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President and CEO

September 11, 2017

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

SUBJECT: CMS-1676-P. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Dear Administrator Verma:

The Federation of American Hospitals (“FAH”) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching full-service community hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (“CMS”) about the referenced Notice of Proposed Rulemaking on the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program.

II.C. Medicare Telehealth Services

The FAH supports CMS’s modest expansion of telehealth services in this year’s proposed rule. Health care services and data collection provided via telecommunications are becoming more important to the health care delivery system as improvements in technology reduce costs and increase speed and data storage capacity. These trends are occurring under the Medicare telehealth benefit— which covers

“face-to-face” video consultation between patients and physicians—as well as technologies which collect and forward data to various types of providers for analysis of health behaviors and indications of changes in patient health status. For many beneficiaries, as well as providers, telehealth allows for the delivery of more efficient and low-cost care, especially when patients may be homebound or live a far distance from providers they need to access.

We also appreciate CMS soliciting comments on how the Agency could further expand the use of telehealth services for Medicare beneficiaries. The current Medicare coverage and payment rules for telehealth services create challenges for many providers seeking to improve access to and coordination of patient care through these technologies. Reforming the coverage and payment rules for telehealth and remote monitoring technologies would lead to improved access for beneficiaries in both rural and urban areas to primary as well as specialty and subspecialty care. By substituting video consultations for in-person visits, the telehealth benefit could also lead to reduced costs for the Medicare program and reduced burden on beneficiaries. In order to promote care coordination for beneficiaries with multiple chronic conditions, we suggest that Medicare coverage and payment for telehealth should be more broadly expanded.

Currently, Medicare only covers 86 services via telehealth, and CMS must approve new services for telehealth coverage on a case-by-case basis. Such restrictions limit the ability of providers to deliver a broad range of services to Medicare beneficiaries who lack access to care. The process of approving services for Medicare telehealth coverage should be simplified. For example, CMS could approve all Medicare-covered services for telehealth, unless services are determined inappropriate for the benefit on a case-by-case basis. Telehealth offers great promise in delivering efficient primary, specialty, and care coordination services for providers as well as Medicare beneficiaries and CMS should consider a more expansive approval process for adding new services.

II.F. Payment Rules under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

In the Proposed Rule, CMS proposes halving reimbursement to nonexcepted off-campus PBDs, despite acknowledging the absence of any new data to support such a change. In the CY 2017 OPPS/ASC final rule with comment period (81 Fed. Reg. 79,713), CMS finalized the PFS as the “applicable payment system” for most covered items and services furnished by nonexcepted, off-campus PBDs. It then established payment policies under the PFS for items and services furnished by nonexcepted, off-campus PBDs starting January 1, 2017 in the CY 2017 interim final rule with comment period (81 Fed. Reg. 79,720 through 72,729) (“CY 2017 IFC”). Based on an analysis of the PFS and OPPS payment rate differential for 22 frequently billed codes, the PFS and OPPS payment rate differential for evaluation and management services, and the ambulatory surgical center (“ASC”) fee schedule and OPPS payment rate differential, CMS arrived at a 50 percent PFS Relativity Adjuster. CMS further indicated its intent to keep this transitional policy in place “*until such time that [it] had more precise data to better identify and value items and services furnished by nonexcepted, off-campus PBDs and billed by hospitals*” (82 Fed. Reg. 33,982). At the time, the FAH and other stakeholders expressed concern that this analysis underestimated the PFS-to-OPPS payment ratio, advanced a more refined methodology for CMS’ consideration, and urged CMS to adopt a PFS Relativity Adjuster of 64 percent.

For CY 2018, CMS proposes narrowing the data underlying the PFS Relativity Adjuster and basing the PFS Relativity Adjuster exclusively on its comparison of evaluation and management payment rates under the PFS and OPSS (HCPCS code G0463, CPT codes 99201 – 99205, and CPT codes 99211 – 99215) despite acknowledging the absence of any new data to inform the PFS Relativity Adjuster. Instead, CMS expresses a desire to ensure that it does “not overestimate the appropriate overall payments for these services” (82 Fed. Reg. 33,983). To achieve this goal, CMS wholly ignores the PFS and OPSS payment rate differential for 22 frequently billed codes and the ASC-to-OPSS payment rate differential, fails to use the full PFS practice expense amount, and does not account for the significant impact of packaging on OPSS payment.

Contrary to CMS’ assertion, the FAH’s analysis shows that the current 50 percent PFS Relativity Adjuster already underestimates appropriate payment levels for items and services furnished in nonexcepted, off-campus PBDs because it was calculated without using the full non-facility practice amount and without accounting for packaging difference between the PFS and the OPSS. ***The FAH strongly opposes any further reduction in the PFS Relativity Adjuster. Undertaking a reduction in the absence of new data by excluding significant and relevant data points would be an arbitrary and capricious exercise of CMS’ authority. Instead, the FAH urges CMS to take a larger picture of the relevant data, which includes the payment rate differential between the full non-facility practice expense amount under the PFS and OPSS for hospital outpatient visits (adjusted for packaging) and between the full non-facility payment amount under the PFS and OPSS for 22 other commonly billed codes (adjusted for packaging). Doing so would support a significantly higher PFS Relativity Adjuster of 60 percent.***

A. The FAH Recommends Including the 22 Frequently Billed HCPCS Codes Previously Identified by CMS in its Comparison of the PFS and OPSS Payment Rate Differential.

In evaluating the HCPCS codes frequently billed in CY 2016 on the 13X claim form with the “PO” modifier signifying that they were furnished in an excepted, off-campus department of a hospital and paid under the OPSS, the FAH identified approximately 23.7 million claim lines. Of these, hospital outpatient visits (HCPCS Code G0463) accounted for roughly 10.3 million claim lines. The other 22 HCPCS codes identified in CMS’ CY 2017 IFC account for nearly 5.2 million claim lines, or 39.9 percent of claim lines excluding hospital outpatient visits. ***The FAH strongly supports using these 22 HCPCS codes in any comparison of PFS and OPSS reimbursement rate because they provide a more complete picture of the wide breadth of items and services commonly provided in off-campus PBDs.*** Although the FAH shows that these 22 HCPCS codes along with evaluation and management codes and packaging adjustments support a PFS Relativity Adjuster of 60 percent, we note that CMS’s own analysis in the CY 2017 IFC concludes that 50 percent is an appropriate PFS Relativity Adjustment when payment differentials for these 22 HCPCS codes are considered alongside the payment differential for evaluation and management codes and the ASC-to-OPSS payment differential. ***The FAH further contends that the data concerning these 22 HCPCS codes and evaluation and management payment rates should be adjusted to use the full non-facility practice amount and to account for packaging, as described below, when setting an appropriate PFS Relativity Adjuster for CY 2018.***

B. The FAH Recommends that CMS use the Full Non-Facility Practice Expense Amount to Compare PFS and OPFS Payments.

In the Proposed Rule, CMS exclusively relies on a comparison between the OPFS national payment rate for HCPCS code G0463 (\$102.12) and the difference between the non-facility and facility PFS payment amounts under the PFS using CY 2017 rates for the weighted average of outpatient visits billed by physicians and other professionals in an outpatient hospital place of service. By way of example, CMS calculated that the difference between the non-facility payment rate and the facility payment rate under the PFS in CY 2016 as \$21.86 for CPT code 99213 (21 percent of the OPFS payment rate) and \$29.02 for CPT code 99214 (28 percent of the OPFS payment rate).

This calculation, however, is based solely on a portion of the non-facility PFS rate and not the full payment rate that Medicare makes under the PFS for practice expenses in a physician's office (the full PFS non-facility practice expense amount).¹ Thus, CMS did not use the full Medicare payment under the PFS for practice expenses when comparing payment rates for clinic visits. Instead CMS used an amount that represents only the direct costs of the visit and includes no compensation for the indirect costs that a hospital continues to incur when a service is provided in the hospital outpatient department, irrespective of whether it is excepted under section 603. Previously, in the CY 2017 IFC, CMS similarly used a portion of the non-facility PFS rate instead of the full payment rate for a number of the 22 HCPCS codes analyzed.²

The FAH recommends using the full non-facility PFS practice expense payment in all cases as a hospital continues to incur indirect costs when a service is provided in the off-campus outpatient department. Section 603 does not require that CMS implement site-neutral payment between physician offices and nonexcepted, off-campus PBDs or even reference site neutrality. Instead, Section 603 merely directs the Secretary not to pay for services provided in a nonexcepted, off-campus PBDs under the OPFS and instead pay for these services under the "applicable payment system." Further, section 603 does not change the status of a non-excepted off-campus PBD as being part of a hospital. If site neutrality was the goal of section 603, Congress could have stripped these sites of their provider-based status and required them to be treated like physician offices. Because these sites retain their provider-based status, it is critical that CMS recognize that non-excepted off-campus PBDs are hospital departments with indirect costs that should inform the appropriate reimbursement rate.³ ***If CMS used the full amount that Medicare makes for practice expenses, the PFS payment as a percent of the OPFS payment would be 35.4 percent rather than 21 percent for CPT code 99213 and 49.8 percent rather than 29 percent for CPT code 99214. The PFS payment as a percent of the OPFS payment for***

¹ The full PFS non-facility practice expense amount is the non-facility practice expense resource value unit ("RVU") multiplied by the conversion factor. For example, for CY 2016, CPT code 99214 has a non-facility practice expense RVU of 1.42, which, when multiplied by the conversion factor of 35.8043, yields a full PFS non-facility practice expense amount of \$50.84.

² The logic of using this methodology is certainly belied by the use of CPT code 90834 in the weighted average calculation. If CMS were to pay the difference between the non-facility and facility practice expense payments for CPT code 90834, CMS would pay the hospital only \$0.36 for use of the hospital's facility during a 45-minute psychotherapy session. On its face, this amount would be inadequate to cover the practice expenses associated with the service in any setting.

³ While FAH rejects the notion of site neutrality, using CMS' own logic results in a PFS Relativity Adjuster that will pay *less* than a site neutral amount for all but seven of the 22 services used to determine the CY 2017 Relativity Adjuster (e.g. column 5 of Table 9 is less than 25 percent) and one of the two evaluation and management services used to determine the CY 2018 Relativity Adjuster.

the 22 HCPCS codes used in the CY 2017 IFC would also be substantially higher than the 45 percent weighted average used by CMS to support a 50 percent PFS Relativity Adjuster in CY 2017.

In the following table, we illustrate how the comparison of the estimated PFS technical payment amount and the OPSS rate would change if the full PFS practice expense payment amount were used rather than the difference between the non-facility and the facility amount for the two most common evaluation and management services (current procedural terminology (“CPT”) codes 99213 and 99214) and the 5 procedures⁴ among the 22 HCPCS codes where the PFS payment is differentiated between facility and non-facility sites. In each case, the inclusion of the full PFS practice expense rate increases the estimated PFS payment rate by between 3.4 and 21.4 percentage points.

