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President and CEO

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Via electronic submission

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

RE: CMS-1832-P; Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; 90 Fed. Reg. 32,352 (July 16, 2025).

Dear Dr. Oz:

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 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies proposed rule and our comments on specific proposals are discussed below.

II. Provisions of the Proposed Rule for the PFS

B. Determination of Practice Expense (PE) Relative Value Units (RVUs)

5.c. Updates to Practice Expense Methodology – Site of Service Payment Differential

CMS proposes to refine its methodology to change how indirect costs are allocated to services furnished to a facility setting in its PE methodology. Specifically, CMS proposes to reduce the portion of facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs beginning in 2026. The proposal creates large redistributive effects from services provided in facility-based settings to office-based settings which, in turn, results in a disproportionate impact on physician specialties that provide most of their services in the facility-based setting, including many surgical specialties, such as neurosurgery, cardiac surgery, general surgery, orthopedic surgery, and thoracic surgery.

The FAH urges CMS to withdraw this policy proposal. CMS has not provided sufficient data and justification to support this arbitrary 50 percent reduction in physician work as a means to allocate indirect costs to facility-based services within its PE RVU methodology. For example, CMS has not provided specialty-specific data on the costs to maintain an office-based practice or how the proportion of physicians employed or contracted by a hospital varies from physicians that own their own practices. We are concerned that implementing such a broad and untargeted redistribution would have unintended consequences, including impacting hospitals' ability to contract with certain physician specialty groups to maintain sufficient coverage and access for Medicare beneficiaries. In addition, the proposed efficiency adjustment to work RVUs arbitrarily exacerbates the negative impacts of this proposal on facility-based providers as the PE methodology allocates indirect costs based in part on work RVUs. We also note that these proposals are being made in the midst of increasing physician costs, for example, labor costs and regulatory compliance (e.g., electronic health records, interoperability, cybersecurity).

The FAH recommends that CMS develop additional data that would identify a more precise set of service differences in the allocation of PE RVUs among facility and non-facility settings, and then develop more effective and more targeted alternatives that take into account other overlapping proposals, such as the efficiency adjustment.

If CMS proceeds to finalize this proposed policy, the FAH recommends that CMS, at a minimum, phase-in this change over four years, consistent with similar phase-in policies for new practice cost data, to allow the health care market to adjust and mitigate unintended consequences given the significant redistributive effects observed among specialties in CMS's regulatory impact table. This phase in also would allow the necessary time to amend and re-negotiate contracts currently in place between hospitals and physicians to ensure continuity in access to care for beneficiaries.

6. Payment for Services in Urgent Care Centers

In the CY 2025 PFS proposed rule, CMS sought public comment on how urgent care centers (UCCs) could serve as an appropriate setting to treat patients with non-emergent urgent care needs, and how UCCs could play a role in addressing some of the capacity issues confronting many emergency departments (EDs). In this rule, CMS follows up on that comment solicitation by requesting further input on whether separate coding and payment would be needed to advance this objective. CMS specifically references the possibility of a new add-on code and a new place of service code to differentiate between UCCs that more closely resemble a physician office and "enhanced" UCCs that have more advanced capabilities and more extensive operating hours.

The FAH is pleased that CMS continues to be interested in exploring ways to improve system capacity and workforce issues broadly, and that CMS is specifically looking at how UCCs can help address these challenges. We believe that CMS should establish payment policies that incentivize the creation of enhanced UCCs to provide Medicare beneficiaries with more and better access to clinician services for urgent but non-emergent needs in settings outside of both EDs and physician offices. By bridging the gap between these settings, enhanced UCCs can alleviate system capacity constraints, reduce avoidable ED visits, and offer a timely, cost-effective alternative for patients who require same-day attention.

As CMS references, services delivered in enhanced UCCs are paid at the same rate as services provided in other non-facility settings, such as physician offices. Current codes do not adequately capture the additional complexity of the clinical work inherent in enhanced UCC visits or the additional practice expense costs associated with enhanced diagnostics capabilities and extended operating hours. This level of preparedness

requires substantially greater investment in staffing, onsite equipment, technology and infrastructure than is typically required in non-facility settings, such as physician offices and walk-in retail clinics. These investments, rather than discrete services, are what enable enhanced UCCs to consistently deliver care at high quality.

Therefore, we urge CMS to take steps necessary – including payment policy changes such as an add-on code – that would appropriately recognize the additional cognitive effort and higher practice expense associated with enhanced UCC visits and that would help support these centers going forward.

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

1.d. 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, during the COVID-19 public health emergency (PHE), through CMS’s *Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* interim final rule (COVID-19 IFC),¹ CMS temporarily removed frequency restrictions on how often physicians and other practitioners may furnish an approved service via telehealth. Although frequency limitations resumed on May 12, 2023 (upon expiration of the PHE), these Medicare telehealth frequency limitations were suspended for CY 2025 for Subsequent Inpatient Visits, Critical Care Consultation, as well as other Subsequent Nursing Facility Visits. CMS now proposes to permanently remove frequency limitations on how often practitioners may furnish certain services via Medicare telehealth. **The FAH strongly supports implementing this measure and believes, as CMS notes, that physicians and practitioners have the greatest familiarity and insight into the needs of individual beneficiaries and can use their professional judgement to determine if a service may be safely furnished via telehealth.**

FAH member hospitals extensively provided services to patients at home during, and subsequent to, the PHE and have demonstrated the ability of providers to determine the appropriate service modality given the entirety of the circumstance. Removing frequency limitations will significantly enhance continuity of care for clinicians who manage patient populations, especially those in rural areas or those with limited mobility, chronic diseases, or other limitations to reaching a practitioner for an in-person visit. **We commend CMS for recognizing the value of telehealth beyond the PHE in these proposed provisions and appreciate CMS’s proposals to continue to advance the use of telehealth in Medicare.**

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

a. Direct Supervision via Use of Two-way Audio/Video Communications Technology

In the COVID-19 IFC, CMS amended the definition of “direct supervision” to incorporate that the presence of the practitioner necessary for direct supervision may include virtual presence through audio/video real-time communications technology through the duration of the PHE. In the CY 2025 PFS final rule, CMS revised the regulation at § 410.26(a)(2) to extend the inclusion of virtual presence of a supervising practitioner through audio/video real-time communications technology (excluding audio-only) only for

¹ 85 *Fed. Reg.* 19,230 (April 6, 2020).

certain “incident to” services. CMS now proposes to build upon this approach and permanently adopt a definition of direct supervision that allows “immediate availability” of the supervising practitioner using audio/video real-time communications technology (excluding audio-only) for all services (described under § 410.26 and § 410.32), except for services that have a global surgery indicator of 010 or 090. CMS notes in the proposed rule that because the definition of direct supervision applicable to cardiac, pulmonary, and intensive cardiac rehabilitation services relies on the definition of direct supervision set forth at § 410.32(b)(3)(ii), the definition of direct supervision for these services would similarly be modified to include virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator. **The FAH appreciates and supports this proposal, as it would permit greater access to these services, especially amid ongoing workforce shortages.**

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 transfer 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, we urge CMS not to impose 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.

