



Charles N. Kahn III
President and CEO

September 27, 2019

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

RE: CMS-1715-P. Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching full-service community hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the referenced Notice of Proposed Rulemaking on the Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to

Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations (Proposed Rule). While our detailed comments follow below, our key recommendations include the following:

- ***Evaluation and Management (E/M) Visit Codes***

The FAH supports CMS's proposal to adopt the office and outpatient E/M visit codes determined by the American Medical Association (AMA) Workgroup and Current Procedural Terminology (CPT) Editorial Panel for CY 2021. The FAH appreciates CMS's decision to adopt the AMA/CPT recommendations – and maintain the separate E/M codes and levels – rather than continuing with the previously finalized code collapse for office and outpatient E/M visits. The FAH also supports CMS's proposal to maintain separate payment rates for the E/M levels, as recommended by the RUC.

- ***Communication Technology-Based Services/Telehealth***

The FAH supports CMS's modest expansion of telehealth services in this year's Proposed Rule and continues to encourage the Agency to reform the coverage and payment rules for telehealth and remote monitoring technologies. Additional reforms will lead to improved access for beneficiaries in both rural and urban areas to primary as well as specialty and subspecialty care.

- ***Quality Payment Program***

The FAH appreciates CMS's efforts to assist clinicians, groups, and organizations participating in the Quality Payment Program (QPP) and facilitate success under the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (Advanced APMs). The annual changes, however, have placed a strain on many providers, and the FAH encourages CMS to implement some of the proposed changes, such as the increased weighting of the cost performance category, at a slower pace to allow providers time to fully implement these changes. Similarly, the FAH opposes CMS's proposal to move towards MIPS Value Pathways (MVPs) as the MVPs represent yet another large-scale change to the MIPS and will lead to increased provider burden and confusion.

- ***Aligning the MSSP and MIPS Quality Scores***

The FAH strongly disagrees with replacing the Medicare Shared Savings Program (MSSP) quality score with the MIPS quality performance category score until such time that CMS can ensure that the measures and patient populations included are aligned across both programs. Given the differences between the MSSP vs. MIPS approaches to attribution, likely invalid representations of quality, and added complexity to the program, the FAH does not support adding any MIPS claims-based measures for Accountable Care Organizations (ACOs).

- ***Opioid Use Disorder Treatment Services / Bundled Payments for Substance Use Disorders***

The FAH supports CMS's proposals to add two bundles for opioid use disorder (OUD) treatment provided by Opioid Treatment Providers (OTP) and other professionals and encourage CMS to consider how to coordinate those services that may need to be provided alongside those captured in the bundle that are important to the successful completion of the OUD treatment.

II.F. Payment for Medicare Telehealth Services under Section 1834(m) of the Act

In the CY 2020 Proposed Rule, CMS proposes to add three Healthcare Common Procedure Coding System (HCPCS) G-codes related to treatment for OUD that it believes are sufficiently similar to services currently on the telehealth list. CMS believes that adding these codes will complement the existing policies related to flexibilities in treating SUDs under Medicare telehealth.

The FAH supports CMS's modest expansion of telehealth services in this year's Proposed Rule. Health care services and data collection provided via telecommunications are becoming more important to the health care delivery system as improvements in technology reduce costs and increase speed and data storage capacity. These trends are occurring under the Medicare telehealth benefit – which covers “face-to-face” video consultation between patients and physicians – as well as technologies which collect and forward data to various types of providers for analysis of changes in patient health status. For many beneficiaries, as well as providers, telehealth allows for the delivery of more efficient and low-cost care, especially when patients may be homebound or live a far distance from providers they need to access.

Unfortunately, the current Medicare coverage and payment rules for telehealth services create challenges for many providers seeking to improve access to and coordination of patient care through these technologies. Reforming the coverage and payment rules for telehealth and remote monitoring technologies would lead to improved access for beneficiaries in both rural and urban areas to primary as well as specialty and subspecialty care. In order to promote care coordination and enhanced access for beneficiaries, we suggest that Medicare coverage and payment for telehealth should be more broadly expanded.

As such, we were pleased that CMS, in the CY 2019 Physician Fee Schedule (PFS) Final Rule, recognized the evolving state of physician services, including noting that many of these services are currently being performed via telecommunications technology. We also appreciated CMS acknowledging that technology and its uses have evolved in the many years since the Medicare telehealth services statutory provision was enacted. We supported CMS's expansion of payment for communication technology-based services, outside of the 1834(m) requirements and suggest the Agency continue to consider how CMS can take additional steps to expand the use of these important technologies.

II.G-H. Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs / Bundled Payments Under the PFS for Substance Use Disorders

In the CY 2020 Proposed Rule, CMS proposes to add two bundles for OUD treatment provided by OTP and physicians and other professionals. We support CMS's move to create these bundles as it seeks to ensure beneficiaries have access to and are provided the comprehensive set of services required for successful treatment.

It is clear from the proposal, that CMS acknowledges that in the course of treatment, there may be instances where additional services may be required that calls for the appropriate adjustment of the bundle to account for these required services. Mindful of that reality, we encourage CMS to also consider that there are likely services beyond those captured in the bundle that are important to the successful completion of the OUD treatment.

For example, in these cases, appropriate medication treatment management (MTM) is important to identify any potential drug interactions or side effects that need to be properly managed. Additionally, once side effects are identified, CMS should consider how the beneficiary will obtain any services needed to treat those side effects if that treatment is not otherwise appropriately provided by the OTP or treating physician.

Along those same lines, CMS should consider how co-occurring conditions that may be impacted by the OUD treatment will be managed. Successful completion of the OUD treatment is likely to be impacted by these co-occurring conditions and consideration should be made to how to best assist the beneficiary in managing these interactions.

We appreciate CMS's consideration of the coordination of the types of supports and services that may need to be provided alongside services provided in the OUD treatment bundle to ensure the successful implementation of these bundles.

II.J. Review and Verification of Medical Record Documentation

CMS has received feedback that undue burden is created when physicians and other non-physician practitioners, including those serving as clinical preceptors for students, must re-document notes entered into the medical record by other members of the medical team. Therefore, to reduce this burden, CMS proposes establishing a general principle to allow physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives who furnish and bill for their professional services to review and verify (sign and date), rather than re-document, notes in a patient's medical record made by other physicians, residents, nurses, students, or other members of the medical team. The FAH supports this burden reduction proposal and appreciates the Agency's acknowledgement of the concerns raised and flexibility in addressing this needed change.

II.K. Care Management Services

To increase utilization of Transitional Care Management (TCM), a care management service provided to Medicare beneficiaries after discharge from an inpatient stay or certain outpatient stays, CMS proposes to increase payment for these services and permit TCM codes to be billed concurrently with certain CPT codes that, when medically necessary, may complement TCM services rather than substantially overlap or duplicate services. In addition, CMS is proposing to replace a number of the Chronic Care Management (CCM) service codes with Medicare-specific G codes, as well as implement changes meant to reduce the burden of billing the complex CCM codes. CMS is also proposing new coding for Principal Care Management (PCM) services. The FAH supports these proposals and believe they will help to increase utilization of these services, while at the same time decrease the burden and billing complexity for these codes.

II.P. Payment for Evaluation & Management Services

The FAH supports CMS's proposal to adopt the office and outpatient E/M visit codes determined by the AMA Workgroup and CPT Editorial Panel beginning with CY 2021. Specifically, the FAH appreciates CMS's decision to adopt the AMA/CPT recommendations to maintain separate E/M codes and levels rather than continuing with the previously finalized code collapse for office and outpatient E/M visits. The FAH also supports CMS's proposal to maintain separate payment rates for the E/M levels, as recommended by the RUC. Collapsing payment rates for multiple E/M codes into two levels would have had unintended consequences that undercut CMS's important burden reduction efforts and would not have substantially reduced clinicians' documentation burdens.

III.D. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals

In the Proposed Rule, CMS proposes modifications to the requirements that eligible professionals participating in the Medicaid Promoting Interoperability Program (PIP) must meet to demonstrate meaningful use of Certified Electronic Health Record Technology (CEHRT).