Table 1 - PFS Non-Facility Practice Expense as a Percent of the OPSS

Code	Title	CY 2016 PFS Payment Amount Used by CMS	CY 2016 OPSS Payment Rate	PFS as % of OPSS	CY 2016 PFS Full Non-Facility Practice Expense	Revised PFS as % of OPSS	Percentage Point Difference
99213	Office/outpatient visit est	\$ 21.86	\$ 102.12	21.4%	\$ 36.16	35.4%	14.0%
99214	Office/outpatient visit est	\$ 29.02	\$ 102.12	28.4%	\$ 50.84	49.8%	21.4%
93798	Cardiac rehab/monitor	\$ 11.10	\$ 103.92	10.7%	\$ 14.68	14.1%	3.4%
90853	Group psychotherapy	\$ 0.36	\$ 69.65	0.5%	\$ 3.94	5.7%	5.1%
20610	Drain/inj joint/bursa w/o us	\$ 13.96	\$ 223.76	6.2%	\$ 28.64	12.8%	6.6%
11042	Deb subq tissue 20 sq cm/<	\$ 54.78	\$ 225.55	24.3%	\$ 77.70	34.4%	10.2%
90834	Psytx pt&/family 45 minutes	\$ 0.36	\$ 125.04	0.3%	\$ 11.10	8.9%	8.6%

The largest increases in the PFS payment rate as a percentage of the OPSS payment rate are for evaluation and management services, upon which CMS exclusively relies when proposing the CY 2018 PFS Relativity Adjuster. Using the full PFS practice expense amount provides a fuller and more appropriate comparison of PFS to OPSS payment rates for evaluation and management services as well as other HCPCS codes commonly billed by hospitals with the “PO” modifier, particularly when these numbers are adjusted to account for packaging under the OPSS.

⁴ Table X.B.1 indicates six procedure codes where CMS used the difference between the non-facility and facility PFS amount in the comparison but payment is not differentiated by non-facility and facility for one of these procedure codes (96365).

C. The FAH Strongly Urges CMS to Adjust for Packaging Differences Between the PFS and the OPSS

In the CY 2017 IFC, CMS excluded evaluation and management codes from the calculation in Table X.B.1, acknowledging that the “extensive packaging” that occurs under the OPSS for services provided along with clinic visits would heavily skew the calculation. (81 Fed. Reg. at 79,723; 82 Fed. Reg. 33,980.) Instead, CMS considered its comparison of the PFS-to-OPSS payment rate for evaluation and management services alongside its calculation of the PFS-to-OPSS payment rate differential for the other 22 common HCPCS codes in the CY 2017 IFC. In the Proposed Rule, however, CMS proposes exclusively relying on a calculation of the PFS-to-OPSS payment rates for evaluation and management services, making no adjustment for the impact of “extensive packaging” on clinic visits and completely excluding the payment rate comparison for other common services.

In its comments to the CY 2017 IFC, the FAH presented its analysis of the amount of packaging included in the 22 commonly billed HCPCS codes to address this known limitation to CMS’s analysis. We have updated this analysis for the 22 commonly billed HCPCS codes in Table 2, below, which shows the calculations of packaging percentages for single procedure claims used in rate-setting in the CY 2017 IFC. Overall, we estimate the geometric mean for the OPSS relative weights was approximately 22 percent of the total cost.

**Table 2– PFS as a Percentage of OPSS Adjusted for Packaging Estimate
Mean Procedures Costs and Mean Packaging Costs**

HCPCS	Short Descriptor	Procedure	Packaging	Procedure plus packaging	Percentage packaging
	<i>Total: Top 22</i>	\$ 172.73	\$ 49.71	\$ 222.44	22%
96372	Ther/proph/diag inj sc/im	\$ 50.18	\$ 79.76	\$ 129.95	61%
71020	Chest x-ray 2vw frontal&latl	\$ 64.84	\$ 19.29	\$ 84.13	23%
93005	Electrocardiogram tracing	\$ 34.72	\$ 146.35	\$ 181.07	81%
96413	Chemo iv infusion 1 hr	\$ 181.97	\$ 191.42	\$ 373.39	51%
93798	Cardiac rehab/monitor	\$ 207.96	\$ 0.05	\$ 208.01	0%
96375	Tx/pro/dx inj new drug addon	\$ 52.11	\$ 0.04	\$ 52.15	0%
93306	Tte w/doppler complete	\$ 508.76	\$ 13.53	\$ 522.30	3%
77080	Dxa bone density axial	\$ 99.11	\$ 27.71	\$ 126.82	22%
77412	Radiation treatment delivery	\$ 215.72	\$ 39.11	\$ 254.83	15%
90853	Group psychotherapy	\$ 115.59	\$ 0.52	\$ 116.11	0%
96365	Ther/proph/diag iv inf init	\$ 145.91	\$ 117.57	\$ 263.48	45%
20610	Drain/inj joint/bursa w/o us	\$ 272.52	\$ 96.75	\$ 369.27	26%
11042	Deb subq tissue 20 sq cm/<	\$ 450.70	\$ 99.97	\$ 550.67	18%
96367	Tx/proph/dg addl seq iv inf	\$ 71.05	\$ 0.19	\$ 71.23	0%

93017	Cardiovascular stress test	\$ 229.44	\$ 78.39	\$ 307.83	25%
77386	Ntsty modul rad tx dlvr cplx	\$ 603.76	\$ 9.09	\$ 612.84	1%
78452	Ht muscle image spect mult	\$ 769.34	\$ 555.53	\$ 1,324.87	42%
74177	Ct abd & pelv w/contrast	\$ 288.25	\$ 110.40	\$ 398.65	28%
71260	Ct thorax w/dye	\$ 175.14	\$ 91.39	\$ 266.53	34%
71250	Ct thorax w/o dye	\$ 131.93	\$ 15.72	\$ 147.65	11%
73030	X-ray exam of shoulder	\$ 72.42	\$ 43.43	\$ 115.85	37%
90834	Psytch pt&/family 45 minutes	\$ 156.38	\$ 0.93	\$ 157.31	1%

Notes:

- Calculations based on CY 2016 data used in CY 2017 rate-setting.
- Proposed Rule data and policies were followed.
- Based on costs for single procedure claims used in CY 2017 IFC rate setting.
- Costs have been standardized to account for wage index.
- Means are arithmetic.

The table above shows a weighted average packaging portion of 22 percent with a range from a low of 0 percent to a high of 81 percent. We believe that to do a more appropriate comparison between PFS and OPPS rates, the CMS analysis needs to adjust the OPPS payment amounts to address packaging. Therefore, as a reasonable approximation, we recommend adjusting the OPPS denominator to be 78 percent of the value (to account for the 22 percent of packaging). Using the full PFS non-facility practice expense amount (as described in the previous section) and adjusting for a packaging portion of 22 percent, the PFS-to-OPPS ratio for the 22 commonly billed HCPCS codes identified by CMS is 60 percent.

This packaging calculation does not include evaluation and management services, which are extensively packaged under OPPS. As such, it likely underestimates the true extent of packaging under OPPS for items and services commonly billed by off-campus PBDs. Nonetheless, even if we use 22 percent as an (under)estimate of packaging for evaluation and management services and adjusted the ratio of full PFS non-facility practice expense amounts to OPPS amounts accordingly, the PFS-to-OPPS ratio would increase to 45 and 64 percent for CPT codes 99213 and 99214, respectively. Along with the other 22 commonly billed HCPCS codes, this would produce a weighted average PFS-to-OPPS ratio of 57 percent. Again, this ratio would increase if the calculation accounted for the more extensive packaging for evaluation and management services. As such, when evaluation and management services are included, an overall PFS-to-OPPS ratio of 60 percent is an appropriate estimation of the actual ratio using presently available data.

Based on this packaging analysis, and, importantly, further refining the methodology to incorporate data for the 22 commonly billed HCPCS codes, to use the full non-facility practice expense in lieu of the difference between the non-facility and facility PFS amount to account for the indirect costs associated with off-campus hospital department services, the estimated PFS-to-OPPS ratio far exceeds the 50 percent PFS Relativity Adjuster used for CY 2017 or the 25 percent PFS Relativity Adjuster proposed for CY 2018. The FAH, therefore, strongly urges CMS to increase the payment rate to 60 percent of OPPS for nonexcepted items and services furnished in off-campus

PBDs for these items and services. In any case, a reduction from the 50 percent PFS Relativity Adjuster used in CY 2017 is not supported by any change in the data and it is inappropriate to exclude a wide swath of relevant data in order to achieve a reduction in the PFS Relativity Adjuster. As noted above, CMS underestimates the PFS-to-OPPS payment ratio when it excludes commonly billed HCPCS codes other than evaluation and management codes, declines to use the full PFS payment for non-facility practice expenses, and fails to undertake any adjustment for packaging under the OPPS.

III.E. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act (PAMA) requires CMS to establish a program that promotes appropriate use criteria (AUC) for advanced diagnostic imaging whereby the clinical decisions support mechanism (CDSM) would be consulted prior to a clinician ordering an advanced diagnostic imaging. The legislation directed CMS to implement the program in stages: establishing AUC; establishing ways for clinicians to consult with AUC (i.e., via CDSMs); requiring consulting with and reporting of AUC by clinicians; and identifying outlier clinicians. There are some exceptions to the program, such as ordering imaging for an individual with an emergency medical condition, if the ordering clinician documents the condition that manifested as sufficiently severe to bypass the AUC process.

The AUC program was originally slated to begin January 2017, but CMS has proposed delaying the implementation date for ordering clinicians to consult with specified AUC – and for furnishing clinicians to submit claims-based documentation – until January 1, 2019. CMS proposes that clinicians can begin voluntarily consulting and reporting in July 2018 pending readiness of CMS claims processing systems. CMS also proposes the development of new HCPCS codes and modifiers for the furnishing clinician to report the consultation information.

The FAH appreciates CMS’s recognition of the complexity of implementing the AUC program by undertaking a phased-in implementation. The FAH supports this delay – as well as CMS’s proposal to pay claims regardless of whether the claims contain the required information during the first year – as positive first steps in developing a more flexible, user-friendly AUC program. As the FAH stated in comments to previous years’ Proposed Rules, our members generally are supportive of using AUC. However, they remain concerned about current timeline expectations and the growing complexity of the program with limited potential benefit in its present form.

Now is the time for CMS to pause and reevaluate the AUC program to ensure that it is focused on the goal of helping clinicians with decision-making rather than resulting in a “check-the-box” exercise. At a minimum, the FAH recommends that CMS further delay the implementation date, paired with a real, robust test period, as opposed to a voluntary reporting period that will begin too soon and end too quickly. Testing of the CDSM systems should use real claims and engage hospitals in test submissions similar to testing for the switch from ICD-9 to ICD-10. Additionally, more time is needed for the development of the new codes and modifiers CMS discusses in the Proposed Rule, as well as for providers to add to them to their coding and billing systems. CMS could improve the consultation and reporting process for clinicians by requiring that the CDSMs provide the necessary billing codes and modifiers to the clinician consulting the AUC. This would significantly ease the burden on providers of converting the AUC results for billing and reporting purposes.