E. Valuation of Specific Codes

4. Valuation of Specific Codes for CY 2026

24. Use of the Relationship Between OPPS APC Relative Weights To Establish PE RVUs for Radiation Oncology Treatment Delivery (CPT Codes 77387, 77402, 77407, 77412, and 77417), Superficial Radiation Treatment (CPT Codes 77X05, 77X07, 77X08, and 77X09), and Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

For several kinds of PFS services, CMS proposes to deviate from the use of the AMA survey data, and instead utilize data from auditable, routinely updated hospital data to either set relative or absolute rates, especially for technical services paid under the PFS. For CY 2026, CMS proposes to:

- Use the relationship between OPPS ambulatory payment classification (APC) payment rates to establish PE RVUs for radiation oncology treatment delivery and superficial radiation therapy services.
- Use OPPS cost data to establish the value for the PE portion of remote physiologic monitoring and remote therapeutic monitoring services.
- Use hospital outpatient utilization patterns to set payment rates for three categories of skin substitutes. (Note the FAH comments specific to the proposal on skin substitutes under Section II.K. of this comment letter.)

Although the FAH appreciates CMS’s focus on maintaining the accuracy of these codes, we oppose the use of OPPS data in establishing relative values for the PFS. Under current law,² to establish practice expense RVUs, CMS is required to: (1) utilize, to the maximum extent practicable, generally accepted cost accounting principles which recognize all staff, equipment, supplies and expenses, not just those which can be tied to specific procedures, and use actual data on equipment utilization and other key assumptions; and (2) consult with organizations representing physicians regarding methodology. CMS’s proposal to use hospital OPPS data in establishing RVUs under the PFS is not consistent with existing law.

Further, the use of hospital data as a proxy for PEs incurred in the provision of physicians’ services will distort the relative values among the services furnished under the PFS. Specifically, hospital outpatient data is unlikely to accurately reflect the relative resource costs involved in furnishing physicians’ services, especially without examining such data. In fact, significantly different methodologies and data sources are used in PFS and OPPS rate-setting. For example, the PFS methodology for establishing PE RVUs takes a granular “bottom up” approach and examines the line-item costs associated with performing a service paid under the PFS. By contrast, OPPS payments are calculated based on the geometric mean cost of services in the same APC. **Thus, we encourage CMS to withdraw this proposal and ensure that physician PEs are relevant to the costs that physicians actually incur in providing these services.**

K. Payment of Skin Substitutes

CMS proposes to pay for skin substitutes as separately payable supplies under the PFS when used during a covered application procedure. It proposes to pay for these items as “incident to” supplies as they are an integral, although incidental, part of the physician’s professional services. CMS also proposes a single payment rate per square centimeter (\$125.38 cm²) using a volume-weighted average sales price (ASP) methodology that would apply regardless of product or payment category based on its Food and Drug Administration (FDA) approval. These proposed changes would result in significant reductions in the amount paid for skin substitutes as CMS estimates savings of about \$9 billion, a 90 percent reduction in spending relative to the status quo.

While the FAH recognizes that CMS’s intent is to address some of the significant Medicare spending increases and usage of skin substitute products with limited clinical evidence, **CMS’s proposed payment reductions are too drastic and arbitrary, and could stymie long-term innovation in wound care technologies and their application in non-traditional clinical applications.** In addition, the FAH is concerned that these drastic one-size fits all payment reductions could have unintended consequences on applications where these skin substitute products are essential in the treatment of Medicare beneficiaries, such as in burn care units within hospitals and other advanced wound care settings. Without a prudent and cautious approach, the FAH is concerned that significant market disruption could result from these payment reductions and could inadvertently lead to reduced beneficiary access to these products and potentially

² See Section 4505 of the Balanced Budget Act of 1997.

negative patient outcomes such as an increase in infections, and in the most serious cases, even amputations. **The FAH urges CMS to focus on more targeted, alternative approaches that provide appropriate payment for skin substitutes for certain clinical indications, such as in burn care units, where this type of wound care is critical for better patient outcomes.**

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

2. Average Sales Price: Price Concessions and Bona Fide Service Fees

CMS is proposing new policies and guidance relating to bona fide service fees (BFSFs) and price concessions in terms of how they affect the calculation of a manufacturer's ASP. For example, CMS proposes:

- New regulatory language to specify when certain fees are presumed to be price concessions to be deducted from the calculation of ASP unless the manufacturer determines such fees to be fair market value (FMV) using a cost-based approach which may be further validated with market-based data.
- Revising the definition of BFSFs by (1) specifying the methodology that should be used to determine FMV and the time period after which manufacturers should reassess the FMV; and (2) further explaining what CMS considers to be sufficient evidence of whether or not a fee is passed on in whole or in part to an affiliate, client, or customer of an entity.
- In the absence of specific guidance, manufacturers would be required to submit any reasonable assumptions they utilize for manufacturer's ASP calculations (which is currently voluntary), including documentation of the methodology used to determine FMV and periodic reviews of FMV.
- Manufacturers also would be required to submit a warranty or certification from the recipient of the fee that it is not passed on in whole or in part to an affiliate, client, or customer of an entity.
- Non-exhaustive examples of fees that CMS considers to be price concessions and not BFSFs. For example, CMS proposes that a manufacturer payment to an entity for tissue procurement would not be considered a BFSF since CMS believes this is an integral part of the manufacturing process for autologous cell-based immunotherapy or gene therapy and should be included in the price of the product.

Whether a fee is considered a price concession or a BFSF will have a material impact on ASP, which in turn affects payment for drugs. Thus, the above proposals substantially modify the calculation of ASP, which is a very complex formula. Material changes to the ASP, such as these proposals, threaten to disrupt the entire drug supply chain – a highly complex ecosystem including many entities affected by changes to ASP, for example, manufacturers, group purchasing organizations (GPOs), distributors and wholesalers, payers, healthcare providers, including hospitals, and Medicare beneficiaries and other patients. This disruption, in turn, will affect the delivery and availability of drugs, including life-saving drugs, to Medicare beneficiaries, especially in a hospital setting.

The FAH has many concerns about these proposals. For example, it is not clear from the discussion in the proposed rule why certain fees would no longer be considered BFSFs and instead would be considered price concessions. In addition, while certain fees may be considered price concessions and therefore reduce ASP, many price concessions are not passed onto the end user, such as providers. Those providers are paid for that drug based on ASP, which means they often experience a loss in payment by reason of the ASP calculation methodology and the exclusion of price concessions and the treatment of certain costs not considered BFSFs.

If providers continue to sustain losses under changing ASP calculations, especially for complex and resource-intensive services, for example, Chimeric antigen receptor T-cell (CAR– T) therapy and other similar services, providers may not have the capacity to continue to provide these services to patients. This would result in a potentially severe reduction in Medicare beneficiary access to life-saving services.

The proposed policy changes to the calculation of ASP and the treatment of BFSFs and price concessions could cause a major disruption to the supply chain. The changes also would threaten beneficiary access to care. Further in-depth analysis and careful review of these proposals is critical. **Therefore, instead of finalizing these proposals, we urge CMS to work with providers and other stakeholders to better understand the incentives and impact of price concessions and BFSFs on the calculation of ASP. We recommend establishing a technical advisory panel that includes representatives of stakeholders, including providers and beneficiaries among others, to provide recommendations to the Secretary on the impact of the policy changes proposed in the rule. The Secretary could then reconsider these issues after receiving those recommendations along with stakeholder input if appropriate.**

4. Payment for Chimeric antigen receptor T-cell Services (CPT code 38228)

In May 2023, the AMA CPT Editorial Panel approved the addition of four new codes to report CAR-T Services, in place of the then existing Category III codes, added a new subsection with guidelines in the CPT book. These codes describe steps of a complex process that involves physicians either performing or supervising the service.

