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President and CEO

September 6, 2022

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-1770-P, Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts; Proposed Rule (Vol. 87, No. 145), July 29, 2022.

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 above referenced proposed rule and provide our comments on specific proposals below.

II. D. Telehealth Services

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

Throughout the duration of the COVID-19 public health emergency (PHE), the use of telehealth modernized the provision of essential health services. We commend CMS for recognizing the value of telehealth beyond the PHE in the proposed provisions for the payment of Medicare telehealth services and appreciate CMS' proposals to continue to advance the use of telehealth in Medicare.

d. Services Proposed for Removal From the Medicare Telehealth Services List After 151 Days Following the End of the PHE; and

e. Implementation of Telehealth Provisions of the CAA 2021 and CAA 2022

In the physician fee schedule final rule for calendar year (CY) 2022, CMS discussed that when the PHE ends, the associated waivers and interim policies will expire and payment for Medicare telehealth services will be limited by the requirements of section 1834(m) of the Social Security Act. Services that had been added to the Medicare Telehealth Services List on a Category 3 basis will remain on the list through the end of 2023.

Further, under current policy, all services that CMS temporarily added to the Telehealth Services List on an interim basis but have not been added on a Category 1, 2, or 3 basis would not remain on the list after the end of the PHE. CMS proposes that these services would remain on the Telehealth Services List for a period of 151 days following the end of the PHE consistent with provisions in the *Consolidated Appropriations Act, 2022* (CAA, 2022). **The FAH supports this proposal, including CMS implementation of the telehealth provisions in CAA, 2022, and in particular we support the proposal to delay the in-person visit requirement for mental health services furnished via telehealth for 151 days after the end of the PHE (although we note our support for Congressional action to repeal this in-person requirement prior to its implementation).** This extension will provide the flexibility needed to offer many types of non-Category 3 services through telehealth, which is essential to ensure that patients have access to care in a reasonable timeframe. It will also ensure that providers have adequate time to phase out these telehealth services in a careful and deliberate manner that does not undermine patient care, while also allowing providers the time needed to collect data supporting a clinical benefit for purposes of adding them to the Telehealth List.

Moreover, exclusion of mental health audio-only services from the in-person visit requirement during the 151-day extension will increase access to care, particularly in geographic areas and populations without widespread access to broadband and will help alleviate the persistent shortage of mental health care professionals.

2. Other Non-Face-to-Face Services Involving Communications Technology under the Physician Fee Schedule

a. Expiration of PHE Flexibilities for Direct Supervision Requirements

Current Medicare regulations permit supervising professionals to satisfy direct supervision requirements using real-time audio-visual technology through at least the end of the

CY in which the COVID-19 PHE ends.¹ **The FAH continues to support making this method of providing direct supervision permanent.** In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic, or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to admit the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary.

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

E. Valuation of Specific Codes

4. Proposed Valuation for Specific Codes

26. Cardiac Ablation

The FAH is concerned that for the second year in a row, CMS is proposing not to finalize the April 2021 RUC recommendations for cardiac ablation services. Because of technologic innovations and changes in clinical practices associated with Cardiac Ablation Services (CPT codes 93653 – 93657), the specialty societies recommended referral of this code family to the CPT Editorial Panel to have the code descriptors for these services updated and bundle services commonly performed together. In October 2020, the CPT Editorial Panel revised CPT code 93653 to bundle with 3D mapping and to include “induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus” and revised CPT code 93656 to add 3D mapping and “left atrial pacing and recording from coronary sinus or left atrium” and “intracardiac echocardiography including imaging supervision and interpretation” to their descriptors. After receiving the survey data, the specialty societies were concerned that the survey respondents were confused about the coding changes and requested the CPT panel to rescind the code changes for one year; this request was denied.

¹ See 42 C.F.R. § 410.32(b)(3)(ii).

These codes were re-surveyed, reviewed at the April 2021 RUC meeting, and were included in the RUC comment letter submitted in response to the 2022 physician fee schedule proposed rule. Because they were not submitted in time for consideration of the 2022 physician fee schedule proposed rule and instead submitted as comments, CMS would not consider these RUC recommendations for the CY 2022 physician fee schedule final rule.

In the CY 2023 physician fee schedule proposed rule, CMS recommends significantly lower work relative value units for these codes. The FAH is concerned that CMS' proposed relative value units for cardiac ablation services will significantly impact the delivery of these important services and **recommends CMS does not implement the proposed values but instead finalizes the RUC recommendations**. Coding changes to reflect the evolving technology changes and changes in clinical practice are important but do not necessarily equate to reduction in work intensity and time. CMS' proposed reductions do not reflect the intensity and work time required for performing cardiac ablation services on critically ill patients and are based on a completely inappropriate comparator code for lower limb revascularization. Our hospital members remain concerned about the proposed reimbursement changes will have on contracts with clinicians, physician staffing firms, and managed care organizations. Instead of reducing payment for individual services, CMS should be working to maintain reimbursement levels and ensure that all Medicare patients have access to this life-saving procedure.

34. Proposed Revisions to the “Incident to” Physicians’ Services Regulation for Behavioral Health Services; and

35. New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)

The proposed rule includes two new proposals to help address the increasing demand for behavioral health services and the projected shortage of behavioral health practitioners. First, CMS proposes to amend the direct supervision requirement under the “incident to” regulations to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioner (NPP) when these services or supplies are provided by auxiliary personnel (such as licensed professional counselors and licensed marriage and family therapists), incident to the services of a physician or NPP.

In addition, CMS proposes to create a new General BHI service personally performed by CPs or CSWs to account for monthly care integration where the mental health services furnished by a CP or CSW are serving as the focal point of care integration. Further, CMS proposes to allow a psychiatric diagnostic evaluation to serve as the initiating visit for the new general BHI service.

The FAH appreciates CMS initiatives to improve access to, and quality of, mental health care services and support these proposals that can help reduce existing barriers to these important services while at the same time allowing greater use of services of behavioral health professionals.

F. Evaluation and Management (E/M) Visits

14. Split (or Shared) Services

The FAH applauds CMS' proposal to adopt the revised CPT Evaluation and Management (E/M) guidelines regarding medical decision-making (MDM) for E/M services. The update to the code descriptions and guidelines further emphasizes the critical role of MDM in the treatment and associated payment methodology for these services.

The FAH also appreciates CMS' delay of implementation of the definition for "substantive portion" of split (or shared) E/M visits in the facility setting until January 1, 2024, recognizing there is a need for additional comment on this definition. As currently defined, the billing provider would be determined based on the provider that spent more than half of the time with the patient when an NPP and physician from the same group perform visits to the same patient on the same day.

We strongly believe this definition diminishes the potential role of the physician in a split (or shared) E/M visit. While a physician may ultimately spend less time with the patient, the physician is performing key tasks such as updating a patient's diagnosis and/or treatment plan, reviewing diagnostic testing, and analyzing patient risk. Key aspects of MDM would not be used to consider the billing provider for a split/shared service under the current definition, which only reflects the amount of time spent with the patient.

Regardless of time spent with the patient, a physician that personally performs and documents his/her MDM during an encounter is a more accurate reflection of a "substantive portion" of a patient encounter. On quantifying MDM, CMS states "MDM is not easily necessarily quantifiable and can depend on patient characteristics..."². We respectfully disagree with this rationale. MDM, when performed by a physician and/or NPP, should be documented as part of each independent encounter.

