providers are forced to dedicate additional resources to understand and then implement the updates CMS finalizes within weeks. ***With all the health care industry is managing due to COVID-19, the FAH reiterates our ask that CMS opt for a slower pace related to QPP changes so that providers have time to fully implement what have become constantly changing programs.***

As CMS is well aware, the COVID-19 pandemic has placed pressure on the entire health care industry, and hospitals are facing incredible challenges this year – and likely next year as well. Our members continue to make great efforts to ensure that they are providing quality care to the patients in their communities throughout the pandemic. Whether preparing for a possible surge of COVID-19 patients, caring for those patients, or addressing the economic strain of maintaining critical health care services, our members have been significantly impacted by the pandemic. Trying to track and maintain measures for success in a year such as this has proven to be a new and unexpected challenge.

The FAH appreciates CMS' efforts to address the burden of the pandemic such as the changes to the extreme and uncontrollable circumstances policy exception and reduction of the 2023 MIPS payment year performance threshold. However, continuing to move forward with implementation of the MIPS Value Pathways (MVPs), even with CMS' proposed delay, will only increase the burden. ***The FAH once again urges CMS to reconsider MVP implementation***

all together. Particularly in light of the ongoing PHE, we ask that CMS recognize the impact of the pandemic and focus on supporting providers and lessening the burden of their participation in the QPP.

Merit-Based Incentive Payment System

MIPS Value Pathways

In the CY 2020 PFS final rule CMS introduced the concept of MVPs and discussed the agency's intent to progress incrementally toward the use of MVPs by developing subsets of measures and activities established through rulemaking based upon stakeholder input. The FAH's comments emphasized our members' concerns related to this new concept under MIPS, and these concerns remain even with the additional information included in the CY 2021 proposed rule.

CMS intended to begin transitioning to MVPs in the 2021 MIPS performance year; however, due to the COVID-19 pandemic, the proposal for initial MVPs will be delayed until at least the 2022 performance year. ***The FAH appreciates the delay to this significant change when resources are being dedicated to the pandemic and related PHE and agree that MVPs should not be implemented in the 2021 performance year. The FAH further implores CMS not to implement MVPs as part of MIPS at all.*** It remains unclear how the MVPs will be created and implemented in a reasonable and equitable way. If CMS continues to pursue implementation of MVPs, the FAH asks that the MVPs be voluntary, with clinicians retaining the option to participate via the current process in which they have already invested significant time, energy, effort, and funds.

Although CMS presents MVPs as a mechanism to bring greater clarity and ease of participation to stakeholders, the FAH does not believe that the MVPs will provide the simplicity that CMS and many clinicians are seeking from MIPS. Instead, the MVPs represent more changes in an ever-changing program, this time on a much broader scale. CMS noted that the MVP-related proposals this year focus on the collaborative development of MVPs, however, the proposed progression towards MVPs in general causes concern. The FAH sees MVPs as a reversal of much of the work stakeholders have been committed to in order to succeed under MIPS since the beginning of the program.

Based on the information provided by CMS both this year and last, the FAH does not agree that MVPs will decrease clinician burden. The transition to MVPs is a significant overhaul that will not only require additional resources going forward, but also will negate many of the efforts that have been under way for years at the direction of CMS in order to comply with program requirements. For example, hospitals and clinicians have made significant investments in EHRs, including implementing and using EHRs that meet the requirements under meaningful use and the PIP; moving from claims-based measures to electronic clinical quality measures (eCQMs) at CMS' urging; and implementing MIPS. These efforts have been costly for health care providers in terms of time and money. They require significant annual investments to continually update EHRs and other systems to accommodate new government programs and requirements and also require clinician time and participation, including continual education and adaptation to workflow changes.