The RUC forwarded recommendations for CMS’s consideration for CY 2025 and CMS shared these in the CY 2025 OPSS Proposed Rule. Specifically for CPT code 38228 for the administration of autologous CAR-T, CMS finalized active pricing for CY 2025 by assigning a work RVU of 3.00 and the RUC direct PE inputs for purposes of physician payment. However, CMS assigned in the final rule files released for CY 2025 a PC/TC indicator in the MPFS RVU file of “5” (“incident to”) for CPT code 38228 – indicating that this code is non-payable for physicians provided when in a facility.

Notably, CMS previously provided separate payment for the predecessor Category III CPT code 0540T under carrier pricing regardless of whether administration was performed in a facility or non-facility setting. Additionally, the predecessor code had a PC/TC indicator of “9”, which recognizes payment for the service for facility-based physicians.

We do not agree with CMS’s approach since CPT Code 38228 is not an “incident to” service. Given that the majority of CAR-T is provided in the facility setting, and primarily to hospital inpatients, we disagree with CMS’s non-payment approach when these services are provided in a facility. The physician personally supervises the initiation of the product infusion and is present for the first 15 to 30 minutes. The physician remains immediately available to manage toxicities and complications that occur during the infusion and evaluates the patient at the end of the infusion.

Accordingly, we urge CMS to update the PC/TC indicator for CPT Code 38228 from a “5” to a “0” (physician service codes) to capture the nature of the service and align even better with other similar services (e.g., 38240, 38241, 38242), for example bone marrow disorders.

C. Ambulatory Specialty Model (ASM)

CMS is proposing to implement and test the ASM under the Center for Medicare and Medicaid Innovation (CMMI). The ASM would be a mandatory alternative payment model (APM) with five performance years, beginning January 1, 2027, and seven years of testing with final data submission of measures and activities in 2032 and final model payment adjustments in 2033. The model would be focused on care furnished by two cohorts of select specialists to Medicare beneficiaries with the chronic conditions of heart failure and low back pain. Participation would be mandatory for ASM specialists in these two cohorts practicing in mandatory geographic areas randomly selected to constitute approximately 25 percent of core-based statistical areas (CBSAs) and metropolitan divisions.

The ASM would use the MIPS Value Pathway (MVP) framework and policies as the foundation for the model, while deviating from those policies in specific ways. The MVPs use sets of measures and activities that are focused on performance in furnishing care for a specific specialty or clinical condition. Under the ASM, reporting and assessment of performance would be focused on the individual clinician level. ASM participants would be scored based on their performance on ASM quality, cost, improvement activities, and promoting interoperability performance categories, but with quality and cost each constituting 50 percent of their final score and performance on the remaining categories having the potential for a negative adjustment to that score. Payment adjustments would be applied based on how final scores of participants compare to scores of the other specialists within the specific cohort. The ASM participants would assume 2-sided risk, with a risk factor initially set at 9 percent and increasing to 12 percent over the course of the model. In addition, CMS proposes to apply a redistribution percentage to the payment adjustment methodology, which would guarantee a specified level of savings to the Medicare program.

The FAH continues to strongly oppose mandatory provider participation in any CMMI testing. The FAH has repeatedly expressed significant legal and policy concerns with mandatory CMMI models and has urged HHS to ensure that CMMI acts only within its designated authority to test voluntary APMs. As detailed below, these objections to mandatory demonstrations are particularly acute with respect to the proposed ASM because of the broad geographic application, arbitrary selection of specialists mandated to participate, reliance on the MVP structure (for which there is insufficient feedback and data), significant and consequential deviations from the known MIPS statutory requirements that do not address underlying concerns with MIPS and instead raise additional concerns, and the substantial financial risk and unpredictable payment swings to which individual clinicians would be subjected. **As currently structured, the FAH therefore opposes the ASM proposal as we are concerned it would threaten patients' access to medically necessary services, impose excessive burdens on providers, and incentivize an unbalanced focus in clinical decision-making on cost savings over quality improvement.**

Large Mandatory Models Must be Voluntary

Mandatory provider participation in CMMI models, including as proposed for the ASM, affects an impermissible mandatory change to the Medicare program and runs counter to both the letter and spirit of the law that established the CMMI. CMMI's demonstration authority is limited to the testing models under section 1115A and the making of recommendations to Congress, but Congress reserved for itself the authority to make permanent or mandatory changes to the Medicare program, including the PFS and MIPS, through legislation. CMS nonetheless proposes the ASM, seven years of testing a mandatory model under which the ASM participants will face significant burden and be involuntarily committed to five performance years of financial risk under unpredictable new reporting requirements and scoring parameters, with no glide path and no transitions.

As the FAH has previously outlined, case law confirms that CMS’s assertion of authority under section 1115A to mandate a demonstration model is misplaced. In recent years, courts have continued to make clear that constitutional limits inform the scope of agency authority. In particular, grants of authority to agencies must be narrowly construed and delegations of broad authority should not be presumed to exist. For example, the Supreme Court has been explicit that agencies must have clear Congressional authorization to exercise extraordinary regulatory authority.³ “Agencies have only those powers given to them by Congress, and ‘enabling legislation’ is generally not an ‘open book to which the agency [may] add pages and change the plot line.’”⁴ As such, Congress does not typically use “modest words,” “vague terms,” “subtle devices,” or “oblique or elliptical language” to empower an agency to make a fundamental change to a statutory scheme.⁵

Mandating provider participation in the ASM (and other CMMI models) transforms the methodology through which providers receive Medicare payments from the statutorily mandated MIPS (and, alternatively, APM) incentive payment structure with very detailed statutorily defined performance categories, data reporting (including as individual clinicians and groups), scoring methodology, and payment adjustments to an uncertain restructuring of the incentive-based system with potentially higher burden on the individual specialists, greater financial risk on the individual specialists, and greater emphasis on cost-savings that will drive clinical decision-making of specialists. No such authorization should be presumed to exist here—Congress has not included in the authorizing statute any statements indicating that it intended to, and actually did, delegate its lawmaking role to CMS to require providers to accept this different, unpredictable payment scheme in lieu of the detailed statutory incentive construct. Rather, section 1115A(g) indicates Congress reserved the authority to adopt such fundamental alterations for itself. Notably, were Congress to have clearly articulated such a broad delegation of authority to CMS to alter the Medicare reimbursement scheme (again, it has not), it would need to provide intelligible principles defining the scope of its delegated authority to ensure such a delegation to the agency was constitutionally sound. This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority under section 1115A(d)(2) to permit the testing of models.

We therefore strongly oppose the implementation of the ASM demonstration as proposed. Instead, we urge CMS to ensure that all CMMI models are voluntary and designed to test—at an appropriate scale—APMs.