One such proposal would allow Medicaid eligible professionals to conduct the required Protect Patient Health Information analysis at any time during calendar year, starting with 2021, even if the analysis is conducted after the eligible professional attests to meaningful use in his or her state. Thus, the eligible professional will attest to either having already completed the analysis or that the analysis will be completed by the end of the calendar year (e.g., December 31, 2021). This is a departure from the current process, which requires eligible professionals to complete the analysis prior to a state's meaningful use attestation deadline, which is usually on or before October 31st of each year.

The FAH supports flexibility in the date by which eligible providers must complete the Protect Patient Health Information analysis and encourages CMS to finalize this proposal.

III.E. Medicare Shared Savings Program Quality Measures

Proposed Changes to the CMS Web Interface and Claims-based Measures

CMS proposes a substantive change to the previously finalized quality measure ACO-43: Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91). While the FAH supports the removal of dehydration as one of the diagnoses included within the ACO-43, Ambulatory Sensitive Acute Care Composite, we ask that CMS carefully consider whether a measure that has not been tested for reliability and validity at the ACO level should continue to be included in this program. With only one of the two submeasures (pneumonia) tested and endorsed at the facility level, it is not known how well the two measures together represent the quality of care provided by ACOs. The FAH requests that CMS ensure that this composite is tested at the ACO level and reviewed by the National Quality Forum (NQF) as soon as possible.

The FAH supports CMS's proposal of designating the ACP-17 measure, Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, as pay-for-reporting only due to the undue burden collection of this measure poses for clinicians.

Seeking Comment on Aligning the Shared Savings Program Quality Score with the MIPS Quality Score

The FAH strongly disagrees with replacing the MSSP quality score with the MIPS quality performance category score until such time that CMS can ensure that the measures and patient populations included are aligned across both programs. Currently, the MIPS attribution methodology uses a retrospective approach to assign patients to an individual clinician or practice. However, MSSP identifies the individuals for which an ACO is responsible prospectively; replacement of the MSSP quality score with the MIPS quality performance category score would lead to inconsistent and incorrect comparisons. ACOs are able to better assess the quality of care across the continuum because they have processes in place to identify and collect performance data outside of their network. These efforts enable them to provide targeted interventions for their patients and ensure that the performance scores submitted to CMS provide a complete picture of the quality of care their participants receive. Allowing the measures and associated quality performance category score as a substitute will add complexity and confusion to the program in a way that does not add value and may misrepresent an ACO's quality of care.

Given the differences between the two approaches to attribution, likely invalid representations of quality, and added complexity to the program, the FAH does not support adding any MIPS claims-based measures such as the MIPS All-cause Unplanned Admission for Patients with Multiple Chronic Conditions or the All-cause Readmission measures for all ACOs. CMS must first align the MIPS measures to prospectively attribute patients and ensure that the measure specifications, risk adjustment approaches and any other details are harmonized before these measures and associated scores are used as equivalent substitutes to the MSSP measures and scoring.

III.K. CY 2020 Updates to the Quality Payment Program

General Comments

The QPP began in 2017, and since that time, CMS has made proposals each year to update the MIPS and Advanced APMs. Some proposals are meant to implement Congressional directives related to the QPP while others have been in response to comments received from stakeholders. Although CMS has undertaken these efforts to assist clinicians, groups, and organizations participating in the QPP and facilitate success under MIPS and Advanced APMs, the changes that result from these proposals have placed strain on many providers. The effort required to remain informed of the annual changes and then operationalize those changes in a short time period places a significant burden on providers trying most intently to fully participate in the opportunities presented by the QPP. ***As the detailed comments below explain further, the FAH encourages CMS to implement some of the proposed changes at a slower pace to allow providers to fully implement one strategy before having to change course yet again months later.***

In addition to implementing changes at a more measured and manageable pace, the FAH suggest that CMS consider a different approach to the annual reallocation of weighting the Performance Categories. Clinicians not only have to react to and plan for the programmatic adjustments that follow the issuance of CMS's final rule for the next performance year, but they must also consider how the reweighting will impact their performance under MIPS. The FAH believes that clinicians will be more successful under the MIPS if they have the opportunity to adjust to the structure of the program and required activities – without also having to worry about the annual reallocation of points related to those activities. Providing more time between QPP revisions would afford clinicians time to see if their efforts are having an impact. Being in flux year to year makes it challenging to truly achieve success in any one performance category that could then be built upon in subsequent years. For example, the proposed increase in the cost performance category makes this even more challenging. With greater weight, and therefore clinician focus, allocated to cost, providers are uncertain as to how to succeed in the cost category, as well as in the other three performance categories, while managing the ongoing changes and adjustments proposed across the program.

CMS proposes to address some of these concerns via the MVPs. ***As discussed more fully below, the FAH does not believe that the MVPs will provide the clarity and consistency that many clinicians are seeking from MIPS. Instead, the FAH believes the MVPs represent yet another large-scale change to the MIPS and will lead to increased provider burden and confusion.***

Merit-based Incentive Payment System

Scoring Thresholds

As in previous years, CMS proposes increases to both the performance and exceptional performance thresholds. The performance threshold for performance year 2019 is 30 points, and CMS proposes to increase this to 45 points for performance year 2020 and 60 points in 2021. The

exceptional performance threshold is currently set at 75 points, and CMS proposes to increase this to 80 points in performance year 2020 and 85 points in 2021.

The FAH is concerned about the ability of clinicians to meet the proposed increased performance and exceptional performance thresholds for performance years 2020 and 2021. Clinicians and groups that invested time and resources over a number of years into electronic health records (EHRs), quality measurement, and performance improvement were able to participate in MIPS successfully during the first years of the program. However, the increased thresholds proposed for 2020 and 2021 would require clinicians to be nearly perfect in all performance categories to avoid a penalty, which is nearly impossible for clinicians given the structure of some of the performance categories and the many changes to MIPS that have to be accounted for on an annual basis. For example, clinicians are unable to forecast their performance in the cost category because the benchmarks are established after the performance period closes. And, in proposing to increase the performance and exceptional performance thresholds, CMS did not properly account for the promoting interoperability category changes starting in performance year 2019. Those changes make the promoting interoperability category completely performance based, and it is now impossible to achieve a perfect score in that category.

The FAH also believes that hospital-based MIPS-eligible clinicians will categorically struggle to meet the performance threshold proposed for 2020, let alone the proposed threshold for 2021. While the FAH appreciates CMS's efforts to address the characteristics unique to this group of clinicians, some of these accommodations will make it difficult to achieve the performance threshold score going forward. For example, CMS established that a hospital-based MIPS eligible clinician is assigned a zero percent weight for the promoting interoperability performance category, and the points associated with the promoting interoperability performance category will be redistributed to another performance category or categories. The reallocation of the promoting interoperability performance category weight to the quality performance category makes performance on the quality category that much more important for those clinicians. However, the FAH does not see a path for achieving all the points available in the quality performance category with the measures available for hospital-based MIPS clinicians. To address this concern, the FAH encourages CMS to consider allowing these clinicians to submit the hospital-level promoting interoperability scores as the clinician's scores for the promoting interoperability category. Similar to what is permitted in submitting measures under the quality category, this would enable these clinicians to achieve scores more in line with the efforts of the hospital where they are based and does not unintentionally punish this category of clinicians.

Category Weights

CMS proposes to modify the performance category weights for the 2022, 2023, and 2024 payment years – specifically increasing the weight of the cost category while decreasing the weight of the quality category. This redistribution of the category weights continues to raise concerns for clinicians, and the FAH does not believe that the proposed increases to the cost performance category weight are appropriate at this time. Clinicians are still working to understand what truly comprises their cost category score, and the lack of data for this calculation presents challenges. The FAH is concerned that CMS's proposed increases to the cost category weight do not appropriately account for the current lag time associated with this data, which

impacts the ability of clinicians to implement changes to improve performance in this category. FAH members have reported that they have yet to receive data from CMS on the current cost episodes. Without the ability to review and understand the data that was used in the cost score calculation, clinicians are not equipped to make any changes or adjustments that would improve their score in future years. The FAH urges CMS not to finalize the proposed increases to the cost performance category weight and instead allow clinicians the time to receive and digest their cost data and then to implement meaningful changes that result in better cost category performance in the future.

