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President and CEO

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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-1693-P. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability 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 CY2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (Proposed Rule).

As we all agree, it is imperative that providers focus on the care and well-being of their patients without unnecessary regulatory burden getting in the way. To that end, we appreciate CMS identifying a number of areas where policies can be updated, and burden reduced. However, we do have significant concerns with a number of CMS's proposed policies including

the proposal to collapse the payment rates for E/M visit codes. While our detailed comments follow below, our key recommendations include the following:

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

The FAH enthusiastically supports CMS’s proposals to reduce administrative burdens by targeting extra or redundant E/M documentation requirements, as well as CMS’s overall focus on reducing administrative burden while improving care coordination, health outcomes, and patient autonomy. **The FAH, however, strongly urges CMS not to adopt the proposed coding and payment changes for office and other outpatient E/M visits.** The E/M code collapse would have a destabilizing effect, violate Congressional direction that work RVUs be based on physician time and intensity, and not meaningfully reduce documentation burdens.

- ***Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital***

The lack of transparency in the proposed rule prevents stakeholders from meaningfully commenting on the proposed PFS Relativity Adjuster. Based on prior analyses, the FAH continues to urge CMS to adopt a PFS Relativity Adjuster of at least 60 percent, which better captures the actual non-facility practice expenses associated with the services and the impact of packaging.

In addition, the FAH urges CMS to use all items and services billed with either a “PN” or “PO” modifier when calculating the PFS Relativity Adjuster so that the calculation accounts for a more representative sample of the range of items and services furnished in off-campus PBDs.

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

The FAH supports CMS’s proposal to expand payment for communication technology-based services while encouraging the Agency to reform the coverage and payment rules for telehealth and remote monitoring technologies. Additional reforms will lead to improved access for beneficiaries in both rural and urban areas to primary as well as specialty and subspecialty care.

- ***Quality Payment Program***

The FAH appreciates CMS’s continued gradual implementation of the QPP, such as the gradual increase in the Merit-Based Incentive Payment System (MIPS) performance threshold to 30 points, as well as CMS’s proposal to permit facility-based reporting for hospital-based clinicians and groups. The FAH also urges improvements to the program, such as adjusting the low-volume threshold to include more clinicians, as the current exclusion of a significant number of clinicians from MIPS participation has resulted in extremely low positive payment adjustments for those clinicians and groups that do successfully participate. The FAH also appreciates CMS’s proposal not to increase the

financial risk parameters for Advanced Alternative Payment Models (Advanced APMs) through performance year 2024 and encourages CMS to focus on boosting participation in Advanced APMs.

- ***Clinical Laboratory Fee Schedule***

The FAH agrees with CMS’s reasoning that Congress intended to “effectively exclude hospital laboratories as applicable laboratories...” and opposes the suggested alternative approaches to defining applicable laboratory. Use of the CLIA certificate or bill type 14x would be administratively burdensome for hospitals and would likely require many hospital laboratories to report data, which is clearly inconsistent with Congressional intent.

- ***Appropriate Use Criteria***

The FAH has continued concerns about the ability of providers to implement the changed required under the current timeline, the continued complexity of AUC implementation, and its potential impact on patient care. For example, the FAH believes that AUC consultation information should only be reported on the furnishing professional’s claim, not the facility claim and that CMS should exclude Emergency Departments from the AUC program entirely.

II.D. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

As CMS notes, in the CY 2018 Physician Fee Schedule (PFS) proposed rule, CMS solicited comments on how the Agency could further expand the use of telehealth services for Medicare beneficiaries. We noted then that 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. We believe that reforming the coverage and payment rules for telehealth and remote monitoring technologies will lead to improved access for beneficiaries in both rural and urban areas to primary as well as specialty and subspecialty care.

As such, we are pleased that CMS, in the CY 2019 PFS, recognizes the evolving state of physician services, including noting that many of these services are currently being performed via telecommunications technology. We also appreciate CMS acknowledging that technology and its uses have evolved in the many years since the Medicare telehealth services statutory provision was enacted. We appreciate and support CMS’s interpretation of section 1834(m) of the Social Security Act (the Act) as not applying to all physicians’ services whereby a medical professional interacts with a patient via remote communication technology. Given CMS’s interpretation, we support the Agency’s proposed expansion of payment for communication technology-based services and suggest some additional modifications to CMS’s proposal below.

Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVC11)

CMS is proposing to pay separately for a newly defined type of physicians' service furnished using communication technology. Under the proposal, this service would be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology, to assess whether the patient's condition necessitates an office visit. CMS proposes if the service originates from a related Evaluation and Management (E/M) service provided within the previous 7 days by the same provider the service would not be separately payable. Additionally, if the service leads to an E/M in-person service within the next 24 hours, the service would not be separately payable. CMS seeks to limit the benefit to established patients, would require the patient to initiate the service, and would reimburse at a rate lower than the existing E/M in-person visit rate.

