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

***SUBJECT: CMS-5522-P, Medicare Program; CY 2018 Updates to the Quality Payment Program, June 30, 2017.***

Dear Administrator Verma:

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 June 30, 2017 (82 FR 30010). 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 focused on value. The CMS Quality Payment Program (QPP) includes two 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 requires 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.

We appreciate that CMS has provided this opportunity for input on the Proposed Rule, and we have focused our comments on concerns that reflect the diverse partnerships between FAH members and their clinicians.

### *General Comments*

#### *Additional Education Needed*

As the FAH and its members continue to learn about the QPP and the impact it has on clinicians, their groups and the hospitals in which they work, certain themes consistently arise. Although CMS has gone to great lengths to provide educational resources related to MIPS implementation, clinicians and those helping them to administer MIPS request more education. Now that the transition year is underway, many of the general principles of MIPS are better understood and the application of the program raises questions for the clinicians trying to participate meaningfully. Some of our members have suggested that CMS create a dynamic forum for FAQs. This would enable clinicians and administrators to ask the detailed questions as they arise, rather than trying to interpret general guidance in the rulemaking record and possibly unknowingly thwart their success in MIPS.

#### *More Timely Feedback*

Related to the request for more education on the nuances of the program, our members are seeking clearer and more frequent scoring predictions. The FAH recommends that CMS develop tools that clinicians could use to predict their score in performance measure categories with examples personalized to the clinician's type of practice and specialty. In order to implement value-based decisions to improve the care provided to patients and affect a clinician's score, timely and actionable claims data is needed. Feedback received a year after it is reported does not provide MIPS-eligible clinicians with meaningful guidance on actions that can be implemented in the present to impact payment in the future. Once the data is received, it is too late to implement any changes that will impact that performance period. **We request that CMS develop mechanisms to provide feedback on a more frequent and timely basis. Clinicians would benefit from receiving feedback reports monthly, or at a minimum, quarterly.**

## *Consistent Terminology*

In developing the QPP and drafting related regulations and guidance, CMS has created an additional challenge to understanding and implementing the program by changing the terms used within the program. The FAH requests that CMS endeavor to use consistent terms from proposed to final rulemaking to lessen confusion for clinicians interpreting these complex guidelines and requirements. For example, MACRA requires the MIPS performance categories to be based on quality, resource use, clinical practice improvement activities, and meaningful use of certified EHR technology (CEHRT), which would then comprise a composite performance score. CMS initially published proposed regulations with these terms, and organizations began MACRA educational programs based on these terms. Between the Proposed and Final MACRA rules for the transition year, CMS unfortunately changed the name of “clinical practice improvement activities” to “improvement activities,” “resource use” to “cost,” and “composite performance score” to “final score.” CMS also renamed the “meaningful use” program as the “advancing care information” category. Clinicians had already begun familiarizing themselves with terms that quickly became outdated. CMS also renamed several terms related to APMs and Advanced APMs. **To support a more comprehensive understanding of the elements of QPP, we ask that CMS be sensitive to the challenge this poses for clinicians before making additional changes in the future.**

## *Merit-Based Incentive-Payment System*

### *Low-volume Threshold*

For the second performance year, CMS has set out a modified low-volume threshold that would exclude a larger number of clinicians and groups from MIPS participation than in the first year of the program. The 2018 performance year will exclude individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to \$90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries. CMS estimates that this will exclude approximately 134,000 additional clinicians from MIPS. **The FAH supports the flexibility this increased low-volume threshold provides to those small practices that would struggle under MIPS, able to earn only a modest positive payment adjustment due to the costs and expenses required for participation.**

Although an adjustment to the low-volume threshold will provide a reprieve for many clinicians during the 2018 performance year, this will potentially impact the clinicians remaining in the MIPS as well. **With the exclusion of such a large number of eligible clinicians, the FAH questions the possibility of positive payment adjustments for those clinicians and groups who successfully participate in MIPS.** Unless a clinician or group achieves the high-performance threshold and becomes eligible for the additional bonus, the current composition of MIPS-eligible clinicians does not create many resources to share with successful clinicians. CMS estimates that 96.1 percent of eligible clinicians will receive a positive or neutral adjustment and just 3.9 percent of eligible clinicians will face a negative adjustment.<sup>1</sup> Due to the budget neutrality requirement of MIPS, the larger number of positive payment adjustment eligible clinicians will have a very small pool of funds for this component of the program.

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<sup>1</sup> 82 Fed. Reg. 30010, 30240 (June 30, 2017) (*see* Table 88).

The FAH appreciates the flexibility CMS is providing low-volume practitioners. These clinicians will not have to invest in MIPS participation activities and will not be penalized. However, we are concerned that in granting this flexibility, a two-tiered system among clinicians may develop: one tier would consist of those clinicians actively engaged and moving forward with MIPS as it develops, and the other tier of either excluded physicians making efforts to avoid inclusion in MIPS or those with only limited participation. **We encourage CMS to continue to offer flexibility to low-volume clinicians and groups during the initial years of MIPS while still engaging with all clinicians to align their practices with the goals supported by MIPS.**

#### *Low-Volume Opt-In*

CMS proposed additional flexibility to those clinicians who fall below the low-volume threshold and, therefore, are excluded from participation in MIPS. For performance periods beginning in 2019, CMS is seeking comment on expanding options for clinicians and is offering clinicians the ability to participate in MIPS if they otherwise would not be included, for purposes of the 2021 MIPS payment year. Clinicians would be provided the ability to opt-in to MIPS if they meet or exceed one, but not all, of the low-volume threshold determinations, including as defined by dollar amount, beneficiary count, or, if established, items and services.