Redistributing Category Weights

CMS proposes to change the process for redistributing category weights. Specifically, CMS proposes to stop redistributing category weight to the improvement activities category starting with performance year 2020 and instead begin redistributing weight to the cost category starting with performance year 2021. As discussed above, the FAH urges CMS not to assign any additional weight to the cost category due to the lack of available data for clinicians regarding their performance on the current cost episodes and thus their inability to undertake informed activities to improve their performance. In addition, eliminating the improvement activities category as an option for redistributing any weight from other categories lessens the efforts clinicians have in place to succeed under this pillar of MIPS. As such, the FAH urges CMS to maintain the current redistribution policy.

Hospital-Based Clinician and Non-Patient Facing Clinician Groups

Currently, CMS reweights the promoting interoperability performance category to zero and redistributes the associated points to other categories for hospital-based clinicians and non-patient facing clinicians. For these MIPS eligible clinicians participating as a group, CMS currently requires that, in order for the promoting interoperability category to be reweighted, all eligible clinicians in the group or virtual group must qualify for reweighting (i.e., must meet the criteria for a hospital-based clinician or non-patient facing clinician). This 100 percent threshold restricts groups that may have clinician turnover or regularly use locum tenens physicians from benefiting from the reweighting.

In the Proposed Rule, CMS proposes revising the threshold for the group to qualify for reweighting from 100 percent to 75 percent starting in performance year 2020. The FAH supports this revised definition as it reduces burden for groups that currently do not qualify for reweighting because they have a small number of MIPS eligible clinicians who do not meet the hospital-based or non-patient facing clinician criteria.

While reweighting the promoting interoperability performance category is helpful for some groups and virtual groups, others find that the reweighting results in increased pressure on the other categories and can make it difficult for hospital-based or non-patient facing clinicians to achieve the performance threshold and exceptional performance threshold. To help address this concern, the FAH encourages CMS to consider allowing groups that choose to do so to submit the hospital-level promoting interoperability scores as the clinician's scores for the promoting interoperability category, similar to what is permitted in submitting measures under

the quality category.

Targeted Review Process

The Proposed Rule contains several proposed clarifications and changes to the targeted review process. CMS addresses who is eligible to request a targeted review; the timeline for submitting such a request; additional criteria for denial of a targeted review request; requirements for requesting additional information; who will be notified of targeted review decision; and codifying the policy on scoring recalculations. The FAH appreciates CMS allowing MIPS-eligible clinicians or groups to request a targeted review of the calculation of the MIPS payment adjustment factor. Due to the impact a positive or negative payment adjustment has on a clinician or group, it is critical to have a mechanism to pursue clarification if a party believes an error has been made.

CMS also proposes to modify the timeline for targeted review requests. Beginning with the 2019 performance period, the timeline would require that all targeted review requests be made during the targeted review request submission period, which would be the 60-day period that begins the day that CMS makes the adjustment factors available. The FAH supports this clarification as it provides a full 60 days to clinicians for review of their calculation of the MIPS payment adjustment factor; if CMS is delayed in releasing the information, clinicians will still be afforded the full 60 days to review the information and request a targeted review, if appropriate. The FAH also supports the release of revised performance feedback during October of the year prior to the MIPS payment year so that this information is available earlier than CMS was able to accomplish for the first year of targeted reviews.

Quality Performance Category

Measure Addition for 2021 Performance Period: All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions

The FAH does not support inclusion of this measure in the MIPS due to several factors, including: there is insufficient evidence to support attribution to individuals or groups, particularly with the attribution assigned retrospectively; the minimum sample size and reliability threshold remain too low; and additional information on the validity of the measure when applied at these levels is needed. In the addition, the measure is not currently endorsed by the NQF, and the FAH believes the measure should go through the NQF process and receive endorsement prior to being utilized in the MIPS.

The FAH applauds CMS for including social risk factors within the risk adjustment model and strongly advocates that dual eligibility also be included since it was a strong predictor of whether a patient would be admitted. However, even with the addition of these variables in the risk model, the FAH does not believe that it is appropriate to attribute these admissions to clinicians. On review of the methodology report released for public comment in May 2019, CMS did not provide sufficient data and empirical evidence to demonstrate that individual clinicians or groups can meaningfully influence unplanned admissions in this population. The supportive evidence demonstrated that improvements in unplanned admissions could be made when

coordinated programs or payment offsets were also in place, but much of these efforts in those studies required involvement of larger entities such as health plans or ACOs. In addition, MIPS participants do not know which patients were assigned to them until well after the reporting period ends (i.e., retrospectively), making it impossible for clinicians and practices to implement near real time interventions. This measure should not be implemented until MIPS clinicians can actively engage in activities that minimize and prevent those hospitalizations that could be avoided, and the FAH encourages CMS to explore avenues by which attribution of patients could be done prospectively to allow for such engagement.

CMS must ensure that the data produced yields scores that more accurately and consistently represent the quality of care. As such, the FAH recommends that CMS increase the minimum sample size to a higher number – such as 62 patients or greater – in light of the low reliability threshold produced with only 27 patients. Ensuring that the resulting performance scores produce information that appropriately represents the quality of care provided by an individual clinician or group is imperative. While an increase in the sample size would result in a decrease in the number of clinicians to which the measure would apply, over 80 percent of the patients with multiple chronic conditions would continue to be factored into the measure.

Lastly, CMS has not released information on the results of validity testing, which should be publicly disseminated and reviewed by the NQF prior to implementation. In addition, the FAH does not believe that face validity is sufficient to demonstrate that the measure as attributed provides appropriate and evidence-based representations of the care provided by these clinicians. We strongly encourage CMS to validate these measures through additional testing, such as predictive and construct validity, to ensure that application of the measure to each of the accountable units is appropriate and yields scores that are valid and useful.

Measure Changes for Web Interface Reporters

The FAH supports removal of the Influenza Immunization measure and the addition of the Adult Immunization Status measure once the Measure Application Partnership's (MAP's) recommendations are addressed. The MAP recommended that challenges such as vaccine shortages, reimbursement of vaccinations, and feasibility of data capture be explored prior to implementation. The group also noted that there is a need to harmonize the requirements of this composite to align with any individual related measures in MIPS and that the measure still required testing at the ACO level. These recommendations should be addressed prior to finalization of this measure.

Data Completeness Criteria

The FAH recommends that CMS 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 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. The FAH also disagrees with any policy that would create different data completeness thresholds within the quality performance category, such as increasing the data completeness threshold for topped out quality measures. Lastly, 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.

Linking Quality Measures to Existing Cost Measures and Improvement Activities

The FAH supports requiring measure stewards to link the MIPS quality measures to existing and related cost measures and/or improvement activities when available. This linkage could facilitate the selection of groups of measures and improvement activities in a more meaningful and actionable way.

Measure Removal Criteria

CMS is proposing to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive CY performance periods. The FAH cautions CMS to carefully consider whether removal of measures under these circumstances is prudent at this time. MIPS is not currently structured to incentivize reporting on new measures, and clinicians and organizations may elect not to report on a new measure for a time while they determine how to incorporate the measure into their practices, including assessing the burden and utility of collecting the measure and enabling the requisite analytic capability. As a result, measures for which reporting is initially low may be due to slow uptake and not necessarily indicative that the measure is not meaningful. As we move toward measures that are more complex, such as composites or patient-reported outcomes, these measures could experience slower uptake due to data collection burdens and limitations of analytic capacity. As such, the FAH does not believe that CMS should assume that measures that have not achieved the case minimums and reporting volumes do not provide meaningful measurement.