Using the New MVPs as a Framework: Need More Time to Allow for Sufficient Data and Analysis

The FAH recognizes and appreciates the agency’s goals for transitioning from traditional MIPS to MVPs, including to streamline and reduce the complexity of the program, reduce provider burden, and to provide for more accurate and meaningful assessment of the provision of quality of care. We also understand the importance of ensuring the availability of MVPs to specialties and of ensuring the appropriate and accurate applicability of assessment measures to specialties. **To that end, the FAH recommends that if CMS finalizes an ASM, it finalizes such a model as a voluntary model and uses the model as an opportunity to test approaches that address specific concerns experienced with MIPS and MVPs. The FAH believes that, as proposed, the ASM would instead introduce more burdens, concerns, and unintended negative consequences.**

³ *W. Virginia v. Env’t Prot. Agency*, 597 U.S. 697, 732 (2022).

⁴ *Id.* at 723.

⁵ *Id.* (citing *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001); *MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U.S. 218, 229 (1994)). See also *Biden v. Nebraska*, 143 S. Ct. 2355, 2372–75 (2023) (Congress did not provide “clear congressional authorization” for the Secretary to act in ways that would in effect fundamentally revise the statutory scheme).

Of particular concern, the proposed ASM would use the MVP framework, but there is not yet enough information on the strengths and weaknesses of MVPs in order to capitalize on the opportunity of testing a model that could specifically enhance MVPs' observed strengths and address its observed weaknesses. Since the MVPs first became a reporting option in 2023, participation has been limited and there has only been limited feedback on performance, with the 2023 reporting period being the most recent period for which there is performance data.⁶ More data and information are needed based on clinician performance and experience reporting on MVPs before a model can effectively be crafted to test modifications, especially a model such as the proposed ASM which would impose extreme and uncertain financial risk on its participants.

The FAH, therefore, urges CMS to delay further this proposal (or at least the mandatory requirement) and extend the comment period to allow for no less than one additional year of public performance data on the MVP reporting option to be available for review and analysis. As proposed, the ASM would impose significant financial risk and impacts on clinicians, which would drive clinician decision-making. It is imperative that sufficient data first be collected and analyzed from the new MVPs before proposing or imposing further changes on clinicians with such drastic implications.

If CMS finalizes its proposal without such a delay or extension, the FAH encourages the agency to delay implementation of the ASM until January 1, 2028, or later, to allow for further data and feedback to be available and taken into consideration sufficiently in advance of the first year of the model. Delaying implementation would allow more data to be available from MVP reporting to better understand how the MVP approach affects reporting, scoring, and payment consequences as compared to traditional MIPS. This is essential and necessary data to have before further changing what has barely been implemented.

Selection of Conditions, Participants and Cohorts in Model: Concerns Highlighted in Context of a Mandatory Model

CMS is proposing the model focus on two chronic conditions: heart failure and low back pain. A clinician would be selected as an ASM participant if the clinician bills claims under the PFS, is identified by a TIN/NPI as a selected specialty type, meets the episode-based cost measure (EBCM) episode volume threshold applicable to heart failure or lower back pain, and is located in one of the selected mandatory geographic areas. Once a clinician is determined to satisfy the criteria for being an ASM participant, the clinician would remain an ASM participant for the duration of the model unless for a model year the clinician is determined (during the previous year) to no longer satisfy the eligibility criteria. While the clinician is an ASM participant the clinician is exempt from the MIPS program, but if for a model year the clinician is determined to no longer meet the ASM eligibility criteria, then the clinician would be responsible for reporting under MIPS and would receive a payment adjustment under MIPS.

If CMS determines to finalize the ASM as a mandatory and not voluntary model, the FAH has strong concerns about the identification of specialty cohorts, broad selection of mandatory geographic areas, and duration of the model.

We are also concerned that there are physicians and other clinicians who see a sufficient volume of heart failure or low back pain Medicare beneficiaries who would be excluded from the cohorts. Even in a cohort that is perceived to be of limited scope, there is a range of types of clinicians associated with treating each

⁶ See the June 2025 report on the 2023 QPP Experience data, which can be found here: <https://data.cms.gov/quality-of-care/quality-payment-program-experience/data>

specified chronic condition and range of practice type. One size does not fit all. What may be relevant to one clinician providing care to a beneficiary with a specified chronic condition may not be relevant to another clinician of the same specialty type given other variables beyond the episode-based volume and type of conditions treated by the clinician.

The composition of each specialty cohort is integral to the impact the proposed ASM scoring methodology would have on an ASM participant and would therefore also have a strong impact on the adjustment factor calculation and financial risk seen by the participants. Especially in the context of a mandatory model that does not provide choice to participate nor choice on what measures may be selected for reporting, it is essential that data has been presented, analyzed, and supported for determining the composition of the specialty cohorts. **Therefore, the FAH requests clarification on and reasoning for including the proposed identified clinicians within each cohort while excluding other clinicians who provide essential care for beneficiaries with these chronic conditions.**

The FAH strongly objects to CMS’s proposal to operate the ASM at the individual NPI level. Many specialists practice in employed settings, where administrative, reporting, and compliance responsibilities are managed by the employer. Requiring specialists to independently submit quality measures, improvement activity attestations, and promoting interoperability data create duplicative burdens and undermine the division of responsibilities between the specialist and their employing organization. In addition, mandating specialists independently establish collaboration agreements with primary care physicians disregards the existing contractual obligations managed at the employer level. This structure imposes unnecessary complexity and administrative burden on both specialists and their employers.

Further, for purposes of selecting ASM participants, CMS is proposing that approximately 25 percent of CBSAs and metropolitan divisions be included as mandatory geographic areas. One-quarter of all geographic areas is simply too large-scale for a pilot model, such as ASM. Whereas the FAH would agree that wide geographic representation and diversity may be appropriate for a voluntary model, the proposed geographic selection is too expansive for **testing a model** in which there is no choice or ability to opt out of participation. We therefore encourage CMS to apply the model on a more limited geographic scope initially and expand it only in compliance with the very specific statutory requirements under section 1115A(c) of the Social Security Act – that is only if, after required evaluations of the effects of the model, (1) the Secretary determines expansion of the model is expected to either reduce spending without reducing the quality of care or increase the quality of care without increasing spending; (2) the CMS Chief Actuary certifies expansion would not increase net program spending; and (3) the Secretary determines the expansion “would not deny or limit the coverage or provision of benefits”.

Once selected, ASM participants would not have any choice but to participate in a high-risk-based uncertain payment model and would be required to maintain participation for each subsequent model year (unless they are determined no longer eligible). The model should not be conducted at the risk of practice closures and eroding beneficiary access to providers, especially for specialists to whom beneficiaries already may have limited access options. A provider should not be forced to close its doors rather than be presented with a choice or opting out of participation. Clearly, Congress did not intend for that possibility as it unambiguously provided in statute the prohibition on expansion of a model that would be expected to deny or limit coverage or provision of Medicare benefits to Medicare beneficiaries.

Additionally, the FAH recommends that CMS exclude anesthesiologists from the lower back pain cohort. Anesthesiologists are typically hospital-based specialists who engage with patients primarily at the time of procedures and document care in the hospital’s electronic medical record. Their involvement is ancillary, and they do not manage the ongoing care decisions—such as prescribing, depression screening, or

functional assessments—that are included in the proposed quality measures. Including anesthesiologists in this model would unfairly hold them accountable for orthopedic specialists’ decisions and care plans. Patients do not select anesthesiologists for their treatment, but rather rely on their orthopedic surgeons, who oversee the treatment trajectory. Thus, anesthesiologists should be excluded from the lower back pain cohort.