The FAH believes there are many clinicians who would be excluded due to the low-volume threshold but are prepared and would choose to participate in MIPS. Without the possibility of participating in MIPS, these practices will be subjected to frozen payment updates in the upcoming years. Many of these practices have invested large sums of money in developing functional EHRs and undertaking practice-improvement efforts and do not want to lose momentum on these efforts, nor miss the opportunity to earn payment increases. Willing clinicians should be provided the opportunity to have their efforts towards high quality and value acknowledged and rewarded. **We urge CMS to allow clinicians and groups with the resources and interest to opt-in to MIPS participation on an annual basis regardless of whether they exceed any one of the low-volume threshold parameters beginning in the 2018 performance year.**

#### *Virtual Groups*

The option to participate in MIPS as a virtual group is new for the 2018 performance year. The Proposed Rule includes CMS's proposal to establish requirements for MIPS participation at the virtual group level. For the 2018 performance year, eligible clinicians must inform CMS of their intent to participate in MIPS as a virtual group by December 1, 2017. Once this election is made for the performance year, an eligible clinician or group is unable to change this election for that year. The implementation of the virtual group requirements for the 2018 performance year presents many challenges for clinicians and groups. **The short timeline for implementation of the requirements coupled with the complexity of how virtual groups can be formed and will participate in MIPS have resulted in caution for most groups considering participation via this option.**

## Timing

Individual clinicians and groups interested in forming a virtual group for the 2018 performance year must comply within a very short timeline to register with CMS as virtual group by December 1, 2017. **The FAH is concerned that this does not afford clinicians and groups adequate time to review final guidance once issued by CMS, consider their options and potential outcomes for participating as part of a virtual group, and make an informed decision on participation in MIPS as a virtual group.**

CMS plans to provide virtual groups with an opportunity to make an election prior to the publication of the Final Rule. In conjunction with this timeline, CMS anticipates publicizing the specific opening date via subregulatory guidance to enable virtual groups to make an election for the 2018 performance year from mid-September to December 1, 2017. This option to elect virtual group status prior to the December 1, 2017 deadline does not provide the assistance and flexibility that the FAH believes would be beneficial to solo practitioners and groups. Once the final guidance is issued by CMS, solo practitioners and groups need time to evaluate the prospects of joining a virtual group. CMS proposes to allow solo practitioners and groups with 10 or fewer eligible clinicians that have elected to be part of a virtual group to have their performance measured and aggregated at the virtual group level across all four performance categories. Evaluating this aggregated data in advance of virtual group formation will take time. It is unlikely that many clinicians will be able to ensure that the aggregated score of a virtual group will exceed what they are able to achieve as an individual or group.

**For the above reasons, the FAH proposes that CMS consider a modified timeline for virtual group participation during the first performance year. If those clinicians willing to participate in a virtual group had the option of a 90-day performance period during the 2018 performance year, the FAH believes CMS would see a larger number of virtual groups participating.** This option would provide these groups additional time to put in place the administrative mechanisms needed based on the final guidance that CMS will issue later this year. We also suggest that CMS create an option for virtual groups to operate on a trial basis for the first performance year to compare the virtual group performance to an individual eligible clinician or group's actual performance.

## Complexity

**Without the full picture of what will be required of a virtual group and how the groups will operate under MIPS, it is challenging to assess how solo practitioners and small groups will fare as a virtual group compared to their individual or group score absent a virtual group.** The requirement to have agreements in place among all virtual group members in addition to the preparation that must occur to track and report on the applicable performance measures for the 2018 performance year will take more time than CMS has provided for in the proposed timeline.

The FAH agrees with CMS that there is opportunity for small and rural providers to benefit from the concept of virtual groups. The aggregation of administrative requirements among the members of the virtual group is favorable for those solo practitioners and groups

overwhelmed by the implementation of systems and oversight needed to participate successfully in MIPS. Ideally, these solo practitioners and groups will be able to achieve positive payment adjustments for their efforts. However, at this time, the FAH is concerned that the administrative complexity is daunting and perhaps more burdensome than initial participation in an APM. The complexity of putting into place a functional virtual group and ensuring successful implementation of all requirements is likely going to prevent many solo and small or rural practices from participating in a virtual group until the function and impact of these groups are better understood.

### Guidance Needed

**As the FAH has noted above, the implementation of virtual groups is a daunting task at this time. In order to support those solo and group practices willing to pioneer this new concept under MIPS, additional guidance and education is needed.** More interest in virtual groups may be created once CMS is able to provide a more defined and certain framework to implement this change. The current lack of clarity on how this concept will work may decrease participation. The FAH supports CMS in providing further clarification and resources to support potential virtual groups, which may result in more groups willing to take on the challenge.

### *Subgroups/Split TINs*

In the Proposed Rule, CMS recognizes that groups, including multi-specialty groups, have requested an option that would allow a portion of a group to report as a separate subgroup on measures and activities that are more applicable to the subgroup and be assessed and scored accordingly based on the performance of that subgroup. **The FAH supports the possibility of such an option.**

MIPS relies 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 acknowledges the efficiency of using common, existing identifiers rather than superimposing new ones. However, the FAH remains concerned about 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 regarding clinical activities. Many TINs comprise multi-specialty groups spanning a wide range of medical specialties. Requiring such a TIN-sharing multi-specialty group to report collectively on a uniform set of MIPS measures 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. **The FAH, however, cautions CMS against any proposal that would require multi-specialty TINs to divide into multiple TINs. This is impracticable 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.**

CMS proposes a unique identifier for MIPS-eligible clinicians participating in a virtual group. Specifically, in order to accurately capture all the MIPS-eligible clinicians participating in a virtual group, CMS proposes that each MIPS-eligible clinician who is part of a virtual group

would be identified by a unique virtual group participant identifier. The unique virtual group participant identifier would be a combination of three identifiers: (1) Virtual group identifier; (2) TIN (9 numeric characters); and (3) NPI. For example, a virtual participant identifier could be VG-XXXXXX, TIN-XXXXXXXXXX, NPI-1111111111. For those clinicians not participating in virtual groups, the FAH encourages CMS to consider revising clinician and group identification instead of basing it solely upon the TIN. **An option the FAH supports is adding similar identifying alphanumeric characters to the TIN to define subgroups for whom shared quality and resource use reporting are more appropriate. The add-on code to the group-level TIN will assist groups in reporting on the measures most applicable to the subspecialties within the group.** This, in turn, will provide more relevant clinical data for the clinicians practicing in the subspecialty as they will report on the measures most meaningful to their patients and their practice.