The FAH has additional recommendations for improving the AUC program, including the treatment of emergency imaging services and ensuring that beneficiaries can receive timely services when the ordering clinician does not appropriately consult CDSM. Specifically, emergency departments (EDs) should be excluded from the AUC program entirely due to the significant hardship emergency clinicians will incur attempting to meet the current exclusion criteria. This burdensome process will divert precious time away from treating the patient during an emergency and severely disrupt EDs' workflow. Additionally, clinicians do not always know whether a patient is truly emergent upon initial presentation; attempting to bifurcate workflow and treatment protocols depending on whether the clinician feels the patient meets the emergency exclusion will lead to confusion and inconsistency across clinicians and providers.

Finally, the FAH recommends modifications to the program to ensure that it is the ordering clinician who is incentivized and required to consult CDSMs. Specifically, any payment reductions or restrictions should be associated with the ordering clinician instead of the furnishing provider. Denying payment to the furnishing provider penalizes that provider rather than the ordering clinician and will likely impact beneficiary access to imaging services. At a minimum, CMS should develop a pathway for a furnishing provider to perform and receive reimbursement for advanced imaging when the ordering clinician either does not consult CDSM or does not properly record that consultation. For example, the furnishing provider could note "Not Applicable" on the claim for reimbursement in the case of non-compliance by the ordering clinician. This mechanism is essential to ensure that beneficiaries receive necessary, timely services.

III.F. Criteria for 2018 Physician Quality Reporting System Payment Adjustment

In the proposed rule, CMS describes a path for streamlining physician quality reporting in the PQRS program to align with quality reporting in the Merit-based Incentive Payment System (MIPS) reporting requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The FAH supports the proposed changes to require reporting of only six measures instead of nine and the elimination of the requirements to report on specific domains of care. The FAH also appreciates the proposal to align the Medicare EHR Incentive Program eCQM reporting requirements with the modified PQRS requirements. Reducing the number of required measures and domains will help physicians meet the goals of both programs and reduce the complexity of reporting.

The FAH also appreciates that the modified criteria will be applied to data already collected and that physician practices will not need to amend or resubmit data. The FAH supports the proposal to align the MIPS and PQRS programs by eliminating the requirement for individual EPs and group practices to report a measure of high priority or outcome. Finally, the FAH supports the proposed flexibility for voluntarily reporting the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures to better align with the MIPS quality performance category.

The FAH supports the CMS proposal to forego reporting of the value-based modifier (VM) in the Physician Compare downloadable file for 2018 payment. The FAH agrees that reporting EP or Group data designated as high, low or average rate on cost and quality for only one year would do little to inform the public or help individuals make decisions on the care they might seek.

III.H. Medicare Shared Savings Program

We appreciate the changes proposed by CMS that seek to reduce burden on Medicare Shared Savings Program (“MSSP”) participants. Since its inception, we have appreciated CMS’s diligence in modifying the program based on the experiences of Accountable Care Organizations (“ACOs”) that have made a commitment to the program and especially to those ACOs that have made a commitment to shared risk.

In our CY 2017 Physician Fee Schedule comments, the FAH agreed with CMS that the quality data reported through the group practice reporting option (GPRO) Web Interface for purposes of complying with Medicare Shared Savings Program (MSSP) rules should be reviewed and audited to ensure its validity. We continue to believe, as we did in 2016, that the system being used by CMS prior to the finalization of the CY 2017 Physician Fee Schedule to review and audit the data is sufficient to ensure CMS is receiving accurate data while also ensuring that providers have the opportunity to address errors in reporting.

Given that CMS decided to proceed with the proposed updates to the audit rules, the FAH reiterates our suggested improvements to the audit system. CMS should continue to allow providers to resubmit and correct data submissions. The GPRO data submission exercise is laborious and requires manual extraction and clinical interpretation. Simple errors in data submission are not uncommon and providers should have the ability to correct these errors. While technological challenges with CMS’s Web Interface system may make it difficult for CMS to accept resubmitted data, provider participants shouldn’t be negatively impacted due to a CMS system’s shortcomings. While we appreciate CMS acknowledged that simple data errors not linked to diminished patient quality have the potential to negatively impact an ACO’s quality score, we encourage CMS to go further than it did in the final FY 2017 rule and allow ACO’s to resubmit and correct data submission errors.

In our CY 2017 comments, the FAH suggested that CMS lower the 90 percent confidence interval for the proposed overall audit match rate. Additionally, we argued that CMS should discount errors that do not result in a change of quality score and these errors should not be included in CMS’s overall calculation of the error rate. For example, if a DM HbA1c of 6.7 was submitted but the actual result was 6.8, CMS should not include this immaterial difference in CMS’s calculation of the error rate. While CMS acknowledged the need for some flexibility in this area, it granted itself discretion to take these types of errors into consideration in “unusual circumstances” and finalized the 90 percent confidence interval.

We support CMS’s continued review of the appropriateness of the 90 percent confidence interval and appreciate that CMS, after reviewing the data submissions, has proposed moving the confidence interval to 80 percent. While the FAH believes the confidence interval should be closer to the CMS observed mean of the data (72 percent), we appreciate CMS’s continued review of this audit tool and suggest that CMS should continue to adjust the confidence interval to reflect attainable performance standards.

Finally, the FAH reiterates that that CMS reconsider its policy to adjust an ACO’s overall quality score based on the ACO’s audit performance. CMS’s policy over-weights the measures reported through the Web Interface to the detriment of CG-CAHPS and claims-based measures. Performance on GPRO

Web Interface reported measures should be considered commensurate with other measures reported by the ACO.

III.L. Request for Information on CMS Flexibilities and Efficiencies

We appreciate CMS's request for comments on regulatory, subregulatory, policy, practice, and procedural changes that would reduce unnecessary burdens for hospitals, physicians, and patients, improve quality of care, decrease costs, improve program integrity, ensure that patients and their providers and physicians are making the best health care choices possible, and make the health care system more effective, simple and accessible.

In mid-May, the FAH submitted to HHS an extensive list of regulatory reform items that we believe warrant review and action by CMS. That list is attached as Attachment A to this comment letter, and includes a broad range of issues, *e.g.*, proposed reforms to CMS's post-acute care (PAC) payment policies, Medicaid DSH and supplemental payment policies, and Medicare compliance policies.

We believe the regulatory items on this list would make important improvements to a number of CMS's priority initiatives. For example, HHS should ensure that the Center for Medicare & Medicaid Innovation (CMMI) acts only within its designated authority to voluntarily test alternative payment models (APM), not make permanent or mandatory changes to the Medicare program. Additionally, HHS should indefinitely suspend the troubled Hospital Star Ratings system while the Agency collaborates with stakeholders on appropriate risk adjustment.

Further, HHS should provide hospitals with flexibility to relocate their provider-based departments to meet community needs and still retain hospital outpatient payments. These items, and additional regulatory relief and program reform items included in the FAH list, are highlighted further below.

Delivery System Reform

The Important and Appropriate Role for CMMI

The FAH supports the purpose of the CMMI to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care, with an emphasis on models that improve coordination, quality, and efficiency of health care furnished to Medicare and Medicaid beneficiaries. Such models could, for example, include a voluntary population-based demonstration project under which networks are paid prospective monthly capitated payments for coordinated care furnished to Medicare beneficiaries. Episode payment models, when realistically constructed with sufficient stakeholder preparation time, hold promise as part of CMS's strategy to move from volume to value, and we appreciate the opportunity to be involved with testing these innovative care models.

However, the FAH shares concerns expressed by Secretary Price and others that CMS has overstepped its authority with respect to mandatory demonstrations. We believe that any proposed or finalized requirement for such mandatory provider and supplier participation runs counter to both the

letter and spirit of the law that established the CMMI and its scope of authority to test and expand models under section 1115A of the Social Security Act.

Any permanent or mandatory changes to Medicare payment systems must be enacted by Congress after taking into account results of models that have been tested. CMS may not impute that Congress granted the agency this authority. The Agency's aggressive and incorrect interpretation of the statute raises issues of impermissible delegation of lawmaking authority where none was intended. This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority. CMS has successfully demonstrated that it is fully capable of testing models under section 1115A solely through providers of services and suppliers that volunteer to participate in those models. Experience with the Bundled Payment for Care Improvement (BPCI) program shows a substantial number and range of providers and suppliers willing to participate in carefully crafted models. Encouraging voluntary participation by providers and suppliers was the intent of Congress in enacting section 1115A, the manner in which previous demonstrations were conducted, and is the proper and appropriate use of legislatively granted demonstration authority.

CMS's policy mandate under the Comprehensive Care for Joint Replacement (CJR) and the Episode Payment Models (EPM) was imposed on providers and suppliers without any testing, as required under section 1115A, and failed to account for difference in types of providers or suppliers, or their particular circumstances. We appreciate and support CMS's proposed rule to cancel the EPM rule, as many hospitals would have been challenged significantly in developing these capabilities, including small hospitals that often have limited financial resources, those that are located in lower income geographic regions, or that incur high amounts of uncompensated care, have low case volume on which to spread financial risk, do not yet have experience with episode-based payment, or lack existing networks with physicians and other providers. The potential consequences for patient care are real. These challenges and potential consequences continue regarding CJR, including hospitals that would be mandated to continue participation in CJR under CMS's recent proposal to maintain a more limited CJR mandate.

Keys to Delivery System Reform

Provider investment and payment adequacy. APMs need to have the ability to recover their significant investment in infrastructure necessary for providers to coordinate and manage care for beneficiaries with chronic illnesses (e.g., clinical staff, case managers, upgrades in health information technology and exchange), while at the same time providing some level of predictability and certainty in prices and payments. Medicare beneficiaries with chronic conditions have an expectation that hospitals will continue to provide them with access to a broad range of services, and hospital investment in new infrastructure as well as the rehabilitation of aging infrastructure will be necessary in order for hospitals to continue serving the community adequately. Thus, delivery system reform program must be structured to ensure providers have the opportunity to offset their up-front investment costs.

Transition period. Transformative policies should be adopted incrementally, beginning with voluntary participation and broadening as more providers gain experience with managing financial risk and patient care across the continuum. The transition must be measured and orderly so that the marketplace can adjust to the new incentives of value based purchasing and a culture oriented more towards social and community services and population health. The financial viability of providers

participating in APMs needs to be protected through this transition in order to maintain beneficiary access to necessary care.

Flexibility. APMs should continue to offer providers the flexibility to choose different levels of risk-taking—in terms of the types of patients and services at financial risk, the length of time over which care is delivered, and the amount of financial risk—in order to promote broad participation.