This position is further supported by the revised CPT code definitions that CMS has proposed for adoption in CY 2023. An update to the "substantive portion" definition based on MDM documentation is a more accurate reflection of services to support the billing provider, regardless of whether an independent or shared encounter. This definition will still meet CMS' intent of refining the definition of "substantive portion" to exclude components of history and exam from consideration, while allowing physicians to bill for services where their involvement plays a critical role in the visit.

I. Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services

The FAH supports CMS' proposed new codes in 2023 for RTM services provided by a physician or NPP and RTM assessment services. RTM provides needed tools to monitor non-

² 86 Fed. Reg. 39104 at 39,205; Medicare Physician Fee Schedule Proposed Rule (July 23, 2021).

physiologic data, which helps better manage, and promote compliance with, a patient's therapeutic care plan.

We are concerned, however, with the proposal that prior to billing these codes, supply codes must be billed, even though there is such linkage from the CPT descriptions. The supply codes currently require at least 16 days of data in a month. Thus, if a provider does not first collect 16 days of data, the provider is precluded from billing these codes. Further, there are only two supply codes for two specialties, so this would limit RTM billing to those two specialties. Although CMS discusses that RTM should be newly covered for cognitive behavioral therapy (CBT) services, this supply code requirement prevents the new CBT code from actually being billed. We urge CMS to reconsider the requirement that 16 or more days of data be collected to effectively provide and bill for remote monitoring services. Instead, we urge a requirement consistent with the physician or clinical staff order for that patient.

J. Payment for Skin Substitutes

CMS proposes to revise its payment policies for wound care management products (currently known as "skin substitutes") to achieve certain objectives, including ensuring a consistent payment approach across the physician office and hospital outpatient department settings. Specifically, CMS proposes to establish a consistent pricing policy for all wound care management products used in the physician office setting by categorizing them as "incident to supplies," effective January 1, 2024. Under the proposal, CMS would no longer pay separately for skin substitute products under the ASP+6 percent payment methodology in the physician office setting. Treating these products as incident to supplies would mean that the resource costs for these products would be included in establishing practice expense relative value units for the associated physicians' service with which they would be furnished. However, as detailed further below, CMS would not adopt this policy on January 1, 2023, but would instead adopt a phased approach.

Further, CMS proposes to retire all wound care management Q codes by January 1, 2024, while providing 12 months from January 1, 2023, for interested stakeholders to apply for A codes for wound care management products. For all wound care management products meeting the criteria for a HCPCS Level II code, CMS proposes contractor pricing for these codes effective January 1, 2024. CMS would use the next 1 to 5 years to explore bundling payment into the physician fee schedule skin substitute application procedures while allowing sufficient time to consider input from interested parties on coding and policy changes primarily through the rulemaking process, and to account for FDA's regulation of these products, with the goal of avoiding unintended impacts on access to medically necessary care involving the use of these products.

The FAH appreciates CMS' goal of establishing a consistent payment policy for skin substitutes. However, the proposals present significant changes that will need adequate time for

implementation by both stakeholders and government agencies, for example, stakeholders need to apply for and receive an A code, as well as FDA approval, for wound care management.

The FAH believes the January 1, 2024, implementation deadline will be too soon to accomplish these changes, and we urge CMS to monitor this process and maintain flexibility in delaying this January 1 deadline if needed. We also urge CMS to ensure transparency in its data analysis regarding development of payment for skin substitutes – under both the physician fee schedule and the hospital outpatient prospective payment system. For example, until such time as CMS bundles payment into the physician fee schedule for skin substitute application procedures, we urge CMS to report the complete Part B drug pricing on its web pricing files for these products. Further, prior to bundling payment into the physician fee schedule for skin substitute application procedures, the FAH urges CMS to ensure that adequate analysis is available, with an opportunity for public comment, throughout the process of developing and adopting appropriate practice expense adjustments for payment of these products as an “incident to” service. This is particularly important given that there is not a single or merely a few skin substitute products that readily lend themselves to a “typical” price – rather, there are hundreds of varying products with substantial variation in the types of products available. And, it is important to ensure appropriate payment so that patients maintain access to these important products.

III. Other Provisions of the Proposed Rule

A. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds With Respect to Discarded Amounts §§ 414.902 and 414.940)

Refundable Single-Dose Container or Single-Use Package Drug

Per Section 90004 of the *Infrastructure Investment and Jobs Act* (the Act), CMS is implementing a requirement that manufacturers provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund is the amount of discarded drug that exceeds 10 percent of total charges for the drug in a calendar quarter.

The impact of this new requirement is unclear and could potentially increase the cost of health care delivery – including drug acquisition costs as well as overhead and labor costs. It also could increase operational burden due to decreased package sizes. For example, many drugs are dosed in a variable manner and are based on the patient’s body weight. These weight-based dose products may need larger than single use package sizes to provide the appropriate volume of a drug depending on the patient’s weight. If package sizes decrease as a result of this new requirement, there could be a cascading effect on providers by increasing the time and resources needed to prepare the proper dose. Thus, CMS should actively monitor potential downstream outcomes and mitigate any adverse impacts, as necessary.

Discarded Amounts

Under current policy, CMS requires hospitals and physicians to apply the JW modifier to identify the amount of discarded drug being billed from a single use vial. To implement the Act, which is effective on January 1, 2023, CMS proposes that the JW modifier would be required on claims for all single-dose container or packages for which any amount is discarded (as reflected in current policy), and a separate new JZ modifier would be required on claims for these drugs when there are no discarded amounts. Currently, no modifier is required when there are no discarded amounts from a single use vial or single use package drug – and the absence of a modifier speaks for itself.

The new proposed JZ modifier would apply to over 450 different separately payable HCPCS coded items and would present an extensive, burdensome, and wholly unnecessary provider mandate, as compared to the current system. Implementing the modifier, as proposed, by January 1, 2023, is unrealistic as providers will have very little time to work with vendors to build the new modifier into their clinical and billing systems and integrate the new system into their clinician and staff workflow. Further, as CMS notes in the proposed rule, the JW modifier is often omitted on claims forms, which CMS acknowledges could be due to provider burden. The addition of the new modifier would only increase provider burden and is unlikely to improve data integrity.

Since the JW modifier already is current policy and provides CMS with the data needed to indicate discarded amounts, we urge CMS to reconsider use of the new modifier. We believe the best way to improve compliance is not with the creation of a new modifier but instead using provider education. CMS must educate providers that accurate use of the JW modifier is needed to ensure compliance with section 90004. If CMS does implement the modifier, we urge the agency to delay its implementation date well beyond January 1, 2023.

G. Medicare Shared Savings Program (MSSP)

CMS proposes numerous changes to the MSSP. In aggregate, the package of proposals touches on almost every aspect of the program and the future impacts on the program would be far-reaching if finalized. The most recent set of program changes of similar breadth and depth was termed a “redesign” by CMS when it was published four years ago as the “Pathways to Success” MSSP proposed rule.³ CMS indicates that in aggregate its proposals are intended to reinvigorate accountable care organization (ACO) growth (in numbers of ACOs and aligned beneficiaries) and to better capture patient populations with higher costs and/or those who have been otherwise underrepresented in the MSSP.