The FAH is disappointed that CMS is intent on moving forward with a proposal that would reduce the measures available for MIPS-participating clinicians while also backtracking on the progress providers have made transitioning from claims-based measures to eCQMs. Particularly in the midst of the COVID-19 pandemic, it is unrealistic to expect meaningful comments on a proposal under development that will increase the uncertainty so many organizations are currently experiencing. ***As discussed above, while the FAH urges CMS to abandon the MVPs, should the agency move forward, the FAH believes it would be beneficial to clinicians, as well as CMS, if the MVPs were implemented on a voluntary basis.*** Many groups, organizations, and clinicians have found success under the MIPS program as it stands. These participants have worked through the initial years and implemented systems that comply with current requirements and have been able to do so even with the evolving performance standards to date. These participants should be permitted to continue via the path CMS previously established. If others believe that MVPs will provide a better option for successful participation, those stakeholders should be permitted to make use of MVPs on a voluntary basis. This would also provide CMS with the opportunity to view the true impact of MVPs and whether they can be implemented in an effective manner.

Should CMS move forward with the MVPs, the FAH offers additional comments on their development, including the process CMS laid out for submission and evaluation of MVPs and the potential for unintended consequences.

The FAH agrees with the proposed rolling submission of potential MVPs and encourages CMS to create a review system that is nimble, enables representations from all relevant specialties and sub-specialties, and ensures that only those MVPs that drive toward valid representations of value are proposed for inclusion in MIPS. The FAH also agrees that patient participation in the review process contributes a valuable perspective but believes that the proposed set of criteria is lengthy and requires significant refinement. Most of the criteria are subjective and several are duplicative. For example, at least three evaluation questions ask whether the quality measures have sufficient variation or are topped out:

- Are there opportunities to improve the quality of care and value in the area being measured?
- Do the quality measures included in the MVP meet the existing quality measure inclusion criteria? (For example, does the measure demonstrate a performance gap?)
- To the extent feasible, does the MVP avoid including quality measures that are topped out?

The FAH urges CMS to address instances of duplication and work toward a concise set of criteria. The FAH also urges CMS to include a burden question in its evaluation of an MVP to examine whether the inclusion of MVPs will lead to decreased or increased work by clinicians and practices in reporting for MIPS.

The FAH remains unclear regarding the manner in which the responses to the various questions will be evaluated. For example, how will the questions on whether the MVP is comprehensive and understandable by the clinician or group or by patients be applied? If an MVP does not include any patient-reported measures, will it not be selected? Will the MVP not be considered if

the denominators for the quality measures do not have consistent eligible populations across the measures and activities but still fit within the intent of the MVP? If no relevant episode-specific cost measures are available, and the broadly applicable cost measures do not apply, will this mean that MVPs cannot be developed for every participating clinician in MIPS? This last question emphasizes that MVPs will not be applicable or available to all clinicians and groups, further supporting the FAH's belief that, should CMS move forward with MVPs, they should be optional.

The FAH also urges CMS to ensure that the MVP selection process is as open and transparent as possible, allowing any relevant clinician, specialty, or interested party to participate in the evaluation process and provide feedback. The selection 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 through the use of these MVPs. Including measures and activities that are not relevant to those targeted groups will increase burden and hinder rather than advance quality improvement.

Further, the FAH urges CMS not to include administrative claims-based measures in the definition of digital quality measures (dQMs). In the proposed rule, CMS states "3a(1): Over time we intend to provide greater amounts of population health measurement data using administrative claims information while decreasing the amount of clinician reported measurement data used for MIPS." The intent of MIPS should be to facilitate quality improvement that is clinically meaningful, actionable, and timely while also allowing clinicians and groups to participate in a value-based payment program. Actualizing this intent requires increasing numbers of quality measures generated from electronic health records and other electronic sources – a focus that CMS promotes through the PIP, and an emphasis on eCQMs and other activities. Utilizing more measures that rely on administrative claims information runs contrary to the true intent of the program, reverses years of CMS' push toward eCQMs, and will result in a reporting requirement with little to no useful or meaningful data.