### *Facility-Based Clinicians*

The Proposed Rule includes CMS's proposal to implement facility-based measures for the 2018 MIPS performance period and future performance periods to add more flexibility for clinicians to be assessed in the context of the facilities at which they work. The proposed facility-based measures policies relate to applicable measures, applicability to facility-based measurement, group participation, and facility attribution. CMS presents a method for clinicians whose primary professional responsibilities are in a health care facility to assess performance in the quality and cost performance categories of MIPS based on the performance of that facility in another value-based purchasing program. The FAH is encouraged that CMS is proposing facility-based MIPS reporting accommodations for hospital-based physicians. **The FAH agrees with CMS in moving forward to allow hospital-based clinicians to utilize hospital quality measures, specifically those measures from the Hospital Value-Based Purchasing (VBP) Program, for the MIPS quality category. This not only simplifies participation in the quality category for these clinicians, it promotes alignment between quality and value goals among hospitals and clinicians.** Engaging clinicians further in the quality goals of the hospitals in which they practice creates greater collaboration among the parties to achieve common goals.

**The FAH supports CMS's proposed definition of facility-based clinicians with the 75 percent threshold as an appropriate measure in identifying those clinicians who provide their covered professional services in a facility and contribute to the quality measures of the facility in which they practice. As this is a new component of MIPS, the FAH encourages CMS to offer the use of facility-based measurement as an option, rather than requiring use of the facility measurements for all qualifying eligible clinicians.** CMS has emphasized flexibility for eligible clinicians in many aspects of MIPS, and we believe that allowing these physicians the option to use the hospital-based measures or their individual reporting measures supports this goal.

We agree that many facility-based MIPS-eligible clinicians contribute substantively to their respective facilities' performance on facility-based measures of quality and cost, and that their performance may be better reflected by their facilities' performance on such measures. We support CMS in offering those clinicians or groups who are eligible for, and wish to elect, facility-based measurement to submit their election during the data submission period as

determined through the attestation submission mechanism established for the improvement activities and Advancing Care Information (ACI) performance categories.

### *Performance Threshold*

The FAH supports the proposal to increase the performance threshold to 15 points, rather than the alternate proposals of 6 or 33 points. The FAH believes this proposal strikes a balance between providing a meaningful increase in preparation for the 2021 payment year, while still providing flexibility and opportunities for achievement of this threshold. The Proposed Rule provides examples of how clinicians can achieve the new performance threshold. **While these examples establish basic guidelines for success in the performance measurement categories, further guidance is needed to demonstrate the intricacies clinicians encounter in selecting the measures to report for a performance year.** For example, the ACI category alone is complicated in applying the base and bonus score. The FAH requests that CMS include examples of how the proposed performance threshold can be positively impacted by ACI measures. **Providing a dynamic resource where clinicians can submit questions and receive answers at the time they arise would assist clinicians grappling with these sorts of complexities in this developing program.**

### *Quality*

The FAH has previously recommended that clinician quality improvement as well as achievement be recognized, so that pay-for-performance continues to incentivize all providers and 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 and hopes that CMS will extend such a reward mechanism to those clinicians who consistently achieve high quality performance.**

### Performance Period

The performance period for the quality category for the 2018 performance year was established in prior rulemaking as the full 2018 calendar year. In the Proposed Rule, CMS included a proposal that the performance period, for purposes of the MIPS payment in year 2021 and future years, would remain as the full calendar year. **The FAH urges CMS to reconsider the full year performance period for 2018 and future performance years and instead establish a 90-day performance period. For many reasons, the inclusion of a full year of data reporting for quality measures will present challenges for eligible clinicians and groups.** A component of these challenges is linked to competing efforts required under the ACI performance category. The impending CEHRT transition from technology certified to 2014 Edition criteria to 2015 Edition criteria will be resource intensive for many clinicians. Although we appreciate CMS's additional flexibility extended for the 2018 performance period related to ACI, the efforts required for this transition are not to be minimized. The transition to 2015 Edition criteria will take time and adjustment for the clinicians. Anytime a provider makes a major IT transition such as this, tracking data consistently for a full year is challenging. If those providers implementing the 2015 Edition of CEHRT must report quality data for a full calendar



year, they will struggle to report data from multiple systems while learning to implement the 2015 Edition and participate successfully in MIPS.

Additionally, when providers undergo an EHR vendor transition, it is extremely challenging to obtain data from one certified EHR and combine that data with data from 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, whenever an EHR transition occurs, a 90-day performance period utilizing the new EHR vendor would allow the provider to report successfully on all MIPS performance categories.**

As CMS discusses throughout the Proposed Rule, use of certified health IT by clinicians is important not only for performance under the ACI performance category, but also for reporting data for other measures and activities. As such, the FAH requests that CMS revise the quality reporting period for the 2018 performance year to a 90-day period. This will not only provide consistency among other performance categories, it will afford providers the opportunity to focus resources on the 2015 Edition transition and achieve some of the goals established related to health IT that CMS has encouraged for years.

#### Multiple Submission Mechanisms

The Proposed Rule, beginning with performance periods occurring in 2018, suggests allowing individual MIPS-eligible clinicians and groups to submit data on measures and activities, as applicable, via multiple data submission mechanisms for a single performance category (specifically, the quality, improvement activities, or ACI performance category). Under this proposal, we understand that CMS would allow, but not require, individual MIPS-eligible clinicians and groups that have fewer measures and activities that are applicable and available under one submission mechanism to submit data on additional measures and activities via one or more multiple submission mechanisms, as necessary.