The FAH commends CMS for undertaking a holistic and futuristic view when proposing changes to the MSSP. As of January 1, 2022, the MSSP’s 483 ACOs and their 528,966 health care providers are serving over 11 million Medicare beneficiaries; collectively, these ACOs

³ 83 Fed. Reg. 41,786; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success Proposed Rule (August 17, 2018).

represent the largest value-based purchasing program in the country.⁴ We agree with CMS that the MSSP is positioned to play a key role as CMS works to realize its stated vision of driving accountable care as measured by having all Medicare fee-for-service (FFS) beneficiaries in a care relationship with accountability for quality and total cost of care by 2030.⁵

Proposals Effective for Agreement Periods Beginning with CY 2023

Our comments will focus first on the subset of proposals that if finalized would be effective for agreement periods beginning January 1, 2023. Many of the proposals in this subset pertain to the MSSP's quality standard and its associated measures and scoring, as well as the intersection between the quality standard and ACOs' eligibility for shared savings and responsibility for shared losses. The remaining proposals are primarily operational or technical in nature. The FAH supports many though not all of these proposals for performance year 2023 as detailed below.

Quality Performance Standard and Reporting Requirements

1. *Extension of eCQM/MIPS CQM Transition Incentive:* CMS proposes to extend the incentive for ACOs to transition from reporting quality data through the CMS Web Interface to using the APP's eCQMs/CQMs measure set through performance year 2024. The FAH supports this extension.
2. *Health Equity Adjustment for ACOs that Report All-payer eCQMs/MIPS CQMs, and are High Performing on Quality, and Serve a High Proportion of Underserved Beneficiaries:* CMS proposes to adopt a health equity adjustment into the MSSP beginning with PY 2023. The adjustment would be incorporated into calculation of quality performance scores and shared savings and losses and into the extreme and uncontrollable circumstances policy. CMS further proposes that ACO eligibility for the adjustment would be determined by the proportion of assigned beneficiaries who are dually eligible or reside in disadvantaged neighborhoods and would be restricted to ACOs with relatively higher quality performance scores. The adjustment would be implemented through two proposed quality performance score adjusters and be capped at ten points.

The FAH supports the inclusion of a health equity adjustment for ACOs but requests that CMS consider some additional revisions to the proposed calculation and application of the bonus. First, we recommend that the bonus include both the individuals who live in deprived neighborhoods and those who are dual eligible equally rather than only

⁴ Shared Savings Program Fast Facts, available at <https://www.cms.gov/files/document/2022-shared-savings-program-fast-facts.pdf>.

⁵ CMS Innovation Center. Strategic Direction. <https://innovation.cms.gov/strategic-direction>. Also see Seshamani, M, Fowler E, Brooks-LaSure C. et al. Building On The CMS Strategic Vision: Working Together For A Stronger Medicare. Health Affairs. January 11, 2022. Available at <https://www.healthaffairs.org/doi/10.1377/forefront.20220110.198444/full/>.

considering the higher of the two proportions. Considering these two variables – which are in themselves proxies, measure different characteristics, and are imprecise – to be equivalent does not meet the intent of this adjustment.

CMS should also replace the current cutoff of the 85th or higher percentile for the Area Deprivation Index (ADI) both with the percentage of patients in neighborhoods with above-average ADI values and on the magnitude of the ADI in those neighborhoods, such as by summing the ADI percentiles for the neighborhoods of each patient assigned to the ACO. The current cutoff is arbitrary and has a greater potential of misrepresenting the characteristics of the individuals served by an ACO. For example, a recent study found that hospital readmission rates were significantly higher for patients living in neighborhoods above the 50th percentile of ADI, and that those living in neighborhoods in the 85th – 95th percentile had lower readmission rates than those from neighborhoods with lower ADI levels.⁶ We believe that CMS should not set cutoffs until such time that there is evidence to demonstrate that it would better capture those individuals who truly reside in disadvantaged neighborhoods.

We also encourage CMS consider other variables such as the Low-Income Subsidy for potential inclusion in this calculation. The current set of variables used to identify individuals at risk remains insufficient and we urge CMS to continue to refine and improve on the data that are used. In addition, we believe that the use of a “Measure Performance Scaler” creates an overly and unnecessarily complex calculation and encourage CMS to simplify it by instead using the ACO’s Merit-Based Incentive Payment System (MIPS) quality performance score.

3. *Proposed Benchmarking Policies for CMS Web Interface Measures for Performance Years 2022, 2023, and 2024:* CMS proposes to create benchmarks according to previously established MSSP Program policies for the measures in the Web Interface set for performance years 2022 through 2024. CMS further proposes to score two Web Interface measures using flat percentage benchmarks for performance year 2022: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Q226) and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Q134).

While the FAH supports continuing the previous policy for establishing benchmarks for the Web Interface measures, we object to switching Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 226) from pay for reporting to pay for performance for the 2022 performance year. Changing whether a measure will be scored or not this late within the reporting period is unreasonable and will likely require additional data collection effort and burden on ACOs while they are

⁶ Hu J, Kind AJH, Nerenz D. “Area Deprivation Index (ADI) Predicts Readmission Risk at an Urban Teaching Hospital,” *American Journal of Medical Quality*. 2018;33(5):493-501.

still operating under the COVID-19 PHE. We believe that this change sets an unreasonable precedent and CMS should not make these kinds of significant revisions this late in the reporting period.

4. *Clarifying the Use of Unweighted MIPS Quality Performance Category Scores for Quality Performance Standard Determinations under the MSSP:* CMS discovered that the historical reference values published during CY 2022 rulemaking were erroneously determined using a weighted rather than unweighted distribution of MIPS quality performance category scores. The unweighted distribution had been used in prior years' calculations, and CMS clarifies that the unweighted distribution will continue to be used in future years.

While the FAH supports this clarification, we were unable to determine what the difference is between the “weighted” versus “unweighted” MIPS quality performance category score. We ask CMS to provide definitions on these differences to ensure that it is transparent to all ACOs how these scores are calculated.

5. *Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development – Request for Information (RFI):* CMS seeks comment on the potential future inclusion of two new measures in the APP Measure set if they first are adopted into the MIPS Measure Inventory for use in the traditional MIPS program.

The FAH supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Measuring the degree to which an individual's social needs are met would be well suited to application at the ACO level; however, the two measures referenced in this RFI required further specification and testing prior to implementation in any quality program.

While the FAH supports the overall intent, we do not believe that either measure is sufficiently specified and tested, nor is it clear on the degree to which the selected factors are aligned with the work of the Health Level 7 (HL7) Gravity Project. Our specific concerns around the lack of specificity and standardization of the screening measure are outlined below in the MIPS Quality Performance Category section. Regarding the rate of positive screens measure, it does not appear to be based on evidence demonstrating that reporting of the positivity rate for one or more of these factors is linked to improvements in health outcomes and we do not believe that it is an appropriate measure for any accountability use.

Regardless of who is attributed, we believe that it is necessary to understand the degree to which each entity has been equipped with the necessary resources and tools to address the individual's needs for any one of the selected factors. Any implementation of either

measure is premature until these resources and tools are widely available, the specifications are well defined, the social determinants of health are standardized through the HL7 Gravity project, and both measures are fully tested for feasibility, reliability, validity, and achieve National Quality Forum (NQF) endorsement.

