Charles N. Kahn III
President and CEO

September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

RE: CMS-1784-P; Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments; 89 Fed. Reg. 61,596 (July 31, 2024).

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. 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 to the Centers for Medicare & Medicaid Services (CMS) about the *CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies* proposed rule (Proposed Rule) and provide our comments on specific proposals below.

CY 2025 PFS Ratesetting and Conversion Factor

CMS proposes to cut the calendar year (CY) 2025 Medicare conversion factor by 2.8 percent, to $32.36, as compared to $33.29 in CY 2024, which is a decrease of $0.93 (or 2.80 percent) from the current conversion factor. This reflects the expiration of the 2.93 percent statutory payment increase for CY 2024, along with a zero percent baseline conversion factor update under the *Medicare Access and Children's Health Insurance Program Reauthorization Act* (MACRA), and a .05 percent budget-neutrality adjustment to account for changes in work relative value units for some services. Unfortunately, these cuts coincide with ongoing growth in the cost to practice medicine, which is underscored by the fact that CMS projects a 3.6 percent Medicare Economic Index increase for 2025.

Physicians cannot continue to absorb increasing costs while their payment rates decrease. Both the Medicare Physician Payment Advisory Commission (MedPAC) and Medicare Trustees warned that the growing gap between Medicare physician payment rates and the actual cost of furnishing quality care may result in access to care problems for Medicare beneficiaries. The FAH strongly shares these concerns. **Thus, we urge CMS to support and work with Congress to avert cuts to the conversion factor for CY 2025 and develop a longer-term approach that provides adequate Medicare payment for physicians' services.**

II.D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

CMS discusses that the *Consolidated Appropriations Act* (CAA), 2023, extended Medicare telehealth services to beneficiaries regardless of geographic location or site of service until the end of 2024. CMS further notes that absent congressional action, the geographic location and site of service restrictions on Medicare telehealth services will take effect on January 1, 2025. There are exceptions for behavioral health services and ESRD-related clinical assessments, but otherwise most Medicare telehealth services will be available only to beneficiaries in rural areas and only when the patient is located in certain types of medical settings.

The FAH supports extending Medicare telehealth services regardless of geographic location or site of service beyond December 31, 2024, and urges CMS to work with Congress to ensure enactment of legislation that extends these flexibilities into future years. FAH member hospitals have extensive experience in providing telehealth services to patients at home or in other settings. Based on this experience, we believe that extending these flexibilities is essential for ensuring that patients, including those in rural and under-served areas, have access to care and important clinical benefits in a reasonable timeframe, especially amid workforce shortage challenges.

Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

CMS has previously included frequency restrictions on how often practitioners may furnish a service via Medicare telehealth for certain services on the Medicare Telehealth List, for example, there is a limit of one subsequent hospital care service furnished through telehealth every three days and one critical care consultation service furnished through telehealth per day. However, CMS temporarily removed these frequency restrictions during the COVID-19 public health emergency (PHE or pandemic) and applied enforcement discretion after expiration of the PHE during 2023. Medicare telehealth frequency limitations were suspended for 2024 for Subsequent Inpatient Visits, Critical Care Consultation, as well as other Subsequent Nursing Facility Visits. CMS now proposes to remove frequency limitations for these same codes in 2025. **The FAH supports this CMS proposal since it would extend needed flexibilities and greater access to care for Medicare patients, particularly for inpatient visits and critical care consultation services.**

Audio-Only Communication Technology to Meet the Definition of "Telecommunications System"

In the 2022 Physician Fee Schedule (PFS) final rule, CMS finalized a policy to allow audio-only services under certain circumstances and audio-only equipment for telehealth services furnished to established patients in their homes for the diagnosis, evaluation, or treatment of a mental health disorder (including substance use disorders) if the patient is not capable of, or does not consent to, the use of video technology.