**While the FAH applauds CMS's efforts to extend flexibilities to providers for the reporting of measures and activities, the FAH wants to ensure that the flexibility meant to lessen a burden does not, in fact, create a different burden for eligible clinicians.** Rather than requiring that all measures for a category be submitted via the same mechanism, CMS proposes an option to allow eligible clinicians to submit measures via multiple submission mechanisms to ensure that eligible clinicians are entitled to earn the maximum number of points for those measures. However, for those clinicians and groups who have placed vast resources into fully implementing CEHRT over the past several years, it would be an additional cost and challenge to then contract with additional organizations, such as Qualified Clinical Data Registries, to submit additional data. Implementing CEHRT successfully has been a monumental task for these clinicians and groups with the expectation that the CEHRT program would be sufficient for participation in future data reporting programs developed by CMS. Now it is unclear whether CMS is telling clinicians that, in addition to the costs and effort already expended into their existing CEHRT, as well as their ongoing efforts to fully implement 2015 Edition CEHRT, they may have to incur additional costs and dedicate additional resources for a third party to assist in

submitting their data to CMS. Rather than imposing such a burden on these clinicians, we request that CMS confirm our understanding that the use of multiple submission mechanisms is optional and not required.

**The FAH asks CMS to clarify that clinicians *may choose* to submit measures via multiple submission mechanisms but *are not required* to if they are able to submit applicable measures via CEHRT, regardless of the number of measures submitted via EHR.** For example, an individual MIPS-eligible clinician or group submitting data on four applicable and available quality measures via EHR would be eligible to receive the maximum number of points available under the quality performance category based on those four measures. This ensures clinicians are not burdened with the increased complexity and extra costs associated with establishing relationships with new data submission mechanism vendors to report additional measures and/or activities. This option maintains the flexibility and reduction in burden for clinicians that CMS is striving for in this rulemaking.

#### Topped Out Measures

CMS proposes to cap the score of topped out measures at 6 measure achievement points. The FAH is concerned that limiting the achievable score on topped out measures will penalize those clinicians who have fully implemented CEHRT. We recognize that CMS is trying to address measures that have consistently high performance without meaningful distinction among providers. However, CMS should not overlook the practical impact on EHR systems. Many of these measures are part of EHR systems in which practices and organizations have invested significant time and resources in terms of both the technology and workflow redesign required. **The clinicians and groups who have implemented effective EHR systems and the ability to perform well on the identified topped out measures should have the potential to score the maximum quality points for these measures. Particularly in cases where EHR/QRDA3 is the reporting methodology used, it can take an organization two-to-three years to implement these measures and have the system updated to reflect these changes.**

We request that CMS provide adequate notification regarding topped out measures to afford clinicians time to update their EHR systems. Because updates to EHR systems are complex, the FAH suggests a two-year time period between when a measure is confirmed as topped out and when it is actually removed from the quality measures of MIPS. For example, if a measure is identified as topped out for two years and then the decision to remove the measure is made in the third year, the FAH recommends a two-year time period before the measure is officially removed. **An extension to the current timeline proposed by CMS will support clinicians in incorporating appropriate measures into their EHR systems as MIPS evolves and their practices take steps to evolve along with it.**

#### *Cost*

While the cost performance category was weighted at zero percent for the 2017 performance year and CMS proposes to weight it at zero percent for the 2018 performance year, it is projected to account for 30 percent in the third performance year (calendar year 2019). The FAH has several concerns about the cost category in light of the proposals in the Proposed Rule.

**We support the proposal to maintain a zero percent weight for the cost category in the second year of MIPS.** Clinicians are still adapting to the new program and evaluating the best paths to make an impact on the various performance measures. The additional time will allow clinicians to focus resources to determine accurate and actionable patient attribution formulas in preparation for an increase in weighing of the cost category in future years. Although CMS intends to increase the weight of the cost performance category to 30 percent in the third MIPS program year, we caution CMS regarding this sharp increase. Clinicians will encounter challenges in implementing appropriate cost measure activities that represent such a large component of the final score. So many variables are at work in the early years of MIPS participation that **the FAH urges CMS to consider a schedule to increase cost performance weight over a longer period of time. A weight of zero percent in 2018 followed by incrementally increasing the weight of the cost performance category over several years will best allow clinicians to adapt to the MIPS program.**

A gradual increase in the weight of the cost category will also allow more time for CMS to provide clinicians with the additional feedback they need to prepare for full implementation of the cost performance weight. **The proposed feedback schedule at this time will not offer the meaningful insight the clinicians require for success in cost measures. Not only are we concerned about the timeliness and completeness of data provided by CMS, the FAH also believes that further education is needed to assist clinicians in understanding the feedback that will be provided.** CMS is considering utilizing the parts of the Quality and Resource Use Reports (QRURs) that user testing has revealed beneficial while making the overall look and feel usable to clinicians. While the FAH supports the user-friendly aspect of this consideration, we ask that CMS increase educational offerings regarding interpreting and optimizing QRURs.

In further support of an extended phase-in regarding the weight of the cost measures in a clinician's final score, we note the additional processes that must be put in place to implement cost-saving measures via care coordination. Implementing efforts that will impact the total cost per episode will require more care coordination, often with new organizations and entities. The time needed to prepare for these arrangements is likely longer than clinicians have before the next performance year begins. **Additionally, once the cost performance measure is included in a clinician's score, the FAH believes that a 90-day performance period is appropriate.** As clinicians learn to implement the cost improvement measures under MIPS, a shorter 90-day period will provide meaningful data to CMS as it does in the other performance categories with 90-day reporting periods. This shorter performance period also aligns with CMS's goal of flexibility and burden reduction for clinicians.

Although the FAH is supportive of a slower transition to an increase in the cost performance weight, we want to ensure that when cost measures are taken into account for future performance years, that the results of cost-saving measures do not outweigh the importance of maintaining high quality care for patients as well. A report issued by the Government Accountability Office earlier this year assessed the Hospital Value-Based Purchasing program's impact on Medicare quality and efficiency. The report found, "[s]ome hospitals with high efficiency scores received bonuses, despite having relatively low quality scores, which contradicts CMS's stated intention to reward hospitals providing high-quality care at a lower

cost."<sup>2</sup> We believe that CMS is aware of these concerns, and we support the efforts to balance the four performance categories when developing the measures, activities, and scoring of the performance categories.