Data Submission Requirements: Choice Needed

CMS is proposing individual-based participation and reporting under the ASM. The FAH understands the goals of creating a level-playing field for smaller practices and allowing for appropriate attribution and assessment of care by individual clinicians. However, mandatory individual-based reporting is another layer of required changes and uncertainty that would be introduced. Many MIPS clinicians participate in MIPS as a group or through facility-based reporting, and may not on their own have the technology, training, infrastructure, or resources needed to satisfy reporting requirements as an individual clinician. If forced into individual reporting these clinicians may face substantial burden. In addition, some clinicians during the course of the model may have a change in patient volume or other change that disqualifies them from being an ASM participant. These clinicians would need to change course and revert back to MIPS reporting, potentially opting to participate once again as part of a group – in which case resources would have been required for no long-term, predictable, or consistent path forward. In addition, the FAH believes that alignment with other Medicare value-based programs is a positive way to streamline and reduce unnecessary burden and complexity and therefore should be encouraged. **To that end, we encourage CMS to give MIPS eligible clinicians and ASM participants the choice to be assessed on the care they provide in hospitals and other facilities through their existing arrangements and without having to report duplicative data.**

Specialists are highly trained. A model being tested for potential expansion needs to recognize that. Many of these specialists get their experience and training from practice in group and facility-based settings, including in settings that may by necessity be higher cost. The FAH is strongly concerned that the model, as proposed, would encourage these specialists out of those settings, which may result in losing specialists who are able to maintain their skillsets or who may be forced out of practice completely, which could leave patients without access to care or more limited choice in their care.

Further, CMS proposes to require each of the ASM cohorts to report on a required set of specified measures. In contrast, MVPs use sets of measures and activities that are focused on performance in furnishing care for a specific specialty or clinical condition and still provide MIPS clinicians with a limited choice of measures to report within an MVP group. While the number of measures included within traditional MIPS may be too many and too complex, the FAH believes some choice in measure and improvement activity selection is necessary. **We therefore recommend that for purposes of the ASM, the agency maintain the optional measure and activity approach applied for the MVPs and allow ASM participants to choose from a limited set of specialty and condition relevant measures and activities.**

Final Score Calculation: Strong Concerns with Cost Emphasis and Weighting

CMS is proposing significant changes to the MIPS and MVP structure for calculating final scores under the ASM. Unlike calculating a final score under MIPS, CMS proposes that the scores in the quality and cost ASM performance categories would each be weighted at 50 percent. Since there would be only one EBCM for each cohort, representing the entire cost performance category for the cohort, that one EBCM would constitute 50 percent of the score. Scores in the Improvement Activities ASM performance category (which

is focused on primary care coordination) and Promoting Interoperability ASM performance category would have the potential of negative adjustments to the final score.

The FAH believes strongly that the proposed scoring weighting and structure results in cost is being weighted much too heavily at the detriment of the overall goal of quality improvement. In addition, 50 percent of a score being based on performance on one cost measure provides undue and extreme weight to one measure at the cost of diminishing the value of performance with respect to measures and activities in the other performance categories. We are concerned that this scoring structure focuses incentives for clinical decision-making, changes, and action points predominantly around the cost of care rather than on improving and valuing the quality of care furnished. Instead, the central driving force behind performance within all the performance categories should correspond to improving the delivery of quality care – meaning the assessment and scoring of performance on cost, improvements, and interoperability should all be linked to the contextual goal of quality improvement.

The emphasis on cost, tied with substantial financial risk and consequences, will result in clinicians being forced to make choices heavily weighted on the financial cost of clinical options. The FAH is particularly concerned that this combination of cost-based emphasis and severe financial consequences will result in needed specialists turning away from furnishing care in facilities such as inpatient and outpatient hospital settings, rural hospitals, critical access hospitals, and rural emergency hospitals, all of which by necessity require more resources than a non-facility setting but are the clinically appropriate best choice for specific procedures and patients.

Payment Adjustment Methodology: Concerns with Degree of Required Risk

CMS proposes to make positive, neutral, or negative adjustments to ASM participants' Medicare Part B payments based on their performance relative to the performance of their peers in their ASM cohort. Under MIPS, the MIPS maximum percent of risk is 9 percent, representing the maximum and minimum range of potential MIPS payment adjustment factors. In contrast, for the ASM, CMS proposes to increase the amount of Part B payments at risk under the model from 9 percent for the initial 2027 performance year/2029 payment year to 12 percent by the 2031 performance year/2033 payment year. In addition, unlike MIPS which maintains budget neutrality overall between those facing negative, neutral, and positive adjustments, ASM would be designed to guarantee savings for the Medicare program by retaining "off the top" a proposed 15 percent of the applicable risk level as savings.

The FAH stresses these changes to the MIPS payment adjustment methodology would require risk that is too aggressive and savings that are too large, especially in the context of a mandatory model with no choice available to participants. A one percent increase in risk level per year for each of model performance years 2029 through 2031 is simply too steep of an increase too quickly. **The level of risk should not go beyond the level of risk under MIPS. We also recommend a lower savings factor be applied and a sufficient transition or glide path be provided.**

Additional ASM Design & Implementation Concerns

Financial Impact Limited to Episode-Based Claims

The FAH is concerned that the financial impact of the ASM extends well beyond the scope of the model itself. Specialists are evaluated on only a narrow subset of cases, but the payment consequences are applied to all of their Medicare Part B claims. This design unfairly penalizes specialists for services unrelated to these episodes of care and may discourage them from treating Medicare fee-for-service beneficiaries with

these conditions. **To address this, the program’s financial adjustments should be limited exclusively to claims included in the targeted heart failure and lower back pain episodes. Likewise, any payment adjustments applied during the program year should only affect those episode-based claims, thereby ensuring fairness and program alignment.**

Inappropriateness of Depression Screening as a Quality Measure

Depression screening is not a clinically valid measure for orthopedic specialists managing lower back pain episodes. While the importance of depression screening is acknowledged, it is most appropriately conducted by primary care providers or behavioral health professionals. Expecting orthopedic specialists to perform depression screenings obligates them to develop follow-up care plans outside of their expertise, creating gaps in appropriate care. Medicare beneficiaries seek orthopedic care for musculoskeletal conditions, not behavioral health services. Including this measure risks misalignment with clinical practice and places undue burden on specialists.

Concerns with Collaborative Care Agreement Requirements

The FAH opposes CMS’s proposal requiring specialists to enter into collaborative care agreements with primary care practices. Such a mandate creates an unequal negotiating environment, as primary care practices will know that specialists are compelled to enter into these agreements. This requirement undermines fair contracting principles and places specialists at a disadvantage. Improvement activities should encourage collaboration without mandating contractual obligations that interfere with existing care relationships. **The FAH recommends removal of this requirement.**

Concerns with Social Needs Screening Requirements

Finally, the FAH urges CMS to remove the requirement for specialists to conduct social needs screenings. While social determinants of health are important, specialists treating heart failure and lower back pain should not be mandated to perform screenings that fall outside their clinical scope. CMS itself, or entities with broader infrastructure, would be better positioned to collect and disseminate this information. Specialists should retain professional discretion to address social needs when clinically relevant, but they should not face a blanket requirement. The proposed requirement is burdensome, misaligned with specialty practice, and should be eliminated.