We appreciate CMS proposing to make these brief, communication based check-ins available for separate reimbursement. For many beneficiaries, especially those in rural areas, providing the opportunity to consult with their provider before determining whether an in-person visit is appropriate will be a useful and important option. As such, we recommend that CMS consider broadening the scope of the proposal to allow both existing and new patients the option to use this new service. We also encourage CMS to consider the capability of the physician offering the check-in service to also offer an appropriate E/M in-person service should it be necessary. As it is likely some of these check-ins will result in needed in-person care, should the provider offering the check-in have no capacity to see the beneficiary in an in-person setting, not only may the beneficiary's care be disconnected, it may also result in more cost to the beneficiary and Medicare, generally. (We acknowledge that some circumstances may warrant an exception as in the instance when a physician providing a check-in service may refer the patient to a specialty provider in the circumstance where the physician is not the appropriate provider to furnish the in-person service.)

In considering the way in which these services should be provided, we recommend that CMS be more expansive rather than limiting. While technologies do exist that allow for both audio and visual transmission, it is likely that the most convenient way this type of service will be provided initially is through audio-only telephone interactions. As such, CMS should be expansive in its final determination, allowing all such technologies to be used.

Given that beneficiaries will be responsible for a small payment related to these services, it is reasonable for the provider to achieve brief, verbal consent from the beneficiary prior to the service being rendered which then can be documented. Additionally, while we believe the proposed payment rate for the check-in service should be equal to that of the in-person E/M rate, given that CMS has proposed a reimbursement rate below that of the existing E/M in-person visit rate, CMS should consider a lower general document burden for these services. To the extent the documentation burden for the check-in service will be equal to that of the in-person service, CMS should consider increasing the proposed payment rate for the check-in service.

Remote Evaluation of Pre-Recorded Patient Information (HCPCS code GRAS1)

CMS proposes to create a specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded “store and forward” video or image technology. Under the proposal, the service is intended to determine whether or not an office visit or other service is warranted. As with the proposed check-in visit, CMS proposes that the service be separately payable to the extent that there is no resulting E/M office visit with 24 hours and no related E/M office visit within the previous 7 days. CMS notes that this is a distinct service, separate from the proposed check-in service.

Unlike with the check-in visit, CMS does not seek to limit the availability of the service to established patients.

We appreciate and support CMS making separate payment available for the evaluation of patient-transmitted information. As with our earlier comments, we encourage CMS to make these services available to both established and new patients. We also encourage CMS to consider the capability of the physician offering the service to also offer an appropriate E/M in-person service should it be necessary. As it is likely some of these services will result in needed in-person care, should the provider offering the evaluation have no capacity to see the beneficiary in an in-person setting, not only may the beneficiary’s care be disconnected, it may also result in more cost to the beneficiary and Medicare, generally. (We acknowledge that some circumstances may warrant an exception as in the instance when a physician providing an evaluation may refer the patient to a specialty provider in the circumstance where the physician is not the appropriate provider to furnish the in-person service.)

Given that beneficiaries will be responsible for a small payment related to these services, it is reasonable for the provider to achieve brief, verbal consent from the beneficiary prior to the service being rendered which then can be documented.

We also encourage CMS to consider a more expansive view of the type of patient transmitted information that is evaluated and thus eligible for reimbursement. There are a number of remote patient monitoring technologies that utilize “store and forward” to transmit patient data to providers for later evaluation. Based on that later evaluation, a patient’s care plan may be altered or remain unchanged. The benefit of the ongoing evaluation of this transmitted patient data is the opportunity to manage any change in health condition in the early stages. Given the benefit of this ongoing monitoring to managing a beneficiary’s health over the long term and the investment by providers to the time and expense of the monitoring, we suggest that CMS also consider the evaluation of this data as payable under this new service.

Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

We support CMS’s proposed inclusion of the six Current Procedural Terminology (CPT) codes that relate to interprofessional telephone/Internet assessment and management service provided by a consultative physician. We agree with CMS that allowing separate payment for

these codes reflects the changing nature of medical practice trends and represents an opportunity to improve the ability for providers to better manage patients' chronic conditions.

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

In the Proposed Rule, CMS proposes maintaining a PFS Relativity Adjuster of 40 percent for CY 2019 and in future years unless and until updated data or other considerations indicate that an alternative adjuster or a change to CMS's approach is warranted for future years. Although the proposed PFS Relativity Adjuster for CY 2019 is the same as the CY 2018 PFS Relativity Adjuster, the data and underlying calculations diverge, and CMS has not provided stakeholders with the information that would be necessary to replicate, analyze, and validate CMS's methodology and calculations. In fact, CMS simply states that its "updated analysis supports maintaining a PFS Relativity Adjuster of 40 percent" without presenting the actual calculated percentage or explaining whether their methodology included any adjustment to account for packaging. ***This lack of transparency prevents stakeholders from meaningfully commenting on the proposed PFS Relativity Adjuster.*** Moreover, the FAH and other stakeholders have previously provided specific recommendations to improve the accuracy of the methodology used to calculate the PFS Relativity Adjuster. ***Based on prior analyses, the FAH continues to urge CMS to adopt a PFS Relativity Adjuster of 60 percent, which better captures the actual non-facility practice expenses associated with the services and the impact of packaging.***

CMS's PFS Relativity Adjuster Calculations Should be Replicable, and the FAH Urges CMS to Disclose Sufficient Information to Enable Stakeholders to Test and Comment on its Methodology and Calculations