### *Advancing Care Information*

**The FAH broadly supports CMS's recent proposed modifications in the Proposed Rule to the ACI performance category of MIPS.** Previous commentary from the FAH to CMS focused on the need for added flexibility in the ACI performance category, and CMS has made several changes that will help clinicians successfully participate in the MIPS program. Several of CMS's proposals and policy decisions were welcomed by FAH, including the reinstatement of the exclusion criteria pertaining to electronic prescriptions, many of the hardship exceptions, commitment to end the "all-or-nothing" requirement from the Medicare EHR Incentive Program, and, overall, adding needed flexibility for clinicians in reporting obligations and requirements for clinicians. The FAH believes CMS has taken vital steps towards achieving parity among CMS programs, aligning incentives, and encouraging collaborative participation in the implementation of EHR technology by clinicians and hospitals.

#### Decertification Exception and Hardship Exception

The FAH finds the CMS proposals for adding exceptions to the ACI performance category scoring, notably the several hardship exceptions and the decertification exception, as pragmatic approaches to issues faced by clinicians when implementing EHR technologies. Decertification of EHR systems has made headlines, and in the vast majority of those headlines, the EHR vendor erroneously (or misleadingly) achieved certification. CMS's proposal to allow eligible clinicians to apply for exemption from the ACI performance category because of an EHR system's decertification is a sensible approach that supports clinicians who encounter serious issues with EHR technology that are outside their control.

**As part of the QPP's process for claiming an exception under the ACI performance category, the FAH respectfully requests that CMS change the submission deadline for exception applications to July 31, 2018 instead of December 31, 2017.** The preamble of the Proposed Rule states that CMS is proposing that "a MIPS eligible clinician seeking to qualify for this exception would submit an application in the form and manner specified by us by December 31st of the performance period, or a later date specified by us."<sup>3</sup> CMS notes that using December 31, 2017 as the submission deadline would help clinicians learn whether CMS approved their application prior to the data submission requirements of the 2017 performance year on March 31, 2018. However, in using the language "or at a later date specified by us," CMS acknowledges that a December 31<sup>st</sup> deadline may not be appropriate; the FAH agrees that this deadline is not in the best interest of providers. It has been the experience of FAH's members that organizations and practices cannot effectively analyze eligibility for the hardship exceptions without a full year of data available. Moreover, providers may not discover that their EHR technology was decertified until well after the proposed submission deadline of December 31, 2017. By allowing

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<sup>2</sup> U.S. Government Accountability Office, *Hospital Value-Based Purchasing. CMS Should Take Steps to Ensure Lower Quality Hospitals Do Not Qualify for Bonuses*, June 2017.

<sup>3</sup> 82 Fed. Reg. 30078 (June 30, 2017).

more time for providers to apply for an exception, providers can better position themselves to make decisions on whether to seek applicable exceptions to the ACI performance category.

The FAH believes a submission deadline of July 31, 2018 provides an appropriate amount of time for providers to seek any available exceptions; however, if CMS disagrees with that submission deadline, the FAH alternatively requests that CMS move the submission deadline to no earlier than March 31, 2018.

#### Removal of the "All-or-Nothing" Requirement

The FAH is pleased that CMS eliminated 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 under the ACI performance category of MIPS. The previous absolutist approach in the Medicare EHR Incentive Program was not in the best interests of encouraging clinician participation, and we agree with CMS that eligible clinicians should receive some points under MIPS for reporting EHR measures. We further agree that clinicians should receive a score of zero for only a complete failure to report under MIPS.

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

#### Added Flexibility in Reporting Obligations in the ACI Category Strikes an Ideal Balance

**The FAH broadly supports CMS's proposal to allow eligible clinicians to use the 2014 Edition, the 2015 Edition, or a combination of the two editions for attesting to CEHRT.** Provider readiness in adopting the 2015 Edition can be subject to delays for a multitude of reasons. Notably, as of this year, very few providers have implemented EHRs that have achieved 2015 Edition of CEHRT because of various setbacks. Allowing continued use of the 2014 Edition will afford providers time to address implementation issues and plan for the inevitable delays in upgrading EHR systems. **For many of the same reasons, the FAH also approves of CMS's acceptance of 90 consecutive days of data for the ACI performance category.** This added flexibility in performance period and reporting obligations reduces burden and allows eligible clinicians flexibility to work towards fulfilling CEHRT requirements.

Providers are unlikely to meet the 2015 Edition of CEHRT by year-end and in time for the 2018 performance year. Adoption of new EHR technology takes significant time in coordinating implementation among vendors, staff, clinicians, and other affected parties. When implementing or upgrading EHR technology, providers must grapple with major adjustments to their technological capabilities, workflow, and data management processes. These various elements make adoption of the extensive requirements in the 2015 Edition CEHRT by the first

day of the 2018 performance year highly unlikely. It also inhibits providers' abilities to report data over lengthy periods of time because transitioning EHR vendors, upgrading technology, or other EHR investments can limit accessibility to data, or the interoperability of such data when transitioning EHR technology. **For those reasons, the FAH believes CMS's proposal for flexibility in the continued use of the 2014 Edition, in combination with the 90-day performance period, allows clinicians time to fully evaluate their EHR optimization in a meaningful way that ensures EHR systems are in place, tested thoroughly, and operating as intended in advance of increased reporting obligations.**

With that said, some providers will be ready to attest to the 2015 Edition, and the FAH agrees with CMS's proposal to award bonus points for those who can meet the increased obligations of the 2015 Edition. Those providers have been making essential investments in their EHR technology and should be rewarded for their substantial commitment in doing so.