The FAH is steadfast in our belief that CMMI models, including the proposed ASM, must be based upon voluntary participation. In addition, beyond what we have noted above, we believe that, as proposed, some fundamental problems would be repeated from traditional MIPS and MVPs rather than addressed and tested under ASM. First, those who do not score well and need to improve would face significant risk and financial consequences, making it harder for them to have the resources needed to make improvements, whether in technology, staffing, training, or otherwise. A pathway forward is needed to encourage actionable data collection and to enable, not diminish, providers’ ability to make improvements, based on that data, while keeping their doors open. Ultimately, investment and resources in training and staffing could in the long run better enable improved care coordination and quality care, including by encouraging clinically appropriate referrals and admissions.

In addition, for value-based and quality incentive programs to achieve their goals, giving providers feedback and information on their performance is essential. Improved feedback and access to performance data with significantly more lead time before any payment consequence or public posting is needed to enable providers to review and analyze their performance and take any necessary measures to improve quality

performance. Especially under a model that imposes such high financial risk, consequences of the model reporting, performance, and scoring on performance need to be discovered sooner than later to allow for providers to course correct before the payment consequences are seen.

IV. Updates to the Quality Payment Program

A.3.a.(3) Proposal to Modify the MVP Group Registration Process

Removing the option for multi-specialty group reporting increases the complexity of MVP participation without a clear upside. This reporting option has historically suited organizations that truly operate as a multi-disciplinary team with representation from different specialties relevant to the care they provide their patient population. If the changes proposed are finalized, there will be additional administrative burden on these organizations to divide up into subgroups based on specialties, make changes to their performance measurement approach accordingly (potentially changing registries or vendors), and coordinate the additional MVP submissions at the end of each performance year. The result is an increase in the amount of time spent on administrative activities instead of focusing on their patients.

A.3.b. Core Elements Request for Information (RFI)

CMS seeks comments on a potential Core Elements MVPs reporting requirement, which would identify a subset of quality measures in each MVP to comprise the MVPs' Core Elements, the intended goals and ideal number of Core Elements in an MVP, and the role of measure collection types, the limitations of measure applicability for some clinicians, the policy implementation timeline, and any anticipated impacts on clinicians' transition to MVP reporting.

The FAH cautions CMS on moving forward with identifying and requiring any Core Elements within a MVPs until clinicians have gained more experience with MVPs. Since just over 16% of clinicians who registered for an MVP received a final score and only about 8% of all MIPS eligible clinicians even registered to potentially report on an MVP in the first year of MVP reporting, more time and experience are needed to determine how clinicians select and report specific measures within an MVP. It is possible that some of the concerns around the potential lack of comparative performance data may not occur as reporting of MVPs increases with participants selecting those measures most relevant to their specialty and subspecialty.

We continue to reiterate that the current design of MVPs does not reduce burden and complexity, nor does it allow clinicians to make meaningful connections across measures and activities. MVPs must serve as the "glidepath" to APMs and demonstrate value as envisioned. CMS must be cautious when introducing additional requirements to MVPs without first addressing the following areas:

- 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;
- Evaluate existing data to determine 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 to 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 again urge CMS to reduce the complexity of this program and allow participants sufficient time to adjust to reporting MVPs before any additional requirements are added or the sunseting of traditional MIPS.**

We also encourage CMS to consider the potential unintended consequences that could occur if clinicians were required to report on the same measure(s) within an MVP. The measure(s) may become quickly topped out, which has been an ongoing challenge within this program and result in CMS identifying a replacement measure as the Core Element for an MVP within a few years. This scenario would reduce the potential for ongoing comparative data and create additional burden for clinicians as new clinical workflows and reporting strategies would need to be developed as that Core Element requirement changes. In addition, we believe that it will be difficult for CMS to select a measure within some of the MVPs that are intentionally broad in scope. Many of the MVPs address specialty areas with multiple subspecialties and may lead to the selection of a measure as a Core Element that is more general (e.g., QID 130 Documentation of Current Medications in the Medical Record), which is contrary to a goal of an MVP to provide a more comprehensive representation of the quality of care provided by a clinician or practice. In addition, any measure that is identified as a Core Element must be useful in correlating quality against the costs for that specialty or subspecialty.

We recommend that CMS monitor reporting trends of the quality measures within an MVP for additional years before considering an approach such as the Core Element requirement. Given the reframing of MVPs by clinical condition and/or episode of care, it may facilitate more consistent reporting of measures and lead to comparative data without any additional requirements.

A.3.c. Medicare Procedural Codes Request for Information (RFI)

CMS seeks input on the use of procedural billing codes to assign clinicians to an MVP to facilitate specialty reporting of MVPs most relevant to their scope of care. They specifically request feedback on the assignment of MVPs based on procedural codes and the data sources that should be used to assign clinicians to an MVP, the eligibility determination period to establish procedural code utilization and relevant volume threshold, and anticipated impacts on clinicians' transition to MVP reporting.

The FAH opposes any approach that does not allow a clinician or practice to select the MVP(s) that are most relevant and appropriate to their patient populations and internal goals for quality improvement. We do not believe that CMS should continue to explore using procedural billing codes to assign an MVP to a clinician given the known challenges and errors that already exist when coding is used to identify a clinician's specialty or patient populations (e.g., the ongoing challenges with attributing the Total Cost Per Capita measure correctly). We also do not agree with using a case threshold of 20 patients or episodes since it may not accurately reflect a clinician's current practice as it may increase the chances of incorrectly attributing a clinical condition and/or episode of care. In addition, such a low case minimum will likely lead to the identification of more than one condition and/or procedure, and it is not clear what further factors would be used to assign an MVP if multiple ones could be considered applicable. This

concern increases when primary care clinicians are considered as we believe that this type of occurrence of multiple applicable MVPs will be frequent.

It is also not clear what the process would be for a clinician who intended to report an MVP relevant to his or her patient population that also aligns with the practice's quality improvement efforts, yet CMS assigns a different MVP based on the codes analysis. Requiring an appeals process or other way by which an assignment can be reconsidered only adds burden and further complexity to this program. We caution CMS from moving forward with this process as it will increase burden and complexity.

A.3.d. Well-Being and Nutrition Measures Request for Information (RFI)

The FAH appreciates CMS's interest in exploring the development of well-being and nutrition measures within the Quality Payment Program (QPP). While the FAH supports efforts to advance prevention and holistic patient care, we emphasize that any new measures must be grounded in scientific validity, clinical feasibility, and meaningfulness to patients and providers.

Well-being is multi-dimensional, encompassing physical, emotional, and social health, but currently there is no consensus on standardized and clinically reliable tools to assess these constructs, in the hospital setting. Introducing measures without a robust evidence base could result in inconsistent reporting and unintended administrative burden. **The FAH urges CMS to adopt a deliberate and phased approach, beginning with pilot testing and voluntary reporting (at least two years or more is needed), to evaluate feasibility and reliability before considering programmatic adoption.** Further, these measures should be designed to complement, not duplicate, existing hospital and public health surveillance efforts.