The Proposed Rule does not include the same detailed information that allowed public commenters to replicate CMS' calculation of the PFS relativity adjuster in past years. For CY 2017 and CY 2018, CMS published a table that listed the codes it used for the analysis, the number of claim lines used for weighting and the methodology (either the technical component, the full non-facility amount, or the difference between the non-facility and facility amounts) used to determine PFS rate as a proportion of the Outpatient Prospective Payment System (OPPS) payment. Further, CMS provided the outcome of its analysis and explained why it proposed and adopted a rounded figure (e.g. 50 percent, 40 percent, or 25 percent) rather than the precise percentage obtained from its analysis. For future years, the FAH requests that CMS provide sufficient information in the proposed and final rules for stakeholder analysis of the PFS Relativity Adjuster methodology and calculations. This information can be provided in an electronic version made available on the CMS website along with other rulemaking files and addenda if it is impractical to publish it in the Federal Register. This practice will make CMS's policies more transparent and allow public commenters to replicate CMS's analysis without having to return to the agency for answers to clarifying questions. It will also allow public commenters to understand the methodological issues earlier in the comment period and provide CMS with better informed and more useful comments.

CMS also made changes to its methodology for calculating the PFS relativity adjuster that are not explained in the Proposed Rule. The absence of an explanation for these changes

significantly and materially affects the FAH’s ability to meaningfully comment on the Proposed Rule. For instance, CMS is using all codes from 2017 with the “PN” modifier rather than 22 high expenditure codes plus a clinic visit that CMS used in past years. In addition, CMS has transitioned from using claims data for services submitted with the “PO” modifier to excluding “PO” claims data and only using claims data for services submitted with the “PN” modifier. In the Proposed Rule, CMS indicates that the PFS Relativity Adjuster “reflects the overall relativity of the applicable payment rate for nonexcepted items and services furnished in nonexcepted off-campus provider based departments (PBD) under the PFS compared with the rate under the OPFS.” 83 Fed. Reg. at 35,739. CMS, however, does not provide any rationale for this shift, or any explanation as to why a PFS Relativity Adjuster that reflects the PFS-to-OPFS ratio for items and services furnished in off-campus PBDs more generally. Because relatively few item and services were billed with the “PN” modifier in CY 2017, and the resulting mix of items and services may reflect historical accident rather than the mix of items and services typically furnished in off-campus PBDs, the FAH believes that the PFS Relativity Adjuster should be calculated using both “PN” and “PO” claims data. In addition, the FAH is concerned that over time, application of the PFS Relativity Adjuster will cause the mix of items and services billed with the “PN” modifier to diverge from the mix of items and services furnished in off-campus hospital outpatient departments more generally. The resulting service-mix shift—which would be a product of the PFS Relativity Adjuster itself—would then depress the PFS Relativity Adjuster further, creating a negative cycle of rate reductions and market responses. This process thus risks unintended negative consequences (e.g., decreased access to certain specialties and PBD types in underserved areas). ***The FAH, therefore, urges CMS to use all items and services billed with either a “PN” or “PO” modifier when calculating the PFS Relativity Adjuster so that the calculation accounts for a more representative sample of the range of items and services furnished in off-campus PBDs.***

Furthermore, in explaining the methodology it used to calculate the proposed CY 2019 PFS Relativity Adjuster, CMS states that it imputed PFS values for “a limited number” of contractor-priced codes and for “some” codes that are statutorily excluded from the PFS. 83 Fed. Reg. at 35,740. The Proposed Rule provides no rationale for these methodological changes, does not confirm whether CMS imputed PFS rates for all or a selection of the codes described, and does not explain the methodology used to impute the PFS values for these codes. In addition, we are uncertain as to whether CMS changed the utilization it used to determine the weights for services in the comparison. The Proposed Rule indicates that CMS weighted the Healthcare Common Procedure Coding System (HCPCS)-level rates by “the number of HCPCS claims,” but in past years, CMS has weighted the rates by “total claims lines” (e.g., 82 Fed. Reg. at 53,030, Table 10). We are uncertain of the meaning of “HCPCS claims” and whether or not this represents a methodological change from past years.

The FAH, therefore, requests that CMS set forth a more detailed explanation of its methodology and sufficient information to validate its calculations in the CY 2019 PFS final rule and any future proposed and final PFS rules (or electronic addenda thereto). To aid CMS in this process, the FAH has compiled the following list of selected clarifying questions arising from the Proposed Rule’s discussion of CMS’ methodology:

1. What are “HCPCS claims”?
2. What was the level of observation (claims lines, claims, units, or other)

- used to calculate values?
3. What accounting, if any, was made for payment policies such as multiple procedure reductions (“MPPR”)?
 4. Were PFS rates imputed for all codes that are contractor priced under the PFS and all codes with status indicator “N”? If not, which codes were imputed?
 5. What were the PFS values for imputed codes?
 6. What were the PFS values for all other codes?
 7. Were all codes with the specified status indicators included or were some excluded, such as vaccines?
 8. What year is payment rates were used?
 9. Why were claims submitted with the “PO” modifier excluded from the analysis?
 10. How were values computed when there was no OPPS rate?
 11. How were values computed when there was no PFS rate?
 12. Were there any other adjustments or overrides on values?