CMS now proposes that an interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system, but the patient is not capable of, or does not consent to, the use of video technology. **The FAH supports this proposal as it would provide needed flexibility for patients.**

Distant Site Requirements

CMS finalizes through 2024 that it would continue to permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. Further, CMS proposes that through 2025 it would continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. **The FAH supports this proposal as we have heard numerous concerns from physicians and other clinicians regarding the need for flexibility to ensure these clinicians' safety and privacy.**

2. Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Direct Supervision via Use of Two-Way Audio/Video Communications Technology

Proposals to Extend Definition of "Direct Supervision" to include Audio-Video Communications Technology through 2025 and to Permanently Define "Direct Supervision" to Include Audio-Video Communications Technology for a Subset of Services

During the PHE, CMS changed the definition of "direct supervision" to allow the supervising professional to be immediately available through a virtual presence. In the 2024 PFS final rule, CMS extended this definition of direct supervision through December 31, 2024, to align the timeframe for the policy with other PHE-related telehealth policies that were extended under the CAA, 2023. Under the proposed rule, CMS would extend this flexibility for all services on a temporary basis only, i.e., CMS is proposing to continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2025.

CMS further, proposes to adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), but only for the following subset of incident-to services:

- Services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and
- Services described by CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional).

CMS proposes an incremental approach whereby it would adopt without any time limitation the definition of direct supervision permitting virtual presence for services that are inherently lower risk: services that do not ordinarily require the presence of the billing practitioner, do not require direction by the supervising practitioner to the same degree as other services furnished under direct supervision, and are not services typically performed directly by the supervising practitioner. For all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, CMS is proposing, as described above, to continue to define "immediate availability" to include real-time audio and visual interactive telecommunications technology only through December 31, 2025.

The FAH supports each of these proposals, however, we believe that "direct supervision" should be permanent for all services. 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.

In addition, 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 supervision via audio visual technology, without the requirement for a new modifier.**

Teaching Physician Billing for Services Involving Residents with Virtual Presence

CMS proposes to continue its current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings when the service is furnished virtually (e.g., a 3-way telehealth visit, with all parties in separate locations) through 2025. CMS discusses that the teaching physician's virtual presence would continue to require real-time observation (not mere availability) and exclude audio-only technology. **The FAH supports this proposal as it creates greater access to care. Further, we agree that teaching physicians have gained clinical experience providing services involving residents with virtual presence during the PHE and can routinely provide sufficient personal and identifiable services to the patient through their virtual presence during the key portion of the Medicare telehealth service.**

Request for Information (RFI) for Teaching Physician Services Furnished under the Primary Care Exception

The primary care exception permits a teaching physician to bill for certain lower and mid-level complexity physicians' services furnished by residents in certain types of residency training settings even when the teaching physician is not present with the resident during the services as long as certain conditions are met, including that:

- The services are furnished by residents with more than six months of training in the approved residency program.

- The teaching physician directs the care of no more than four residents at a time, remains immediately available and has no other responsibilities while directing the care, assumes management responsibility for beneficiaries seen by the residents, ensures that the services furnished are appropriate, and reviews certain elements of the services with each resident during or immediately after each visit.

The FAH appreciates that CMS is considering requests to permanently expand the list of services that can be furnished under the primary care exception and welcomes the opportunity to provide thoughtful comments on specific proposals. We agree that broadening this exception could support primary care workforce development and improve patient continuity of care without compromising patient safety, while increasing access to, and use of, high value services, such as preventive services.

II.H. Certification of Therapy Plans of Care With a Physician or Non-Physician Practitioner (NPP) Order

Payment for Medicare therapy services may be made for outpatient physical therapy, occupational therapy, and speech-language pathology services only if a physician certifies (and recertifies, where such services are furnished over a period of time) that: (a) the services are or were required because the patient needs or needed therapy services; (b) a plan for furnishing such services was established by a physician or qualified therapist providing such services, and is periodically reviewed by the physician; and (c) the services are or were furnished while the individual was under the care of a physician. Further, Medicare regulations require that a physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) who has knowledge of the case sign the initial certification for the patient's plan of treatment.