Regarding additional measures that may address health equity, the FAH believes that the essential first steps are to standardize the definitions for sociodemographic variables to be collected and improved self-reported data collection methods. CMS has not yet shared standardized definitions nor conducted a systematic scan of the frequency and range of variables already being collected by ACOs and other health care providers. We are concerned that the current rush to incorporate measures focused on health equity ignores these fundamental initial steps. We believe that CMS should first identify measures that are suitable for reporting stratified by race and ethnicity. Ideally, this can set the stage for thoughtful expansion over time to developing new health equity measures that are tested and found to be important to measure, able to perform as designed, and feasible to collect. The FAH also believes that practical work can begin on improving data collection, particularly data element definitions, a complete environmental scan of existing measures and efforts, and exploration of strategies for safeguarding privacy at every step.

Initiatives in which some ACOs would voluntarily attempt to collect race, ethnicity, and language preference for submission to CMS and would receive incentives for meeting a reporting threshold could advance the data available and inform future measure development. The timing of data collection should be left to ACOs so as not to interfere with clinical care. We further advise CMS to explore multiple data sources (e.g., insurers, health plans) and venues for data collection (e.g., Medicare enrollment, school registration).

6. *Addition of New Consumer Assessment of Healthcare Providers and Systems (CAHPS) for the Merit-based Incentive Payment System (MIPS) Survey Questions – RFI:* CMS poses questions about several potential changes to the current CAHPS for MIPS survey including the addition of new questions to address health equity and health care price transparency. CMS also requests input on two options for modifying the CAHPS for MIPS survey to make it more broadly applicable to specialty groups in addition to primary care groups: (1) shortening the survey by removing items relevant only to primary care providers and using the shorter survey with all practitioner groups; or (2) creating a separate shorter survey version for use in assessing specialist care and maintaining the existing longer survey for use with primary care groups.

While the FAH supports the goals of ensuring that patients do not encounter discrimination based on their characteristics and have access to clear, accurate and actionable cost-sharing information, we do not support the inclusion of new questions around health equity and price transparency until such time that CMS completes robust

testing on the questions and the impact to this survey and resulting measure. Specifically, the FAH believes that testing on the usefulness and understanding of both questions and how each will be incorporated into measure scoring are needed. Robust testing must also be completed to ensure that patients fully understand the intent of each question and how it relates to the care provided by the ACO or group practice. We note that while CMS indicates that the health equity question is being tested in the Medicare Advantage (MA) program, those results should not be the sole basis on which its inclusion should be determined when evaluating ACO or group practice performance. It must also be tested at the level for which it is intended. Specific attention should also be given to identify any burden associated with data collection for questions.

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

Any consideration of modifying this survey and the resulting measure to evaluate specialty groups must also undergo robust testing with patients and specialists. The survey must produce responses that are psychometrically sound, and the measure should be fully tested to demonstrate that it evaluates specialist care in a reliable and valid manner.

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

Scaled Shared Savings and Shared Losses for Performance Year 2023

For performance year 2023, CMS proposes to adopt a sliding scale approach to calculate shared savings and reductions of shared losses. Eligibility for shared savings or reduced shared losses first requires that the ACO be in good standing with the Medicare program. The proposed savings rate scaling formula then would take into account the ACO's health-equity adjusted quality score and the maximum savings rate for the ACO's participation track and level. Scaled savings would be available for ACOs on either the BASIC track (any level) or the ENHANCED track that: (1) meet the proposed alternative quality standard and fail to meet the existing standard; and (2) satisfy the Minimum Savings Rate (MSR) requirements for their track and level. Scaling of shared loss reductions would be open only to ACOs on the ENHANCED track who have satisfied their previously chosen Minimum Loss Rate (MLR) requirement. The scaled loss formula would take into account the ACO's health-equity adjusted quality score and would be bounded by the track's minimum and maximum shared loss rates (40 percent and 75 percent, respectively). The health-equity adjustment proposed for use in calculating scaled shared

savings and loss rates would take into account characteristics of an ACO's assigned population: dual eligible status and residence in a neighborhood with a high area deprivation index.

The FAH supports CMS' proposals for scaling of shared savings and shared losses for PY 2023 as a way of recognizing genuine efforts by ACOs to meet quality and cost targets but who fall somewhat short of the previously established all-or-nothing savings/loss thresholds. We are pleased that the scaled savings/loss rate proposals are potentially applicable to all ACOs for PY 2023 rather than being restricted on the basis of arbitrary revenue or risk-bearing experience categories. We also specifically support including the proposed health-equity adjustment as part of the scaled savings and loss rate formulas. This adjustment appropriately links eligibility for scaled shared savings/loss rates to criteria related to an ACO's assigned beneficiary population that are associated with clinical health outcomes (*i.e.*, the social risk factors of dual eligibility and residence in a census tract with a high area deprivation index) rather than to ACO categorizations whose relationships to better health outcomes are unclear (*i.e.*, revenue or risk-bearing experience). We are disappointed to note that for PY 2024, CMS proposes to eliminate MSR/MLR requirements with respect to scaled savings/loss rate eligibility but only for certain low-revenue ACOs. Delinking MSR/MLR from scaled savings/loss rate eligibility should recognize quality and cost efforts made by all ACOs rather than the efforts made by a few.

Reopening Initial Determinations of ACO Financial Performance

CMS describes an approach under consideration for reopening ACO financial determinations for good cause when errors are detected in MIPS quality scoring. This scenario can arise because of a timing mismatch between ACO reconciliation reports and the MIPS targeted review process. Once aware of a MIPS error, CMS would exercise its reopening discretion to correct errors affecting shared savings eligibility determination or shared savings/loss amounts. Any corrections – either updates to shared savings or losses – would be made during the following year. CMS states that it would set thresholds for error magnitude or number of ACOs affected that could trigger reopening.

The FAH has serious reservations about this proposal. Reopening of an ACO's reconciliation results for errors outside of its control generally seems unwise, introducing unwanted instability and uncertainty about reconciliation results as well as the possibility that CMS would seek to claw back funds already disbursed by the ACO to its providers and suppliers. We recommend that CMS not proceed with this policy change for PY 2023. Instead, CMS should bring forth a proposal that fully and transparently describes reopening for MIPS errors, including parameters and thresholds for making determination decisions and how errors not in an ACO's favor would be handled. At the very least, CMS should hold ACOs harmless and only reopen financial reconciliations under situations where an ACO would benefit. We note that the MIPS program's error correction process under the Quality Payment Program (QPP) has not gone smoothly and the problems with that process should not be imported into ACO reconciliation.

Technical and Other Administrative Updates

1. *Beneficiary Assignment:* CMS proposes several revisions to the beneficiary assignment process, including expansion of the list of primary care services used for the purpose of beneficiary assignment. The FAH supports these proposals. We also urge CMS to take all necessary steps to retain a full range of telehealth services on the program's primary care service list after expiration of the COVID-19 PHE.
2. *Burden Reduction:* CMS makes several proposals intended to reduce provider burden such as streamlining the documentation required when an ACO applies for permission to use the SNF 3-Day Rule waiver. The FAH appreciates the effort by CMS to reduce provider burden and supports these proposals.
3. *CMS Analysis of COVID-19 PHE Effects on ACO Expenditures:* CMS reviews actions taken to date to mitigate effects of the COVID-19 PHE on the quality and cost performances of MSSP ACOs. CMS believes that no further direct interventions are needed at this time. **The FAH appreciates the many actions taken by CMS to support ACOs during the pandemic and we agree that no additional direct interventions are needed at this time. We encourage CMS to continue its careful monitoring** for impacts of the PHE on the MSSP to allow early detection of the need for further interventions due to previously unanticipated pandemic effects or unintended impacts of actions already taken.