The FAH Urges CMS to Use the Full PFS Non-Facility Practice Expense Amount when Determining the Applicable Site Specific Rates Under the PFS and to Adjust the PFS Relativity Adjuster to Address the Significant Distorting Effect of Packaging

The methodology CMS used to calculate the proposed PFS Relativity Adjuster suffers from the two critical deficiencies identified by the FAH and other stakeholders in the course of CY 2017 and CY 2018 rulemaking: (1) certain applicable practice expenses are under-estimated; and (2) the effect of packaging differences between the OPPS and the PFS is not addressed. In comparing the OPPS rate with the PFS rate for a HCPCS code, CMS uses the technical component rate for the service under the PFS if one is available. But, if there is no separate technical component rate under the PFS, CMS indicates that it estimates the site-specific rate as either the difference between the PFS nonfacility rate and the PFS facility rate or, if payment would have been made only to the facility or only to the physician for the HCPCS code, the full nonfacility rate. ***The FAH maintains that CMS should use 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) in lieu of the difference between the PFS nonfacility rate and the PFS facility rate because a hospital continues to incur indirect costs when a service is provided in the off-campus outpatient department.***¹ CMS’s approach only captures 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.

Moreover, CMS’s methodology fails to adequately account for the more extensive packaging of services under the OPPS. For CY 2017, CMS calculated the PFS Relativity

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 had a non-facility practice expense RVU of 1.42, which, when multiplied by the conversion factor of 35.8043, yielded a full PFS non-facility practice expense amount of \$50.84.

Adjuster without accounting for packaging.² For CY 2018, CMS adjusted the PFS Relativity Adjuster by approximately 5 percent, stating that it was “unable at [the] time to fully calculate the effects of the packaging under the OPSS.” 82 Fed. Reg. at 53,027 (Nov. 15, 2017). In the CY 2019 Proposed Rule, it does not appear that any adjustment was made for packaging when calculating the proposed CY 2019 PFS Relativity Adjuster.

In comments to CMS’s CY 2017 Medicare PFS interim final rule with comment period (81 Fed. Reg. 79,562) and CMS’ CY 2018 Medicare PFS proposed rule (82 Fed. Reg. 33,950), the FAH presented its analysis of the impact of packaging on the PFS-to-OPSS payment ratio. These calculations produced a weighted average packaging portion of approximately 20 percent that should be incorporated in any PFS Relativity Adjuster. ***The FAH continues to urge CMS to adjust the PFS Relativity Adjuster to account for the significant distorting effect of packaging.*** In its comments to CMS’s CY 2017 Medicare Physician Fee Schedule, the FAH calculated a PFS Relativity Factor of 60 percent once the full PFS non-facility practice expense amount is used in lieu of the difference between the PFS nonfacility rate and the PFS facility rate and the PFS-to-OPSS ratio was adjusted for the weighted average packaging portion of approximately 20 percent. Based on the FAH’s current analysis, a PFS Relativity Factor of approximately 60 percent continues to be appropriate. ***The FAH therefore, strongly urges CMS to increase the payment rate to 60 percent of OPSS for nonexcepted items and services furnished in off-campus PBDs for these items and services.***

II.I. Evaluation & Management (E/M) Visits

The FAH Urges CMS to Relieve Administrative Burdens by Addressing Extra and Redundant Document Requirements for E/M Services but to Retain Current Coding for E/M Services

CMS proposes significant changes to documentation and coding for E/M services, particularly in the office or outpatient setting. ***The FAH enthusiastically supports CMS’s proposals to reduce administrative burdens by targeting extra or redundant E/M documentation requirements, as well as CMS’ overall focus on reducing administrative burden while improving care coordination, health outcomes, and patient autonomy.*** The FAH, however, urges CMS to wholly forego or, at a minimum, postpone adoption of the proposed coding and payment changes for office and other outpatient E/M visits because collapsing payment rates for eight E/M codes into two levels would have unintended consequences that undercut CMS’s important burden reduction efforts. ***Instead, the FAH requests that CMS work with the panel of experts convened by the American Medical Association (AMA) and other stakeholders to develop an alternative proposal for implementation in 2020.***

² In the CY 2019 Proposed Rule, CMS states that it made a 5 percent upward adjustment to the PFS Relativity Adjuster for CY 2017 “because of its inability to estimate the effect of the packaging difference between the OPSS and the PFS.” 83 Fed. Reg. at 35,739. In the CY 2017 interim final rule, however, CMS states that it “arrived at 50 percent by examining the 45-percent [calculated PFS-to-OPSS ratio], the ASC payment rate—which is roughly 55 percent of the OPSS payment rate on average—and the payment rate for the large number of OPSS and MPFS evaluation and management services.” 81 Fed. Reg. at 79725 (Nov. 14, 2016). No mention is made in the interim final rule of any packaging adjustment for CY 2017.