#### Flexibility and Alignment Under the EHR Incentive Programs

**The FAH appreciates CMS's efforts to ensure that requirements for the use of certified EHRs and exchange of health information are aligned across all providers by providing additional flexibilities to hospitals and critical access hospitals under the Medicare and Medicaid EHR Incentive Program.** Hospitals experience many of the same setbacks as clinicians when implementing or upgrading EHR technology. The FAH welcomed the flexible reporting and participation options for hospitals finalized in the FY2018 Hospital Inpatient PPS Final Rule (IPPS Final Rule) for the EHR Incentive Programs. **In particular, the FAH believes the recently published changes to the EHR Incentive Programs in the IPPS Final Rule will more closely align obligations and incentives with CMS's proposals for the ACI performance category of MIPS in the Proposed Rule.** Alignment among CMS programs is possible due to the conforming changes CMS has made to existing requirements to the EHR Incentive Programs. The FAH expresses our thanks to CMS for allowing the 2014 Edition of CEHRT in the EHR Incentive Programs for the 2018 performance year, as well as Modified Stage 2 attestations from eligible hospitals under meaningful use requirements.

CMS has made significant efforts to coalesce requirements among its programs; however further alignment among CMS programs is needed. In the Medicaid EHR Incentive Program, for example, some eligible clinicians participate through their physician group, while at the same time other clinicians in that group are participating in MIPS. Those clinicians will face an undue burden of reporting under different program requirements in order to avoid penalties and obtain the incentives meant to support their investments in CEHRT. **To avoid two entirely different workflows for data capture in one physician group, CMS could, and should, consider an eligible clinician's participation in the Medicaid EHR Incentive Program as fulfilling the ACI performance category in MIPS.**

**CMS should also continuously evaluate programmatic requirements for aligning incentives among their programs wherever possible. The best outcomes will be achieved for the Medicare program and all stakeholders when all clinicians and hospitals are working with common goals and under the same incentives and requirements.** As part of the process in attaining further alignment between the EHR Incentive Programs and the ACI performance

category in MIPS, the FAH strongly encourages CMS to consider delaying some aspects of the programs, such as Stage 3 meaningful use. Parity among the programs should take priority, and the FAH urges CMS to delay parts of the programs as appropriate to ensure alignment around common goals and to avoid, to the greatest degree possible, unintended complexity in the reporting obligations of clinicians and hospitals.

#### *Complex Patient Bonus, Bonus for Small Practices, and Rural Bonus*

**The FAH supports CMS's proposal to implement bonuses for complex patients, small practices, and rural practices during the MIPS final score calculation.** Accounting for the complexities inherent in patient populations and the unique hurdles encountered by small and rural practices is not an easy task. A multitude of factors can affect patient health outcomes, and those factors can be more pronounced in small practices or practices located in rural settings. For those reasons, the FAH believes CMS's proposed policy of providing bonuses in the MIPS final score calculation can help account for such factors and circumstances.

#### Complex Patient Bonus

**The FAH supports the addition of a complex patient bonus** and believes this bonus will encourage eligible clinicians to take on patients who are more complex while addressing the potential drawback for clinicians of those patients negatively affecting their overall final MIPS score. CMS seeks comment on the use of an indicator for this bonus, and CMS proposed either the Hierarchical Condition Category (HCC) risk score or the proportion of patients who have dual eligibility status. The FAH finds the HCC as a more complete measure than simply dual eligible status because, as CMS mentions in the Proposed Rule, HCC includes dual eligible status as one of the factors in its calculation. Additionally, HCC is widely used in other CMS programs, and health care providers are accustomed to its usage. **Therefore, the FAH suggests that CMS implement the HCC risk score as the indicator for the complex patient bonus.**

#### Bonus for Small Practices

**The FAH agrees with CMS's proposal to add a bonus for small practices** and believes this bonus will provide adaptability for those practices to participate actively in MIPS. Small practices often encounter performance and reporting disadvantages due to their size, and by providing a bonus to help account for those inherent disadvantages, CMS is recognizing, and accounting for, barriers to participation that are unique to small practices.

#### Rural Bonus

**For many of the same reasons the FAH supports a bonus for small practices, the FAH encourages CMS to implement a bonus for rural practices.** Barriers to participation in performance and reporting obligations disadvantage eligible clinicians who practice in a rural setting similar to eligible clinicians in small practices. With the addition of the unique challenges added by a rural setting, CMS's adoption of a bonus for rural-eligible clinicians will help account for those disadvantages while encouraging participation.

## *Adjusting for Risk Factors – Considerations for Social Risk*

In the Proposed Rule, CMS seeks comments pertaining to accounting for social risk factors under the MIPS program. The FAH has long believed that appropriately accounting for social risk factors, such as sociodemographic status, is essential for accurately assessing health care provider performance for public reporting and accountability programs, particularly with respect to outcome measurement. All beneficiaries, including those with social risk factors, should receive the best possible care. At the same time, where social risk factors affect patient outcomes in ways that are beyond the control of health care providers, they should not be penalized for, nor discouraged from, treating these patients. The metrics used for holding clinicians accountable need to properly balance these goals.

The FAH is pleased to offer some guiding principles for implementing social risk factor adjustments. First, CMS recently finalized a stratification approach under the Hospital Readmissions Reduction Program (HRRP) and sought comments on using a similar approach in MIPS. While stratification is a reasonable first step for addressing social risk factors, it should be viewed as a stopgap tool, not a permanent solution. Second, a clinician's share of patients who are dual eligible beneficiaries should also be viewed as a short-term proxy for assessing the extent to which a clinician has patients facing social risk factors. Third, a process in which clinicians receive confidential reports showing their results must accompany any adjustment for social risk factors. Fourth, public reporting of social risk factor-adjusted information on *Physician Compare* or a similar site must be useful to patients, families, and providers.