Cost Performance Category

The FAH understands that CMS is striving to meet the balance of weighting the cost and quality performance categories as required by the statute by performance year 2022. ***However, the FAH disagrees with CMS's proposal to increase the weight of the cost category each year through performance year 2022. Instead, the FAH urges CMS to maintain the weight of the cost performance category at 15 percent for as long as possible under the statute.***

The FAH believes that the ultimate balance of the cost and quality categories will be more impactful if clinicians gain more familiarity with cost measures and have the time and information needed to understand their performance under the cost category. Clinicians are currently unable to assess how the changes that are being made regarding patient care may be impacting the cost of care for those patients. As CMS acknowledges in the Proposed Rule, cost measures are still being developed, and clinicians do not have the same level of familiarity or understanding with cost measures as they do with quality measures. Even if clinicians gained a better understanding of the measures themselves, there is a lack of information regarding how performance under these

measures affects patient care or the clinician's score under MIPS. Maintaining the cost category weight at 15 percent for as long as permitted under the statute will allow clinicians to gain experience with the cost measures. It will also allow clinicians to receive and evaluate their cost data and implement practice changes.

If, after review of the comments to this Proposed Rule, CMS decides to move forward with increasing the weight of the cost performance category, the FAH urges CMS not to change other elements of the cost category. For example, CMS should not implement additional cost category measures. The FAH believes that clinicians, and their patients, would benefit from additional time working with the current measures. Implementing new measures while also increasing the weight of the cost performance category will increase the complexity of the cost category, as well as clinician confusion.

Attribution

The FAH appreciates CMS's consideration of the attribution methodology as a fundamental element of a cost measure. The FAH supports CMS's proposal to include this information with the measure specifications as long as substantive changes, including changes in attribution, continue to be addressed in the rulemaking process. This is similar to what is done for quality measures and will simplify the process while still allowing for stakeholders to provide input on substantive changes that might impact their ability to report on and use these measures.

Episode-based Measures for the 2020 and Future Performance Periods

The FAH does not support adding additional episode-based costs measures at this time. Prior to moving forward with any new measures, the FAH strongly believes that additional testing must be completed. Specifically, CMS must complete empiric validity testing to demonstrate how each of these measures correlate to quality measures reported within MIPS. The FAH's recent review of the NQF's submissions for three of the cost measures finalized for the 2019 reporting year identified that no such analyses (i.e., quality of care correlated to the costs for individual clinicians and practices) have been performed. Cost should never be evaluated outside of the context of quality, and it is imperative that CMS and health care providers understand whether the costs reported indicate reasonable costs and/or whether there are outliers.

In addition, CMS must reevaluate the current benchmarking approach for the cost measures where higher cost is associated with lower deciles and points. Lower cost should not automatically achieve higher scores, and for several of the measures, the variation in costs is limited, which could lead to determinations on costs being made based on small differences in spending. These assumptions are inherently flawed and could lead to negative unintended consequences such as misleading clinicians and the public on what constitutes reasonable costs. The FAH recommends that CMS explore alternative ways to analyze costs, such as identification of outliers, and redesign the cost benchmarking approach to correctly communicate what costs would be considered appropriate and where additional improvement efforts are needed.

Lastly, the FAH urges CMS to develop a process by which the same or similar costs are not counted across multiple measures. As the list of episode-based cost measures grows, the potential for double counting is likely, particularly if Total Per Capita Cost (TPCC) or Medicare Spending per Beneficiary (MSPB) are attributed along with one or more episode-based measures to the same individual. The FAH recommends that either the TPCC and MSPB measures be removed or they be excluded and not attributed to a clinician or group if one or more episode-based cost measures also apply.

Total Per Capita Cost

The FAH does not support the proposed revisions to the TPCC and urges CMS not to finalize any changes to this measure until additional testing and analyses are performed. The FAH agrees with the MAP's recommendation of "do not support with potential for mitigation" in light of the numerous comments received during the MAP process and the MAP conditions placed on the revised measure. The FAH believes that the revised attribution approach is too broadly applied and has significant risk of assigning patients to a clinician or group for whom responsibility of monitoring a patient's total cost of care is inappropriate. Specifically, the validity of the approach has not demonstrated that all specialties to which the measure is not intended to apply are truly excluded (e.g., whether physician assistants who work within a surgical practice are removed as intended) nor has CMS demonstrated that the TPCC results are correlated to existing quality measures. In addition to these concerns, the MAP also questioned how the measure addresses small case minimums, the inclusion of social risk factors in the risk adjustment approach, and how CMS will avoid double counting of costs across the cost measures. The FAH believes CMS must undertake the work needed to answer these questions and ensure that this measure attributes costs appropriately and validly prior to its use in the MIPS. In addition, the measure is not currently NQF endorsed, and the FAH believes the measure should go through the NQF process and receive endorsement prior to implementation in MIPS.

Medicare Spending Per Beneficiary

The FAH encourages CMS to ensure that the MAP conditions placed on this revised measure are addressed prior to finalization. Specifically, the MAP recommended review of this measure by the NQF since it has not yet been submitted or endorsed at the clinician or group level. In addition, the MAP outlined concerns with the lack of information on reliability and validity of the measure, particularly at the individual reporting level; the need to incorporate social risk factors into the risk adjustment when appropriate; the potential for unintended consequences to patients, including stinting of care; the need for education on the measure; and that CMS avoid double counting of costs across the cost measures.

Episode-based Measure Reliability

CMS proposes to include the Lower Gastrointestinal Hemorrhage episode-based measures in the cost performance category only for MIPS eligible clinicians who report as a group or virtual group given that the measure does not meet the reliability threshold of 0.4 that was established for the cost performance category. The FAH supports the application of the

Lower Gastrointestinal Hemorrhage to group reporting only due to the lower reliability threshold produced at the individual reporting level.

The FAH encourages CMS to reexamine the current average reliability threshold of 0.4 it has set for revised cost measures. CMS set this threshold in the CY 2017 QPP Final Rule with an eye towards maximizing levels of participation. However, the use of the average threshold of 0.4 brings into question the reliability of cost measures and will call into question the accuracy of assessments. The FAH urges CMS to ensure that the most reliable and accurate information is provided to clinicians and patients.

Request for Comments on Future Potential Episode-Based Measure for Mental Health

The FAH supports CMS's decision not to propose the Psychoses/Related Conditions measure at this time. The FAH agrees with the MAP's assessment regarding concerns with the validity of the measure due to the attribution approach and the associated unintended consequences of its implementation. The FAH strongly encourages CMS to thoroughly consider these concerns for any future cost measure that may apply to these important patient populations.

Improvement Activities Performance Category

For the first three performance years, CMS established the group reporting threshold for improvement activities at one clinician for the group. In other words, if at least one clinician within the group performed an activity for a continuous 90 days during the performance period, the entire group could report on that activity. While this was an extremely low threshold to meet for the improvement activities category, it permitted groups and clinicians to test out this category and understand what activities could be selected and how they could be implemented successfully.

As we prepare to enter the fourth performance year for MIPS, CMS proposes to increase the minimum threshold of clinicians in a group that must complete an improvement activity for the entire group to receive credit. Beginning in performance year 2020, CMS proposes to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent of the group. The FAH agrees that the one clinician threshold was not the most impactful measure of the effectiveness of improvement activities and supports increasing this threshold. However, the FAH is concerned that 50 percent is too large an increase for one year. Instead, the FAH believes that 25 percent is a more appropriate increase to the threshold for the first increase since the inception of MIPS.

While the FAH agrees that adoption of improvement activities by a larger number of clinicians in a group should yield improved outcomes, the increase from 1 clinician to half of the clinicians is a steep increase to manage in one year. For a number of groups, this will require reporting on entirely new activities. ***Readjusting the activities they perform will take time for clinicians and groups such that many of them cannot achieve 50 percent participation during the upcoming performance year. A 25 percent threshold represents a meaningful, yet feasible, increase that does not dramatically increase clinician confusion and burden.***

Promoting Interoperability Performance Category

The FAH continues to believe that health information technology (HIT) holds enormous potential to 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 CMS's efforts to further the exchange and use of information and offers the below comments in response to proposed changes to the promoting interoperability performance category.