The FAH Supports CMS's Commitment to Reducing Administrative Burdens by Addressing Extra and Redundant E/M Visit Documentation Requirements

The FAH agrees with CMS's assessment that existing Medicare documentation requirements for E/M visits are administratively burdensome and outdated. To this end, the FAH supports CMS's proposals to minimize documentation burdens where possible. The Proposed Rule identifies three areas where Medicare documentation requirements produce extra or redundant documentation: (1) home visit documentation, (2) established patient history and exam documentation, and (3) practitioner re-documentation of the patient's chief complaint and history. In each case, CMS has proposed eliminating current requirements that necessitate extra or redundant documentation, thereby reducing administrative burdens and allowing practitioners to focus documentation around clinically relevant information. Notably, although all three of these proposals are set forth alongside proposals for coding and payment changes, these proposals are not intrinsically related to CMS's E/M payment proposal. ***Thus, the FAH maintains that these proposals can and should be implemented without any corresponding changes to E/M coding or payment.***

In the case of an E/M visit provided in the home, the Medicare Claims Processing Manual currently requires documentation of the medical necessity of the home visit in lieu of an office visit. Pub. 100-04, ch. 12, § 30.6.14.1.B. CMS's proposal would remove this additional documentation requirement, recognizing that the practitioner and patient should be responsible for determining whether a visit is most appropriate for the home or the office. ***The FAH therefore supports CMS's proposal to eliminate the extra documentation requirement for home visits.***

Documentation requirements that produce redundant entries are also an appropriate target for reform because they create unnecessary administrative burdens that detract from face-to-face patient encounters and may even interfere with patient care by burying pertinent and notable entries amidst re-entered information. First, CMS proposes expanding the change-focused documentation policy for review of symptoms (ROS) and pertinent past, family, and/or social history (PFSH) to the broader history and exam for established patients. Second, CMS proposes permitting practitioners to indicate that they reviewed and verified information in the chart concerning the patient's chief complaint and history instead of requiring that the practitioner re-enter this information. ***The FAH supports both of these policies, which target the unnecessary re-entry of information by practitioners. Moreover, the FAH would support a broader policy that permits change-focused documentation for new patients where prior visit information is available (e.g., through a health information exchange).*** Like the proposal to eliminate extra documentation for home visits, these proposals targeting redundant documentation are severable from CMS' other E/M coding and payment proposals and are appropriate for immediate implementation in 2019.

The FAH Encourages CMS to Consider An Alternative Approach to Eliminating Prohibition on Billing Same-Day Visits

The Medicare Claims Processing Manual prohibits Medicare from paying for two E/M office visits billed by a physician or physician of the same specialty from the same group practice for the same beneficiary on the same day unless the physician documents that the visits

were for unrelated problems. In the Proposed Rule, CMS notes that this prohibition may not reflect the current practice of medicine as the Medicare enrollment specialty may not always coincide with all areas of medical expertise possessed by the practitioner. CMS provides an example of a practitioner with an enrollment specialty of geriatrics who may also be an endocrinologist. Under the CMS example, if such a practitioner is one of many geriatricians in a group practice, she would not be able to bill separately for an E/M visit focused on a patient's endocrinological issues if that patient had a more generalized E/M visit by another geriatrician on the same day.

We appreciate CMS recognizing an issue that may cause an unnecessary burden and inconvenience on Medicare beneficiaries and which may lead to delayed care. We believe an alternate approach to the elimination of the current prohibition may meet CMS's same policy goal while avoiding potential unintended consequences. We suggest CMS consider a technical edit to the manner in which it processes claims which would allow, using CMS's example, the practitioner to bill with the NPI/geriatrics when performing geriatric services and with the NPI/endocrinology when performing endocrinology services. Under this mechanism, the provider would be responsible for ensuring that her clinical note accurately reflected the work expected of the taxonomy for the NPI reported for billing while also permitting more than one service on the same day to be billed.

The FAH Supports CMS's Exploration of E/M Coding Flexibility and Burden Reduction, but Opposes the Proposal to Document to a Level 2 Visit in Light of the Disruption and Burdens that Would Result from the Associated E/M Code Collapse

The FAH appreciates CMS' commitment to reducing documentation burdens on practitioners, and its consideration of stakeholder comments regarding the need for greater flexibility in documenting E/M visits and practitioner preferences to document medical decision making (MDM) or time. As CMS observes, Medicare documentation requirements have not kept paces with changes in the practice of medicine, and the time is ripe to modernize Medicare documentation requirements and eliminate unnecessary documentation burdens. The FAH, however, urges CMS to abandon any reform of documentation requirements undertaken as part of the proposed E/M code collapse for the reasons set forth below.

Although CMS presents its documentation requirement proposal as intrinsically related to its proposal to alter PFS payment for E/M visits, significant elements of the proposal are not intertwined with the E/M code collapse proposal and could be adapted for independent adoption. CMS proposes permitting practitioners "to choose, as an alternative to the current framework specified under the 1995 or 1997 guidelines, either MDM or time as a basis to determine the appropriate level of E/M visit." 83 Fed. Reg. 35,836. This proposal—which would provide practitioners the flexibility to document E/M visits in the most efficient and clinically appropriate manner—can be separated from CMS's proposal to limit documentation requirements to the documentation associated with the current level 2 CPT visit code. It is only the latter proposal that is premised on an E/M visit code collapse. Significant burden reductions could still be achieved from the former proposal that practitioners be permitted to choose to use MDM or time as a basis to determine the appropriate E/M visit level.