Need for Appropriate Administrative Waivers to Allow Hospitals the Needed Flexibility to Delivery System Reform Goals While Managing Legal and Regulatory Risk

As the FAH has noted in commenting on past CMMI bundled payment proposals, the need for protection from various legal and regulatory risks that are inherent in developing coordinated care arrangements between hospitals, physicians and post-hospital providers are necessary for payment model success. Thus, CMMI or other similar CMS-led models must include waivers of program integrity laws, such as the federal anti-kickback (AKS), physician self-referral (Stark Law), and civil monetary penalties (CMP) laws to ensure the integrity of gainsharing and preferred provider network arrangements. Further, these waivers must be coordinated through both CMS and the HHS Office of Inspector General (OIG).

In the absence of such waivers, hospitals and their partners could be exposed to significant risks, and law enforcement and whistleblowers are not likely to be swayed from taking action by the public policy goals of these bundled payment programs. If providers do not have legal certainty in their arrangements to share risk or reward with physicians and post-hospital suppliers, then lawsuits are a distinct possibility.

Accordingly, the FAH recommends that CMS set aside its current piecemeal approach to bundled payment fraud and abuse waivers and develop a single, overarching waiver, a “Bundled Payment Waiver” of the Stark law and AKS, applicable to all gainsharing arrangements, developed and administered pursuant to the terms of any CMS-led bundled payment program. The Bundled Payment Waiver would apply to models such as CJR, the EPM model, and any future CMS-led, bundled payment programs, with the understanding that CMS could issue program-specific waivers where circumstances warrant a different approach. We have noted in detail, including in our comments to the March 21, 2017 Proposed EPM Rule⁵, how such a Bundled Payment Waiver could be constructed.

In addition to such an all-inclusive program-specific waiver, we encourage CMS to evaluate other waivers that would remove barriers and help level the competitive playing field among PAC providers, and would furnish these providers with the incentives and tools needed to be able to offer PAC care in a manner that contributes to improved quality and efficiencies, while containing costs.

Existing COPs and other regulatory requirements restrict fair competition across PAC providers.

Timely and Regular Data Sharing is Required to Achieve Program Goals

Prior to implementation of a new payment model, it is critical that providers receive relevant and timely historical data, be permitted enough time to analyze the data, and take appropriate action with

⁵ 82 Fed. Reg. 14464 (March 21, 2017)

participant partners. The data must be provided prior to the start of the program, and at regular intervals (e.g., monthly) throughout the program.

To successfully manage risk, hospitals must have sufficient time and data to analyze and understand the composition, characteristics, and needs of their patient population. If healthcare providers are expected to improve patient care and outcomes and enhance their value to other healthcare providers, then they must have greater access to information and data about their patients following their treatment of them. Otherwise, they will not have a meaningful baseline on which to improve.

Appropriate Quality Measurement

In a value-based healthcare delivery model, payment is adjusted to reflect the quality of care delivered under the model. As such, the quality measures used for adjusting payments should have clear links to the condition or treatment upon which the model is focused. Additionally, the measures must be aligned with the parameters of the model. For instance, in the EPM mandatory bundled payment model, CMS proposed using at least two clinical measures that are 30-day measures while the payment model pays for 90-day episodes. This misalignment creates potential issues such as how to generalize results to the 90-day episode. The models should also incorporate measures that are relevant to each part of the delivery model, avoiding measurement gaps. Importantly, prior to implementation of any model, participants need full access to their historical quality data, some of which is available to them only through CMS. Meaningful, collaborative, quality improvement initiatives do not happen overnight, and implementation should not be undertaken until providers have had sufficient time to analyze and act upon their data. Further, quality improvement programs are most likely to succeed when frequent, actionable feedback is provided to program participants. Participants should be provided with automatic performance updates at least quarterly.

Supporting Post-Acute Hospital Care

PAC providers are an essential component of episodic-based care delivery and reimbursement models and a key ingredient toward improving and expanding care coordination and provider collaboration activities.

In order for these models to fully succeed, PAC providers must be provided reimbursement flexibility and regulatory relief, including with APMs, for example, being permitted to carry more risk in bundling programs, while rescinding the 60 percent and three-hour rules. Inpatient rehabilitation facilities (IRFs) could test a CMMI bundling program that 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 three-hour rule. PAC providers electing to test a bundling program should receive relief from the effects of burdensome rules and regulations that were designed in the 1980's and early 1990's in the era of fee-for-service reimbursement. These rules include the "60 percent rule," which is intended to distinguish IRFs from acute hospitals and to justify IRF Prospective Payment System (PPS) rates, and the "3-hour rule," which requires that each patient must receive at least 3 hours of therapy per day for at least 5 days per week.

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 stringent rules, such as the 60 percent and 3-hour rules. 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. Their decision-making should be influenced by what is best for the patient, and not by whether a patient's diagnosis satisfies the 60 percent rule. 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 three-hour rule undermines patient-centered care, especially in a bundled payment and coordinated care environment. 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.

Achieving the Promise of HIT

The FAH appreciates the recent flexibilities finalized by CMS in the Inpatient Prospective Payment System (IPPS) Final Rule (e.g., 90-day reporting period for CY2018; flexibility to use either the 2015 Edition CEHRT or the 2014 Edition CEHRT; flexibility to attest to either Stage 3 or Modified Stage 2), as these flexibilities will help hospitals in complying with the Program. However, these flexibilities will not address the underlying Program issues of extensive cost and burden, yet lack of interoperability. Further, they do not address the lack of alignment of the hospital Meaningful Use Program requirements with the Advancing Care Information (ACI) category of the Merit-Based Incentive Payment System (MIPS).

Therefore, the FAH recommends re-evaluating the Meaningful Use Program, particularly the move to Stage 3, to allow for a meaningful evaluation of whether the Program is meeting its goals and to further align the hospital Program with the ACI category of the MIPS for physicians, including eliminating the "all-or-nothing" standard. At a minimum, a 90-day reporting period is needed in any year in which Stage 3 is first implemented – with appropriate and timely notice to affected stakeholders to enable providers to implement system updates and train staff.

Making the Hospital Quality Programs Work

The FAH believes public reporting of provider quality data that is reliable, valid, and meaningful to consumers is vital to creating the patient-centered health care delivery system that we strive to achieve. Numerous studies have shown patient care improvement and greater efficiencies in care provided by acute and post-acute care hospitals through the public reporting and payment programs. However, the three major value-based purchasing programs: Hospital Value-based Purchasing (HVBP), Hospital Readmission Reduction program (HRRP), and the Hospital Acquired Condition Reduction Program (HACRP) have significant overlap and are ripe for reconsideration, including the addition of appropriate risk adjustment for critical sociodemographic status (SDS). The FAH believes these programs should be refined to focus on rewarding both improvement and attainment of established goals.

The FAH supports the CMS work to make provider quality measurement and payment data more transparent, reliable, and useful for patients and their families. Unfortunately, the latest CMS transparency effort - the Hospital Star Ratings system - suffers from significant deficiencies, including the lack of SDS adjustment, resulting in unintended consequences and misleading information that could do more harm to consumers than good. These deficiencies should be addressed.

Further, for the federal quality payment programs to work well, providers need quick and complete access to their own data as well as patient data post-discharge in order to use it for quality improvement. Providing acute and post-acute hospitals with timely and complete patient level data for outcomes measures such as readmissions is essential.

In a refined quality payment structure the number of quality measures should be reduced and only those measures that truly make a difference in patient health and are predictors of value should be implemented. Hospitals also must be able calculate their own measure performance, which currently is not possible with many of the claims-based outcomes measures. In the evolving world of quality payment, the FAH is hopeful that quality measurement data eventually will be drawn directly from the electronic medical record (EMR). However, much additional work is needed before that will become an effective quality measurement tool.

In addition, integral to meeting the goals of the CMS pay-for-value programs is the role of the National Quality Forum (NQF) and its public-private partnership, the Measure Applications Partnership, which provides input into the quality and performance metrics used in those programs for hospitals and other health care providers. The role of the NQF in this process is now well established and accepted and has assisted with providing greater transparency in measure selection for the wide variety of federal payment programs.

An efficiently functioning infrastructure to support federal quality data collection and reporting is essential to producing valid data to inform payment adjustments. The FAH strongly encourages CMS to ensure there are sufficient resources available for appropriate oversight and testing of all data collection and reporting systems to ensure full functionality of the CMS and Centers for Disease Control and Prevention (CDC) data system and warehouses. The hospitals represented by the FAH regularly experience system failures at both CMS and CDC, adding considerable and avoidable costs, in resources and time, to both HHS and the reporting hospitals, and eroding trust and confidence. The payment and quality programs are ineffective if the data being used to inform consumers and calculate payment are inaccurate or incomplete.

Evaluating CMS Regulations

Hospitals are committed to ensuring patients receive high-quality care and believe a comprehensive review and repeal or revision of regulations that are outdated, ineffective, or otherwise overly burdensome will further our shared goals of improving health outcomes and efficiencies in care delivery. As noted earlier, we submitted an extensive list of items, which we believe warrant CMS review and action. Listed below are two examples of regulations that deserve attention.

Permit Hospital Provider-Based Departments to Relocate to Meet Community Health Needs

CMS should provide hospitals with broad flexibility to relocate provider-based departments, whether on- or off-campus, and retain hospital outpatient payments. At minimum, a number of exceptions, such as lease expiration and organic growth and community needs, are necessary for hospitals to deliver efficient, high quality care in a safe location. In addition, this flexibility would enable hospitals to successfully renegotiate favorable lease terms, comply with local building codes, and preserve access to care in the aftermath of a natural disaster. Rural hospitals, for example, serve communities spread across larger geographic areas, making off-campus outpatient departments an important avenue to providing services needed by the community. As new employers arrive, expand, and contract or new housing developments are constructed, a rural community's needs can shift dramatically, and hospitals ought to be in a position to adapt to meet those needs. CMS regulations, however, unreasonably restrict a hospital's ability to do so by stipulating that under most circumstances an existing provider-based department that relocates would forfeit its ability to be paid as a hospital outpatient department.

Ensure Meaningful MIPS Measurement and Maximize Advanced APM Participation

The FAH continues to support a path for the Quality Payment Program (QPP) for 2018 and beyond that ensures meaningful measurement in the Merit-Based Incentive Payment System (MIPS) reporting and that maximizes participation in Advanced APMs. As the FAH commented in response to the June 30, 2017 Proposed Rule⁶ (Attachment B), our members support a number of CMS's proposals, while noting areas for improvement as the Program continues to ramp up. With regard to MIPS, the FAH supports CMS's proposals to: allow hospital-based clinicians to utilize hospital quality measures for measurement; increase the performance threshold to 15 points; reward quality improvement; allocate bonus points for complex patients and small practices; and to permit the continued use of the 2014 Edition of CEHRT and a 90-day performance period in the Advancing Care Information performance category. The FAH also made recommendations for improvements, including: additional CMS-led education, including a dynamic forum for FAQs; monthly, or at a minimum, quarterly, CMS feedback; allowing clinicians or groups to opt-in to MIPS participation on an annual basis regardless of whether they exceed any one of the low-volume threshold parameters; creating a mechanism to reward clinicians and groups with consistently high-quality performance; a 90-day performance period across all of the performance categories; and allocating bonus points for rural practices. Additionally, the FAH is suggested improvements to ensure that CMS's proposed flexibilities to providers to use multiple submission mechanisms for reporting measures and activities does not result in an unintended reporting burden for eligible clinicians.