Goals of Proposed Changes to the Promoting Interoperability Performance Category

The FAH supports the goals of the proposed changes to the promoting interoperability performance category outlined in the Proposed Rule, including providing stability, reducing administrative burden, improving patient access to their medical records, and continued use of the 2015 Edition CEHRT. In response to the recent Office of the National Coordinator for Health Information Technology (ONC) interoperability and information blocking Proposed Rule, the FAH commented that the proposed changes to the 2015 Edition necessitates a new name to avoid stakeholder confusion. Should ONC finalize the proposed 2015 Edition changes and adopt a new moniker, the FAH notes that CMS should change references to the 2015 Edition in the QPP references within the promoting interoperability performance category.

Electronic Health Record Reporting Period

The FAH supports CMS's proposal for the 2023 MIPS payment year, to add §414.1320(f)(1), which would establish a performance period for the promoting interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs two years prior to the applicable MIPS payment year, up to and including the full calendar year (CY 2021). This proposal aligns with the proposed EHR reporting period in CY 2021 for the Medicare PIP for eligible hospitals and CAHs (84 FR 19554).

Proposed Changes to Measures for the e-Prescribing Objective

Query of a Prescription Drug Monitoring Program (PDMP) Measure

The FAH appreciates CMS's recognition that "PDMPs are still maturing in their development and use," that "is considerable variation among state PDMP programs as many only operate within a state and are not linked to larger systems," and that "[h]istorically, health care providers have had to go outside of the EHR workflow in order to separately log in to and access the State PDMP."¹ As such, the FAH supports CMS's proposal to remove the numerator and denominator for the Query of PDMP measure and replace it with a "yes/no" response for the CY 2019 and CY 2020 EHR performance periods, with a "yes" response meaning that the eligible clinician used data from the CEHRT to query a PDMP for at least one Schedule II opioid electronically prescribed using CEHRT. The FAH also supports CMS's proposal to make this measure optional in CY 2020 as well and appreciates CMS's clarification that a "yes" response for this measure would earn the full five bonus points for CY 2019 and CY 2020.

¹ 84 Fed. Reg. 40767 (Aug. 14, 2019).

In response to CMS's request for comment on future timing for an EHR-PDMP integration measure, the FAH believes that CMS should not implement such a measure until the state PDMPs mature and platform variation across states is mitigated. There will also need to be sufficient time for HIT vendors to design and build the EHR-PDMP integration and then time for clinicians to implement the systems, including testing and staff training. Implementing such a measure too quickly would lead to similar confusion and workarounds as occurred with the public health reporting requirements where some states are simply unable to perform the bidirectional information exchange.

Verify Opioid Treatment Agreement Measure

The FAH echoes the concerns noted by CMS in the Proposed Rule with regard to the Verify Opioid Treatment Agreement measure and strongly supports CMS's proposal to remove the measure beginning with the CY 2020 performance period. The FAH believes the concerns with this measure are insurmountable. As such, the FAH would not support implementation of this measure in future rulemaking.

Proposed Changes to the Scoring Methodology for the 2020 Performance Period

For the 2020 performance period, CMS is proposing to: remove the Verify Opioid Treatment Agreement measure; make the Query of PDMP measure optional and eligible for five bonus points; and change the e-Prescribing measure to a maximum of ten points. The FAH strongly supports these changes and, as noted above, appreciates CMS's recognition of the concerns associated with these two opioid-related measures.

Future Direction of the Promoting Interoperability Performance Category

Request for Information (RFI) on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category

CMS seeks comment on possible future promoting interoperability measures relevant to clinical priorities related to addressing opioid use disorder prevention and treatment. The FAH believes that CMS must implement a broader focus on pain management to provide a more comprehensive picture of the quality of care to patients and whether a set of measures on this broader topic could drive improvements as intended. The FAH does not believe that narrowly focused measures on opioids in the absence of understanding the root cause of the pain and pain management strategies will solve this public health concern; rather, examining pain and standardizing pain assessments and alternative therapies in addition to understanding current opioid prescribing practices would prove more beneficial to hospitals and the patients they serve.

The FAH also recommends that CMS explore the development of measures that better define the processes and outcomes that hospitals can improve, such as:

- Naloxone education and referral at discharge;
- Use of high-risk medications in the elderly, such as initial doses of hydromorphone and use of morphine in patients with renal failure;

- Elimination or reduction of Demerol administration and other drugs that have an increased potential for addiction; and
- Education on and appropriate wasting of opioids.

As noted in the FAH’s comments in response to the FY 2020 Inpatient Prospective Payment System (IPPS) Proposed Rule, the FAH also strongly urges CMS to complete more in-depth and broad assessments of feasibility to collect many of the individual data elements required for electronic clinical quality measures (eCQMs) in the hospital setting. The FAH identified several areas in our comments that are unique to the inpatient setting and directly impact a hospital’s ability to collect the required data to ensure valid assessments of the quality of care delivered. These challenges include but are not limited to the:

- Documentation practices and clinical workflows in EHRs that differ in the inpatient setting such as the capture of only new prescriptions rather than continuing prescriptions;
- Lack of integration of PDMPs with EHRs, the limited ability to allow broad access to these data due to privacy concerns, and the simplicity of these systems that do not allow tracking of what specific information was accessed by health care professionals.

These challenges must be balanced with the changes to EHRs, documentation practices, and clinical workflows that would be required. Prioritization must be given to those areas that can lead to improvements in care delivery and the quality of care provided to our patients. Measures that lead to modifications that do not directly result in these improvements and are not based solidly in evidence should not be considered.

RFI on NQF and CDC Opioid Quality Measures

The FAH does not support the potential inclusion of any of the NQF measures in the promoting interoperability category due to misalignment of the measures with current evidence and the inapplicability of a measure designed to assess health plan performance to a setting using EHRs. The FAH does support exploring the development of some of the Centers for Disease Control and Quality (CDC) Quality Improvement (QI) opioid measures for potential inclusion in the promoting interoperability category.

The FAH provided extensive comments on the NQF measures and CDC QI measures in response to the FY 2019 IPPS Proposed Rule and refers the Agency to that letter for additional details on the FAH’s recommendations.²

RFI on a Metric to Improve Efficiency of Providers Within EHRs

CMS is seeking comments on how implementation of more efficient workflows can be effectively measured as part of the promoting interoperability performance category, as well as

² Federation of American Hospitals comment letter Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals (June 24, 2019), available at: https://www.fah.org/fah-ee2-uploads/website/documents/IPPS_2020_FAH_Comment_FINAL_6-24-2019.pdf

to how to measure and incentivize efficiency as it relates to the use of CEHRT and the furthering of interoperability. The FAH believes this could be valuable but is unclear how such efficiencies would be measured (e.g., number of clicks, time on a screen, time to complete an encounter, time to complete medication reconciliation) and whether CMS is interested in measuring health care providers or the HIT vendors. While health care providers can control some aspects of HIT systems (e.g., customization of user interfaces and staff training), most aspects of the systems, particularly the technical functionality, is entirely in the purview and control of the HIT vendors.

As CMS notes in the Proposed Rule, stakeholders must address challenges with EHR vendors placing burdensome workflows on the providers' staff because the vendors certify software to meet the bare minimum requirements and do not develop solutions that actually fit "real world" workflows. Throughout testing phases of developments for EHRs, users often must duplicate information, toggle in and out of multiple routines to complete a single workflow or enter information manually that is already available in the EHR, but the vendor has not programmed it to be pulled in automatically. When EHR vendors are certified, consideration should be given to the efficiency of the product to make data entry on the end user as simple and seamless as possible. For example, to capture the data needed, some EHRs require physicians to document part of the discharge information in the discharge desktop, and other parts in the physician desktop. To be efficient and accurate, physicians want to enter this information in one place, and FAH members struggle with clinician adoption of these cumbersome workflows. Other platforms have this fully integrated where information flows seamlessly between these areas, so a physician can do everything in the Physician Desktop and it will flow over to the discharge desktop to the nurse, but our members have been told that the vendors have no plans to duplicate this in their other EHR platforms to optimize.