The FAH Strongly Urges CMS to Set Aside the Proposed Changes to Coding and Payment for Office or Other Outpatient E/M Services

The FAH has deep concerns about the redistributive effects, patient care impacts, and legality of collapsing level 2 through level 5 E/M visits into a single E/M code level, and therefore strongly urges CMS to forego the proposed coding and payment changes for office and other outpatient E/M services. E/M services are the most commonly billed Medicare PFS services, comprising approximately 40 percent of all allowed charges under the PFS each year. As a result, even a small reduction of the documentation burdens associated with E/M services can produce significant burden savings, but coding and payment changes can also have larger than intended negative consequences. Because the proposed payment simplification for office and outpatient E/M services would be disruptive and destabilizing, the FAH urges CMS to forego this proposal and instead work with stakeholders to develop an alternative proposal for 2020.

- *The Office and Outpatient E/M Visit Code Collapse Would Not Substantially Reduce Practitioner's Documentation Burdens*

CMS estimates that its proposals concerning documentation requirements for E/M visits would save approximately 51 hours per year for a full-time practitioner with whose panel of patients is 40% Medicare. 83 Fed. Reg. at 36,068. Some of these burden savings are based on the proposed elimination of extra and redundant E/M visit documentation requirements, discussed above. Burden savings associated with CMS's proposal to collapse office and outpatient E/M visit codes (thereby limiting documentation requirements to those required for a level 2 E/M visit), however, are likely overstated. As CMS notes, substantial documentation will still be required for clinical, legal, operational, quality reporting and other purposes. Notably, most E/M visits are level 4 visits, and the clinical complexity of these visits would necessitate more in-depth documentation than is required for a level 2 E/M visit. Likewise, supporting continuity of care for Medicare beneficiaries would typically necessitate more extensive documentation than is required for a level 2 E/M visit. In addition, practitioners will still need to provide sufficient documentation for higher level E/M services for other payers and might, therefore, continue their current documentation practices for all patients to minimize the risk that a visit will be under-documented and thus under-paid by another payer. Practitioners that practice in multiple settings might maintain their current documentation practices across the board to avoid documentation deficiencies in settings not impacted by this proposal (e.g., inpatient and skilled nursing facilities). In fact, for many practitioners, the operational burdens of maintaining separate workflows for Medicare office and outpatient visits and all other visits (including where Medicare is a secondary payer) would preclude them from realizing any of the potential burden reductions associated with the proposed code collapse. Moreover, the burdens associated with the add-on codes—including both making operational changes to include Medicare-specific add-on claims as appropriate as well as documenting that the criteria for the add-on code has been satisfied—would further lessen any burden reductions associated with the code collapse.

Because the E/M code collapse proposed by CMS would be unlikely to meaningfully reduce documentation burdens and the code collapse would separately have a destabilizing effect as described below, the FAH strongly urges CMS to forego adoption of its E/M code collapse proposal. Instead, the FAH requests that CMS work with the panel of experts convened by the AMA and other stakeholders to develop an alternative proposal that can be implemented by CMS in 2020 and may be adopted by a broader range of other payers as well.

- ***The Proposed Single Relative Value Unit (RVU) Amounts for Level 2 through 5 Office and Outpatient E/M Visits Would be Destabilizing and Violate Congress' Direction that Work RVUs be Based on Physician Time and Intensity***

The current system of ten levels of codes for office and outpatient E/M visits burdens providers, both in terms of the time associated with selecting and documenting to an appropriate code level for a visit and in terms of the audit risks associated with each E/M claim. The FAH is supportive of CMS's attention to these issues, particularly with regard to documentation burdens, but the proposed solution of collapsing codes (essentially increasing reimbursement for the level 2 and 3 codes and cutting reimbursement for the level 4 and 5 codes) and documenting to the lowest level of the collapsed codes would be disruptive and have unintended consequences. The proposal would effectively increase payment for a level 2 E/M visit by approximately 78% for a new patient and by 107% for an established patient, while decreasing payment for a level 5 E/M visit by 36% for a new patient and by 37% for an established patient, not including the add-on payments that would apply for primary care and inherent visit complexity.

The existing large payment differences between these E/M code levels reflect the differing RVUs associated with these codes. For example, a level 2 E/M visit for an established patient (99212) has a work RVU of less than one-quarter of the work RVU for a level 5 E/M visit for an established patient (99215). Collapsing codes with such widely divergent RVUs to a weighted average RVU would have significant redistributive effects—a fact that CMS implicitly acknowledges by proposing a number of add-on payments, alternative codes, and payment reductions to temper these impacts. Moreover, the coding collapse is inconsistent with Congress' explicit direction that the Medicare PFS work RVU “reflect[] physician time and intensity in furnishing the service.” Social Security Act § 1848(c)(1)(A), (2)(C)(i). The proposed code collapse would apply a work RVU of 1.90 for CPT codes 99202 through 99205 and a work RVU of 1.22 for CPT codes 99212 through 99215 despite the immense differences between in physician time and intensity that is associated with each of these code ranges. Because the proposal would apply a weighted average work RVU in lieu of the actual work RVU for that service, it would effectively divorce the assigned work RVU from the actual physician time and intensity applied in furnishing the service. ***The FAH, therefore, maintains that the proposed E/M code collapse is contrary to explicit, statutory Medicare PFS requirements and urges CMS to maintain separate RVUs for each E/M code that takes into account the physician time and intensity associated with that service.***