With regard to Advanced Alternative Payment Models (Advanced APMs), the FAH appreciates CMS's proposal not to increase the financial risk parameters for Advanced APMs for 2018 and 2019 and the previously finalized changes to the CJR model that qualifies it as an Advanced APM. However, our members remain 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. CMS can encourage more clinicians to participate in APMs by using its discretionary authority to allow more APMs to be designated as Advanced APMs, such as BPCI. CMS should also consider financial risk

⁶ 82 Fed. Reg. 30010 (June 30, 2017)

options that: provide Advanced APM status to APMs transitioning from one-sided to two-sided risk; begin at lower levels of financial risk that gradually increase over time; and capture upfront APM infrastructure costs in its risk framework. Additionally, given the statutory language regarding what can be counted toward determination that a clinician is eligible for the Advanced APM bonus, as well as CMMI's limited resources, the FAH recommends that CMMI focus on developing Advanced APMs under the Medicare fee-for-service.

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 "Andrew M. Kohn". The signature is fluid and cursive, with a large initial "A" and "M".



Charles N. Kahn III
President & CEO

May 17, 2017

The Honorable Dr. Tom Price
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Dear Secretary Price:

The Federation of American Hospitals (FAH) appreciates your commitment to undertake regulatory reform and reduce the regulatory burden on health care providers, as directed by the February 24, 2017 Executive Order. 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 diverse membership includes 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 committed to ensuring patients receive high-quality care and believe a comprehensive review and repeal or revision of regulations that are outdated, ineffective, or otherwise overly burdensome will further our shared goals of improving health outcomes and efficiencies in care delivery. The attached document recommends actions the Department of Health and Human Services (HHS) could take to implement regulatory reform across a variety of areas, such as alternative payment models, Medicaid, hospital and post-acute payment policies, and quality measurement and reporting. For example, HHS should ensure that the Center for Medicare & Medicaid Innovation (CMMI) acts only within its designated authority to voluntarily *test* alternative payment models, not make permanent or mandatory changes to the Medicare program. HHS also should indefinitely suspend the troubled Hospital Star Ratings system while the Agency collaborates with stakeholders on appropriate risk adjustment. Additionally, HHS should provide hospitals with flexibility to relocate their provider-based departments to meet community needs and still retain hospital outpatient payments.

Thank you again for your attention to these critically important policies. We look forward to working with you as you continue these efforts and would be happy to meet with you and your staff to discuss any of the recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Bremberg". The signature is fluid and cursive, with a large initial "A" and a stylized "B".

cc:

Seema Verma
Jared Kushner
Andrew Bremberg
Gary Cohn
Mick Mulvaney

REGULATORY REFORM

Alternative Payment Models / MACRA Implementation

- **Halt Mandatory CMMI Models** – *The FAH does not believe that section 1115A authorizes the Centers for Medicare & Medicaid Services (CMS) to mandate provider participation in Center for Medicare & Medicaid Innovation (CMMI) models such as the Episode Payment Model (EPM) or the Comprehensive Care for Joint Replacement (CJR) models. As such, CMS should make them voluntary.* CMMI authority is designed to test models and make recommendations to Congress for permanent or mandatory changes to the Medicare program. Specifically, CMMI’s general authority is to test innovative payment and services delivery models to reduce program expenditures while preserving or enhancing quality of care. The law further directs CMS to evaluate CMMI models and, if appropriate, allows CMS to expand “the scope and duration” of an existing model to a “Phase II,” provided certain requirements are met. CMS is required to report periodically to Congress on CMMI models and make proposals for legislative action on models it deems appropriate. Notably, nowhere does the law expressly state that CMS can make models mandatory.
- **Ensure Meaningful MIPS Measurement and Maximize Advanced APM Participation** – *CMS should set a path for the Quality Payment Program (QPP) for 2018 and beyond that ensures meaningful measurement in the Merit-Based Incentive Payment System (MIPS) reporting and that maximizes participation in Advanced Alternative Payment Models (APMs).* As CMS transitions to the QPP, so far the Agency has chosen a large set of potentially reportable measures from which clinicians can choose. Instead, FAH encourages CMS to rapidly move to a streamlined set of standardized high-priority measures that would align incentives and actions across the health care system. The move to streamlined measures should include allowing hospital-based clinicians to utilize hospital quality measures for measurement under MIPS, as envisioned in the *Medicare Access and CHIP Reauthorization Act (MACRA)*.

In last year’s final QPP rule, CMS projected that the vast majority of physicians would not reach Advanced APM Qualifying Participant (QP) status and thus would not be eligible for the five percent bonus. CMS should allow more APMs to be designated as Advanced APMs, particularly the Bundled Payments for Care Improvement (BPCI) and Medicare Shared Savings Program (MSSP) Track 1. Additionally, as the CJR model is currently underway, CMS should implement the finalized changes to the model on July 1, 2017 in order for CJR to qualify as an Advanced APM. Post-acute care (PAC) providers should also be included in the development of APMs, such as through a “shared accountability” payment methodology that features price flexibility for inpatient rehabilitation facilities (IRFs). Adopting additional options – other than payment amount and patient count – for use in determining the Advanced APM Threshold Score will also increase Advanced APM participation by not disadvantaging multispecialty practices. Finally, CMS should revise the financial risk definitions: to provide Advanced APM status to APMs transitioning from one-sided to two-sided risk; and begin at lower levels of financial risk that gradually increase over time.

- **Recalibrate Bundling Programs – CMS – with robust stakeholder input – should reexamine the bundling programs, such as the BPCI to ensure they are successful in achieving program goals.** Existing health care bundling programs have been rolled out in a manner that is “too much too soon” without the opportunity to evaluate ongoing programs to determine best practices and implement mid-course program adjustments. There is a need to reexamine and recalibrate numerous program requirements to ensure they are operationally feasible and actually improve value-based, coordinated care, such as providing timely data to providers; length of episodes; stop-loss and stop-gain limits; areas used to establish regional prices; downside risk; target price discount factors; payment flexibility for PAC providers to better achieve efficiencies; appropriate waivers under fraud and abuse laws for gainsharing purposes; gainsharing caps; development of preferred provider networks; and duplicative beneficiary notice requirements.
- **Implement Prospective Beneficiary Assignment to Medicare ACOs – CMS should prospectively assign beneficiaries to an Accountable Care Organization (ACO) in Track 1 and Track 2 of the MSSP.** CMS performs a preliminary prospective assignment that provides ACOs with information about the fee-for-service population that is likely to be assigned to it for the performance year. However, the final list of beneficiaries assigned to the ACO is determined based on a retrospective reconciliation completed after the end of the performance year, which drives the calculations of average per capita expenditures for the performance year.

The current retrospective methodology creates significant uncertainty for ACOs, as they are unable to clearly identify the patient population they are responsible for until after the performance year has ended. ACOs are undertaking significant investments to redesign care delivery to better serve patients, and they must have clear information regarding their assigned patient population in order to proactively and effectively serve the patients for whom they are responsible.

- **Increase Flexibility in Developing Preferred Provider Networks for APMs – CMS should waive statutory and regulatory requirements for alternative payment models (APMs), or adopt a more flexible interpretation of current law, that would permit hospitals to offer beneficiaries a “preferred provider list” to promote better care and patient experience. At a minimum, hospitals should be permitted to exclude from the list certain post-acute providers with objectively poor quality scores.** In recent years, the value of preferred provider networks has emerged as a critical factor in facilitating care coordination and optimization of care in APMs. Yet, hospital APM participants are required to provide Medicare beneficiaries with a full list of area home health and skilled nursing facilities in the discharge planning process. This is confusing for patients, has little value, and prevents hospitals from highlighting high quality providers that can best coordinate care under an APM arrangement.
- **Create Single Bundled Payment Program Stark and Medicare Anti-Kickback Waiver – CMS should replace its current piecemeal approach to bundled payment program fraud and abuse waivers and develop a single, overarching “Bundled Payment Waiver” of the Stark physician self-referral law (Stark Law) and Medicare**

anti-kickback statute (AKS), applicable to all gainsharing arrangements under a CMS-led bundled payment program. Alternatively, CMS should consider a new “Bundled Payment Program Exception” to the Stark law, or revisit and modify current Stark law exceptions (e.g., risk-sharing exception) to permit gainsharing under CMS-led bundled payment programs. Outdated laws and regulations, such as the Stark Law and AKS, undermine hospital efforts to achieve successful coordinated care arrangements and participate in new APMs. Gainsharing is a critical component of APMs, such as CJR or the EPM bundled payment programs, and serves to align participating providers’ otherwise disparate financial interests. Yet, to facilitate such gainsharing arrangements, hospitals need legal certainty that such efforts will not run afoul of federal fraud and abuse laws, and an overarching waiver from these laws would provide that certainty and in a timely manner. Gainsharing programs take careful deliberation on the part of numerous stakeholders, involve painstaking drafting of sharing arrangements, and further entail drawn out negotiations with potential gainsharing partners. An overarching waiver, rather than issuance of waivers with a final rule, would allow participants the time needed to enter into effective gainsharing arrangements.

- **Provide Payment and Regulatory Flexibility for IRFs in CMMI Bundling Programs** – *CMS should provide IRFs an optional, voluntary discount to the standard payment amount, or otherwise enable them to assume more risk, for relevant IRF cases discharged from an acute care hospital participating in a CMMI bundling program.* At the same time, regulatory relief under the 60 Percent Rule and Three-hour Rule would be granted to provide IRFs treating these patients at payments below the current IRF prospective payment system (PPS) rates with the flexibility needed to participate in the program without jeopardizing their Medicare status. This shared accountability payment model would strengthen the relationship between acute care hospitals and IRFs and reduce costs by enabling IRFs to pass along savings from accepting payments lower than the IRF discharge-based PPS.

Medicaid

- **Preserve Medicaid Supplemental Payments in Managed Care** – *CMS should revisit its recently implemented rule restricting the use of pass-through payments in Medicaid managed care arrangements and restore the ability of states to use this financing mechanism.* Medicaid provider payment rates already fall far short of the cost of care, and by restricting the use of and phasing out supplemental pass-through payments as a permissible financing mechanism, CMS has imposed unreasonable pressure on providers with adverse consequences for patients, especially since approximately 70 percent of Medicaid beneficiaries are enrolled in managed care plans.
- **Withdraw Regulation and FAOs Regarding Treatment of Third Party Payers in Calculating Medicaid DSH Uncompensated Care Costs** – *CMS should rescind its recently finalized regulation, which defined uncompensated care costs for Medicaid disproportionate share hospital (DSH) purposes in a manner not supported by the statute.* In determining a hospital’s specific-DSH limit, CMS has sought to define the cost as the costs of providing care to Medicaid eligible individuals minus payments made

by third-party payers. Such a definition is in direct conflict with the Medicaid statute. CMS's interpretation has resulted in many hospitals facing significantly reduced or eliminated Medicaid DSH payments, which could well limit access to care.