Proposals Effective for Agreement Periods Beginning with CY 2024

The remainder of our MSSP comments will focus on the subset of proposals that if finalized would be effective for agreement periods beginning January 1, 2024. These proposals pertain to ACO payment and its principal determinants including participation options, benchmarking, and risk adjustment, supplemented by provisions intended to advance health equity. CMS states that its overarching goals for this group of proposals to reinvigorate recruitment and retention of ACOs, especially those containing previously underrepresented providers and beneficiaries; incorporate the MSSP as the strategic centerpiece for moving beneficiaries into accountable care relationships; and advancing health equity through all aspects of the program. While the FAH generally supports CMS' goals, the proposals are broad and extensive, and the combined impacts of the proposals are difficult to estimate for a full analysis of the future program. We provide comments on the CY 2024 subset of proposals related to complexity and context, imbalance in proposals to incentivize low-revenue ACO participation, other redesign proposals, and program stability.

Complexity and Context

The CY 2024 set of MSSP proposals made by CMS is noteworthy first for its breadth and depth; few aspects of ACO payment policy would be left untouched if all proposals were to be finalized. Many proposals have multiple layers, components, applicability limitations, and/or

require multi-step calculations. The FAH notes that the proposed changes are similar in scope to changes made in the August 2018 “Pathways to Success” MSSP proposed rule and the magnitude of the proposed “redesign” of the program in this rule may warrant additional time and analysis for stakeholders to give CMS fulsome comments. We encourage CMS to consider its administrative options to allow full and thoughtful consideration by stakeholders of all proposals and potentially stage some of the 2024 changes over time.

Imbalance in Proposals to Incentivize Low-revenue ACO Participation

The FAH is concerned that access to several of the CY 2024 proposals that are ostensibly designed to facilitate ACO success would be sharply limited based on ACO revenue, Medicare performance-based risk-bearing experience, or both. The net result would be sharply increased support for new, inexperienced, and low revenue participants with few incentives offered to existing ACOs, especially those that are categorized as renewing, experienced with risk-bearing, or high revenue. The distinctions between low and high revenue ACOs and between experienced and inexperienced ACOs were created as part of the 2018 “Pathways to Success” MSSP redesign, a redesign whose predominant goal was to accelerate the pace of ACO transition to performance-based risk bearing.

The FAH finds it difficult to understand the applicability of revenue and experience distinctions to ACO payment realities in 2022 and even more difficult to understand their relevance to a redesign effort whose stated primary goal is to grow the MSSP and ensure its sustainability. We are further challenged to understand the value of revenue-based distinctions when data provided by CMS in the rule describe a consistent downward trajectory for high-revenue ACOs as a percentage of all ACOs, falling from 52 percent in 2019 to 44 percent in 2022, and when CMS itself acknowledges the risk of incenting ACOs to exclude certain higher-cost providers (*e.g.*, specialists) to avoid meeting the definition of high revenue. CMS also believes that one strategy to improve outcomes for high needs beneficiaries cared for by smaller safety net provider groups is for those groups to join larger ACO groups. Finally, the FAH notes that experienced and high-revenue ACOs are more likely to be larger organizations that arguably are better-capitalized but also have broader delivery footprints such that making transformative changes requires them to make repeated investments over multiple years and to allow more time for implementation and impacts of system-wide policy changes. The FAH believes that distinctions based on revenue and experience should be replaced with criteria accounting for ACO characteristics, its assigned population, and/or its community; for example, CMS could explore using ACO equity bonus point scores for this purpose after removal of the underserved multiplier floor or using the performance scaler alone.

The FAH finds the imbalance of support for new and inexperienced versus existing and experienced ACOs to be unacceptable as well as antithetical to the desire stated by CMS to retain current ACO participants, not merely to recruit new ones. We note that as of January 1, 2022,

nearly 80 percent of ACOs were enrolled in a second or subsequent agreement period.⁷ Existing ACOs continue to serve as the bedrock of the program to which new participants can be added, and the FAH believes that existing ACOs deserve access to at some, if not all, of the expanded supports being offered to new participants. Growth in the MSSP is a function of not only the number of ACOs but also the number of assigned beneficiaries; helping existing ACOs increase their assigned beneficiary populations will be essential if CMS is to meet its goal of having all Medicare beneficiaries in accountable care relationships by 2030.

Absent elimination of revenue and experience distinctions, we present below several examples of ways that CMS could address imbalance by providing additional supports to existing ACOs. In addition to the specific suggestions below, we generally support that the options being made available for agreement periods beginning with CY 2024 be extended as options to current ACOs. This is particularly important for ACOs who will begin new agreement periods in CY 2023. We emphasize that this is far from a comprehensive list, and we recognize the creativity and flexibility that CMS could bring to this effort as displayed during its multi-year response to the COVID-19 PHE:

1. *Advance Incentive Payments (AIPs)*: CMS proposes to limit AIPs to ACOs that are new, low revenue, and inexperienced with performance-based risk bearing. While the FAH supports offering incentive payments for infrastructure and upfront costs, CMS should consider:
 - a. Extending AIP availability, at least, to all new and all inexperienced ACOs; and
 - b. Offering an advance (supplemental) payment option tailored to existing ACOs that could be used under a CMS-approved spending plan for equity-related initiatives and high cost or patient-centered improvements such as health IT upgrades.
2. *Smoothing the Transition to Performance-Based Risk*: CMS proposes to allow new, inexperienced, low-revenue ACOs to remain at BASIC Level A – upside-only risk-bearing – for two full agreement periods (ten years) and to allow new, inexperienced, high-revenue ACOs to complete one full agreement period at BASIC Level A before transitioning to the BASIC glide path. Instead, CMS should consider allowing all inexperienced ACOs to remain at BASIC Level A for two full agreement periods, consistent with the time CMS has observed for ACOs to develop confidence with assuming two-sided risk. CMS also proposes to allow all experienced ACOs – whether low or high-revenue – to remain at BASIC Level E (two-sided risk bearing) indefinitely. CMS should consider allowing new but experienced ACOs to begin their first agreement period at BASIC Level A regardless of their revenue status (then allowing them to remain indefinitely at BASIC Level E) to offer equitable opportunities to develop confidence before assuming two-sided risk.

⁷ Calculated from data available at <https://data.cms.gov/medicare-shared-savings-program/accountable-care-organizations/data>. Accessed August 23, 2022.

3. *Adjusting the MSR Requirement for Shared Savings Eligibility:* CMS proposes to allow all low-revenue ACOs beginning a new BASIC track agreement period for CY 2024 and future years that: (1) achieve savings (*i.e.*, average per capita expenditures below benchmark) but not enough to satisfy the applicable MSR requirement; (2) have at least 5,000 assigned beneficiaries at the time of reconciliation; and (3) meet either the existing or proposed alternative quality standard to still receive shared savings at one-half the rate that would otherwise apply based on their track and level. The FAH recommends that CMS, at a minimum, allow all ACOs meeting the above criteria to be excepted from the MSR requirement for shared savings and receive savings at a specified lower rate than would otherwise apply (*i.e.*, make this exception agnostic to ACO revenue status). The FAH also encourages CMS to explore how an MSR requirement exception might be tailored to apply regardless of revenue status to all ACOs during their subsequent agreement periods.