Congress has also sought to temper the drastic payment fluctuations that this proposal would produce by requiring that CMS phase-in significant RVU reductions. Under section 1848(c)(7) of the Social Security Act, “if the total relative value units for a service for a year would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total relative value units for the previous year, the applicable adjustments in work, practice expense, and malpractice relative value units shall be phased-in over a 2- year period.” Here, the proposed coding collapse would reduce the total RVU for a level 5 E/M visit by 36.2% (new patient) and 37.8% (established patients). As a result, at a minimum, the proposed policy is statutorily required to be phased-in over a 2-year period. Social Security Act § 1848(c)(7). The FAH, however, would likewise object to a phasing-in of the E/M coding collapse proposal because of the larger disruptive effects of the proposal that has resulted in us opposing the code collapse proposal altogether.

- *Specialty-Specific Add-On Payments, Alternative Codes, and Payment Reductions*

To mitigate the extraordinary redistributive effects of the proposed office and outpatient E/M visit code collapse, CMS has proposed a couple of specialty-specific add-on payments, a separate podiatric E/M visit code, a prolonged services add-on payment, and an expanded multiple procedure payment reduction (MPPR) policy. As discussed below, the FAH supports the adoption of a prolonged services add-on code without the E/M coding collapse. The other proposed add-on payments, alternative codes, and MPPR policy, however, are designed to partially mitigate the significant and widespread negative consequences of the E/M payment collapse proposal and are not appropriate for adoption in 2019. Ultimately, these proposed changes underscore the disruptive impact and fundamental flaws of the E/M coding collapse.

Specialty Add-On Payments. The two proposed G-codes for specialty-specific add-on payments would be billed with “every primary care-focused E/M visit for an established payment” (GPC1X) and with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (GCG0X). The specialties listed for proposed HCPCS code GCG0X “apply predominantly non-procedural approaches to complex conditions that are intrinsically diffuse to multi-organ or neurologic disease.” 83 Fed. Reg. at 35,842.

By statute, the number of RVUs for a physician service cannot vary “based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.” Social Security Act § 1848(c)(6). These proposed add-on codes, however, would effectively vary E/M visit RVUs based on the specialty of the furnishing physician. For example, a level 4, new patient E/M visit furnished by a cardiologist would have a total RVU weight of 4.11 under the Proposed Rule (3.73 for the E/M visit and additional 0.38 RVU add-on), but the same level E/M visit furnished by a nephrologist would have a total RVU weight of 3.73. This difference in RVUs would be impermissibly based on the specialty of the furnishing physician rather than the nature and intensity of the E/M visit. In an August 22, 2018 teleconference, CMS indicated that

this add-on code would not be limited to specific physician specialties. While that may remedy the proposal's statutory defect of paying differentially based on the specialty of the physician, it will require CMS to define the service that is being furnished by HCPCS code GCG0X with sufficient specificity—something CMS did not do in its proposed rule. The Proposed Rule indicates, however, that the code describes “the additional resource costs *for specialty professionals* for whom E/M visit codes make up a large percentage of their overall allowed charges and whose treatment approaches we believe are generally reported using the level 4 and level 5 E/M visit codes rather than procedural codes.” 81 Fed. Reg. at 35,842 (emphasis added). This characterization indicates that HCPCS code GCG0X is proposed to be made available based on a professional's specialty instead of the nature of the service provided, making this an impermissible, specialty-specific add-on payment.

With regard to the primary care add-on code, the Proposed Rule suggests that physicians furnishing primary care visits would be eligible for the primary care add-on payment “regardless of Medicare enrollment specialty,” but it does not set forth any proposal for identifying primary care visits except by reference to the physician's specialty. 83 Fed. Reg. at 35,842. Without a clear delineation of the circumstances in which other specialists could claim this add-on payment, the add-on payment would be essentially reserved for particular primary care specialties (which are also not clearly defined). In addition, although CMS recognizes that an OB/GYN or cardiologist may function as a primary care practitioner in some cases, it appears that these practitioners would also be eligible for the proposed specialty add-on payment (GCG0X). Because the proposed specialty add-on payment amount is nearly triple the primary care add-on payment amount, a cardiologist or OB/GYN furnishing primary care-focused E/M visit to an established patient would likely claim the specialty add-on payment (GCG0X) in lieu of the primary care add-on payment (GPC1X).³ Thus, the RVUs associated with a primary care-focused E/M visit would impermissibly vary based on the physician's specialty.