### ***Alternative Payment Model Incentive Program***

The FAH appreciates that CMS has taken into consideration our previous input on a variety of APM-related topics, including revising the Comprehensive Care for Joint Replacement (CJR) model to qualify as an Advanced APM and not increasing the financial risk parameters for 2018 and 2019. However, the FAH remains concerned about a number of APM-related policies, including the limited number of models that qualify as Advanced APMs, the excessively strict financial risk criterion, and the need for broader exceptions to the Stark and anti-kickback laws and certain civil monetary penalties.

### ***Advanced APM Model Criteria***

In last year's Final Rule implementing MACRA, CMS focused its attention on the current APM portfolio of the Center for Medicare and Medicaid Innovation (CMMI). 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 Medicare Shared Savings Program (MSSP) Track 1, 1244 participants in BPCI Phase 2, and 800 participants in the CJR model.

From this relatively large and diverse portfolio, however, CMS identified a limited number of models that merit designation as Advanced APMs and whose participating clinicians



could reach Qualifying Participant (QP) status. Several of these models are in their early phases, with a small number of total participants. **The FAH believes that the current Advanced APM definitions 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 Advanced APM definitions to allow more APMs to be designated as Advanced APMs, such as BPCI and CJR.** While the FAH appreciates that CMS has exercised its flexibility to modify the CJR model such that it qualifies as an Advanced APM, including recently publishing a proposed rule,<sup>4</sup> those modifications have not yet been implemented, meaning clinicians participating in the model are currently unable to qualify as QPs. Additionally, the FAH applauds the commitment CMS made in January 2017 and again in August 2017 to build on the BPCI model to “design a new voluntary bundled payment model” that would “meet the criteria to be an Advanced APM.”<sup>5</sup> However, this new model is not yet available to clinicians. **The FAH encourages CMS to implement the CJR modifications and new voluntary bundled payment model as soon as possible.**

Ultimately, the success of APMs rests on allowing different payment models to compete on value and efficiency and allowing the marketplace to determine success among the models. However, under the statute, the Advanced APM incentive bonus lasts for only six years (2019-2024). Limited availability of Advanced APMs going into performance year two leaves a narrow window for CMS to use the MACRA-established incentive payments to encourage providers to move into these models. The FAH is concerned that clinicians and their hospital partners ultimately may be unlikely to join together in APMs, and clinicians will instead 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. CMS’s use of its discretionary authority to provide greater flexibility in the determination of Advanced APMs will ensure greater provider participation in APMs and a faster transition of providers to the value-based payment models that MACRA facilitates.

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<sup>4</sup> 82 Fed. Reg. 39311 (August 17, 2017). “We are also proposing...a change to the criteria for the Affiliated Practitioner List to broaden the CJR Advanced Alternative Payment Model (APM) track to additional eligible clinicians.”

<sup>5</sup> 82 Fed. Reg. 215 (January 3, 2017). “However, building on the BPCI initiative, the Innovation Center intends to implement [a] new bundled payment model for CY 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM.” And, in response to stakeholder comments, “We appreciate these considerations as we design a new voluntary bundled payment model.” See also 82 Fed Reg. 39313 (August 17, 2017). “...providers interested in participating in bundled payment models may still have an opportunity to do so during calendar year (CY) 2018 via new voluntary bundled payment models. Building on the BPCI initiative, the Innovation Center expects to develop new voluntary bundled payment model(s) during CY 2018 that would be designed to meet the criteria to be an Advanced APM.”

### *Financial Risk Definitions: Risk-Bearing and Nominal Risk*

The FAH remains concerned that the financial risk criterion for Advanced APM designation 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 socioeconomic 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 two-sided risk exposure. **The FAH continues to urge 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 noted in our previous comments that considerable, upfront financial investments (*e.g.*, health IT and expanded processes and personnel for quality improvement and care integration) are required to successfully operate as an accountable care organization (ACO) or a bundled payment model. These substantial investments and the risks to those investments remain unacknowledged in the Proposed Rule. 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.<sup>6</sup> **The FAH again strongly recommends that CMS promptly and vigorously explore options to capture upfront APM infrastructure costs in its risk framework for APMs.**

Finally, while the FAH welcomes CMS's proposal not to raise the revenue-based nominal risk threshold through performance year 2020, we remain concerned that the financial risk parameters required by CMS are too aggressive for the early years of APM implementation and will stunt the growth of APMs. To ensure robust participation in the APM Incentive program, 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. Reducing the risk thresholds for 2018 and 2019 and then gradually ramping them up would better match the risk targets to the current risk tolerance of the provider community. **The FAH recommends that CMS modify its financial risk parameters to lower levels that gradually increase over time.**

### *Other Medicare APM Issues*

#### Post-Acute Care

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 develop**

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<sup>6</sup> AHA Statement Subcommittee on Health of the Committee on Ways and Means, May 11, 2016.

**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, such as rescinding the 60 Percent Rule and 3-Hour Therapy Rule.

Regulatory relief under the 60 Percent Rule and 3-Hour Rule should be a necessary component in order to provide IRF patients under a bundled payment model with the flexibility needed to participate in the program without jeopardizing their Medicare payment status. Bundled payment and delivery programs require hospitals and other providers to be more accountable for their referral decisions for post-acute care services, including both outcomes and spending. These shifting dynamics have obviated the need for the 60 percent rule, as well as the 3-Hour Rule. Acute-care hospitals and physicians should have broader flexibility to discharge their patients to the most appropriate level of post-acute care needed to meet their patients' needs. Permitting greater shared accountability between hospitals and IRFs would strengthen their relationship and reduce costs by enabling IRFs to pass along savings from accepting payments lower than the IRF discharge-based PPS.

Further, the 3-Hour Rule undermines patient-centered care, especially in a bundled payment and coordinated care environment, and should be rescinded. This intensive therapy requirement should be aligned with the IRF patient's unique medical and therapy needs and rehabilitation physicians' and therapists' clinical judgment, rather than a cookie-cutter approach. Flexibility is needed to address patient need, while ensuring the quality of care and cost efficiencies needed for success in a bundled payment program.