CMS is now proposing an exception to this signature requirement for purposes of initial certification in cases where a signed and dated order/referral from a physician, NP, PA, or CNS is on file and the therapist has documented evidence that the plan of treatment has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation. **The FAH supports this exception as it will help streamline the initial certification process and reduce burden across the healthcare infrastructure.** When the physician or NPP signs and dates the written order or referral and indicates the type of therapy needed, and that written order or referral is on file in the medical record, this should suffice for the physician or NPP signature for purposes of the initial certification of the patient's plan of treatment.

III.G. Medicare Shared Savings Program (MSSP)

Financial Methodology

CMS proposes modifications to the financial methodologies used under the MSSP. The modifications proposed would encourage participation in the program by removing barriers for accountable care organizations (ACOs) serving underserved communities, as well as provide

greater specificity and clarity on how CMS would perform certain financial calculations in the MSSP. Specifically, CMS proposes to create a health equity benchmark adjustment, to potentially provide an upward adjustment to an ACO's historical benchmark based on the proportion of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS).

We strongly support CMS's proposal to modify the financial methodologies under the MSSP. These proposed changes would play a crucial role in encouraging broader participation, particularly from ACOs serving underserved communities. By addressing existing barriers, CMS's modifications will help create a more inclusive program that benefits those most in need.

Specifically, we commend CMS for proposing the creation of a health equity benchmark adjustment. This adjustment has the potential to significantly benefit ACOs that serve a higher proportion of beneficiaries who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS). Providing an upward adjustment to an ACO's historical benchmark based on the demographics of its patient population would incentivize more equitable care for disadvantaged communities.

Additionally, it is important to acknowledge that the current financial methodology places small and rural hospitals at a disadvantage in certain areas. These hospitals, often serving vulnerable populations, struggle to meet benchmarks that do not account for the unique challenges they face. The FAH believes that implementing the health equity benchmark adjustment could address this inequity and help level the playing field for small and rural hospitals. **The proposed modifications are a positive step toward ensuring that all providers, regardless of size or location, have a fair opportunity to succeed in the program while advancing equitable healthcare for all beneficiaries**.

Proposed Collection Types Available for Shared Savings Program ACOs Reporting the APM Performance Pathway (APP) Plus Quality Measure Set

CMS is proposing to streamline the collection types available for Shared Savings Program ACOs reporting the APP Plus quality measure set to the electronic clinical quality measures (eCQMs) and Medicare CQM collection types for performance year 2025 and subsequent performance years. Specifically, CMS is proposing not to include the Merit-Based Incentive Payment System (MIPS) CQM collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set to focus ACOs' efforts on the implementation of the APP Plus quality measure set, while continuing to encourage the adoption of eCQMs. CMS believes its proposed approach would recognize the investments ACOs have made to report eCQMs and their benefits (that is, more efficient data collection, real time provider feedback, and less burden through the use of digital data) and allow ACOs that have invested in eCQMs to continue on that track and align with long term goals of digital quality measurement.

The FAH respectfully requests that CMS consider delaying the sunsetting of MIPS reporting or, at a minimum, making it optional. The transition from eCQMs to fully digital reporting will require significant financial investments, particularly for healthcare organizations and providers. Many organizations have already made substantial investments to meet the existing MIPS requirements, and shifting to digital quality reporting adds further costs and complexities.

Additionally, there is a necessary ramp-up period when onboarding specialty providers, many of whom are not yet prepared to participate in a MIPS Value Pathways (MVP) framework. The immediate shift risks leaving these providers behind without adequate preparation or support. For providers currently participating in MIPS, transitioning from eCQM reporting can introduce new challenges, as vendors often charge additional fees for these services—fees that providers, particularly smaller practices, are unaccustomed to paying. This introduces a substantial financial burden that must be considered when planning the future reporting requirements.