The FAH recommends that EHR vendors be compelled to develop efficient and logical solutions that flow with the way end users actually use the system. The FAH also recommends that CMS consider separating the deadline for EHR vendors to have solutions in place and for hospitals and clinicians to implement the new requirements. The process would work better if vendors were required to have all the functionality delivered, and then the provider would have a year to implement based on these updates. Without these staggered deadlines, our members have been left to piece together solutions at the last minute when a new requirement is instituted, and the vendors simply do not deliver functional software in time.

Should CMS continue to explore such measures, the FAH urges CMS to focus on measurement in such a way that spurs efficiencies, such as through bonus points, rather than simply adding another mandatory reporting obligation.

RFI on the Provider to Patient Exchange Objective

Immediate Access – As CMS notes in the Proposed Rule, the current Provide Patients Electronic Access to Their Health Information measure requires that the eligible clinician provide patients "timely access" to view, download, and transmit their health information and that it must be available to the patient within one business day of its availability to the facility. In this RFI, CMS seeks comment on whether eligible clinicians should make patient health

information available immediately through the open, standards-based application programming interface (API), no later than one business day after it is available to the eligible clinician.

Should CMS move forward in future rulemaking with updating this measure to account for the implementation of open, standards-based application programming interfaces (APIs), the FAH urges CMS to maintain the current timeframe of four business days of its availability to MIPS eligible clinicians to make the information available to patients. The data being available to the eligible clinician in their EHR is not necessarily indicative of that information being immediately available via the API, as some eligible clinicians perform behind-the-scenes work to aggregate a patient's data from all of health system's facilities to ensure the patient is receiving accurate, updated, combined data and a better user experience. In addition, the FAH urges CMS to ensure that any changes to this measure align with any relevant policies (e.g., information blocking) from the recent ONC interoperability and information blocking Proposed Rule that are eventually finalized.

Persistent Access – CMS is seeking comment on whether to revise the existing Provide Patients Electronic Access to Their Health Information measure to align with the technical requirement proposal for persistent access to APIs in the ONC Proposed Rule. Specifically, that proposal would permit third-party applications persistent access to an API via an authorization token that would last for three months, meaning the patient would not need to reauthorize the third-party application he is using to access his information or reauthenticate his identity in that three-month period.

The FAH would not support updating the promoting interoperability performance category to conform the Provide Patients Electronic Access to Their Health Information measure with this proposed ONC policy, as the FAH believes the proposed ONC policy raises privacy and security concerns and should not be finalized. The FAH instead recommends requiring reauthentication each time information is sought via the API. Reauthentication at each use is in line with industry standards for accessing other applications containing sensitive information, such as banking or credit card applications, and would not be unduly burdensome on the consumer.

Available Data – Electronic Health Information (EHI) Export – CMS is seeking comment on an alternative measure under the Provider to Patient Exchange objective requiring clinicians to use “technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR.”³

The FAH would have serious concerns with such an alternative measure. First, the EHI export criteria was proposed in the recent ONC interoperability and information blocking Proposed Rule and have not yet been finalized. These criteria are new, untested, and will not be implemented for a few years, and thus it is difficult for clinicians to provide CMS with fully informed feedback on how such a measure might operate under the promoting interoperability performance category. There are also significant outstanding questions and concerns regarding ONC's EHI export criteria proposal. For example, in the FAH's response to the ONC Proposed Rule, the FAH requested clarity regarding ONC's intent in proposing to require that the data be

³ 84 FR 70782 (Aug. 14, 2019).

exported in “computable” format and noted that some data for export may be “digital” but not “computational” in nature (e.g., a PDF document). In another example, the FAH comments in response to the ONC Proposed Rule noted that data exported to a single patient for use in his own care differs substantially from the data required by a provider about their patient population to facilitate full migration during an IT system transition (the other proposed EHI export criteria function). As such, the FAH recommended that ONC allow for variations in functionality appropriate to the two use cases (i.e., individual patient access; health care provider IT system transition) when assessing HIT modules submitted for certification to the EHI export criterion.

Second, as the EHI export criteria lack standardization and maturity, they cannot currently provide electronic access to all information contained in an EHR in a format that is understandable to patients and their families. Providing the information in a non-standardized format – as it would be implemented under the ONC Proposed Rule – would have no marginal benefit for the patient over providing the information via a paper copy.

Third, the FAH comments in response to the ONC Proposed Rule noted that, under HIPAA, a single patient user is entitled to access his designated record set. As such, the FAH recommended that the EHI export be limited to EHI that is part of the designated record set, which may not be all information contained within an EHR.

Given the concerns raised above, the FAH cautions CMS against developing such an alternative measure – at least until these issues are addressed. Should CMS eventually move forward with such a measure under the promoting interoperability performance category, the FAH recommends that the measure be an attestation (i.e., “yes/no”) measure, with a “yes” response signaling that your EHR has the EHI export functionality.

Available Data – Information Exchange Across the Care Continuum – CMS is also seeking comment on a possible future HIT activity that encourages health information exchange across the care continuum, including exchange with post-acute care providers, behavioral health providers, and community-based service providers.⁴

As FAH noted in response to the recent CMS patient access Proposed Rule, the FAH appreciates CMS’s interest in improving health information exchange across the health care continuum to improve the quality and efficiency of patient care and believes the best way to achieve that goal is through the use of “incentives” – such as financial support and/or regulatory relief – rather than “sticks” – such as Conditions of Participation (CoPs) or complex regulatory requirements. For example, the FAH comments encouraged CMS to explore whether health care providers that do not participate in the Medicare or Medicaid EHR Incentive Programs could receive support through the Center for Medicare & Medicaid Innovation (CMMI), such as providing the fees for those providers to join health information exchanges (HIEs), health information networks (HINs), or prescription drug information exchanges; and/or increasing reimbursements for those providers that engage in information exchange.

The Draft Trusted Exchange Framework and Common Agreement (TEFCA) 2.0 also offers the potential for enhanced interoperability through voluntary engagement with Qualified

⁴ *Id.* at 19568.

HINs. For example, a hospital participating in TEFCA could be deemed to meet the Health Information Exchange objective. While the TEFCA is further revised and implemented, CMS could provide full credit for the Health Information Exchange objective to providers who participate in a HIN. As noted in the FAH comments in response to the Draft TEFCA 2.0, the FAH urges CMS and ONC to align the TEFCA, the information blocking requirements, and the promoting interoperability performance category to the fullest extent possible to encourage greater electronic data exchange and promote interoperability.

Lastly, to encourage exchange of information between acute care and post-acute care providers, the FAH comment letter in response to the recent CMS patient access Proposed Rule recommended incorporating some post-acute care data elements into the US Core Data for Interoperability (USDCI). This incorporation of elements over time would allow acute care providers to collect and exchange some post-acute care data elements consistently across providers.

Patient Matching – The FAH appreciates CMS’s and ONC’s commitment to improving patient matching, including facilitating private sector efforts in the absences of a unique patient identifier (UPI). The FAH provided comments on patient matching in response to the recent CMS patient access Proposed Rule and refers the Agency to that letter for additional details on the FAH’s recommendations.⁵

RFI on Integration of Patient-Generated Health Data Into EHRs Using CEHRT

CMS requested stakeholder feedback on the incorporation of Patient-Generated Health Data (PGHD) into EHRs using CEHRT. Specifically, CMS is seeking comment on ways the promoting interoperability performance category could adopt new elements related to PGHD that are clearly defined uses of HIT; linked to positive outcomes; and advance the capture, sharing, and in requesting this information, CMS highlighted its belief that the promoting interoperability category should consider new ways to incentivize health care providers who take proactive steps to advance the emerging use of PGHD.

