Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW, Room 445-G  
Washington DC 20201

*SUBJECT: CMS-5517-P, Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models, May 9, 2016.*

Dear Acting Administrator Slavitt:

The Federation of American Hospitals ("FAH") appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services ("CMS") on the above notice of proposed rulemaking ("Proposed Rule"), published in the Federal Register on May 9, 2016 (81 FR 28,161). The 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 are diverse, including teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute and ambulatory services. Our members are united, however, by their shared commitment to partnering with their medical staffs to ensure that all patients, including Medicare beneficiaries, have timely access to appropriate medical care in their communities. The FAH believes that equitable and readily understood payment systems contribute importantly to sustaining collegial, collaborative, hospital-physician partnerships that enable optimal care of individual patients while advancing population health.

The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") established a new framework for physician payment. The Proposed Rule outlines the CMS Quality Payment Program ("QPP") as the implementation platform for incorporating MACRA's payment framework into Medicare's evolution from predominantly fee-for-service clinician payment to
payment based upon quality and care integration. The QPP includes two major payment pathways: the Merit-Based Incentive Payment System ("MIPS") and the Alternative Payment Model ("APM") Incentive program. FAH members are engaged in a variety of relationships with their physician partners so that both the MIPS and APM payment pathways likely will have implications for us, including the following:

- Implementation and maintenance of MIPS data tracking and reporting will require FAH members who directly employ physicians to undertake additional practice management functions, defray related expenses, and absorb negative adjustments.
- Independent physicians affiliated with FAH member facilities may seek expanded electronic health record ("EHR") access and functionality from those facilities to support MIPS performance data collection needed by those physicians.
- Some FAH members and their medical staffs may come together as APM participants, with the hospital most often serving as the risk-bearing APM entity, thereby enabling clinicians to qualify for APM bonuses.

While we appreciate that CMS has invited input on almost every section of the Proposed Rule, we will focus our comments on concerns that reflect the diverse partnerships between FAH members and their clinicians.

General Comments

Initial Performance Period Duration

The physician payment provisions of MACRA are numerous, wide-ranging and accompanied by a very aggressive mandatory timeline for their implementation. The FAH appreciates that MACRA thereby challenged CMS to rapidly draft the extensive regulatory framework required for QPP commencement on January 1, 2017. Unsurprisingly, given the nature of the task, the Proposed Rule is lengthy and complex; careful, thorough analysis is required to fully appreciate the rule’s many potential payment and reporting implications for physicians and their hospital partners. The rule’s complexity intensifies the substantial time pressure physicians and hospitals now face as they attempt to analyze the draft QPP, provide comments, and respond to the final rule, while concurrently creating and implementing systems and processes to begin MIPS reporting and APM participation in January. The FAH strongly recommends that CMS delay the start of the first QPP performance period to July 1, 2017, shortening the first performance period to six months. The additional time prior to starting the QPP would permit CMS and stakeholders to reach a higher state of QPP readiness, increasing the likelihood that the launch of this transformational program is successful and sustainable rather than troubled and untenable.

Pace of Progression of Performance Requirements

Initial performance pressures on stakeholders are amplified by the rapid ramping up of multiple performance targets in the early years of the QPP, for example:
• Raising the current 50 percent Meaningful Use data submission completeness standard in the first QPP performance year to 80 percent (Part B claims-based) or 90 percent (all-payer, electronically reported via Qualified Clinical Data Registry – QCDR – or EHR – or Qualified Registry)

• Raising the requirement for APM clinicians to utilize CEHRT to document and communicate clinical care with patients and other health care professionals from 50 percent in the first QPP performance year to 75 percent in the second year, while simultaneously requiring an upgrade from the 2014 Edition Office of the National Coordinator for Health IT (“ONC”) Certification Criteria to the 2015 Edition.

While some performance expectation progressions are mandated directly by MACRA, many are left to specification through regulation. The FAH strongly encourages CMS to design gradual performance expectation trajectories that allow sufficient time for stakeholders to gain experience and confidence in data collection and reporting at each level prior to increasing performance expectations to a higher level. Given the enormous number of stakeholders involved, a series of smaller incremental steps, while requiring more time to implement, is more likely to be successful than rapid sequential jumps in reaching the desired endpoints of value-based healthcare delivery.

**Clinician Identification and Group Scoring Assignment**

The Proposed Rule relies heavily on the use of Tax Identification Numbers (“TIN”) combined with National Provider Identifiers (“NPI”) to identify MIPS-eligible individual physicians and define physician groups. The FAH appreciates the efficiency of using common, existing identifiers rather than superimposing new ones. However, the FAH is concerned about the use of TINs for a purpose other than the one for which they were created. A group that is defined by a single TIN, whose members are united in sharing a financial framework, may represent considerable diversity among its members with regard to clinical activities. Requiring a TIN-sharing multispecialty group to report collectively on a uniform set of MIPS measures seriously undermines the value of quality reporting by limiting the reported measures to those applicable across a group rather than those most relevant to a clinician’s practice. It is impracticable for current TIN groups to subdivide into multiple TIN groups to enable relevant measure reporting, as TIN changes will have collateral financial impacts such as re-writing of group contracts with payers and unwanted consequences for tax reporting by the group.