A.4.c. Toward Digital Quality Measurement in CMS Quality Programs—Request for Information

CMS provides an RFI with updates on their progress in the transition to digital quality measurement (dQM) and seeks input as they continue their path forward in this transition. In this RFI, they solicit comments on the anticipated approach to use Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in electronic clinical quality measure (eCQM) reporting and Accountable Care Organization (ACO) experience with the transition to FHIR-based reporting of eCQMs and opportunities to mitigate reporting burden.

The FAH and our members reiterate our support for the transition to digital data as we believe that it will reduce the burden of data collection and enable the capture of information that is essential at the point of care. However, we do not believe that the field is ready to rapidly move to dQMs as evidenced by the recent challenges encountered by hospitals to report the hybrid measures. We believe that similar challenges exist in the ambulatory setting and CMS must ensure that most practices and ACOs are able to participate in the move to FHIR eCQMs followed by FHIR dQMs before anything is finalized through rulemaking.

We encourage CMS to establish a clear glide path that outlines the essential steps, stakeholders, and milestones required for successful implementation. It should include a detailed timeline specifying when critical actions will be completed, along with the necessary deliverables and readiness criteria to ensure the field is adequately prepared to advance to each subsequent phase. For instance, the timeline could indicate when technical specifications for FHIR-based reporting will be released, allowing vendors sufficient time to incorporate them into their systems, and when these specifications will be integrated into certification requirements.

Simultaneously, CMS should develop the internal infrastructure needed to receive data via FHIR-based application programming interfaces (APIs) and provide guidance and educational resources to support practices and ACOs during this transition. Once CMS confirms that vendors are certified and capable of supporting FHIR-based reporting—and that CMS itself is ready to accept the data—it should establish a reasonable timeframe for groups to begin submitting these measures, which we believe will take more than the proposed two years. Practices must budget, train, and create processes for each eCQM implementation and a two-year timeline will not be sufficient, particularly if they are required to implement multiple measures at one time.

Within this timeline, we also urge CMS to enable widespread testing across multiple vendors and systems to ensure that the required data can be collected. We are especially concerned that small and/or rural practices will need additional time and potentially funding to support these changes. The current approach of testing in two or three EHRs primarily within academic medical centers or health systems is insufficient and real-world testing that represents the practices across the United States will be critical.

The FAH and our members support this shift but caution CMS on moving too quickly without the needed infrastructure and resources in place. We offer our assistance in advising on this glidepath and associated steps and milestones as CMS moves toward digital measurement.

A.4.f.(4) Promoting Interoperability Performance Category

Security Risk Management Measure: We request confirmation, for the proposed *Security Risk Management* measure, that CMS does not seek to require eligible clinicians to go beyond what HIPAA already requires in terms of risk management activities and documentation evidencing those activities.

Further, we request clarification regarding the timing of the completion of risk management activities. If, for instance, a provider begins the year by documenting their risk management activities based on the prior year's risk analysis, and then uses that as a baseline for conducting their risk analysis for the current year, would that satisfy CMS's requirement that the risk management activities be documented within the calendar year (if it was based on the prior year's risk analysis). Many organizations already follow this kind of model, so enabling them to retain their existing schedule would minimize disruption and ensure providers could continue to plan other high-priority activities around a more predictable and fitting timeline.

We also request clarification around the documentation requirements. Some risk management activities may require a longer time horizon for their implementation (e.g., when a risk is identified on a vendor's product and the provider has limited or no control over its resolution). **We seek to ensure that CMS would not intend to penalize providers for risk management activities that may show limited progress during a period of time, taking into account situations like the example just provided.** We understand CMS's intent to be that actions are taken on risks identified to develop a mitigation plan and implement it over time, without explicit thresholds established for the quality of the mitigation activity or the period over which it must be completed. Because all risks and mitigation activities are unique and situation-dependent, any attempt to establish these sorts of thresholds would be arbitrary at best.

SAFER Guides: We thank CMS and ASTP/ONC for updating the SAFER Guides. However, because the new version of the SAFER Guides was released in August 2024, some providers may have inadvertently used the newer version to document their 2024 assessment. **We would appreciate CMS clarifying that it will not penalize providers who adopted the newest version of the Guides early.**

Prescription Drug Monitoring Programs (PDMP) Measure: We appreciate the opportunity to offer feedback on a future PDMP measure. While we certainly understand the intent behind this measure applying to Schedules II- IV, Schedule III and Schedule IV medications inherently pose proportionally less risk of dependence when compared to Schedule II medications. If the ultimate goal of implementing this measure is to allow CMS to drive and support healthcare processes and structures that assist in addressing the opioid crisis and misuse of methamphetamine/methylphenidate-derived stimulants, **we believe this measure would be best served by limiting the denominator to the following medication types:**

- All Schedule II medications
- Schedule III opioid medications
- Schedule IV benzodiazepine medications

Providers clearly understand the risks that these medications pose, and many providers have already incorporated processes in their practices to check the PDMP prior to prescribing these. However, the rationale behind checking the PDMP for all or most prescriptions written for other Schedule III and Schedule IV medications is not as clear. Ultimately, the complication of including Schedule III and Schedule IV medications (other than those outlined above) in the denominator seems to outweigh the benefits gained from tracking providers' utilization of PDMP data to inform their prescribing decisions.

While most providers check the PDMP in real-time as they are in the prescribing workflow, we have found that a subset of providers proactively check the PDMP up to 48 hours before an encounter as they prepare for a patient's visit. It seems unfair to punish these providers for being proactive or requiring them to check the PDMP a second time when they are physically with the patient, especially in cases where they have a long-term relationship with a patient who has a chronic condition and are simply checking the PDMP to ensure there has not been a change in the patient's risk profile that would affect their existing approach.

Some states allow provider-designated delegates to check the PDMP. **We would seek clarification from CMS that PDMP checks by delegates, where allowed by law, meet the numerator requirement for this measure.**

Public Health and Clinical Data Exchange: We appreciate CMS's recognition of the real and persistent barriers that providers and public health agencies (PHAs) face in establishing live, production-level interface connections. Specifically, in the context of electronic case reporting, the use of a single intermediary to manage data exchange in a federated model presents clear advantages. However, this approach also introduces a significant trade-off: the potential for demand to exceed the limited onboarding capacity of the Association of Public Health Laboratories (APHL) and local PHAs. **Suppressing this measure for the 2025 reporting period reflects CMS's thoughtful commitment to strengthening the public health infrastructure without overburdening stakeholders or risking rushed implementations.**

Similarly, hospitals and providers experience related barriers with the remaining *Public Health and Clinical Data Exchange* measures. **As such, we support CMS's proposal to establish a measure suppression mechanism that allows flexibility in extenuating circumstances. We urge CMS to apply this mechanism across the entirety of the *Public Health and Clinical Data Exchange* objective when suppression criteria are met.** This approach will help prevent broader programmatic failures, particularly when PHAs lack capacity to onboard participants.

Additionally, we urge CMS to re-examine the current public health landscape, which has evolved significantly since the most recent revisions to the active engagement requirements. Recent funding

cuts have considerably reduced resources at several state health departments, resulting in long delays between registration and validation. As CMS previously acknowledged, eligible hospitals and providers "should not be held accountable for factors beyond their direct control,"⁷ particularly when progress depends on the readiness, capacity, and technical capabilities of the reporting PHA.