Other Redesign Proposals

CMS makes a number of other proposals to redesign the program but for which revenue and experience distinctions are irrelevant or not stipulated. The FAH generally supports these proposals in whole or in part as noted below.

1. *Incorporate a Prospective, External Factor in Growth Rates Used to Update the Historical Benchmark:* The FAH continues to support the incorporation of regional trend factors during benchmark setting but we are less certain about adding the proposed Accountable Care Prospective Trend (ACPT) to create a 3-way blend, particularly holding the ACPT growth factors constant over the entire 5-year agreement period. We would like to see more details of modeling or other analyses performed by CMS and consideration of a phased transition to the 3-way blend (*e.g.*, characteristics of ACOs with benchmark increases versus decreases). We recommend that current ACOs be permitted to opt-in to the 3-way blend for the remainder of their current agreement periods. Further, the FAH supports the proposal for CMS to recalculate an ACO's updated benchmark using the national-regional blended factor (2-way blend) and to hold the ACO harmless if the 2-way but not the 3-way blend generates savings for a performance year if unforeseen circumstances occur.
2. *Adjust ACO Benchmarks to Account for Prior Savings:* The FAH supports adjusting an ACO's benchmark for shared savings earned in prior performance years, but we question the proposed formulas as they seem quite complicated, and the impact is unclear. CMS should provide additional modeling or analytical results on the impacts. Based on the information available, the FAH prefers the alternative of either the direct removal of an ACO's beneficiaries or expanding the regional service area used during regional calculations – or the combination thereof – to the more complicated formulas that require CMS to make multiple comparisons that are hard for ACOs to model internally.

3. *Reduce the Impact of the Negative Regional Adjustment:* The FAH supports the proposals to reduce the cap and to apply an offset factor to negative regional adjustments.
4. *Addressing Concerns About Assigned Beneficiary Effects on Regional Adjustment Calculations:* The FAH does not support at this time the proposal to adjust assignment windows used in calculating regional adjustments, as this penalizes renewing ACOs whom CMS presumably wishes to retain in the program. We appreciate the data files released by CMS to allow for modeling this change but the time available to do so simultaneously with assessing the many other proposed financial methodology changes is insufficient (see our prior comments about Complexity and Context).
5. *Improve the Risk Adjustment Methodology to Better Account for Medically Complex, High-Cost Beneficiaries and Guard Against Coding Initiatives:* The FAH supports the proposed changes and we encourage CMS to determine if they go far enough to capture year-to-year population risk increases. We recommend that current ACOs have the ability to opt-in to the proposed methodology for the remaining years of their current agreement periods.

Stability of MSSP

The ACO community has regularly shared with CMS that not only resources, but time, are required for each ACO to mature to a state in which high-quality, coordinated, and collaborative care is continuously delivered to a growing population of aligned beneficiaries while generating savings to the Medicare program. A period of stability – several years with minimal program changes after the proposed CY 2023 and CY 2024 reforms are fully implemented – would enhance predictability for ACOs to more accurately determine the optimal investment of their resources and give time for those investments to come to fruition. While ACOs were able to handle the instability and unpredictability of the COVID-19 PHE better than many other delivery system entities, they too need time now to reach a stable state in a health care world that has been permanently changed in numerous ways by the pandemic. The FAH urges CMS to consider a deliberate or phased approach when implementing these reforms to maximize near- and intermediate-term program stability.

ACO and MSSP success cannot occur without the delivery of care every day by their dedicated ACO professionals. These clinicians have been pushed to their professional and human limits during the pandemic and need time to return to equipoise. Keeping their ACO practice environments stable for several years will be key to avoiding churn among professionals that would seriously harm the program's future. ACO clinicians need stable tangible reward systems to permit them to focus their time and efforts on what they uniquely bring to the ACO – furnishing clinical services to their patients.

Upcoming changes in Medicare reimbursement to physicians will be seriously counterproductive to ACO stability. Most notable are the expiration of the ability to earn the

five percent APM bonus incentive payment and the increase in the thresholds of payments or patients that will be required to reach qualifying participant eligibility. CMS elsewhere in the physician fee schedule proposed rule projects that clinicians will be able to earn higher positive rewards for MIPS participation than continuing to practice predominantly through Advanced APMs (such as MSSP ACOs) through CY 2038. Other changes such as conversion factor decreases due to budget-neutrality requirements exacerbate this situation.

ACO clinicians may very well find themselves voting with their feet to find other potentially more predictable and higher-rewarding practice situations and their ACOs will be deprived of revenues that helped to fund the infrastructure that enables ACO and MSSP success. Alternatively, clinicians may feel pressured to accept the influx of capital into physician-led ACOs from sources outside of the mainstream of Medicare and other payer revenues with unknown long-term consequences. The FAH recommends that the near-term CMS legislative agenda include support for ways to stabilize the economic environment of the physician community. We acknowledge and appreciate the RFI appearing elsewhere in the physician fee schedule proposed rule that invites input about administrative options that CMS might pursue for this purpose.

RFI Admin Benchmarking Approach

CMS states that benchmarks are a core policy instrument for providing sufficient incentives for ACOs to enter and remain in the MSSP and that ACO performance relative to benchmarks carries significant implications for the Medicare Trust Funds. CMS has observed that the current linkage between realized FFS spending – including ACO spending reductions – and benchmark-setting can lead to undesirable “ratcheting” effects at both the individual and MSSP-wide levels. Downward pressure on an individual ACO’s benchmark results from the impact of its achieved spending reductions on its historical benchmark expenditures, regional adjustment, and update factor and occurs when an ACO’s own savings reduce its benchmark during historical benchmark resetting by CMS at the start of the ACO’s second or subsequent agreement period. MSSP-wide ratcheting is possible when downward pressure is exerted on benchmarks due to MSSP-wide spending reductions across all ACOs and occurs through the method for updating benchmarks each performance year for changes in expenditures between Base Year 3 and the performance year (*e.g.*, trending forward). CMS seeks input into eliminating ratcheting by transitioning from the program’s current benchmarking methodology to administratively set benchmarks that are decoupled from ongoing observed FFS spending by ACOs.

The FAH agrees with CMS and the Medicare Payment Advisory Commission (MedPAC) that eliminating ratcheting effects is essential for long-term sustainability of the MSSP. This RFI is extensive, detailed, and of seminal importance to the future of the program. We appreciate that CMS is sharing its vision for administratively set benchmarking early in the process so that stakeholders can begin understanding, assessing, and assimilating this vision within the context of their own experiences. We note, however, that the time required for full evaluation by

stakeholders of administratively set benchmarking as described by CMS, as well as proposals elsewhere in the physician fee schedule rule that create spillover effects for ACO professionals (*e.g.*, eliminating incentive bonus payments to clinicians participating in Advanced APMs), will far exceed that of the current proposed rule comment period. As a result, the FAH regards our response to this RFI as the first step in what must be an ongoing dialogue with CMS on this topic and our comments will remain at a high level, emphasizing concepts over details.