The FAH suggests that CMS consider revising clinician and group identification based upon TIN, such as adding alphanumeric characters to the TIN to define groups for whom shared quality and resource use reporting are more appropriate. The FAH is concerned also about appropriate scoring of physicians who change groups (and thereby change TINs) during a performance period. The vast majority of such changes occur for easily understandable reasons (e.g., relocation, group restructuring or consolidation to facilitate ACO participation) rather than attempts to “game the system”. In the interests of fairness and administrative simplicity, the FAH suggests that the MIPS composite score for a physician who has changed groups be that of his/her final group during each performance year.
Unintended Consequences

Seminal legislation such as MACRA and the extensive regulations required for its implementation carry a substantive risk of unintended consequences. Examples include stakeholder discouragement, clinical workflow disruption, diminishing physician-patient interactions and increasing costs of care.

Stakeholder Discouragement

CMS projections suggest that the vast majority of physicians will not reach APM Qualifying Participant ("QP") status in the early years of the QPP and will be MIPS participants. The complexity of the proposed MIPS component and composite scores combined with the short time to prepare for their scheduled January 2017 implementation is likely to dampen physician enthusiasm to invest additional time and energy to work with their hospital partners on advanced delivery systems. The FAH observes that setting the MIPS adjustment performance threshold and the exceptional performance bonus eligibility threshold to reward or at least to avoid penalizing most practitioners could mitigate initial physician discouragement and motivate their continued engagement with their hospital partners in improving systems of care. Consistent with the goals of MIPS, the average performance is very likely to improve over time. The MIPS adjustment performance threshold should be carefully set to ensure that good performers are not penalized. The proposed process for recognizing improvement as well as achievement should also facilitate recognition and reward of good performance.

We recognize that MACRA statute establishes budget neutrality for the MIPS program. However, we urge CMS to monitor the program over the long-run, as assessing penalties for good performance would be inequitable and would undermine MACRA’s incentives to improve performance and provide high quality care.

Clinical Workflow Disruption

Participation in existing quality reporting programs requires substantial investments of time by physicians and their office support staff members, estimated at nearly 800 hours annually per physician.¹ The time that will be invested by physicians and hospital staff members is also substantial, particularly for hospital-based physicians. Assimilating the MIPS program into the clinical workday will increase the number and duration of nonclinical interruptions in caring for patients in both the outpatient and inpatient settings. The FAH supports the proposal by CMS to study clinical practice improvement activities ("CPIA") and clinical quality workflows. The FAH urges CMS to undertake analogous efforts to determine clinical workflow impacts of other aspects of the MIPS program in a variety of care delivery settings.

Diminishing Physician-Patient Interaction

The FAH recognizes the many potential benefits of a complete yet cogent EHR that spans multiple healthcare venues, is fully interoperable and easily accessible by patients as well as

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healthcare professionals. Our member hospitals and their physician partners have made large investments in health information technology ("IT"). However, the exam room or bedside computer increasingly dominates the clinical encounter, giving rise to increasing complaints from patients and families that the physician focuses more on taking care of the computer (i.e., the EHR) than of the patient. To the extent that MIPS participation requires expanded documentation during the clinical encounter, patient dissatisfaction is likely to increase. The FAH suggests that CMS seek ways to measure this phenomenon (e.g., questions on Medicare beneficiary surveys, focus groups, patient-reported outcome measures, HCAHPS) and to incorporate the results when designing health IT specifications and regulations for use across the spectrum of healthcare delivery venues. Attention to the clinical workflow disruption described above would also improve the physician-patient interaction.

Increasing Costs of Care

The FAH and its physician partners support the commitment of CMS to a high-performing, high-value healthcare system. Pursuing such a system brings additional costs, such as the health IT hardware and software investment discussed above. The decline in care delivery efficiency associated with clinical workflow disruption is similarly costly. A less obvious source of expense is the increasing level of sophistication and education necessary for non-physician healthcare workers (e.g., office staff, hospital employees) to function competently within a healthcare system full of high-technology devices and computer-based processes. Recruiting and retaining such workers is an ongoing challenge, particularly for small physician practices and rural hospitals. The FAH encourages CMS to assess both obvious and hidden costs when estimating regulatory cost burden and when evaluating payment adequacy.

Merit-Based Incentive-Payment System Performance Categories

Quality

As longstanding participants in the National Quality Forum ("NQF"), the former Hospital Quality Alliance and Measures Application Partnership ("MAP"), the FAH continues to welcome methodologically sound, data-driven, quality measurement across the healthcare program.