APM Performance Pathway (APP)

In addition to MVPs, CMS also proposes a new APM Performance Pathway (APP) in 2021, which is meant to be complementary to MVPs. CMS noted that the APP would be available only to participants in MIPS APMs and may be reported by the individual eligible clinician, group (TIN), or APM Entity. CMS proposes to permit MIPS eligible clinicians who are participants in MIPS APMs to report through the APP at the individual level or to have groups and APM Entities report through the APP on behalf of their constituent MIPS eligible clinicians. ***The FAH suggests that the APM Entity level reporting should be optional to ensure that the eligible clinicians and groups retain control of how their data is reported. The FAH also asks CMS to consider providing additional time before removing the Web Interface reporting option.*** CMS should use this time to answer questions regarding how the remaining reporting options will impact whether ACOs are evaluated on quality metrics for *all* patients versus just those patients assigned to the ACO.

CMS also proposes that the APP would replace the current MIPS APM Scoring Standard and that the Quality performance category would be composed of six measures specifically focused

on population health that would be reported on by all MIPS APM participants. ***While the FAH supports the reduction in the overall number of measures that MIPS APMs must report, we do not support CMS' proposed one-size-fits-all approach to the specific measures.*** For example, the FAH supports reducing the number of measures on which MSSP APMs must report from 23 to 6, but 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.*** For instance, primary care-focused models would report on one, smaller established measure set, while cardiology models would 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. ***In addition, similar to our comments on the MVPs, the FAH urges CMS to make the use of the APP standard voluntary for MIPS APMs.***

The measures selected by CMS in the proposed rule include Quality ID: 134: Preventive Care and Screening: Screening for Depression and Follow-up Plan. The FAH is concerned with the inclusion of this measure as it was previously a pay-for-reporting measure and has not yet been scored. It is unclear how CMS is prepared to accurately evaluate providers on this measure – or provide any sort of benchmark – as part of the APP.

Finally, CMS should coordinate across the various APMs and as it develops the APP. It is vital that the measures CMS selects for the APP "specialty sets" align with those on which Center for Medicare and Medicaid Innovation (CMMI)-developed APMs must report. Without this alignment, APMs other than MSSP models could be in the unfortunate situation of having to report *more* measures than they do currently – the measures they must report as part of their CMMI model requirements as well as the APP measures. Such an outcome would increase rather than minimize burden for participants in these programs.

Performance Thresholds

In recognition of the challenges clinicians and organizations are facing related to the COVID-19 pandemic, CMS proposes changes to the performance threshold for the 2023 MIPS payment year. Rather than the 60 points that was previously finalized, CMS proposes to set the performance threshold at 50 points. The FAH believes that this adjustment is appropriate and appreciates the modification. CMS did not propose any changes to the additional performance threshold of 85 points for exceptional performance, and the FAH agrees with maintaining this threshold.

The FAH is concerned, however, about the ability of clinicians to meet the proposed increased performance thresholds for the 2024 payment year and beyond. Hospitals, clinicians, and groups have invested time and resources over a number of years into EHRs, quality measurement, and performance improvement to successfully participate in MIPS. But even before the COVID-19 pandemic, the FAH was concerned about clinicians being able to meet the ever-escalating performance threshold. And the effects of the COVID-19 pandemic further heighten these concerns. While our members will continue to strive for success under MIPS, this will become significantly more difficult as the threshold increases.

The FAH urges CMS to finalize the proposed performance threshold of 50 points for the 2023 payment year and to consider and utilize all available flexibility when setting the thresholds for the 2024 payment year and future years.

MIPS Categories

Performance Category Weights

CMS proposes to weight the cost performance category at 20 percent and the quality performance category at 40 percent for the 2023 MIPS payment year. In the following payment year, CMS proposes that the cost and quality performance categories would each represent 30 percent of the score.