The FAH agrees with CMS that a transition to administratively set benchmarking has the potential to mitigate and eventually eliminate the ratcheting effects of the current MSSP methodology. CMS' plan depends heavily on the accuracy of projected trends for Medicare expenditures and ACO savings. Projections are inherently imperfect so that all possible approaches to improving their accuracy must be considered. It is fundamentally important to allow benchmarks to rise above realized expenditure growth as ACOs generate savings and we appreciate the flexible thinking that CMS demonstrates about factors for use in trend projections and specifically in the ACPT. Careful consideration needs to be given to all possible permutations of the relationship between actual national trends and Office of the Office of the Actuary (OACT) projections and how each might be handled through methodologic adjustments and over what time period. For example, while in aggregate ACOs may reduce spending, how will individual ACOs be handled when they do not? If the MSSP and the MA program as currently structured continue to exist concurrently, how might ACO demographics be affected? If MA and ACO populations are of similar size, will the anticipated effect of ACO service volume and intensity reductions be smaller since MA plans employ utilization-restriction strategies (*e.g.*, prior authorization)?

The FAH supports the stability and understands the value of setting the future ACPT (*i.e.*, not necessarily configured as proposed for use in CY 2024 benchmarking) over a multi-year period but we are concerned about the potential for the ACPT to change during an ACO's agreement period. Changing the rules midstream has not worked smoothly for other CMS-sponsored APMs (*e.g.*, BPCI-Advanced). The FAH encourages CMS to consider additional approaches to adjusting the future ACPT's components during its fixed applicability window as mentioned in the RFI (*e.g.*, account for changes in county-level relative pricing, exceptions for extraordinary and uncontrollable circumstances along with criteria for granting them), and we also agree with CMS that it will be essential to establish a process through which currently unanticipated additional factors are identified and considered during the five-year future ACPT resets. The importance of creating guardrails to ensure forecasting error does not unfairly penalize ACOs or discourage program participation cannot be overemphasized and those described by CMS represent a good starter set for ongoing discussion (*e.g.*, limit how much the national mean benchmark could fall below national FFS spending).

Finally, CMS requests specific comments about addressing health equity through ACO benchmarking. The FAH commends CMS for its continuing commitment to equity across the agency and for thinking futuristically about equity early in the development of administratively set benchmarking. We believe, however, that specific comments on this subject at this time

would be quite premature. In the past two years, CMS has launched numerous equity-related initiatives that apply to one or more of its quality and payment programs (*e.g.*, equity-based scoring adjustments, program-level measure additions). A pause to determine the collective effects of these multiple interventions seems appropriate and such analysis could meaningfully inform potential equity focused ACO benchmark provisions. We believe particular care should be exercised when making adjustments in the context of penalties and pay-for-performance programs. Lessons learned about the stacking effects of overlapping hospital pay-for-performance program features should be reviewed for applicability to overlapping equity initiatives.⁸ We have similar reservations about choosing the ACO-REACH model’s equity design elements as a reference standard or guidepost since this model has not yet started its first implementation year. Instead, that model should be regarded as a valuable test bed for the identification of unintended consequences or perverse outcomes. Additionally, the known effects of peer grouping by dual eligibility status on results of the Hospital Readmissions Reduction Program deserve thoughtful analysis for lessons learned.⁹

In closing, we extend our appreciation to CMS for opening a dialogue that is critical to the future of the MSSP.

IV. Updates to the Quality Payment Program

A. CY 2023 Modifications to the Quality Payment Program

Quality Performance Category

1. *High Priority Measure Definition:* Starting with the 2023 performance period, CMS proposes to expand the definition of a high-priority measure to include health-equity related quality measures.

The FAH applauds CMS’ ongoing efforts to prioritize those measures that are best suited to positively impacting inequities in care and we support the expansion of this definition. We note that no definition or guidance was provided on what information would be needed to enable a measure to be classified as health-equity related. For example, if stratification of a measure identified disparities in care, could a measure then be considered high priority? We encourage CMS to provide a definition, guidance, and/or examples on what would lead a measure to be classified as health-equity related.

2. *CAHPS for MIPS Survey Case-Mix Adjustment Model:* CMS proposes to revise the CAHPS for MIPS Survey measure case-mix adjustment model to remove the existing adjustor for Asian language survey completion and to add adjustors for Spanish language spoken at home, Asian language spoken at home, and other language spoken at home.

⁸ Kahn CN, Ault T, Potetz L et al. Assessing Medicare’s Hospital Pay-For-Performance Programs And Whether They Are Achieving Their Goals. *Health Affairs* 2015; 34:1281-1288.

⁹ Shashikumar SA, Waken RJ, Aggarwal R, et al. Three-Year Impact Of Stratification In The Medicare Hospital Readmissions Reduction Program. *Health Affairs* 2022; 41:375-382.

The FAH supports this refinement to the CAHPS for MIPS Survey measure as long as it truly demonstrates that the revised scoring better reflects the care provided. Specifically, we ask CMS to provide more detailed information on the results of the analysis of the 2019 performance period data that led CMS to propose this change.

3. *Adding Items Related to Health Disparity and Price Transparency to the CAHPS for MIPS Survey Measure – RFI:* CMS poses questions about several potential changes to the current CAHPS for MIPS survey including the addition of new questions to address health equity and health care price transparency. CMS also requests input on two options for modifying the CAHPS for MIPS survey to make it more broadly applicable to specialty groups in addition to primary care groups: (1) shortening the survey by removing items relevant only to primary care providers and using the shorter survey with all practitioner groups; or (2) creating a separate shorter survey version for use in assessing specialist care and maintaining the existing longer survey for use with primary care groups.

The FAH refers CMS to our comments on this RFI under the MSSP section.

4. *Data Completeness Criteria:* CMS proposes to retain the current threshold of at least 70 percent through performance year 2023 and to raise the threshold to 75 percent in performance years 2024 and 2025.

The FAH supports retaining the current threshold of 70 percent in performance year 2023 and urges CMS to postpone any increase in the data completeness requirements until CMS addresses what impact the additional requirement might have on individual clinicians and practices.

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

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

5. *Screening for Social Drivers of Health Proposed Measure:* The FAH supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the MIPS program for several reasons.

While the FAH supports the overall intent, we do not believe that the measure is sufficiently specified and tested nor is it clear on the degree to which the selected factors are aligned with the work of the Health Level 7 (HL7) Gravity Project. The measure currently does not provide information on what encounters are included and appears to be specified so broadly that there is significant potential for the measure to be attributed to specialists and others for whom requiring this broad screening approach would not be appropriate. It also does not include any exclusions such as patients living in skilled nursing facilities where individuals should be at reduced risk for most, if not all, of these drivers.

We also note that this measure is not aligned with the specifications provided for the hospital level measure finalized in the Hospital Inpatient Quality Reporting (IQR) Program. For example, that version's numerator definition allows a hospital to screen a patient on "one or all" of the five factors. While there is significant risk that comparisons will be made where one hospital only focuses on screening on one health-related social need while others focus on all five factors, the measure as proposed for MIPS does not provide this level of detail and is not consistent with previous statements regarding the need to ensure alignment in specifications of related measures across CMS quality programs.