For the first performance year, CMS has chosen to make available a very large set of potentially reportable measures, including multiple specialty-specific sets. The FAH understands this effort to be inclusive and user-friendly, but strongly encourages CMS to move rapidly to a streamlined set of standardized high-priority measures that would align incentives and actions of organizations across the health care system. The recent report from the National Academy of Medicine, Vital Signs: Core Metrics for Health and Health Care Progress, offers a framework for the next iteration of quality measures.

In support of a measure set that is standardized, evidence-based and reliable, the FAH continues to recommend that NQF endorsement should be sought and obtained for all measures involved in any of Medicare’s pay-for-performance programs. While it may not be realistic in
the short-term to apply this as a requirement to the wide range of measures required to cover all physician specialties, where they are available, measures with NQF endorsement should be given priority. The FAH also continues to recommend strongly that all quality metrics should undergo review as part of the annual multi-stakeholder MAP process. The MAP has a well-established track record of providing CMS with practical insights into the appropriateness and feasibility of measures from a breadth of perspectives.

CMS must make aligning metrics across its various quality programs a high priority, and we note that the MAP can serve as a filter to facilitate that alignment. Alignment is critical to ensuring that providers are focused at the same time on the same quality improvement goals, which will lead to the best patient care outcomes while reducing provider burden. Quality reporting by hospital-based physicians offers a clear opportunity to align quality metrics, and MACRA allows the Secretary to apply inpatient hospital measures in the MIPS quality and resource use performance categories. We are encouraged that CMS is proposing MIPS quality reporting accommodations for hospital-based physicians (e.g., fewer measures, no cross-cutting measure), but we are disappointed that CMS was not able to incorporate inpatient hospital measures for use by hospital-based physicians at this time. In the Proposed Rule, CMS indicates that it will propose to implement this option in future rulemaking. The FAH strongly recommends that CMS move forward expeditiously to allow hospital-based clinicians to utilize hospital quality measures for MIPS reporting. Alternatively, the FAH observes that the same rationale for exempting hospital-based physicians from meaningful use (and its MIPS successor Advancing Care Information (“ACI”) performance category) could be applied to quality reporting by hospital-based physicians until substantial alignment of physician and hospital measures is achieved. Alignment between Medicare and Medicaid measures wherever possible also would be a valuable step towards reducing provider burden.

The FAH has previously recommended that clinician quality improvement as well as achievement be recognized, so that pay-for-performance does not become synonymous only with penalizing poor performance. The FAH appreciates that CMS has proposed a mechanism to reward improvement in the Proposed Rule.

The FAH continues to believe that quality measure data submitted for MIPS scoring should be subject to a rigorous review and validation process to ensure reliability and fairness of Medicare’s physician pay-for-performance adjustments. The FAH appreciates that CMS outlines both data validation and auditing processes in the Proposed Rule and looks forward to more details about implementation in subsequent rulemaking, including a timeline for making performance reports available to clinicians at a minimum on an annual basis.

*Resource Use*

While the Resource Use performance category initially represents only 10 percent of the MIPS composite score in the first performance year, it rises to 30 percent – equal to the contribution of the quality performance category – in the third performance year (calendar year 2019). The FAH has several concerns about the Resource Use category as described in the Proposed Rule. We have previously commented about the importance of appropriate risk-
adjustment when measuring resource use, particularly when calculations are based on claims data. In addition to traditional risk-adjustment for clinical characteristics, we note the mounting evidence that socioeconomic risk factors also significantly impact resource use. While CMS acknowledges the many comments received about the necessity for robust risk-adjustment, no proposals for enhancing socioeconomic risk-adjustment are offered at this time. The FAH remains seriously concerned at the lack of application of systematic, validated risk-adjustment of resource use measures for socioeconomic risk factors. The FAH notes similar risk-adjustment concerns are applicable to outcome measures in the quality performance category.

CMS proposes 41 clinical conditions and treatment episode-based resource use measures for the 2017 MIPS performance period, while retaining the total per capita cost measure and the Medicare Spending Per Beneficiary measure (with slight modifications) from the prior value-based modifier program. The FAH is particularly concerned about the 41 episode-based measures, and suggests CMS modify their implementation timeline. These measures have never been used for payment purposes and the transition of the diagnostic codes within the definitions of these episodes from ICD-9 to ICD-10 is incomplete.