PAMA Implementation

- **Delay PAMA Implementation and Ensure Beneficiaries Receive Timely Services** – *CMS should delay the January 1, 2018 implementation date for ordering providers to consult appropriate use criteria (AUC) and for furnishing providers to submit claims-based documentation.* Specifically, CMS should allow a 12 to 18 month implementation timeframe after CMS approval of the clinical decision support mechanisms (CDSMs) providers can use to consult AUCs. The list of approved CDSMs is not expected until this summer, leaving very little time for providers to work with their health information technology vendors to implement these new requirements under the *Protecting Access to Medicare Act of 2014* (PAMA). Additionally, in order to enable beneficiaries to receive necessary, timely services, CMS should develop a pathway for a furnishing provider to perform and receive reimbursement for advanced imaging when the ordering physician does not consult CDSM.

PAC Payment Policies

- **Retire the LTCH 25 Percent Rule** – *CMS should completely retire the 25 percent Rule as it is no longer necessary in light of the new two-tiered payment system.* The new long-term care hospital (LTCH) patient criteria and two-tiered payment system address the same policy concern that the 25 Percent Rule was initially developed to address: that patients may have been transferred to the LTCH setting to maximize reimbursement and not because the LTCH was the most appropriate care setting. Now that payment at the LTCH PPS standard Federal payment rate is only available for a subset of historic LTCH patients with LTCH approved, very specific conditions, the FAH does not think the 25 Percent Rule is necessary.

Further, the FAH believes it is arbitrary for CMS to pay for care rendered to LTCH-appropriate patients at different rates (e.g., LTCH rate or IPPS equivalent rate) solely based on the number of patients discharged to the LTCH from the discharging hospital. If the patient is appropriately treated and classified such that the LTCH is eligible for reimbursement at the LTCH PPS standard Federal payment rate, the patient's care should be paid as such, regardless of the percentage of discharges to the LTCH from the discharging or transferring hospital.

- **Clarify IRF 60 Percent Rule ICD-10 Compliant Codes** – *For purposes of presumptive testing, CMS should clarify that it will not exclude IRF ICD-10 codes used for a case that would have been included under ICD-9 as a result of the effects of its prior coding modifications.* The FAH is very concerned that the transition to ICD-10 has limited the extent to which IRFs can use the “presumptive testing” methodology to demonstrate compliance with the 60 Percent Rule. Patient cases in impairment group codes for traumatic brain injury, hip fracture, and major multiple trauma are especially vulnerable

to exclusion. These cases were previously eligible and counted, but are now not eligible due solely to the way in which the General Equivalence Mappings translates, which alters the clinical definitions from ICD-9 to ICD-10 in ways IRFs do not recognize. The FAH believes that this is an unintended oversight with negative consequences for IRFs and patients, which CMS could and should seek to correct through rulemaking. This is a straightforward fix that would help ensure the 60 Percent Rule is functioning properly, and as CMS intends – to reduce reliance on the costly and burdensome “medical review” process in favor of its “preferred” method, “presumptive testing.”

More broadly, CMS should consider supporting efforts to eliminate the 60 percent rule, introduced some 30 years ago. It is arguably an anachronism today and impediment to the ongoing transformation of health care delivery into a system of seamless, patient-centered care. The rule imposes significant burden and cost both on government agencies to administer, and on providers to comply, with diminishing and questionable benefit.

- **Expand 60 Percent Rule Data Transparency** – *CMS should provide IRFs with access to their patient-level data submitted for presumptive testing under the 60 Percent Rule.* Currently, IRFs do not know which cases satisfied the rule and which cases did not and have been unable to access this patient-level data from CMS. This information would enable IRFs to reconcile their internal 60 Percent Rule testing procedures against CMS’ presumptive testing procedures and thus reduce the burden and cost of compliance.
- **Publish Clear, Consistent IRF Coverage and Patient Admission Criteria Through a Transparent Public Process** – *CMS should remove the current sub-regulatory restrictions and clarification documents in favor of clear, formal policy implemented through notice and comment rulemaking with stakeholder input.* In 2010, CMS implemented a series of patient admission criteria governing Medicare’s coverage of IRF benefits that have since been the subject of inconsistent interpretation and enforcement by Medicare contractors. For example, the so-called “Three-Hour Rule” has resulted in a series of sub-regulatory restrictions, “regulation by conference call” via Q&A documents, and “clarification” documents pertaining to the extent to which rehab and therapy delivered in individual, group, and concurrent modes satisfy this rule. CMS declares in Proposed and Final Rule preambles and policy manuals that the “preponderance” of therapy provided to IRF patients must be via the individual modality. Yet, Medicare contractors routinely claim their denials of IRF claims involving 50 percent or more of individual therapy is consistent with CMS policy and requirements.
- **Harmonize IRF Appeal Rights Under the PRRB** – *The Department of Health and Human Services (HHS) should grant IRFs access to the Provider Reimbursement Review Board (PRRB) process for Low-Income Patient (LIP) appeals.* While acute care hospitals can appeal DSH payment determinations by their contractors to the PRRB, IRFs’ cannot appeal parallel LIP payment adjustment determinations by their contractors. Instead, IRFs are forced to seek such appeals through the federal court system, which is more burdensome, costly, and time-consuming.

Other Payment and Compliance Issues

- **Reform the RAC Program** – *The Administration should reform the Recovery Audit Contractor (RAC) program by holding RACs accountable for their performance.* The current RAC program design, in which RACs receive payment based on their claim denials, has resulted in overzealous denials, delayed payments to health care providers for appropriate services, and a years-long backlog of appeals. CMS should improve the RAC program by: recouping payments from hospitals (and paying RACs) only after a final Administrative Law Judge (ALJ) decision upholding the denial; creating one reasonable, balanced standard in the manual provisions for patient status determinations; requiring RAC physicians to review and approve denials before issuing them to a provider; automatically overturning RAC denials deemed inappropriate by a RAC Validation Contractor (RVC) and informing providers of RVC determinations; and applying a financial penalty to RACs for poor performance, as measured by appeal overturn rate at the ALJ level.
- **Withdraw Home-Health Pre-Claim Demonstration** – *CMS should withdraw the Pre-Claim Review Demonstration for Home Health Services.* Last year, CMS implemented a three-year Pre-Claim Review Demonstration for Home Health Services initially intended for staggered implementation in five states (Illinois, Florida, Texas, Michigan, and Massachusetts). In March, CMS paused the demonstration for at least 30 days in Illinois, and announced it will not expand the program to Florida in April, as previously scheduled. The demonstration has been fraught with problems, such as delaying claims due to simple paperwork errors rather than potential fraud, as well as excessive and unanticipated wait times in submitting the pre-claims for approval, including issues with using an online portal. These delays significantly affect workflow, negatively affect outcomes for beneficiaries, and interfere with quality improvement and care coordination, rather than achieving the demonstration program’s goal of reducing fraud and abuse.
- **Streamline Medicare Advantage Compliance Training Requirements** – *CMS should streamline the Medicare Advantage compliance training requirements for first tier, downstream, and related entities (FDRs), including hospitals, and exempt FDRs from using the CMS compliance training programs if the FDR has an internal, comprehensive compliance training program that includes training similar to the CMS training.* CMS recently implemented new Medicare Advantage compliance training requirements for hospitals and other FDRs based on use of standardized and more generic training modules developed by CMS. Hospitals take compliance training very seriously, and over many years have developed sophisticated compliance programs designed to meet federal compliance training requirements, while using their own internal comprehensive and personalized compliance training programs that are very specific to the compliance protocols in a specific hospital. While CMS has taken steps to provide hospitals with some flexibility in being able to integrate their own compliance training materials with the CMS modules, these modules continue to cause unnecessary burden and confusion for hospital employees. For example, CMS modules often impose training requirements that are not relevant to a particular hospital, and results in training being offered out of context or in a disjointed manner that is not clear and concise. Further,

CMS has been issuing new compliance training requirements for a coming year after the year has started, while many hospital systems that provide thousands of employees with compliance training, have developed and rolled out their compliance training programs well before the start of the year.

- **Withdraw/Simplify “Program Integrity Enhancements to Provider Enrollment Process” Proposed Rule** – *CMS should withdraw the “Program Integrity Enhancements to the Provider Enrollment Process” proposed rule and reconsider a more narrow, tailored approach.* CMS issued this proposed rule in 2016 to implement statutory requirements to help ensure that entities and individuals who pose risks to the Medicare program and beneficiaries are kept out of or removed from Medicare for extended periods. Under the proposal, a provider or supplier that submits a Medicare, Medicaid, or CHIP enrollment or revalidation application must disclose any current or previous “affiliation,” whether direct or indirect, with a provider or supplier that has had one of four specifically enumerated adverse “disclosable events.” In implementing this statutory provision, the proposed rule is much too broad, unworkable, and unduly burdensome. For example, under the proposed rule, in addition to reporting information about its indirect owners (as currently required), providers and suppliers internally would need to identify all affiliation relationships held by the applicant’s indirect owners, which could include large mutual or pension funds or retirement vehicles that have extremely large and diverse investment holdings, and then determine whether any of these “affiliations” are with a provider or supplier that has had a disclosable event. As ownership in health care providers and suppliers has become more complex and indirect, and increasingly non-health care entities are investing in health care solely as passive investment vehicles, compliance with this requirement will be extremely challenging, if not impossible. It also is highly questionable whether the provisions in the proposed rule would achieve the desired result of reducing fraud, waste, or abuse in federal health care programs.
- **Simplify Public Company Reporting Requirements for Medicare Enrollment** – *CMS should simplify Medicare enrollment reporting requirements for publicly-traded companies.* Specifically, publicly-traded companies should not be required to report any direct or indirect ownership interests held by mutual funds or other large investment or stock-holding vehicles on CMS Form 855. Since the ownership percentage of mutual funds or other large investment vehicles in publicly-traded companies may fluctuate daily, thereby rising above or below the five percent reporting threshold, it is unreasonable and burdensome for publicly-traded providers or suppliers to track and report such changes. In addition, the ability of publicly-traded providers or suppliers to gather necessary information to report these mutual fund or other large investment vehicles is oftentimes unreasonably difficult, if not impossible.
- **Broaden and Increase Flexibility in Anti-Kickback Safe Harbor for Free or Discounted Local Transportation Services** – *CMS should broaden and increase the flexibility in the Medicare anti-kickback safe harbor for free or discounted local transportation services.* We appreciate that the HHS Office of Inspector General (OIG) has finalized safe harbor protection under the Medicare anti-kickback statute for free or

discounted local transportation services. This is a step in the right direction, however, providing more flexibility in the safe harbor would increase patient access to quality and integrative care. For example, the safe harbor should: (i) permit transportation services for any patient who has financial or other need, or to whom such transportation would encourage patient compliance or promote preventive care, rather than limiting the safe harbor to established patients only; and (ii) broaden the existing 25-mile threshold (50 miles for patients in a rural area), as these restrictions undermine the purpose of the safe harbor, especially for “special patient populations” such as patients undergoing cancer treatment or who need special behavioral treatment. Often, the quality medical care needed to best treat their condition is available only at facilities over a much greater distance (than 25 miles).