We strongly support CMS’s definition of “capable” of receiving data in the specific standards required. We recommend that the definition be uniformly applied across all measures within the *Public Health and Clinical Data Exchange* objective. Standardization will reduce variability in interpretation and promote alignment across the Promoting Interoperability Program.

Lastly, we seek clarification on whether hospitals and clinicians should continue attesting indefinitely to Option 2: *Validated Data Production* once production status is achieved. For example, if a provider transitions to a new EHR system and is granted a hardship exception for the reporting year, then subsequently re-enters the public health reporting queue with the new system, it is uncertain which *Active Engagement Option* would be most appropriate for attestation in that circumstance. **Clear guidance will help ensure consistent application and support providers’ continued compliance.**

A.4.j. RFI Regarding Performance-Based Measures

The FAH acknowledges CMS’s proposal to transition from attestation-based reporting toward performance-based measures in the Promoting Interoperability performance category. While this shift may strengthen accountability and data quality, the transition carries significant implementation challenges for hospitals and clinicians.

As the FAH has previously emphasized in comments on eCQM adoption, transitioning to performance-based reporting requires substantial lead time to allow providers to map data elements, modify workflows, validate EHR functionality, and assess measure reliability. **We strongly recommend that CMS provide at least two years of voluntary reporting prior to linking new performance-based measures to scoring or payment consequences.**

Additionally, CMS should ensure that measures are limited to domains where clinicians can meaningfully influence outcomes and avoid areas where results are heavily shaped by external factors. To reduce variability, the FAH urges CMS to publish clear technical specifications, testing resources, and vendor certification requirements well in advance of data reporting deadlines. This approach will help mitigate discrepancies across EHR systems, allow hospitals sufficient ramp up time with the technical information, and ensure consistent application of performance standards nationwide.

A.4.k. RFI Regarding Data Quality

The FAH strongly supports CMS’s recognition that data quality is foundational to high-quality care, patient safety, and the integrity of quality reporting systems. Persistent challenges such as inaccuracies, incomplete EHR data, inconsistent coding practices, and lack of interoperability undermine trust in reported outcomes and place providers at risk of unfair evaluation.

The FAH urges CMS to support greater provider–vendor collaboration by holding vendors accountable for ensuring their systems can deliver validated, complete, and interoperable data. Hospitals often lack the leverage to require enhancements on their own, and federal leadership is needed to

⁷ 87 *Fed. Reg.* 49338–49342. (August 10, 2022).

align incentives. In addition, smaller and rural hospitals face disproportionate challenges in implementing advanced data validation processes. CMS should provide technical assistance, financial support, and targeted guidance to ensure equitable participation across all provider types.

We also recommend that CMS prioritize alignment of data definitions across federal programs (including QPP, USCDI, and HEDIS) and promote automated data quality checks at the point of entry to minimize administrative burden. Finally, the FAH emphasizes that providers should not be penalized financially for data deficiencies that result from vendor limitations or systemic interoperability gaps. Any program design should explicitly recognize and mitigate this risk.

Appendix 1: MIPS Quality Measures

CMS proposes the addition and modification of several quality measures for CY 2026 performance period.

Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)

The FAH opposes the inclusion of this measure in MIPS since waitlisting is a decision determined by the transplant center and we do not agree that it should be attributed to an individual clinician. We also are aware that measures focused on this process have not achieved Consensus Based Entity (CBE) endorsement due to concerns around the need for additional exclusions and the potential for incorrect attribution and the Pre-Rulemaking Measure Review (PRMR) process did not reach consensus on this measure for MIPS due to the same concerns. Every patient should be provided with the opportunity to decide whether he or she wants to be added to the waitlist and there is increased risk of this measure pressuring patients to enroll just to achieve a higher performance score on the measure. We do not support moving forward with a measure that has such potential for negative unintended consequences.

Diagnostic Delay of Venous Thromboembolism in Primary Care

We question why this measure has been proposed for inclusion in MIPS as the measure developer previously indicated that it is better suited for use at the integrated delivery network and for quality improvement purposes only. We believe that additional work must be completed to confirm that the current approach of attributing a delayed diagnosis based on only one venous thromboembolism (VTE) symptoms is valid; the use of data from the COVID-19 public health emergency (PHE) is concerning as it may not be representative of typical care outside of a PHE; the low minimum reliability score at the group level (0.37512), which is significantly lower than what we believe is an acceptable threshold of 0.7 or greater; and the limited data element validity testing in EHRs that has been provided. **We do not support inclusion of this measure in the program.**

Screening for Social Drivers of Health

While we understand the rationale for the proposed removal of the *Screening for Social Drivers of Health* measure, we recommend retaining the measure on a voluntary, optional basis only. A patient's full context, particularly in vulnerable populations (e.g., Medicaid patients), can be very relevant to their care plan, improving outcomes, and reducing the consumption of healthcare services. If reducing costs are a priority, this measure should remain an available option for providers to select. Further, some of the providers (e.g., hospitalists) who have selected this measure in the past have an inherently limited pool of measures from which to select, so this removal would disproportionately affect them.

Breast Cancer Screening and Colorectal Cancer Screening Measures

We have been made aware that some EHRs vendors, particularly those for small practices or specialties, have not maintained the capability to extract the data needed for the Breast Cancer Screening (BCS) eCQM and there is potential that it will also occur with the Colorectal Cancer Screening eCQM since they were removed as individual measures in MIPS. This lack of support for the specifications makes it increasingly difficult for participating practices in accountable care organizations (ACOs) to successfully report on this measure. Depending on the number of practices using these vendors, ACOs that opted to report using eCQMs may be forced to select a different reporting option (MIPS CQMs or Medicare CQMs) with increased burden of data collection and cost since practices with these vendors will need to identify other avenues by which the data can be obtained (likely through manual data abstraction).

Even if a vendor can produce the QRDA 1 file, the specification is not aligned with the MIPS CQM and Medicare CQM as it only includes women aged 50-74 years and not the expanded age range of 40-74 years. We believe that CMS must avoid situations where specifications are not clearly supported by vendors and specifications and associated benchmarking are not consistent. **We urge CMS to communicate the need to support these eCQMs to EHRs vendors and in the interim, identify avenues by which ACOs will not have their potential shared savings at risk (e.g., suppress the measure) if they are unable to collect all the data needed to meet the data completeness requirement.**

In addition, we do not support the proposed changes to the MIPS CQM and Medicare CQM specifications for the BCS and CRC measures, specifically the addition of a definition for “reviewed” to qualify as meeting the quality action. This change is an expansion beyond the original intent of the measure that will increase documentation burden without any value added to the patient or physician. In addition, specifications across reporting options should remain aligned and the eCQM specification does not currently include this requirement nor will we support its addition to this specification in the future. This proposed change could lead to a negative unintended consequence of overuse of these procedures since both measures include data from previous years (for CRC this can be up to 10 years if a patient received a colonoscopy). It is very unlikely that a review and discussion of the findings will be documented in an easily accessible way and as a result, a repeat mammogram or CRC screening may be ordered to fulfill the measure and not because the patient is due for this screening. We do not support changes to a measure that could encourage overuse of services, particularly a revision that is not directly tied to improving patient care.

The FAH appreciates this opportunity to submit these comments regarding the PFS proposed rule. If you have any questions or if we can assist CMS as it considers these recommendations, please contact me or any member of my staff at (202) 624-1500.

Sincerely,