It also assesses the rate of screens completed by a clinician or practice in the absence of any information on the degree to which the individual or group has been equipped with the necessary resources and tools to address the individual's needs for any one of the selected factors. Any implementation of this measure is premature until these resources and tools are widely available.

CMS should consider putting forward a measure that leverages social determinants of health that are standardized through the HL7 Gravity project, provides the necessary specification required for widespread implementation, and is fully tested for feasibility, reliability, and validity. The FAH believes that these questions and concerns must be addressed and endorsement by the NQF should be achieved prior to implementation of this measure in MIPS.

6. *Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-Based Incentive Payment System:* The FAH does not believe that the sole proposed modification to attribute this measure to groups with at least one cardiologist sufficiently addresses our concerns. It is appropriate to

attribute these admissions to clinician groups since MIPS participants do not know which patients were assigned to them until well after the reporting period ends (*i.e.*, retrospectively), making it impossible for clinicians and practices to implement near real-time interventions. This measure should not be implemented until MIPS clinicians can actively engage in activities that minimize and prevent those hospitalizations that could be avoided, and the FAH encourages CMS to explore avenues by which attribution of patients could be done prospectively to allow for such engagement. A practice's improvement in avoiding unplanned admissions must be based on its ability to leverage one or more structures or processes of care.

The FAH is also concerned that while the median reliability score was 0.60 for practices with at least 21 patients, the range was from 0.401 to 0.995. The FAH believes that the minimum sample size must be increased to a higher number to produce a minimum reliability threshold of sufficient magnitude (*e.g.*, 0.7 or higher). Ensuring that the resulting performance scores produce information that would not misrepresent the quality of care provided by a group is imperative and while an increase in the sample size would result in a decrease in the number of groups to which the measure would apply, we believe that it would still be a considerable number of patients with heart failure that would continue to be factored into the measure. The FAH appreciates the inclusion of social risk factors within the risk adjustment model and strongly advocates that dual eligibility also be included since it was a strong predictor of whether a patient would be admitted. If the desire is to develop measures that can be used in other programs that may not include an adjustment for complex patients, then it becomes imperative that all variables that are determined to be predictors that are outside of the control of a group be included.

7. *MIPS Quality Performance Category Health Equity RFI*: CMS is considering future inclusion of additional health equity measures in MIPS and posed a series of questions to better understand what measures would be appropriate for MIPS. Regarding additional measures that may address health equity, the FAH urges CMS to develop a coordinated strategy across all quality programs on this important topic. We also encourage CMS to first focus on standardizing the definitions for sociodemographic variables to be collected and improved self-reported data collection methods rather than the development of new measures. As discussed under the MSSP RFI on health equity measures, we believe that work around standardized definitions as well as systematic scans of the frequency and range of variables already being collected by clinicians, practices, facilities, ACOs and other health care providers must first be completed. In addition, CMS must identify incentives for these entities to collect and report these data.

MIPS Final Score Methodology

Scoring administrative claims measures in the quality performance category using performance period benchmarks

CMS proposes to amend the current benchmarking policy to score administrative claims measures in the quality performance category using a benchmark calculated from performance period data rather than from a specified historical baseline period.

The FAH supports CMS' proposal to use data from the performance period rather than using historical data. However, we continue to encourage CMS to proactively consider the degree to which changes in care delivery as a result of the ongoing PHE directly impact the reliability and validity of much of the data used for the quality measures in MIPS. This proposed change will prove beneficial in future years but many of the quality (and cost) measures use lookback periods for risk adjustment or to ensure that case minimums can be met. The data used for these measures will continue to include 2019, 2020, and 2021 – years during which significant disruptions to care occurred and data quality was negatively impacted.

We strongly urge CMS to address the impact that the pandemic has had on the data used for the quality measures as well as other measures such as the cost measures and the risk adjustment lookbacks for the population health administrative claims-based and cost measures. Disruptions to care delivery, impacts to workforce availability and burnout, transitions to telehealth services, and revisions to the data submission process all potentially compromise the reliability and validity of the data used for these measures and risk adjustment models. CMS must evaluate whether any of the impacted measures should be used for any purpose beyond pay for reporting.

Calculating the Final Score

Facility-Based Measurement Complex Bonus Eligibility

Beginning with performance year 2023/payment year 2025, CMS proposes to make facility-based clinicians eligible to receive the complex patient bonus, even if they do not submit data for at least one MIPS performance category.

The FAH appreciates and supports CMS' proposal to make this bonus available to facility-based clinicians.

B. Advancing the Trusted Exchange Framework and Common Agreement (TEFCA) -- Request for Information

The FAH believes that cohesiveness in health information technology management can improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates ONC's leadership efforts to further the exchange and use of health information and offers the below comments in response to the TEFCA RFI.

The FAH and its members are committed to furthering TEFCA's goals in establishing a universal policy for interoperability, simplifying connectivity for organizations to securely exchange health information to improve patient care and access to information. As TEFCA is still in early implementation stages, it needs to be tried and tested before being widely adapted to all CMS programs. It is premature to consider expansion of TEFCA into CMS programs and without specific proposals, our comments cannot thoroughly address such potential expansion. In the event of any future expansion of TEFCA, we urge CMS to provide hospitals and all stakeholders an opportunity for regulatory notice and comment.

In the meantime, the FAH urges CMS to consider the following principles regarding further advancement of TEFCA:

- TEFCA should support a variety of use cases in the health care community, as well as a variety of health care payment purposes, such as streamlined prior authorization, utilization management, and other provider-to-payer communications.
- As discussed above, we believe it is premature to consider expanding the use of TEFCA across CMS programs. In the future, if such consideration becomes appropriate, CMS would need to ensure that TEFCA creates a floor for interoperability across CMS programs, with standardized clinical content and methods of delivery for all data sets – this would promote transparency, provide minimum necessary guardrails for data exchange, and ease burden for use cases.
- CMS also should evolve these data sets in alignment with the ONC Standards Version Advancement Process (SVAP) so that the health care community exchanges data in a more structured way.
- With any CMS-sponsored use of TEFCA, a uniform approach would “right-size” the clinical content needed for a particular service or purpose, increasing health care efficiencies and targeted care.
- CMS also should consider establishing a public health Qualified Health Information Network (QHIN) to participate in TEFCA, which could support public health reporting required by CMS programs and ease the significant burden and expense on providers of working with state public health agencies.

The FAH applauds TEFCA's potential to accelerate interoperability across the country but there are significant concerns that need to be addressed in doing so at such scale. For example, a key obstacle to data exchange is patient matching. A standard patient matching approach across the TEFCA model is critical to ensure participants do not miss or mismatch patients. This will be vital to its maturity while ensuring confidence in patient identity resolution overall. Also, there is a lack of consistency in the availability and use of mapping terminologies and CPT codes. These inconsistencies are a barrier to true interoperability, so advancing the standardization of semantic terminologies and licensing public use of highly adopted terminologies would advantage all participants. We also are concerned about potential bad actors participating in TEFCA – interoperable health data exchange increases efficiency but also

creates the possibility that some may misuse this information, which could undermine the strides taken to promote interoperability. As TEFCA continues to mature, we urge CMS and ONC to work with stakeholders to address these significant challenges.

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) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. Reinhart". The signature is fluid and cursive, with a prominent initial "A" and "M".