Reliable, valid resource use measurement depends heavily upon accurate attribution of patients to providers. CMS proposes to use attribution logic from the 2014 Quality and Resource Use Reports (“QRUR”) program (with minor modifications). As CMS observes, many physicians have not accessed their QRUR reports, so that feedback to CMS about the accuracy of this logic has been limited. Relatedly, MACRA requires that CMS develop codes that describe the various types of relationships between patients and providers to allow identification of the correct provider for attribution. The initial relationship code set is still open for comment and will not be ready for implementation until performance year 2018. Comparison between the 2017 and 2018 performance year resource use results for clinicians, and any related payments for performance improvement, will therefore be compromised. Given the multiple moving parts under the Resource Use category (absence of risk adjustment, incomplete ICD coding transition, pending patient relationship codes), modification of the Resource Use implementation plan seems warranted. It would be prudent to delay use of the new episodes to allow full ICD-10 updating and pilot testing plus analysis of the projected payment effects. Alternatively, CMS could consider data collection for these episodes in 2017, but not initiate actual resource use scoring using them until they are validated and when attribution might be enhanced by patient relationship reporting in performance year 2018. The FAH urges CMS to consider modifications to the Resource Use implementation plan of the Proposed Rule as well as developing provider specific reports, provided directly to the providers, to facilitate provider understanding of their performance under this category.

Clinical Performance Improvement Activities

Much remains to be understood about the completely new CPIA performance category, for which there is no predecessor Medicare program. The FAH appreciates that CMS has taken a very open-minded and inclusive approach to CPIA measurement and scoring, including reduced requirements for small practices, rural clinicians and non-patient-facing physicians. The FAH also commends CMS for undertaking a formal study about CPIA activities and their
measurement. The FAH recommends that CMS continue this open, less-structured approach to the CPIA category until the relationship of such activities to improved quality and more efficient resource use can be clarified.

In the meantime, we offer a recommendation to help streamline the tracking and attestation required for CPIA. Many of the CPIAs proposed by CMS may be used for different performance categories under the MIPS program. For example, many CPIAs reference functionality that is required as part of using Certified EHR technology ("CEHRT") under the ACI Category, e.g., timely communication of test results defined as timely identification of abnormal test results with timely follow up, Health Information Exchange; or use of structured notes. Also, participation in a Qualified Clinical Data Registry QCDR is a "Population Management" CPIA, while at the same time the MIPS quality category allows providers to use ("QCDRs for reporting specific quality measures. We urge CMS to allow providers to receive credit for CPIA activities in more than one MIPS program for purposes of reporting and attestation and including a single process for attesting CPIAs to CMS where there is overlap with other MIPS categories.

Advancing Clinical Information

Flexibility and Alignment Needed for Hospitals under the Medicare EHR Incentive Program

With respect to the ACI performance category of MIPS, the FAH is pleased that CMS proposes to eliminate the "all-or-nothing" approach to assessing performance that has been in place under the meaningful use requirements of the Medicare EHR Incentive Program in favor of a more flexible scoring system. We agree that clinicians should receive some points under MIPS for reporting EHR measures regardless of performance level, and that zero scores should only be awarded for failure to report.

The FAH urges CMS to make similar modifications with respect to the requirements for hospitals under the Medicare EHR Incentive Program, and to eliminate the "all-or-nothing" standards that remain there, which would provide for a more meaningful assessment of hospitals as meaningful users of certified EHR technology. In doing so, CMS should seek the greatest alignment possible between ACI category requirements and the hospital meaningful use requirements.

Further, CMS should work to align requirements of the Medicaid EHR Incentive Program with the ACI category of MIPS. Some clinicians will face an undue burden of reporting under different program requirements in order to avoid penalties and obtain the incentive meant to support their investments in CEHRT. It is when all clinicians and hospitals are working with common goals and under the same incentives and requirements that the best outcomes will be achieved for the Medicare program and all stakeholders. The FAH urges CMS to accelerate efforts to ensure that requirements for the use of certified EHRs and exchange of health information are aligned across all providers by also providing additional flexibilities to hospitals and critical access hospitals under the Medicare and Medicaid EHR Incentive Program.
The FAH appreciates that the Proposed Rule recognizes the special circumstances of hospital-based clinicians and supports the proposal to assign a weight of zero for the ACI performance category for these clinicians, under the same policy that has exempted them from Medicare EHR Incentive Program penalties.

2017 Performance Period

We have strong concerns with operationalizing a full-year 2017 performance period for the ACI category due to ongoing limitations with electronic data submission. Our members are working with vendors that cannot at this point capture and submit elements needed to report measures for the ACI category, and it is unclear that they will be ready to do so in time to report on a full calendar year 2017. The FAH therefore urges that CMS establish an ACI performance period of 90 days for the 2017 performance year (2019 payment year). This would still be an ambitious but more realistic reporting period for the first year of MIPS.

Further, a 90-day reporting period also should apply for providers who:

- Are first time participants in the MIPS program or one of its components;
- Transition employment to a new practice;
- Are required to take extended absences from their practices; or
- Change EHR vendors.