We also note that CMS is proposing to streamline the collection types available for ACOs reporting the APP Plus quality measure set to eCQM and Medicare CQM collection types starting in the 2025 performance year. Specifically, CMS proposes to exclude the MIPS CQM collection type to focus ACOs' efforts on implementing the APP Plus quality measure set while encouraging eCQM adoption.

While we understand CMS's rationale and agree that eCQMs can offer benefits like more efficient data collection, real-time feedback, and reduced administrative burden, we ask that CMS consider the significant investments required to make this transition, particularly for smaller provider offices. The exclusion of the MIPS CQM collection type may place undue financial and operational strain on organizations that have already made substantial investments in MIPS reporting systems. A more flexible, phased approach would allow organizations to better prepare for the transition without compromising the quality of care or their financial stability.

III.K. Expand Colorectal Cancer Screening

For 2025, CMS proposes to modify its policies on payment for colorectal cancer (CRC) screening services by removing coverage for the barium enema procedure, adding coverage for the computed tomography colonography (CTC) procedure, and expanding the existing definition of a “complete colorectal cancer screening” to include a follow-on screening colonoscopy after a positive Medicare covered blood-based biomarker CRC screening test.

The FAH supports these proposals. The removal of the coverage for the barium enema is appropriate given that the procedure fails to meet modern clinical standards of CRC screenings. The FAH believes coverage for the CTC procedure and inclusion of a blood-based biomarker with a follow-up colonoscopy with a positive test result offers patients increased

flexibility for non-invasive CRC screening services. The FAH appreciates CMS for prioritizing patient experience and safety while modernizing CRC screening options.

III.O. Medicare Parts A and B Overpayment Provisions of the Affordable Care Act

The FAH broadly supports CMS's proposal to apply the False Claims Act standard of "knowing" and "knowingly" to the identification of overpayments and to suspend the report and return deadline during a timely, good-faith investigation of related overpayments. The FAH, however, is concerned that the proposed suspension provision assumes a relatively straightforward investigation of related overpayments and the 180-day proposed period is insufficient for more complicated overpayment investigations**. Therefore, the FAH urges CMS to revise proposed 42 C.F.R. § 401.305(b)(3)(ii) to provide that the deadline is suspended for the entirety of a timely, good-faith investigation to minimize the piecemeal report and return of overpayments.** The 180-day limit proposed in subsection (b)(3)(ii)(B) may be a useful benchmark for many simple overpayment investigations, but it is not uncommon for a good-faith investigation conducted with reasonable diligence to necessitate additional time, particularly where the overpayment issue involves complex factual and legal questions.

The FAH continues to generally support CMS's proposal in the December 2022 Overpayment Proposed Rule to abandon the "reasonable diligence" standard for overpayments under 42 C.F.R. § 401.305(a)(2) and instead apply the statutorily required False Claims Act standard of "knowing" and "knowingly." As noted in the December 2022 Overpayment Proposed Rule, the regulations previously promulgated to implement the overpayment provisions of the Affordable Care Act for purposes of Medicare Part A and Part B (42 C.F.R. §§ 401.301 et seq.) "impermissibly created False Claims Act liability for mere negligence" [1] by adopting a "reasonable diligence" standard. The FAH continues to applaud CMS's acquiescence to the court's ruling and confirmation that a violation of the overpayment statute requires knowing conduct. In comments to the December 2022 Overpayment Proposed Rule, however, the FAH expressed concern that the proposed amendment would call into question the continued applicability of the extraordinarily pragmatic and useful "quantification" element in the identification of overpayments and urged CMS to revise the proposal to expressly incorporate "quantification" as part of the identification process.