This redistribution of the category weights continues to raise concerns for clinicians, and the FAH does not believe that the proposed increases to the cost performance category weight – particularly for the 2024 payment year – are appropriate at this time. Providers continue to have difficulty understanding what truly comprises their cost category score, fueled by a lack of – and lagging – data resulting in feedback that is so delayed as to render 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 that was used in the cost score calculation, clinicians are not equipped to make any changes or adjustments that would improve their score in future years. ***The FAH urges CMS not to increase the cost performance category weight – particularly for the 2024 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.***

Quality Category

a. Impact of Changes in Care Delivery

The FAH encourages 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 and cost measures in MIPS. For example, the expansion of telehealth services expands access to care for individuals with complex health and social needs but also presents challenges regarding how care is best provided using this new pathway. Questions such as how to best reach and provide effective care to those individuals with limited digital literacy must be considered. These are substantive changes and will have a downstream effect on the reliability and validity of the quality and cost measures.

b. Benchmarks

The FAH appreciates CMS' response to the COVID-19 pandemic regarding quality benchmarking for the 2019 performance period. Due to the flexibility provided to MIPS eligible clinicians to allow for no data submission for the 2019 performance period, CMS acknowledges that it may not receive a representative sample of data such as would have been possible without

the national PHE for COVID-19. CMS proposes to use performance period benchmarks for the CY 2021 performance period in accordance with § 414.1380(b)(1)(ii), which would mean that benchmarks for the CY 2021 performance period are based on the actual data submitted during the CY 2021 performance period.

The FAH supports this approach for the 2021 performance period benchmark. However, we are disappointed that the proposed rule did not discuss the current year and how this will impact future scoring. The COVID-19 pandemic has presented circumstances beyond a clinician's control such as patients not attending appointments and care being provided via telehealth, among other concerns, which will impact quality metrics. We 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 in order to apply consistent standards.

c. Risk-Adjustment Lookbacks

In addition, the disruptions to care delivery services and data submissions in 2019, 2020, and potentially 2021, administrative claims data used for measurement will also be impacted. CMS relaxed the 2019 reporting requirements due to the pandemic and recommended adjusting the benchmarking methodology to address concerns around the integrity, reliability, and validity of the data. The FAH believes that these data integrity concerns go beyond benchmarking and could also impact the risk adjustment models used in the population health administrative claims-based measures and cost measures. For example, 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. CMS must account for the lookback periods required within many of the risk adjustment models for these measures, as those same disruptions, transitions, and revisions impact how clinical risk factors would be identified and included as variables in risk adjustment. For example, measures that use a 12-month lookback for clinical variables in risk adjustment to identify co-morbidities for measures reported in 2021 will be using data from 2020, which may not be comprehensive.

As such, the FAH encourages CMS to consider the impact of the ongoing PHE on risk-adjustment lookbacks and evaluate whether any of the impacted measures should be used for any purpose beyond pay for reporting.

d. Administrative Claims Measures Performance Periods

The FAH cautions CMS on continuing to include measures that focus on population health as they do not provide actionable, timely, or meaningful data to clinicians or groups. Adding more measures that are far removed from the point of care and also require retrospective timeframes beyond even 12 months further reduces the relevance of MIPS and disincentivizes meaningful participation in the program. The FAH does not believe that measures that require lengthy timeframes to improve their reliability and validity should be included in the program.

e. CAHPS

The FAH opposes the inclusion of a new measure assessing telehealth services within CAHPS until such time that CMS is able to complete robust testing on the questions and impact to the CAHPS. Specifically, the FAH believes that testing on the usefulness and understanding of this new measure and associated questions must be completed to ensure that patients fully understand the new method of care delivery and the effectiveness and appropriateness of telehealth services versus in-person visits. We also ask for clarification on the intent of the question(s) as it is not clear what information will be collected. Will patients be asked whether they received services via telehealth and, if so, will these data be analyzed using administrative claims? If the purpose is to assess digital literacy and understand the degree to which patients believe that the services provided remotely were appropriate and met their needs, then additional education and outreach on telehealth services to patients and testing of the question wording and other psychometric properties must be completed.

The FAH also requests that CMS further examine the impact that the inclusion of telehealth services in the survey solicitation, response rates, and characteristics of the respondents may have on the reliability and validity of CAHPS. CMS must understand the degree to which the survey results are interpretable and meaningful. In addition, it remains unclear whether the inclusion of the telehealth measure is intended to be used in CAHPS scoring and benchmarking performance of clinician groups.