First Time Participants, Employment Changes, or Life Circumstances

CMS proposes that in cases where providers do not have a full year of performance data available, the provider be required to submit all available performance data. Although we support CMS’s stated intent to promote accountability for all performance in the performance period, in our experience, the proposed approach is too high of a bar, and not achievable for most providers. For example, many first time participants, along with providers transitioning to new practices, need time during the performance year to establish new workflows and understand new tools prior to being able to successfully meet performance requirements. Additionally, eligible clinicians may undergo maternity leave or illness within the calendar year, and in such cases need time upon their return to reestablish efficient workflows and rebuild patient volume.

EHR Vendor Transitions

When providers undergo an EHR vendor transition, it is extremely challenging to obtain data from one certified EHR and combine data from that with another certified EHR. Further, many vendors generally are not willing to provide data when the provider is no longer utilizing the system. Even when attempts are made to obtain data prior to transition, the EHR vendor often may not provide the data or will not provide it in a format that can be combined with data from another certified EHR vendor. Therefore, if an EHR transition occurs, a 90-day reporting
period utilizing the new EHR vendor would allow the provider to successfully report on all MIPS performance categories.

**Use of Certified Technology and Stage 3 Measures**

For 2017 reporting only, the proposed rule would allow clinicians who will not yet have adopted CEHRT that is certified to the 2015 Edition flexibility to continue to use technology certified to the 2014 Edition and to report on modified Stage 2 objectives and measures. This means that beginning with the 2018 performance period, MIPS eligible clinicians must only use technology certified to the 2015 Edition to meet the objective and measures for the ACI performance category, which correlate to Stage 3 ("Stage 3-like measures"). **The FAH believes that few clinicians will be ready to report in 2017 using 2015 CEHRT because vendors will not be ready to support this, and therefore we recommend that CMS continue to allow clinicians the option to report using 2014 Edition CEHRT for an additional year. That is, the requirement that all clinicians use 2015 Edition CEHRT and Stage 3 objectives and measures would not apply until the 2019 reporting year (for the 2021 MIPS adjustment).** Clinicians do not yet have experience with Stage 3, and because MACRA is a completely new program, clinicians will have a steep learning curve in understanding all aspects and requirements of this new payment and delivery system. Allowing a more gradual phase-in of the ACI category would acknowledge the delays in adoption of 2015 CEHRT and help clinicians manage all the changes required to be active participants in MIPS.

**Rural Area Challenges**

Clinicians in rural areas face particular challenges with respect to the ACI category. Access to a reliable internet service in frontier and rural areas and the prohibitive cost of investing in CEHRT for small rural practices can be daunting barriers to attaining points in this category. It may be challenging for some rural clinicians to meet the basic requirement for protecting the privacy and security of patient health information, which is a threshold test for receiving any points in this category. **It is helpful that CMS has proposed to continue to permit hardship exemptions from this category for clinicians under limited circumstances, but the criteria should be broadened so that the realities facing rural providers are taken into account.**

**Group Reporting**

While we support the flexibility offered in the rule’s proposal to permit group reporting in the ACI performance category, the FAH seeks clarification regarding how this option will work. Specifically, how will unique patients be handled if they have seen more than one provider in the group? **This is another example of an unresolved technical issue that indicates the need for a delay in the start of the performance period to ensure that providers and vendors are prepared to comply with the proposed reporting requirements and won’t be penalized unfairly for compliance issues.**
Information Sharing

Prevention of Data Blocking

MACRA requires that effective April 16, 2016, to be a meaningful EHR user, an eligible professional, eligible hospital, or Critical Access Hospital must demonstrate that they have not "knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology." CMS proposes that this requirement be met through an attestation with three parts paraphrased as follows:

- Did not knowingly and willfully take action (i.e., disable functionality) to limit compatibility or interoperability of CEHRT;
- Implemented technology and standards to ensure CEHRT was at all times connected, compliant with standards related to information exchange, and implemented in a way that allows for timely patient access; and
- Responded in timely manner to requests made by patients and providers for medical records.

The FAH is concerned that the proposed attestations are so broad that they could result in providers inappropriately being labeled as "data blockers" when they take reasonable actions. For example, would a provider be considered "blocking" if they purchased a CEHRT product, but did not turn on some of the functionalities because they are too costly or are incompatible with the provider’s other technology? **CMS should take steps to modify the attestations or provide clear guidance on how these requirements will be enforced so that all providers understand what actions they need to take and what actions they need to avoid in order to be found in compliance.**

Surveillance and Direct Review

CMS is proposing that as part of demonstrating meaningful use of CEHRT, an eligible professional, eligible hospital or critical access hospitals would be required to attest that they have cooperated in good faith with ONC surveillance and direct review of CEHRT. This cooperation would include responding to ONC or ONC-Authorized Certification Bodies (“ONC-ACB”) requests for access to a provider’s CEHRT as part of the surveillance activities. While we support the ONC’s efforts to ensure CEHRT meets and maintains certification requirements, we have significant concerns with this proposal. Specifically, it could pose a security threat, as active patient records could be compromised when assessing the EHR for appropriate technologies.