**Therefore, the FAH recommends that IRFs that participate in a bundling program should not be subject to the 60 Percent Rule or 3-Hour Rule. Alternatively, at a minimum, IRFs should have the 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.**

#### QP Participation Determination

Additionally, CMS previously finalized three "snapshot" periods for Medicare QP participation determination for each performance year (March 31<sup>st</sup>, June 30<sup>th</sup>, and August 31<sup>st</sup>). In the Proposed Rule, CMS proposed only two "snapshot" periods for all-payer QP participation (March 31<sup>st</sup> and June 30<sup>th</sup>) due to concerns that later "snapshots" would make it difficult for the Agency to complete the QP determinations and notifications before the March 31<sup>st</sup> MIPS reporting deadline. While the FAH appreciates CMS's concerns around timely notification, these limited snapshot periods could end up excluding APMs – and their clinicians – that would qualify for Advanced APM status except for their start date in the latter half of the year. **The FAH recommends that CMS utilize enough "snapshot" periods to cover the entire year (e.g., March 31<sup>st</sup>, June 30<sup>th</sup>, August 31<sup>st</sup>, and December 31<sup>st</sup>) for both the Medicare and all-payer determinations. The FAH also recommends that CMS provide APM entities with preliminary estimates of Advanced APM status, which could be offered on a rolling basis based on participation in a previous year.** Providing preliminary estimates to APM entities

would enable CMS to implement later “snapshot” periods and still provide timely notification – and perhaps even earlier than the current notifications – to APM entities. Even early, preliminary determinations will be beneficial for entities and their clinicians.

CMS requests comments on whether to extend the period during which a model must be actively tested in order to qualify as an Advanced APM from at least 60 days to at least 90 days. Extending the timeframe to 90 days could exclude APMs that form in the last months of the year, especially if CMS does not implement our recommendation for additional “snapshots” covering the entire year. **The FAH suggests that CMS keep the 60-day participation requirement to encourage broader participation, particularly for those joining the program toward the end of the year.**

### *Medical Home Models*

Beginning in 2018, the medical home model-specific revenue-based standard will be available only to medical home APM entities that are owned and operated by organizations with fewer than 50 eligible clinicians. The FAH believes that establishing an upper limit of 50 eligible clinicians in the parent organization of the APM entity of a medical home model is not a reasonable threshold. A significant investment in time and capital is required by the parent organization regardless of whether there are 25 clinicians or 100 clinicians in the model, and the threshold has little bearing on whether the parent organization will make the investment. While the FAH appreciates the proposal to exempt CPC+ Round 1 participants from this limit for CY 2018, this exemption would not be extended to future CPC+ participants or to any other medical home models. **The FAH encourages CMS to remove the clinician participation limit for all medical home models for at least the first three years of the APM Incentive program. Failing such an extension, we would recommend that the upper limit be set at 100 clinicians and that CMS at least exempt all CMMI medical home models.**

### *Medicare Advantage*

The FAH urges CMS to proceed cautiously in considering whether to provide a pathway for Medicare Advantage (MA) plans and their clinicians to count their participation in MA toward QP determinations under the Medicare Option for Advanced APMs. The legislative text of MACRA specifically *excluded* MA from the Medicare Option for Advanced APMs and specifically included MA under the All-Payer Combination Option. CMS expressly notes this statutory construction in the Proposed Rule:

“The Medicare Option for QP determinations under sections 1833(z)(2)(A), (2)(B)(i), and (2)(C)(i) of the Act, is based only on the percentage of Part B payments for covered professional services, or patients, that is attributable to payments through an Advanced APM. As such, payment amounts or patient counts under Medicare Health Plans, including Medicare Advantage...cannot be included in the QP determination calculations under the Medicare option. Instead, eligible clinicians who participate in Other Payer Advanced APMs, including those with Medicare Advantage as a payer, could begin receiving credit for that participation through the All-Payer Combination Option in 2021

based on the performance in the 2019 All-Payer QP Performance Period.”<sup>7</sup>

Thus, while CMS might have flexibility through its waiver and demonstration authorities, the FAH would caution against use of that flexibility, if it exists, in the face of such a clear statutory directive from Congress. Medicare Advantage plans have developed a myriad of contractual models that can distribute a range of risk to providers and clinicians – from minimal to substantial – with little evidence to providers, beneficiaries, or even CMS as to how care incentives are being driven. Should CMS move forward with creating a pathway for MA participation to count towards the Medicare Option, the variety of incentives and relationships between plans, providers, and members under MA make it difficult to differentiate between those health care providers and clinicians taking on sufficient levels of risk and those being paid under a fee-for-service-like paradigm. The FAH believes Congress recognized these difficulties and delayed the counting of MA participation until the 2019 performance period in order to allow CMS to fully examine these considerations. **Given limited CMMI resources and the statutory separation of MA counting toward QP determination, the FAH recommends that CMMI apply its resources to developing Advanced APMs under Medicare fee-for-service.**

*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 for 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 these fraud and abuse laws.

**We urge CMS to put aside its current piecemeal approach to bundled payment fraud and abuse waivers and work with the Office of Inspector General to develop a single, overarching waiver for CMS-led bundled payment programs applicable to the Stark physician self-referral law, the anti-kickback statute, and relevant CMPs. In the alternative, CMS should consider a new, bundled payment program exception to the Stark law, or revisit and modify current Stark law exceptions to specifically address and explicitly permit gainsharing or other compensation arrangements in CMS-led bundled payment programs. This would encourage financial relationships that incentivize collaboration in delivering health care, while rewarding efficiencies and improving care.**

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<sup>7</sup> 82 Fed. Reg. 30190 (June 30, 2017) and 81 FR 77473 (November 4, 2016).

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 or a member of my staff at (202) 624-1500.

Sincerely,

A handwritten signature in black ink, appearing to read "Shirley M. [unclear]". The signature is fluid and cursive, with a large initial "S" and a long horizontal stroke at the end.