The FAH appreciates CMS' consideration of and efforts to address the FAH's and other commenters' concerns regarding removal of the word "quantification" from section 401.305 with new, proposed subsection (b)(3). **The FAH largely supports the proposed suspension of the deadline for reporting and returning an identified overpayment during a timely, good-faith investigation of potential overpayments related to the initially identified overpayment.** Without a suspension period for such an investigation, providers might believe it is necessary to report and return overpayments on a piecemeal basis (e.g., reporting and returning overpayments on specific claims from the probe sample before identifying the full overpayment for related

[1] 87 Fed. Reg. at 79,559 (citing *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140)).

claims)—an outcome that CMS expressly sought to avoid when originally promulgating section 401.305.[2]

As proposed, however, the suspension period for a timely, good faith investigation would include a strict 180-day outer limit, measured from the date of identification of the initial overpayment. Thus, if a timely, good-faith investigation cannot be concluded in that 180-day period, the provider would likely revert to the piecemeal report and return of overpayments, addressing the initially identified overpayments with an initial report and return while continuing its larger investigation and then subsequently reporting and returning any further overpayments that are later identified. Certainly, there are situations where a timely, good-faith investigation can be concluded within 180 days such that the related overpayments can be identified within this time frame and then reported and returned along with the initially identified overpayments. But providers frequently confront circumstances where the underlying facts and circumstances are sufficiently complicated that a reasonable, good-faith investigation would not conclude within 180 days. For example, in some cases the investigation of related overpayments requires complex factual development, including the clinical review of individual medical charts and interviews of staff. These complicated, multi-stage investigations are particularly common for hospitals given the breadth and complexity of their operations. The Proposed Rule does not identify a basis for concluding that 180 days is sufficient for a hospital to investigate and identify related overpayments after the identification of an initial overpayment, and based on member reports, the FAH believes that 180 days is not adequate for the secondary investigation of related overpayments in many cases.

In order to appropriately minimize piecemeal reports and returns of overpayments, the FAH strongly urges CMS to revise proposed 42 C.F.R. § 401.305(b)(3)(ii) to provide for the reasonable suspension of deadlines over the entirety of a timely, good-faith investigation. In the alternative, we request that CMS provide a process for reasonably extending the 180-day period in appropriate circumstances. We agree with CMS that it is appropriate to create a suspension period that "allow[s] time to investigate and calculate overpayments,"[3] and believe that flexibility to go beyond 180 days in appropriate cases is necessary in light of the range of complexity in investigations of related overpayments.

The FAH also requests that CMS confirm that the proposed amendments to section 401.305 would not impose any 6-month or other regulatory clock on the first investigation that results in the identification of an initial overpayment. As the FAH understands the proposed amendments to section 401.305 in the December 2022 Overpayment Proposed Rule and this Proposed Rule, a provider's obligations with respect to an overpayment is triggered by identification of such overpayment, applying a False Claims Act standard rather than a reasonable diligence standard. Thus, the identification of an overpayment would typically occur at the point of actual knowledge of the overpayment. This expressly does away with the six-month "benchmark for timely investigation" that was described in the 2016 Final Rule, and the

[2] Medicare Program; Reporting and Returning of Overpayments, in Medicare Parts A and B, 81 Fed. Reg. 7654, 7,664 (Feb. 12, 2016) (emphasizing that a "provider or supplier should not report and return overpayments on specific claims from the probe sample until the full overpayment is identified," through direct calculation or statistical sampling and extrapolation).
[3] 89 Fed. Reg. at 62,006.

180-day period in proposed section 401.305(b)(3)(ii) would only apply to the investigation of related overpayments, not the investigation that identifies the initial overpayment.

With respect to the investigation of the initial overpayment, the FAH understands, in the absence of deliberate indifference or reckless disregard, identification of an overpayment requires more than credible information or even the factual determination of circumstances that would give rise to overpayments. Because an overpayment is defined as "any funds" that the person received or retained to which the person "is not entitled" under Title XVIII, [4] actual knowledge of an overpayment would not occur until the person has confirmed both the lack of entitlement to the funds (e.g., determined the relevant facts and completed the analysis of whether the claim was payable) and the specific funds at issue (e.g., the dollar amount paid on a claim in excess of the amount to which the provider was entitlement under the Medicare program). Depending on the nature of a particular overpayment, this process might involve factual investigation, legal analysis, and the auditing work necessary to calculate the overpayment amount. [5] For example, a provider that has successfully investigated the relevant facts and flagged suspect claims but has not yet conducted the necessary legal analysis to determine whether or not the provider was actually entitled to the funds paid on the claims (in part or in whole) would not yet have actual knowledge of an overpayment. Thus, the entire process through which a provider initially identifies an overpayment occurs before the start of the 60-day clock or any suspension period under proposed subsection (b)(3).