We do not support the ONC-ACB remotely accessing production EHRs for surveillance activities due to security and patient sensitive information risk. Hospitals invest significant time and resources to protect against attacks to their EHR systems, and unrestricted access to a provider’s EHR could open the door to security threats. A better, alternative approach could be to require direct surveillance of in-the-field clinicians’ utilization of certified EHR technology via an on-site guided review, with a provider or staff member accessing the system. Allowing end-users to demonstrate EHR utilization would provide a more accurate assessment and
demonstration of CEHRT functionality. Additionally, organizations or staff generally do not have the capability to grant new access to the EHR, especially during an impromptu site visit. In accordance with HIPAA requirements, there are stringent security processes in place to ensure new users receive access according to their role and corresponding licenses and certifications. We request that CMS clarify and provide specific guidance surrounding the surveillance process, especially the process of “in-the-field” surveillance.

**MIPS APM Scoring Standard**

The FAH agrees it is appropriate to subject clinicians who are participants in certain APMs to modified scoring standards that do not require duplicative reporting for MIPS. However, we recommend a change to the proposal to give zero weight to the resource use category for Accountable Care Organizations (“ACOs”) under the Medicare Shared Savings Program (“MSSP”) and increasing the weights for the quality and ACI categories. ACOs and their provider participants are subject to resource use performance standards under the MSSP, so the FAH recommends that CMS award full credit for this category under MIPS and the weights of the other MIPS categories remain unchanged.

**Alternative Payment Model Incentive Program**

The FAH appreciates that CMS has taken into consideration our previous input on a variety of APM-related topics such as enabling APM QP determination through either a payment-based or patient-based threshold formula. Conversely, the FAH is disappointed by several provisions of the Proposed Rule related to implementation of the APM Incentive Program, particularly the stringency of the criteria for Advanced APM designation and the impracticable definition of financial risk.

**Advanced APM Model Criteria**

While MACRA provided the criteria for defining APMs, Advanced APMs, and Physician Focused Payment Models (“PFPMs”), the Proposed Rule fleshes out the details of these criteria and their implementation. The Proposed Rule also addresses in detail the definitions, methods, and processes to be used in determining whether clinicians participating in Advanced APMs achieve QP status and become eligible for incentives including lump sum bonus payments, MIPS exclusion, and higher base payment updates. The FAH understands that for the initial years of the QPP, CMS has chosen to focus its attention on the current APM portfolio of the Center for Medicare and Medicaid Innovation (“CMMI”). The FAH observes that the CMMI portfolio of over 20 models includes a variety of APM types, including episode-based (e.g., Bundled Care Payment Initiative, BPCI, and Comprehensive Care for Joint Replacement, “CJR”), disease-based (Comprehensive Care for End-Stage Renal Disease, CEC), and primary care-based (Comprehensive Primary Care Plus, “CPC+”). The FAH also notes that there is widespread participation in several models including over 400 participants in the MSSP Track 1, over 1500 participants in the Bundled Payments for Care Improvement (“BPCI”) program and over 800 participants in the CJR model.
From this relatively large and diverse portfolio, however, CMS identified only six models that merit designation as Advanced APMs and whose participating clinicians could reach QP status (Comprehensive ESRD Care Large Dialysis Organization track, Comprehensive Primary Care Plus, Track 2 MSSP ACOs, Track 3 MSSP ACOs, the Next Generation ACO Model, and the Oncology Care Model 2-sided risk track). Several of these models are in their early phases and the total number of participants in the six models currently is only 55. The FAH believes that the Advanced APM definitions, as proposed for implementation by CMS, are far too narrow to foster growth of new APMs or to attract large numbers of new participants. The FAH understands that because MACRA mandates many aspects of the APM Incentive program, CMS is left with rather limited flexibility in some aspects of APM implementation. However, the FAH believes that such statutory constraints make it critically important for CMS to make full use of the discretion it does retain regarding the APM program. The FAH strongly recommends that CMS use its discretionary authority to make the necessary revisions to the proposed Advanced APM definitions to allow more APMs to be designated as Advanced APMs, especially the BPCI and CJR models and MSSP Track 1. Without more models to choose from and given the very short timeline to the start of the first QP performance period in January, clinicians and their hospital partners are unlikely to be motivated to join together in APMs and clinicians are likely to choose the predictability of remaining in MIPS. The net result will be that Medicare’s movement from volume to value will be considerably slower and much less robust than CMS desires for its beneficiaries. Finally, while CMS considers ways to expand the initial Advanced APM model pool, the Federation requests that CMS offer more detailed explanations why so many current CMMI models failed to be designated as Advanced APMs. The information provided in Table 32 of the Proposed Rule offers only the final determinations of APM designation and not the rationales behind the determinations.