- **Increase Flexibility in Beneficiary Inducement CMP Exception** – *HHS OIG should provide additional flexibility in the newly-created exception to the Civil Monetary Penalty (CMP) rules regarding beneficiary inducement and whether certain payments to beneficiaries are considered “remuneration” under the CMP rules.* We appreciate that the HHS OIG has finalized an exception to the CMP rules regarding beneficiary inducement so that certain payments to beneficiaries are not considered “remuneration,” including, for example: (i) copayment reductions for certain hospital outpatient department services; (ii) certain remuneration that poses a low risk of harm and promotes access to care; or (iii) certain remuneration to financially needy individuals. This exception is a step in the right direction, and we encourage CMS to provide additional flexibility when interpreting “remuneration” so that hospitals can help patients realize the benefits of their discharge plan and maintain themselves in the community. For example, remuneration that “promotes access to care” should be defined to include nonclinical services that are related to a patient’s health, such as social services or dietary counseling.
- **Create Guidance and Refinements to 60-Day Overpayment Rule** – *CMS should work with stakeholders to refine and provide further guidance regarding certain aspects of the Returning and Reporting Medicare Program Overpayments final rule.* The rule became effective in March 2016 and contains certain broad-based standards that should be further clarified. For example, the regulation requires providers to use “reasonable diligence” to determine whether an overpayment may have occurred. The rule discusses that “reasonable diligence” includes both “proactive compliance activities to monitor claims and reactive investigative activities undertaken in response to receiving credible information about a potential overpayment.” Currently, providers have no guidance about the steps necessary to meet these standards. This is problematic because CMS has been asserting that if a provider does not have a sufficiently “proactive compliance” program or does not sufficiently undertake “reactive investigative activities,” the provider is not protected against penalties even if the provider discovers an overpayment. This subjects the provider to liability under the False Claims Act, which is inequitable given that the threshold requirements in the final regulation are ambiguous and lack adequate guidance for compliance.

Quality Measurement / Reporting

- **Suspend Hospital Star Ratings** – *The Administration should suspend indefinitely the Hospital Star Ratings system and work with the industry and quality experts to ensure that any future star rating system includes appropriate risk adjustment and accurately distinguishes among providers.* The Star Ratings system is deeply flawed and does a disservice to patients, their families, and providers by not providing accurate risk-adjusted information on which to make decisions.
- **Adjust Outcome Measures for Socio-Demographic Status (SDS)** – *The Administration should immediately adjust readmission and other outcome measures used in any federal payment program to accurately account for and capture socio-demographic status differences among hospitals.* Hospitals have been required to report several readmission and outcome measures since 2010. These measures also are used in consequential payment programs such as the Hospital Readmission Reduction program, the Hospital Acquired Condition Program, and the Hospital Value-Based Payment Program. Over time, it increasingly has become clear that the readmission and outcome measures do not reflect accurately the care hospitals provide, and the measures should be adjusted to capture differences among hospitals in the socio-demographic characteristics of the patients they treat.
- **Suspend and Refine Electronic Clinical Quality Measure Reporting Requirements for eCOMs** – *The Administration should delay the Stage 3 Meaningful Use Program in order to gather input from stakeholders prior to further implementation and, at a minimum, allow a 90-day reporting period in each year in which Stage 3 is first implemented.* Hospitals currently are required to report electronic clinical quality measures (eCQMs) for purposes of Meaningful Use Stage 3 and also for the Inpatient Quality Reporting (IQR) program. However, the value of these measures for improving patient care is not clear. The requirements around reporting of eCQMs are extensive and require hospitals to expend significant resources re-tooling their EHR systems to capture and report the eCQMs solely for the purpose of meeting arbitrary standards and not for the purpose of improving patient care.
- **Streamline Hospital Quality Measures** – *HHS should step back and focus on measures that really matter and can drive care improvement aligned across care settings.* CMS requires an increasing number of quality measures be reported each year. While improvements in quality in hospitals and other health care facilities continue at a faster pace, the proliferation of measures results increasingly in conflict and overlap across programs. CMS should reassess current measures and review any new measures to focus on the most pressing clinical areas in need of improvement and ensure measures align across programs and care settings. In addition, CMS should consider expanding the programs for which quality data vendors are able to submit data on behalf of hospitals. In particular, it would be extremely helpful for vendors to submit data on the Perinatal Care and Behavioral Health measures just as they do for all other core measures. Allowing vendors to electronically submit the data would alleviate data entry burden for hospitals and improve the quality of the data submitted.

- **Postpone Implementation of PAC Quality Measures to Ensure Appropriate Alignment Across Care Settings** – *CMS should postpone all Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) Act quality measure implementation until the new cross-cutting measures have been tested and refined in the specific setting where they are being used.* The passage of the IMPACT Act reforming PAC payment and subsequent implementing regulations have placed significant burden on post-acute providers and the government quality reporting systems. Implementation time has been inadequate and requirements to report functional status data two different ways, such as for Inpatient Rehabilitation Facilities, causes enormous confusion in the field and does little to improve patient care. Harmonizing quality measures across settings requires significant testing in the actual setting to minimize or eliminate unintended consequences of measures not adequately capturing the patient care provided in the setting. The varying complexity of patients and their care needs across post-acute settings challenges measure developers to effectively capture the differences. Robust setting-specific testing and revision is needed prior to full deployment of the measures in consequential payment programs.
- **Expand PAC Provider Access to Patient-Level Information for Use in Analysis of Quality Reporting Programs for Inpatient Rehabilitation Facilities (IRFs)** – *The Administration should permit post-acute providers access to pre- and post-acute patient-level claims data beyond three days.* Under the current system, post-acute providers receive aggregated claims data, which does not fully inform the facility of the patient’s clinical condition and nuances that may be important for better understanding the facility’s performance on outcomes measures. Permitting access to more robust patient-level data, similar to what acute care providers receive, would better inform the understanding of the patient’s recovery and provide more specific information for the quality improvement work of the IRF. For example, CMS recently began publishing IRFs’ 30-day readmission rates on the “IRF Compare” website. IRFs should be provided with relevant data and information about the patients comprising these rates to facilitate improvement and better outcomes on this measure.
- **Ensure Appropriate Pre-Deployment Testing of all Federal Systems for Collecting and Reporting Hospital Quality Data Both at CMS and CDC** – *The Administration should ensure full testing of any changes to quality measures and the reporting structures to which the data is reported before the new/updated systems are deployed.* Hospitals are required to report a series of quality measures to CMS and Centers for Disease Control and Prevention (CDC). FAH members welcome the opportunity to improve patient care and value the feedback received from reporting data. However, inordinate resources are expended in reporting data to and retrieving data from faulty federal reporting systems. This year alone, CMS has had to recall preview reports, suspend reporting for several weeks, or change reporting deadlines three times in the first quarter due to problems with QualityNet reporting. Deploying systems that cannot either accurately receive the data or report data back to hospitals costs both the government and hospitals hundreds of thousands of dollars each year. Additionally, more robust testing of CDC National Healthcare Safety Network (NHSN) quality reporting systems prior to deployment of any new upgrade would avoid the challenges, downtime, and inability of

hospitals to effectively and efficiently retrieve their data to either check that it was recorded appropriately or inform improved patient care. Each time an upgrade is issued, hospitals experience significant challenges and down time in submitting and retrieving data at CDC.

- **Reform the Data Reporting Mechanisms for the NHSN at the CDC** – *The FAH recommends that CDC develop a vendor submission system similar to the CMS system of certified vendor reporting on behalf of multiple hospitals.* The NHSN was designed to facilitate public health reporting between local and federal health departments, but has been expanded to accept direct reporting of infection measures from 5,000 hospitals. The system is neither designed nor funded to efficiently handle the reporting load, nor can it efficiently generate reports that are needed for care improvement. By implementing a system whereby vendors could collect and report data on behalf of hospitals, the reporting of CDC data could be streamlined and more readily facilitate hospital quality improvement with the timely feedback of quality data to hospitals.

Health Information Technology

- **Delay Stage 3 Meaningful Use and Increase Flexibility** – *The Administration should delay the Stage 3 Meaningful Use Program and, at a minimum, allow a 90-day reporting period in any year in which Stage 3 is first implemented.* The current Meaningful Use Program is costly and burdensome for providers and has not resulted in the desired efficiencies and patient care improvements. Delaying Stage 3 would allow for a meaningful evaluation of whether the Program is meeting its goals and to further align the hospital Program with the Advancing Care Information (ACI) category of the MIPS for physicians, including eliminating the “all-or-nothing” standard. At a minimum, a 90-day reporting period in 2018 – and in any year in which Stage 3 is first implemented – with appropriate and timely notice to affected stakeholders is necessary to enable providers to implement system updates and train staff.
- **Modify MACRA Information Blocking Attestations** – *The Administration should modify the MACRA data-blocking attestations or provide clear guidance on how these requirements will be enforced so that providers understand what actions they need to take and/or avoid in order to be found in compliance.* Effective April 16, 2016, MACRA requires that EHR “meaningful users” 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 requires this be met through a three-part attestation that is so broad that providers could inadvertently be labeled as “data blockers” for taking reasonable actions regarding EHR functionality in response to requests for medical records.
- **Expand Coverage of and Establish Payment Parity for Telehealth Services** – *The CMS should take steps to remove Medicare’s restrictions and expand reimbursement of telehealth services. Medical and behavioral health services that can be appropriately delivered via telehealth technology should be reimbursed by Medicare, Medicaid, private insurance, and other payers at the same level as when those services are*

delivered in person. CMS currently engages in an outdated process for determining which services provided via telehealth are eligible for Medicare reimbursement. The process has resulted in Medicare beneficiaries not having access to appropriate telehealth services.