IV. UPDATES TO THE QUALITY PAYMENT PROGRAM

Quality Payment Program

Transforming the Quality Payment Program (QPP)

CMS seeks feedback on how it can achieve full MIPS MVP adoption and subgroup participation in anticipation of sunsetting traditional MIPS potentially in the 2029 performance year/2031 MIPS payment year. CMS also requests feedback on whether it should consider a maximum subgroup size based on the number of clinicians within a tax identification number (TIN) and what approaches would encourage multispecialty groups to report more than on MVP.

Due to the lack of any meaningful changes to the QPP and specifically the MVP structure and scope based on ongoing feedback from the FAH and others, we reiterate our comments that we provided on the request for feedback from the last proposed rulemaking process. **We continue to urge CMS to focus on ensuring program stability and increasing the meaningfulness of existing requirements.** MIPS reporting continues to be extremely burdensome with little to no direct link to directly improving patient outcomes. As a result, we caution CMS on moving too quickly on requirements around subgroup reporting, particularly

[4] 42 C.F.R. § 401.303.
[5] 81 Fed. Reg. at 7,661 (expressing agreement with commenters emphasizing "the difference between determining that an overpayment has been received and the auditing work necessary to calculate the overpayment amount").

since MVP reporting is still relatively new and the program continues to be extremely burdensome and complex.

As we stated previously, we do not believe that the current design of MVPs reduces burden and complexity and allows clinicians to make meaningful connections across measures and activities. MVPs must serve as the "glidepath" to 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 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 anticipated shift to digital quality measures.

CMS must streamline the processes and reporting requirements so that clinicians can focus on patient care. CMS continues to finalize revisions to each of the performance categories every year in a timeframe that allows little time for practices to dedicate additional resources to understand and then implement the updates. This process contributes to a seemingly constant state of change, and it creates fatigue and frustration for clinicians. We urge CMS to reduce the complexity of this program and allow participants sufficient time to adjust to report of MVPs before any additional requirements are added or the sunsetting of traditional MIPS.

APM Performance Pathway

Establishment of APP Plus Quality Measure Set to Align with the Universal Foundation

CMS proposes to establish the APP Plus quality measure set within the APP to incorporate all of the Adult Universal Foundation measures. An additional five measures would be incrementally added beginning with the 2025 performance period with all Universal Foundation measures included by the 2028 performance period.

While the FAH supports alignment with the Universal Foundation measures, we urge CMS to consider whether the creation of APP Plus is premature, particularly as the Web Interface and MIPS CQM reporting options are proposed for removal. ACOs have

been asked to be responsive to a series of significant changes regarding what must be reported for MSSP over the last few years, and they need more time before CMS adds any additional quality measures. In addition, not every measure that would be added to the APP Plus set is specified and tested across the available reporting options. Only two of the measures (Colorectal Cancer Screening and Breast Cancer Screening) are available as both an eCQM and MIPS CQM. While we are aware of the development of an eCQM for the Screening for Social Drivers of Health (SDOH) measure, based on the drafts released for public comment, this eCQM will be broadened to include an intervention and specified differently than the existing MIPS CQM version. As a result, CMS must release information on their plans to make both versions available for ACO reporting, including how the specifications will be developed and tested and whether that version will be reviewed during an upcoming Pre-rulemaking Review cycle.

We also urge CMS to evaluate whether the expansion of these additional measures should be finalized, particularly given the increased complexity of some of the measures. While at a high-level review, it appears that CMS is only adding five measures over the next four years, several evaluate multiple components, which increases the data collection burden and reporting. For example, the Screening for SDOH measure requires evaluation of four very different social needs and the Adult Immunization Status measure would require ACOs to report performance on four vaccines with varying age ranges.