The Proposed Rule requires that individual Advanced APMs receive an unique percentage “Threshold Score” calculated using two methodologies – Payment Amount and Patient Count. Under the current methodologies, Advanced APM entities that are comprised of multispecialty practices will experience a significant, and unjust, negative impact to their Threshold Score. This is directly tied to the alignment methodology of the APM. If, for example, the APM is comprised of 50 percent primary care and 50 percent specialist providers, the specialist’s spend and number attribution-eligible beneficiaries would still be included in the calculation’s denominator. Conversely, very little of the specialist’s cost and number of attribution beneficiaries are included in the numerator. In addition to the methodology described in the Proposed Rule, we encourage CMS to adopt additional options for use in determining the Threshold Score. In these additional options, the variables included in the methodology should be reflective of the individual APM's framework. For example, for APMs with a focus on primary care, such as ACOs, an additional optional calculation would use the existing methodology framework, but modified, however, to include only primary care providers in the calculation for both the patient count and payment amount methods. We believe that this additional flexibility would more accurately represent CMS’s intent to evaluate the APM entity’s total cost of care scope.
The FAH is very concerned that the financial risk criterion for Advanced APM designation—mandating immediate assumption of downside risk—is excessively strict and sharply limits eligibility. We have previously observed that there are wide variations in the profiles of potential APM participants with regard to size, financial resources, experience with care coordination, infrastructure, size and demographic mix of their patient populations, and the socio-economic conditions of the geographic regions in which they deliver services. These variations create significant differences among APMs in their readiness to accept the operational responsibility inherent with 2-sided risk exposure. It seems relevant to note that 411 out of the 433 MSSP ACOs currently remain in Track 1 with one-sided risk and have not yet progressed to the two-sided risk of Tracks 2 and 3. Yet, these same Track 1 ACOs contributed significantly to achieving the CMS goal for 2016 of 30 percent of payments being delivered through APMs. The FAH urges CMS to consider financial risk options for APMs such as planned, incremental transitions from one-sided to two-sided risk-bearing, and that such APMs be given Advanced APM status during the entire transition period. The FAH notes that the Proposed Rule offered a substantive opportunity to provide current APM entities with insights about ways to alter their models to progressively accept increasing risk, and the FAH asks that CMS include such insights in the final rule.

Considerable, upfront financial investments (e.g., health IT, expanded processes and personnel for quality improvement and care integration) are required to successfully operate as an ACO or a bundled payment model. These substantial investments are totally unrecognized in the Proposed Rule, with CMS noting its inability to measure those investments reliably. Yet, CMS has recognized the burden imposed by such costs in its Advanced Payment ACO Model under the MSSP. CMS should use the model developed to calculate the burden imposed by such costs as part of the Advanced Payment ACO to reliably measure upfront costs in other APM models. Estimates of such start-up costs from the American Hospital Association range from $11.6 million for a small ACO to $26.1 million for a medium ACO. The FAH strongly recommends that CMS promptly and vigorously explore options to capture upfront APM infrastructure costs in its risk framework for APMs.

Finally, the FAH is very concerned that the financial risk parameters required by CMS—total risk of at least four percent, marginal risk of at least 30 percent and a minimum loss rate of at least four percent—are too aggressive for the early years of APM implementation and will stunt the growth of APMs. The experience of the MSSP may be relevant; while there has been steady growth in Track 1 (upside risk only), increases in Tracks 2 and 3 (two-sided risk) have been quite small. In order to ensure robust participation in MACRA’s APM Incentive program in later years, CMS must set and maintain a lower bar in the initial years that will encourage early adopters to remain in the program while transitioning smoothly to higher risk in later years. Gradual ramping up of the risk parameters from less demanding levels over several years to the levels currently proposed by CMS for immediate implementation is an option that could match the risk targets to the current risk tolerance of the provider community. The FAH recommends that CMS modify its financial risk parameters to begin at lower levels and gradually increase to the currently proposed values.

Other Medicare APM Issues

CMS should be continuously monitoring its APM portfolio for potential refinements to the models. For example, we were pleased at CMS’s recent decision to allow ACOs to participate in the CPC+ model. However, we encourage CMS to reconsider its decision not to count CPC+ participation through an ACO towards participation in an Advanced APM. Allowing ACO participation in CPC+ to count towards Advanced APM participation would facilitate the success of the CPC+ model while that model is in its infancy. Similar considerations will no doubt arise periodically about other APM models and a process by which CMS ensures their early identification and resolution are likely to benefit the APM Incentive program as a whole.