Hospital Payment Policies

- **Permit Hospital Provider-Based Departments to Relocate to Meet Community Health Needs** – *CMS should provide hospitals with broad flexibility to relocate provider-based departments, whether on- or off-campus, and retain hospital outpatient payments. At minimum, a number of exceptions, such as lease expiration and organic growth and community needs, are necessary for hospitals to deliver efficient, high quality care in a safe location.* In addition, this flexibility would enable hospitals to successfully renegotiate favorable lease terms, comply with local building codes, and preserve access to care in the aftermath of a natural disaster. Rural hospitals, for example, serve communities spread across larger geographic areas, making off-campus outpatient departments an important avenue to providing services needed by the community. As new employers arrive, expand, and contract or new housing developments are constructed, a rural community’s needs can shift dramatically, and hospitals ought to be in a position to adapt to meet those needs. CMS regulations, however, unreasonably restrict a hospital’s ability to do so by stipulating that under most circumstances an existing provider-based department that relocates would forfeit its ability to be paid as a hospital outpatient department.
- **Refrain from Enforcing CAH 96-Hour Rule** – *CMS should not enforce a condition of payment for Critical Access Hospitals (CAHs) requiring certification that a patient is likely to be discharged or transferred within 96 hours of inpatient admission.* As a Condition of Participation, CAHs are required to have an average length of stay of 96 hours or less per patient for acute care. There is also a separate condition of payment for CAHs that requires physician certification that a patient is expected to be discharged or transferred within 96 hours of admission. Some medical services offered by CAHs have standard lengths of stay greater than 96 hours and thus a physician would be unable to make the certification, which would result in non-payment to the CAH for those services. Enforcing this provision would prevent CAHs from offering necessary services that could extend beyond 96 hours.
- **Increase Flexibility and Simplify the MOON** – *CMS should simplify the Medicare Outpatient Observation Notice (MOON) form by making it an easy-to-understand, one-page form and removing open “free text” fields that are burdensome and unnecessary for patient understanding of their patient status.* The Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), requires hospitals to provide notice to Medicare and Medicare Advantage patients informing them of their outpatient status. CMS has developed the MOON form that hospitals provide to patients informing them of their status. This form is needlessly complex and confusing for patients.

- **Clarify Flexible Timing of a Physician’s Admission Order** – *CMS should clarify that a physician’s order to admit a patient to a hospital need not be finalized (i.e., authenticated by a signature) prior to patient discharge for billing purposes.* CMS adopted a new admission order authentication timing standard (i.e., that the physician’s order must be finalized prior to patient discharge) when the Agency proposed a new physician order and certification scheme as part of its Two Midnight policy. While the Two Midnight policy was largely later modified, effective January 1, 2015, informal CMS policy suggests the new authentication standard for admission orders remains in effect. This is a completely different and unwarranted authentication standard for admission orders than applies to all other types of physician orders that support Medicare inpatient hospital services and also differs from the approach taken by every other payer. Physicians often authenticate (i.e., sign) all relevant orders (including admission orders) during regularly scheduled intervals, but that may occur after a patient’s discharge.

Accreditation

- **Retain Flexibility for Private Sector Accreditation Standards** – *The Administration should retain flexibility for private sector accreditors to innovate while still “meeting or exceeding” CMS survey standards.* HHS has historically deemed that providers meeting certain private sector accrediting body standards (e.g., the Joint Commission) meet or exceed the Medicare Conditions of Participation (COPs). Recently, the Agency has begun requiring these private sector bodies to use the same survey processes used by CMS. Such restrictions limit variation and innovation in the private sector.
- **Promptly Issue Flexible Guidance for Hospital Co-Location Arrangements** – *CMS should promptly issue flexible guidelines regarding co-location arrangements to allow greater access to care and enhance coordinated care for patients.* Hospitals often share medical space with other providers, which is called “co-location.” This allows them to furnish a broader range of services tailored toward the health needs of their patients, which is especially important for providing patients with greater access to care, including in rural areas where specialists can travel to a rural hospital to treat patients. Also, for PAC providers, the ability to co-locate with a hospital is becoming increasingly important as payment and care delivery models continue to be developed throughout the country. Recently, CMS has taken a more restrictive approach to shared medical space, which has caused confusion and infeasible surveyor requirements, such as imposing requirements that a shared space be separate from the hospital and provide, for example, independent entrance and waiting areas. This presents significant obstacles for patient access and quality of care, as well as moving toward more value-based care.

Local / National Coverage Determinations

- **Increase Transparency in the LCD Process** – *CMS should require a transparent process for Medicare Administrative Contractor (MACs) local coverage decision (LCD) determinations, including open meetings and publishing rationales.* LCDs determine whether millions of beneficiaries have access to new procedures and technological advances, but the current decision-making process lacks transparency. Enabling true

beneficiary and stakeholder input into the LCD process will help ensure beneficiaries have access to medically necessary care.

- **Issue National Coverage Decision and Establish an Appropriate Accreditation Timeline for Sleep Labs** – *CMS should develop and issue a National Coverage Decision (NCD) regarding accreditation of sleep labs to supersede several LCDs recently issued by MACs, and in the meantime, there should be a moratorium on the current LCDs.* While we support accreditation of sleep labs, the recent LCDs are inconsistent with prior CMS rulemaking and guidance and establish significant changes in the sleep lab accreditation process. Further, the LCDs lack notice and did not establish an appropriate timeline for accreditation to occur. The LCDs were finalized January 2017 and became effective in February 2017, despite a seven- to nine-month accreditation backlog and that the Joint Commission has not yet issued accreditation standards. This puts patient access to sleep labs at significant risk and thus a national coverage approach is needed.

HIPAA

- **Establish Cybersecurity Safe Harbors** – *The Administration should develop safe harbors for providers that demonstrate a minimum level of cyberattack readiness and mature information risk management programs.* The Health Information Portability and Accountability Act of 1996 (HIPAA) Security Rule requires “covered entities,” such as health care providers, to address and assess cybersecurity risks, so that they can safeguard the confidentiality and security of electronic protected health information (PHI). Providers also are audited to ensure compliance with these requirements. Failure to comply with HIPAA can result in substantial monetary penalties. The FAH recommends the establishment of safe harbors and positive incentives for providers meeting these safe harbors rather than a punitive approach for providers that are the victims of a cyber-attack despite investing in and practicing good cyber readiness and risk management.
- **Remove HIPAA Regulation Barriers to Sharing Patient Information for Clinically Integrated Care** – *The Administration should update the HIPAA regulations to remove the “patient relationship” requirement and permit the sharing and use of patient medical information among clinically integrated providers.* HIPAA limits the sharing of patient medical information for health care operations purposes, such as quality and improvement activities, only to those providers who have a “patient relationship” with the patient. This restriction, while originally well-intentioned, is outdated in today’s era of integrated, team-based care settings where the patient can benefit from care coordination and quality improvement efforts but may not have a “patient relationship” with all the providers in the group.
- **Allow Treating Providers to Access Their Patients’ Substance Use Disorder Records** – *The Administration should align the 42 CFR Part 2 requirements with the HIPAA requirements to allow the use and disclosure of substance use disorder records from a federally assisted program for “treatment, payment, and health care operations”*

without prior written authorization. Currently, 42 CFR Part 2 requires individual patient consent to share addiction records from federally funded substance use treatment programs. Using the HIPAA requirements would improve patient care by enabling providers with a patient relationship to access their patient's entire medical record.

- **Increase Flexibility and Clarity Regarding OCR Guidelines on Charges for Patient and Third Party Requests for PHI under HIPAA** – *The Office for Civil Rights (OCR) should be required to work with affected stakeholders to develop clear guidelines regarding “covered entity” fees and processes that may be charged for individuals’ PHI, and distinguish third party requests for PHI versus requests from individuals or their personal representative.* HIPAA permits a “covered entity” to impose a reasonable, cost-based fee to provide the individual (or the individual’s personal representative) with a copy of the individual’s PHI, or to direct the copy to a designated third party. There is substantial confusion, however, regarding these fees. While guidelines issued by OCR in February 2016 were intended to clarify matters, much confusion remains, especially regarding fees that may be charged for “third party” requests for this information, such as requests for massive amounts of medical records/PHI requested for litigation purposes.

Medicare Beneficiary Identification Numbers

- **Delay the Transition from SSNs to MBIs** – *The Administration should delay the transition in order to address numerous stakeholder timing, operational, and fraud concerns, with negative consequences for beneficiaries.* The transition from using Social Security Numbers (SSNs) to Medicare Beneficiary Identifiers (MBIs) is an enormous undertaking for the Medicare program, the states, beneficiaries, and the providers who serve them. Congress put forth an aggressive timeline for this transition in MACRA, requiring these changes by April 2019. However, given the current state of implementation planning, it is unlikely CMS can meet this deadline without severe consequences for stakeholders, including interruptions in beneficiary access to care. Thus far, stakeholders have raised concerns regarding state readiness; interactions with Medicare Advantage reporting; beneficiary and provider education; the vulnerability of the cards to fraud, especially as millions of new cards are mailed to beneficiaries; and the need for a longer transition period in which both SSNs and MBIs will be accepted. We commend CMS for setting up a mailbox for stakeholders to submit their questions; however, to date there have been no responses from the Agency to those questions, and stakeholders do not believe they have enough time to complete the necessary system changes and training.

Student Loan Repayment

- **Implement Parity for Student Loan Repayment Programs** – *The Administration should eliminate the distinction between non-profit and investor-owned organizations for determining student loan repayment program eligibility.* Registered nurses and advanced practice registered nurses working in a Health Resources & Services Administration (HRSA) defined Critical Shortage Facility (CSF) can receive relief for 60 percent of their unpaid qualifying nursing education loan balance in exchange for two

years of service through the Nursing Education Loan Repayment Program. However, a CSF is defined as a public or private non-profit health care facility located in, designated as, or serving in an area with shortages of primary care or mental health professionals. There is a similar limitation on loan repayment eligibility under the Public Service Loan Program. Thus, nurses and other clinicians who care for patients in investor-owned organizations are not eligible for either program, even if those organizations provide public health and safety services and/or are located in workforce shortage areas. These limitations exacerbate the already significant barriers in recruiting these important professionals to shortage areas, which adversely affects patient access to care. They also discriminate against health care clinicians at investor-owned institutions that provide the same critical services to patients in those areas as those services provided by clinicians at non-profit organizations. The FAH urges the Administration to eliminate barriers to, and propose funding for, loan repayment parity for the health care workforce.

Access to Medications

- **Maintain Timely Patient Access to Compounded Drugs** – *The Administration should drop the “one-mile” radius provision for hospital pharmaceutical compounding for its own patients.* The April 2016 Food and Drug Administration (FDA) draft guidance for hospitals and health systems compounding pharmaceuticals for use with their own patients included a provision that would limit to a one-mile radius the distribution of such compounded products. The FAH encourages FDA to drop this restriction prior to issuing a final guidance document. The one-mile limit is arbitrary and unworkable and does not consider the physical structure of some facilities. The current proposed restriction would significantly hamper appropriate patient care.



Charles N. Kahn III
President & CEO

August 18, 2017

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.¹ 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.

¹ 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."² 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."³ 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 31st 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

² 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.

³ 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,⁴ 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.”⁵ 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.

⁴ 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.”

⁵ 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.⁶ **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**

⁶ 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 31st, June 30th, and August 31st). In the Proposed Rule, CMS proposed only two "snapshot" periods for all-payer QP participation (March 31st and June 30th) due to concerns that later "snapshots" would make it difficult for the Agency to complete the QP determinations and notifications before the March 31st 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 31st, June 30th, August 31st, and December 31st) 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.”⁷

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.

⁷ 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 be "Shirley M. [unclear]". The signature is written in a cursive style with some overlapping lines.