The FAH urges CMS to answer all of these questions prior to implementation of these proposed changes to CAHPS. NQF endorsement should also be achieved.

Improvement Activities

The process for establishing improvement activities was included in the CY 2018 Quality Payment Program final rule where CMS determined the notice-and-comment rulemaking process would be used. In the current proposed rule, CMS proposes to modify two existing improvement activities for the CY 2021 performance period and future years. The FAH would like to highlight once again the challenges encountered by changes that are made by CMS via regulations that are not issued until the end of the year preceding their effective date. The removal of these two improvement activities creates an inconvenience and additional burden for those who may have been planning to include such measures. The timing of this notification does not provide adequate time for those parties impacted by these determinations. We ask that CMS consider this impact and provide additional time to adjust to these changes, perhaps proposing such an edit to improvement activities with a trailing effective date of more than a year.

Promoting Interoperability Program

a. General Comments

The FAH supports CMS' desire to reduce administrative burden associated with the PIP and further align the QPP and PIP and the goals of the CMS and Office of the National Coordinator for Health Information Technology (ONC) final rules under the 21st Century Cures Act.

Hospitals and physicians have been inundated with a myriad of health information technology (HIT)-related upgrades, new implementations (including testing and training), and workflow changes in the last several years and face significant costly and time-consuming changes in the years ahead to comply with these requirements. To truly create alignment between the programs and reduce the administrative burden on health care providers, ***the FAH strongly urges CMS to assess the full breadth and depth of these requirements and view them as a whole rather than as individual programs or policies.*** This includes examining definitions and requirements across the programs and simplifying and removing duplicative or contradictory requirements. It also includes examining effective dates across all the technology-related programs and delaying and/or staggering them where needed to avoid overlap and appropriately account for the time and resources needed for design, build, and implementation.

b. Optional Bidirectional HIE Measure Attestation

CMS proposes a new measure meant to incentivize MIPS eligible clinicians to engage in bi-directional exchange through an HIE. The proposed new measure, Health Information Exchange (HIE) Bi-Directional Exchange measure, would be active beginning with the performance period in 2021. The measure is meant as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. CMS proposes to permit clinicians to report either the two existing measures and associated exclusions or to report the new measure, which would be worth 40 points and would require an attestation.

The FAH seeks clarification from CMS on this high-value action to understand what an attestation response of "yes" means if the vendor is not yet capable of supporting the measure (i.e., the eligible clinician is prepared to implement the measure, but the vendor does not yet support the function). Analogous to the public health measure with a similar attestation, the FAH seeks confirmation that an eligible clinician can attest "yes" to the proposed new measure when the clinician is ready and able to participate in the bidirectional exchange but for a limitation of the vendor.

<u>Scoring - Complex Patient Bonus</u>

In recognition of the impact that COVID-19 has had on patients and providers this year, CMS proposes to continue the complex patient bonus for the 2023 MIPS payment year, and also proposes to modify the complex patient bonus for the 2022 MIPS payment year. The FAH appreciates CMS' efforts to recognize the additional challenges faced by the health care industry as a result of COVID-19 this year by including continuation of the complex patient bonus.

Based on CMS' data analysis from the CY 2020 PFS final rule and the lack of currently available additional data sources, CMS proposes to continue the complex patient bonus as finalized for the 2020 MIPS performance period/2022 MIPS payment year, as well as for the 2021 MIPS performance period/2023 MIPS payment year. CMS also proposes to modify the complex patient bonus for the 2022 MIPS payment year in response to the COVID-19 pandemic to double the calculated score.

The FAH encourages CMS to finalize both of these proposals related to the complex patient bonus and appreciates CMS' acknowledgement of the challenges associated with COVID-19, including increased patient complexity, patients postponing care and/or accessing care in a different way (e.g., via telecommunications), and disruptions to lab results and medications.