Additionally, CMS should consider the provision of services by post-acute care (“PAC”) providers and how those providers can participate in the development of APMs. Specifically, to increase efficiency and competition in the provision of PAC services following hospital discharge, the FAH has recommended in the past and recommends here that CMS implement a “shared accountability” payment methodology that features price flexibility for inpatient rehabilitation facilities (“IRFs”). Specifically, this payment method would provide a discount to the standard payment amount for IRF admissions for patients discharged from an acute care hospital participating in CJR under MS-DRGs 469 and 470. The IRF shared accountability program would be voluntary for IRFs, and would only apply to CJR cases. In addition, flexibility would be provided to further reduce spending by lowering lengths of stay (“LOS”) by incorporating a per-diem payment method for shorter than average stay patients, similar to how IRFs are currently paid for certain transfer cases.

Finally, regulatory relief under the 60 Percent Rule and 3-Hour Rule should be a necessary component in order to provide IRFs treating CJR patients under the shared accountability payment model with the flexibility needed to participate in the program without jeopardizing their Medicare status. IRFs that choose to be paid alternative lower payment rates for treating CJR patients should not be subject to the 60 Percent Rule, and IRFs accepting lower payment rates for CJR patients should have flexibility to provide three hours of therapy through multiple modes, including group and concurrent therapies, without the risk of Medicare contractors denying the claim for an insufficient amount of “one-on-one” therapy.

CMS proposes to identify clinician Advanced APM participation by reviewing a December 31 Participation List for each performance year. CMS acknowledges that this requirement presents challenges in certain APM models including those structured by CMS to have hospitals and not clinicians as participants (e.g., CJR). By not appearing on a Participation List, these clinicians are not considered for QP determinations. Additionally, APMs such as ACOs experience a fluctuation in their physician participation list between the proceeding performance year TIN submission through performance year end. The FAH recommends that a list capturing the entire physician network as of December 31 be submitted to CMS for use in QP determinations. It is not equitable that Advanced APM clinicians be excluded from QP consideration simply because of how CMS has designed the structure of the APM.
The FAH believes that establishing an upper limit of 50 eligible clinicians in the organization of the APM Entity of a Medical Home Model is not a reasonable threshold. We would recommend that there be no size constraint, as CMS already proposes for the first performance year. We would advocate extending the unconstrained threshold for at least the first three years of the APM Incentive program. Failing such extension, we would recommend that the upper limit be set at 100 clinicians.

Other Payer Advanced APMs

The FAH appreciates and supports that CMS has proposed a framework for the development of Other Payer (non-Medicare) Advanced APMs. Such models are important options for improving beneficiary and for clinicians as they seek QP status. These models also enhance harmonization across the entire healthcare system in terms of shared goals such as quality improvement and care coordination. We have concerns about the stringency of the financial risk criterion and associated risk parameters proposed by CMS for Other Payer Advanced APM designation, similar to those that we expressed above about Medicare Advanced APMs.

We support efforts by CMS to provide a pathway for Medicare Advantage (“MA”) plans and their clinicians to participate in the APM Incentive program. As more beneficiaries choose to enroll in MA plans, their care should be aligned on shared goals with that of beneficiaries in APMs outside of MA plans. Clinicians serving these MA plan beneficiaries should be able to count their patients towards QP status thresholds. Similarly, the FAH encourages CMS to explore ways to align current and future APMs associated with the Federal Employees Health Benefits (“FEHB”) program with the Medicare APM Incentive program framework. According to the Congressional Research Service, FEHB provides more than $40 billion annually in health care benefits to federal employees and federal retirees. This large population provides a natural target for expansion of APMs, creating another avenue by which the federal government can foster alternative healthcare delivery models and concomitantly offer better healthcare options to its employees and retirees. Allowing clinicians treating FEHB enrollees to count that care towards QP targets would also engage those clinicians in APM participation.

Need for APM Regulatory Exception

MACRA signals to the provider community the value and importance of APMs in fundamentally reshaping our health care payment and delivery system. Yet, the current health care fraud and abuse regime has not kept pace, and is designed to keep hospitals and physicians and other providers in silos, rather than working in alignment as a team, which is necessary to have success in an APM.

To truly effectuate change, the hospital community must be afforded the flexibility to align physicians’ (as well as other providers’) otherwise divergent financial interests, while promoting incentives to reduce costs and improve quality. While APMs offer the chance to
change this paradigm, the Stark law, anti-kickback statute and certain civil monetary penalties ("CMPS") stand as an impediment. A legal safe zone is needed that cuts across all of these fraud and abuse laws.

We urge CMS to work with Congress to establish a long-term legislative solution that will establish legal certainty around permissible financial relationships in APMs. Specifically, Congress should establish a single, broad exception that applies to the Stark physician self-referral law, the anti-kickback statute and relevant CMPS to encourage financial relationships that incentivize collaboration in delivering health care, while rewarding efficiencies and improving care.

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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 healthcare system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

[Signature]