The FAH does not agree with trying to integrate PGHD into EHRs as there are limited use cases for the capture of most PGHD and doing so would require clinicians to integrate data into the medical record for which they could not verify its accuracy. As such, the FAH does not support the inclusion of PGHD at this time as a promoting interoperability measure. Such a measure would be contrary to the movement away from patient-action measures and towards those measures that are within the clinician’s control. The FAH also remains concerned with the security, privacy and integrity of PGHD. To support the integrity of the data considered in the promoting interoperability category, the FAH suggests focusing on measures that reflect the effort of the clinician rather than place the focus on the patients and their inputs.

⁵ Federation of American Hospitals comment letter Re: Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in Federally-facilitated Exchanges and Health Care Providers (June 3, 2019), available at: https://www.fah.org/fah-ee2-uploads/website/documents/CMS_Proposed_Rule_-_FAH_Letter_-_FINAL.pdf.

Third-Party Intermediary

Under current CMS policy, eligible clinicians and groups may use a qualified clinical data registry (QCDR), qualified registry, HIT vendor, or a CMS-approved survey vendor to submit MIPS data on their behalf. These entities provide valuable assistance to many MIPS eligible clinicians and groups in facilitating the communication of information to CMS in the prescribed manner. In addition to the current requirements these entities must meet in order to qualify as third-party intermediaries, CMS proposes new requirements, particularly for QCDRs and qualified registries. While the FAH agrees with the proposals related to these entities, the FAH also encourages CMS to consider the impact these proposed changes may have on eligible clinicians and groups. Many clinicians and groups engage these intermediaries to relieve some of the burden related to reporting requirements under MIPS, and the FAH asks that CMS ensure that any additional requirements do not have the unintended effect of increasing the burden on the clinicians and groups using these tools.

MIPS APM Clinicians

As the MIPS program has matured, operational limitations have been identified that impact certain groups of clinicians. As CMS noted in the Proposed Rule, for participants in some MIPS APMs, it is not operationally possible to collect and score performance data on APM quality measures to comply with the MIPS requirements. This can occur for a variety of reasons, including that some APMs have episodic or yearly timelines that do not align with MIPS deadlines for its performance period. CMS proposes to address this issue, starting with the 2020 performance period. Specifically, CMS proposes to allow eligible clinicians participating in MIPS APMs to report on MIPS quality measures for the quality performance category, similar to the policy for the promoting interoperability performance category under the APM scoring standard.

The FAH supports CMS's proposal. Allowing MIPS eligible clinicians in MIPS APMs to receive a score for the quality performance category either through individual or tax identification number (TIN)-level reporting based on the MIPS reporting and scoring rules is a beneficial change. This will reduce the burden for MIPS APM clinicians who are unable to respond effectively to MIPS timeline requirements due to the contours of the APMs in which they participate.

Public Reporting and Value Indicators

CMS proposes to post aggregate MIPS data starting in calendar year 2019. CMS also notes in the Proposed Rule that Medicare patients have expressed interest in being able to access narrative reviews, quotes and testimonials by their other patients, and a single overall "value indicator" reflective of each MIPS eligible clinician and group. CMS believes beneficiaries expect to find such information on the Physician Compare website already, based on their experiences with other consumer-oriented websites.

The FAH agrees that providing opportunities for beneficiaries to review data about clinicians could be valuable if it is executed properly. As CMS moves forward with posting

aggregate MIPS data, the FAH urges CMS to consider the successes and challenges that have occurred with other public reporting undertakings. It is critical that the data being reported is accurate and that clinicians understand the information. Clinicians have faced challenges in other public reporting programs and have experienced frustration when they are not provided an effective and timely mechanism to challenge and correct misinformation. A transparent process is critical not only for the beneficiaries seeking care, but also for the clinicians providing the care.

The FAH does not support the public reporting of narrative reviews, as there are concerns not only with the reliability of these reviews, but also with the data collection burden placed on both providers and patients. The FAH views the addition of narratives to the CAHPS survey as useful for quality improvement purposes only and dissuades its use for public reporting. Specifically, the FAH does not believe that comparisons across individual clinicians or groups based on these narratives can be made in a reliable and valid manner and, as a result, no scoring or public reporting of this information should be undertaken. Even for quality improvement purposes only, pilots of the addition of the narratives to the CAHPS survey are needed given the limited testing currently completed, and the FAH strongly encourages CMS to enable multiple modes of data collection including web, paper, phone, or email to increase ease of data collection and the potential for adequate response rates.

MIPS Value Pathways

Implementing MVPs

As noted above, participation in MIPS creates annual burdens for clinicians, groups, and organizations to keep pace with the evolving program. Although CMS proposes changes for each performance year in an effort to improve the program and encourage continued participation, the impact has not always been positive. Many of these revisions or clarifications issued by CMS require changes to be made at the individual clinician, group or even enterprise level. The FAH is concerned that CMS does not appreciate the levels of effort that were required to participate in MIPS to date, nor the sizeable efforts and resources that will be required to participate in MVPs if they are finalized.

CMS is proposing to create the MVPs beginning with the 2021 performance year / 2023 payment year, with the intention of decreasing clinician burden and improving the quality of performance data. Ultimately, CMS's goal is that MIPS eligible clinicians will only be able to participate through an MVP or a MIPS APM. ***At this time, the FAH does not agree that this will decrease clinician burden. Instead, implementing a drastic overhaul, such as the proposed MVPs, will result in a significant loss of momentum for many MIPS participants, as well additional expenses to redirect efforts, some of which have been underway for years.***

In discussing the basis for development of the MVPs, CMS notes it believes the “flexibility in MIPS has inadvertently produced a complex program that is failing to yield the robust practitioner performance information needed to move more quickly towards value-based care.” CMS's proposed solution to address this is the standardization that CMS expects the MVP framework will provide. The FAH does not agree that the flexibility of MIPS is the primary challenge to achieving success under a value-based care model. Rather, the constant

changes that have been made to MIPS each year have impacted the learning curve for clinicians, and there has not been an opportunity for MIPS participants to settle into any sort of standard participation in the program. While we understand that MIPS is an evolving program and that many changes made by CMS have been positive, and in response to comment letters such as this one, the FAH believes that restructuring participation at this stage will cause frustration for participants, not relief.

Rather than reducing burden, the proposed change to MVPs will create a new burden for many groups and organizations that would have to undo much of the work they have focused on for years at the direction of CMS. The investments that have been made in EHRs has been significant for many organizations; implementing and using EHRs that meet the requirements under meaningful use, incorporating eCQMs, and implementing MIPS are just a few of the accomplishments these groups have achieved. But these achievements are costly for health care providers in terms of time and money – and require significant additional annual investments to continually update their EHRs and other systems to accommodate new government programs and requirements. In addition to technology resources, these changes also require clinician time and participation to be successful, including continual education and adaptation to workflow changes. The seemingly constant state of change creates fatigue and frustration for clinicians. The FAH is concerned that the proposed conversion from MIPS to MVPs will complicate these efforts rather than streamline the process so that providers can focus on patient care.

For example, organizations that have implemented EHRs have moved away from claims-based measures, which were previously used as part of the Physician Quality Reporting System (PQRS), at CMS's direction. More specifically, CMS shifted away from claims-based measures towards eCQMs, and health care provider organizations shifted accordingly as well. Now that groups and organizations have EHRs – and eCQMs – in place, the proposal for MVPs and the focus on claims measures is frustrating. Not only does it impact the value of the systems that have been crafted over the past several years but reverting to claims-based measures will also require manual intervention for Medicare claims. For example, Medicare G-codes will be rejected if submitted to commercial payors, requiring significant updates to electronic coding and billing systems and manual intervention to ensure the codes are included on Medicare claims but not on commercial claims. CMS made the push for the transition to eCQMs, and the FAH urges CMS not to force clinicians to undue the efforts they already undertaken to implement those measures. Such a reversion is neither efficient nor fair and will significantly slow momentum under the MIPS.

As another example, the FAH is concerned about the impact of MVPs on large multi-specialty groups. Tracking many specialties, each with potentially different improvement activities (or other performance category measures) based different MVPs would result in a significant additional burden for those practices.