Third-Party Intermediaries

Eligible clinicians and groups are able to use a qualified clinical data registry (QCDR), qualified registry, or HIT vendor, or a CMS-approved survey vendor to submit MIPS data on their behalf. These entities provide valuable assistance to many MIPS eligible clinicians and groups in facilitating the communication of information to CMS in the prescribed manner. In addition to the current requirements these entities must meet in order to qualify as third-party intermediaries, CMS proposes to establish specific data validation requirements for QCDRs and qualified registries. CMS is also seeking comments regarding whether HIT vendors and CAHPS survey vendors should perform similar data validation.

FAH members are committed to ensuring the accuracy of data submitted to CMS under MIPS. The proposal, however, seems as though it will increase burden on those third-party intermediaries who are already validating data prior to submission to CMS and who have established a reputation for accurate reporting capabilities related to MIPS. The FAH asks CMS to reconsider the application of these requirements to QCDRs and qualified registries and not to extend this proposal to HIT vendors.

Advanced APMs

CMS continues to strive towards reducing barriers to encourage clinician participation in Advanced APMs. The FAH appreciates CMS' efforts related to Advanced APMs but continues to believe that Advanced APM participation would be impacted positively by increasing the number of models that qualify as Advanced APMs, such as those incorporating post-acute care providers, as well as providing for broader exceptions to the physician self-referral and anti-kickback laws and certain civil monetary penalty provisions.

Removing Prospectively Attributed Beneficiaries

Qualifying APM Participant (QP) determinations are a critical component of participation in Advanced APMs. CMS proposes to add a new provision to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity. This will effectively remove such prospectively attributed beneficiaries from the denominators when calculating threshold scores for APM Entities or individual eligible clinicians in Advanced APMs that align beneficiaries retrospectively. The FAH supports this proposed change to prevent dilution of the threshold score for those entities and individuals and to assist in accurate and fair QP determinations.

Targeted Review

CMS included a proposal to establish a targeted review process for limited circumstances related to QP determinations. This targeted review would provide a systematic opportunity for eligible clinicians to contact CMS with identified clerical errors made by CMS. The agency proposes a process to review the potential issue and make corrections if warranted. Under the proposed targeted review process, an eligible clinician or APM Entity can request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List used for purposes of QP determinations. The proposed targeted review process is drafted to generally align with the MIPS targeted review process.

The FAH agrees with this approach and believes it will help to reduce the likelihood of confusion and burden on eligible clinicians and APM Entities seeking such a review. ***The FAH appreciates the creation of the targeted review process and also urges CMS to expand the potential errors that can be raised via such a process beyond omission from a Participation List.*** Other clerical errors, such as calculation errors can, and likely do, occur. Eligible clinicians should be granted an opportunity for correction if such an error is suspected or known to have occurred due to the potentially very large impact such an error could have for individuals and groups.

APM Incentive Payment Timing

In the proposed rule, CMS discusses operational limitations encountered during the first year of making APM Incentive Payments. CMS notes that it was difficult in certain cases to distribute the payment to a current billing organization associated with the QP according to the current regulations. Challenges arose when QPs were no longer affiliated with the TIN associated with the QP's participation in the APM Entity through which they attained QP status, and when CMS was unable to make the APM Incentive Payment to the TIN listed on the eligible clinician's CMS-588 EFT Application form. In certain circumstances, CMS found it challenging to locate accurate billing organizations for some QPs two years after they earned QP status.

QPs, groups, and APM Entities have been frustrated and challenged by this process as well. Currently, providers participating in Advance APMs are experiencing significant delays in receiving their earned incentive payment, even when they are operating under the same TIN and should be easy to identify for payment. FAH members report waiting one-and-a-half to two years for these funds. For example, they report receiving the 2017 payment at the end of 2019, and they have yet to receive the 2018 payment. It is quite burdensome for hospitals and clinicians to recreate what occurred more than two years ago to ensure the funds are distributed properly. ***The FAH urges CMS to develop a more streamlined and timely payment schedule so that those who achieve QP status under an Advanced APM can receive the incentive payment closer in time to when the payment was achieved and to incentivize continued efforts to remain in the Advanced APM.***

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The FAH appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact me at 202-624-1534, or Erin Richardson, Senior Vice President at erichardson@fah.org or 202-624-1516.

Sincerely,