Guiding Principles for Patient-Reported Outcome (PRO) Measures (PROMs) in Federal Models, and Quality Reporting and Payment Programs RFI

While we understand that CMS seeks to increase the number of measures that leverage patient-reported information in their programs and models and do not generally disagree with the principles proposed in this RFI, it remains unclear how they will create a meaningful pathway to achieve the implementation and use of PROMs and PRO performance measures (PRO-PMs) without additional burden and costs to practices, health systems and others. We believe many of these principles are already addressed in current requirements for a measure to be included in CMS quality programs, including reliability and validity testing, feasibility of implementation without unnecessary costs or implementation burden, and patient engagement in measure development.

This RFI also mentions that it is important to have a data infrastructure that "allows PROMs and PRO-PMs to be integrated into clinical workflow with minimal cost and administrative burden, with data seamlessly shared across different healthcare settings and systems." Other efforts including CMS's Digital Quality Measure (dQM) Roadmap[6] seek to ensure that all measures including PRO-PMs are deployed using interoperable data standards. As a result, what additional value these principles provide is not clear and we question if they will further ensure that the PRO-PMs selected by CMS have minimal burden to implement and report and result in data that can inform patient decision making and assist clinicians in their quality improvement efforts.

[6] https://ecqi.healthit.gov/dqm?qt-tabs_dqm=dqm-strategic-roadmap

Perhaps more importantly, the FAH advised CMS on the multiple barriers that hospitals currently face with the existing PRO-PM Following an Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in our comments on this year's IPPS proposed rule. **On review of the principles and topics addressed in this RFI, we urge CMS to spend further time examining the challenges identified through the recent implementation of the hospital THA/TKA PRO-PM and propose solutions that will collectively move us toward the capture and reporting of these important data with minimal burden.** We believe that CMS's efforts are better spent addressing these important questions rather than focusing on activities such as "the development of an accessible and unified database of PROMs/PRO-PMs."

The FAH supports efforts to continue to bring the patient voice into measurement efforts but urges CMS to focus their efforts on how to thoughtfully approach some of the potential unintended consequences that may be encountered with increased use of PRO-PMs. Each PROM and resulting PRO-PM requires careful evaluation by practices and others on whether the survey or its results should be captured within an electronic health record system (EHR) or if another source should be leveraged. Even with the increased use of interoperable data standards, these tools and resulting performance measures require mapping of data within the EHRs and potentially with other external databases or systems.

Practices must also spend significant time determining clinical workflows to optimize data capture and build quality improvement activities to ensure that the resulting information can be used to improve patient care. In addition, the potential for patient fatigue when asked to complete one or more surveys during every encounter and across healthcare settings is a real concern and CMS, practices, health systems, and others must identify strategies to ensure that we are prioritizing the collection of data that are most useful to inform clinical care and patient decision making rather than trying to measure everything. The potential unintended consequence of a broad, rather than selective, approach to selecting and implementing PRO-PMs is not adequately prioritized in CMS quality programs.

We urge CMS to focus on creating a process that encourages evaluations of potential PRO-PMs based on strong clinical input and patient perspectives balanced with realistic assessments on whether the value of the PRO (regardless of whether it is broad or condition-specific) outweighs the burden of data collection and reporting. This approach will lead to thoughtful and meaningful selection of PROM and associated PRO-PMs.

MIPS Payment Adjustments

CMS proposes to determine the performance threshold for the 2025 performance period/2027 MIPS payment year by using the mean of the final scores from the 2017 performance period, resulting in maintaining the performance threshold at 75 points.

The FAH supports maintaining the performance threshold at 75 points and encourages CMS to pause any increases until the MIPS program demonstrates more predictability and stability in the category requirements and resulting scores.

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The FAH appreciates the opportunity to submit these comments on these important issues to providers and patients. If you have any questions, please contact me or any member of my staff at (202) 624-1500.

Sincerely,