The FAH does not support the transition from MIPS to MVPs and urges CMS to abandon the proposal. Should CMS pursue implementation of MVPs, however, the FAH strongly urges CMS to make overall MVPs participation voluntary. In addition, CMS should allow clinicians to choose and self-assign the MVPs that are applicable, rather than leaving that

responsibility to CMS, to ensure the measures are appropriate to the clinician's specialty and practice. Clinicians, practices, and organizations that have expended significant time and money to participate in MIPS should not have to change course and once again invest in new tools needed for participation in a new MVPs paradigm.

MVP Population Health Quality Measure Set

CMS's proposal to include population health measures, which continue to use broad attribution approaches and administrative claims data only, is troubling. The FAH believes that measures must serve as evidence-based predictors of the quality of care provided by the individual, group, or organization being measured. In recent years, the FAH has become increasingly concerned by the shift from measures for which an individual clinician, group, or other provider can meaningfully influence to measures for which providers are responsible for performance despite any evidence that they can drive improvements.

In light of these concerns, the FAH does not support automatic application of the population health quality measures within each MVP. These measures should only be included when they would meaningfully drive change and improve the health of the individuals providers serve. In addition, CMS must identify a way in which the data can be provided to clinicians in near real time and can prospectively identify patients as they are attributed to clinicians. Without this information, clinicians and organizations cannot use the measures to drive true improvements.

For example, the FAH previously outlined our specific concerns with the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions under the MIPS Measure Addition for the 2021 performance period, including the lack of evidence to support attribution to individual clinicians and practices, the need to increase the minimum sample size to improve reliability of the performance scores, and the imperative for empiric validity testing to demonstrate that reporting of this outcome at the attributed entities produces valid assessments of quality.

The FAH also questions the potential inclusion of the Ambulatory Sensitive Condition Acute Composite, the HEDIS[®] Acute Hospital Utilization, and the HEDIS[®] Emergency Department Utilization measures. Should CMS move forward with the MVPs, no additional measure should be considered for inclusion unless it:

- Is closely linked to processes and structures that are within the control of individual clinicians and groups;
- Produces a minimum reliability threshold of sufficient magnitude (e.g. 7.0 or higher);
- Represents valid assessments of quality at the attributed levels;
- Yields variation in performance scores that would inform clinicians, practices, CMS, and patients on the quality of care provided; and
- Demonstrates that it is capable of measuring and driving change toward meaningful improvements in patient care.

Advanced Alternative Payment Models (Advanced APMs)

The FAH appreciates that CMS has taken into consideration our previous input on a variety of APM-related topics, including not increasing the financial risk parameters through performance year 2024. The FAH continues to believe that CMS can further Advanced APM participation by increasing the number of models that qualify as Advanced APMs, including models incorporating post-acute care providers, and providing for broader exceptions to the Stark and anti-kickback laws and certain civil monetary penalty provisions.

Advanced APM Participation

The FAH remains concerned about the limited number of models that meet the Advanced APM designation and the limited number of participating clinicians who can reach Qualifying APM Participant (QP) status and encourages CMS to continue to use its discretion wherever possible to boost participation in Advanced APMs.

Expected Expenditures

In the Proposed Rule, CMS proposes to revise the definition of expected expenditures to ensure there are more than-nominal levels of average or likely risk under an Advanced APM that would meet the generally applicable benchmark-based nominal amount standard. The new definition would establish expected expenditures as the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, this would mean the episode target price.

The FAH believes changing the definition at this point in the program would have a negative impact on existing participants in Advanced APMs, as it would impact contracts and participation agreements that are already in place. The decision to participate in an Advanced APM requires significant research, planning, and consideration and is based upon the structure of the program at the time it is entered. Changing an important component, such as the expected expenditures, for those programs already underway undermines the considerations and planning individuals, groups, and organizations examined and undertook when determining whether to participate in the APM. As such, the FAH urges CMS not to revise this definition.

Partial QP Status

Partial QP status currently applies at the national provider identifier (NPI) level across all TIN/NPI combinations. In other words, if a clinician achieves Partial QP status under one entity, that partial QP status is applied to the clinician across all the entities with which the clinician is affiliated. Beginning with performance year 2020, CMS proposes to change this process and only apply Partial QP status to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status. Under this new process, the clinician would not be required to report under MIPS for the TIN/NPI combination through which the clinician earned Partial QP status, but the clinician would need to report under MIPS for other TIN/NPI combinations. CMS believes this change will provide an opportunity for impacted clinicians to earn a positive MIPS payment adjustment in the other TIN/NPI combinations.

The FAH believes this change will add significant complexity for clinicians and groups and urges CMS to maintain the current Partial QP status process. If a clinician devotes a majority of his or her time to an Advanced APM TIN, this clinician could then be impacted by a negative payment adjustment at another, MIPS participating TIN/NPI combination. A clinician who does not provide most services at the MIPS participating entity and does not have as much control over performance at that TIN, should not be subject to a negative payment adjustment.

Withdrawing from an Advanced APM

Currently, eligible clinicians achieving Partial QP or QP status through Advanced APM participation retain that status if the APM Entity withdraws from the Advanced APM prior to bearing financial risk. In the Proposed Rule, CMS proposes to revise this such that an eligible clinician is not a QP or Partial QP for the year if the APM Entity voluntarily or involuntarily terminates from an Advanced APM: before the end of the QP Performance Period; or before the date on which the APM Entity bears financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. CMS proposes this change to prevent situations in which clinicians achieving QP or Partial QP status for participating in Advanced APM Entities that do not ultimately incur financial risk.

While the FAH appreciates CMS's concern, the FAH does not believe this proposed change should apply in instances where an APM Entity involuntarily withdraws from an Advanced APM. The clinicians participating in such an APM Entity will have undertaken efforts to engage in the Advanced APM quality and efficiency activities and should not be treated in the same way as those who choose to withdraw prior to potentially bearing the financial burden related to such participation.

RFI on Full Capitation Arrangements

Currently, Advanced APM Entities participating in other-payer, "full" capitation arrangements meet the Advanced APM financial risk criteria. In the Proposed Rule, CMS discusses that some of these arrangements exclude certain services, such as organ transplants or hospice, and seeks comment on whether such arrangements should meet the criteria for "full" capitation. In examining this issue, CMS should consider how the items and services included under (or excluded from) these capitation arrangements compare to the services covered under or counted toward benchmarks for other Advanced APM models, such as ACOs. The FAH urges CMS to ensure that these exclusions do not inadvertently or unduly advantage one type of Advanced APM over others.

Post-Acute Care

As noted in previous comments, the FAH encourages CMS to consider the provision of services by post-acute care (PAC) providers and how those providers can participate in the development of APMs. The FAH has recommended in the past and recommends here that CMS develop and test a voluntary CMMI bundling program that includes inpatient rehabilitation facilities (IRFs). This bundling program would not be derived from the IRF prospective payment system (PPS), but instead would permit IRFs to assume the risk of caring for certain patients

over a defined period of time and with sufficient regulatory relief, including rescinding the 60 Percent Rule and 3-Hour Therapy Rule.

APM Regulatory Waiver and Exception/Safe-Harbor

As discussed in detail in response to RFIs from CMS and the Office of Inspector General (OIG), the FAH believes the current health care fraud and abuse regime has not kept pace with the transition to value-based care. A legal safe zone is needed that cuts across fraud and abuse laws, including the Stark Law, Anti-Kickback Statutes (AKS), and certain civil monetary penalties, and allows for full APM participation. As such, the FAH urges CMS to put aside its current case-specific approach to fraud and abuse waivers and work with the Office of Inspector General (OIG) to develop a single, overarching waiver for CMS-led APM arrangements. Additionally, the FAH urges CMS and OIG to implement a Stark Law exception and AKS safe harbor to provide parity to non-CMS-led APMs, such as commercial payer arrangements.

The FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership with the CMS as we strive for a continuously improving health care system. If you have any questions regarding our comments, please do not hesitate to contact me at 202-624-1534, or Erin Richardson, Vice President and Associate General Counsel, at erichardson@fah.org or 202-624-1516.

Sincerely,