Lastly, in addition to not being clearly defined, the two add-on codes do not appear not to be resource based. Fully evaluating the proposed add-on codes requires additional information that is not included in the Proposed Rule. CMS proposes a work RVU of 0.07 and physician time of 1.75 minutes for GPC1X but does not provide any information regarding the basis for these numbers, except to note that the proposed value is intended to “maintain work budget neutrality across the office/outpatient E/M code set” and to help mitigate potential payment instability flowing from the E/M code collapse. With regard to the proposed, specialist add-on code, CMS proposes assigning a work RVU of 0.25 and physician time of 8.25 minutes, deriving these numbers from crosswalking GCG0X to 75 percent of the values for 90785, the code used to indicate interactive complexity during a psychotherapy service. The Proposed Rule does not describe how this crosswalk was chosen and what alternatives were considered, if any. The FAH believes that the proposed add-on code GCG0X also is not clearly defined or

³ In addition, if the criteria ultimately used to identify a primary care visit furnished by a specialist required any additional documentation, specialists would be unlikely to use the add-on code because any documentation burden associated with such a low-value code (approximately \$5) would generally be too significant.

based upon actual resource data, offering further evidence of the irreparable flaws in the underlying payment collapse.

Podiatric E/M Visits. CMS also proposes the creation of two new codes for reporting new and established podiatry office visits (HCPCS codes GPD0X AND GPD1X). These codes would receive a lower RVU weight than the general office and outpatient E/M visit codes. For example, an established patient’s E/M visit with a podiatrist in the office setting has a proposed, total RVU of 1.86, which approximately 73% of the total RVU proposed for an established patient’s E/M visit with any other practitioner in the office setting (2.55 RVUs). The FAH maintains that the adoption of a specialty-specific E/M code for podiatry violates Congress’ instruction that the RVUs for a physician service not vary “based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.” Social Security Act § 1848(c)(6).

CMS notes that podiatrists’ billed visits are disproportionately skewed toward Level 2 and Level 3 E/M visits, such that “podiatric E/M visits are not accurately represented by the consolidated E/M structure.” 83 Fed. Reg. at 35,843. The misalignment between the typical resources costs of podiatric E/M visits and the full range of other office and outpatient E/M visits, however, does not necessitate specialty-specific coding. Instead, it demonstrates that the use of a weighted average RVU across four levels of E/M visit codes substantially delinks the actual resource costs of a particular visit from the RVUs used for payment purposes.

MPPR Expansion. CMS has also proposed reducing payment by 50% for the least expensive procedure or visit furnished by the same physician (or a physician in the same group practice) on the same day as a separately identifiable office or outpatient E/M visit. The separately identifiable E/M visit is identified on the claim by an appended modifier –25. This proposed policy would be modelled on CMS’s existing surgical MPPR policy, which reduces payment by 50% for the second and subsequent surgical procedures furnished to the same patient by the same physician on the same day. The surgical MPPR policy is based on efficiencies in practice expenses and pre- and post-surgical physician work. CMS asserts that, in a similar vein, “there are significant overlapping resource costs that are not accounted for” when a standalone E/M visit occurs on the same day as a 0-day global procedure. 83 Fed. Reg. at 35,841. The MPPR expansion proposal is intertwined with the add-on payment proposal insofar as the RVU savings for the MPPR expansion (approximately 6.7 million RVUs) could be allocated toward the values of the add-on codes. Ultimately, the add-on code proposals themselves are necessitated by the flawed E/M code collapse proposal.

The FAH urges CMS to forego expanding its MPPR policy because a separately identifiable E/M visit should remain fully payable when furnished on the same day as a 0-day global procedure. The AMA’s Relative Value Update Committee (RUC) has worked with other stakeholders to ensure that procedure codes typically performed with E/M services do not include duplicate resource costs. Thus, the FAH does not believe that there are significant overlapping resource costs that would warrant a 50% payment reduction on the least expensive procedure or visit. Moreover, the cumulative impact of

the MPPR proposal could result in payment that grossly underrepresents the associated resources. For example, a physician might provide a separately identifiable level 5 E/M visit with medical decision making of high complexity to an established patient on the same day as a same-day procedure. The coding collapse and MPPR policy expansion would combine to reduce the total RVUs assigned to the E/M visit from 4.10 to 1.28 (50% of the proposed 2.55 RVUs). The FAH believes that this policy would inappropriately depress Medicare payments to practitioners that care for sicker patients with complicated health needs. At a minimum, implementation of this proposal should be delayed for further study in conjunction with the RUC.

- *Indirect Practice Expense Impact of Code Collapse*

The proposed office E/M code collapse proposal has an additional unintended effect on the indirect practice expense (PE) allocation for office visits, which produced large changes in the indirect practice cost index (IPCI) and payment for non-E/M services for some specialties. In establishing the office visit single payment rate for E/M visit levels 2 through 5, CMS created a new IPCI for office visits and transferred the indirect practice costs for office visits into the office visit IPCI. As a result, the indirect practice costs for office visits was taken out of the IPCIs for all other specialties. This produced significant IPCI changes for some specialties. For example, the IPCI for rheumatology would fall by 39% under the Proposed Rule; the IPCI change from 2017 to 2018 for rheumatology was only 0.07%. Overall, the IPCIs for 13 specialties (rheumatology, allergy/immunology, medical oncology, peripheral vascular disease, sleep medicine, hematology/oncology, oral surgery, interventional pain management, otolaryngology, pain management, dermatology, urology, and vascular surgery) would fall by more than 10% under the Proposed Rule. In contrast, from 2017 to 2018, no IPCI fell by more than 7%. At the other end of the spectrum, the Proposed Rule would increase the IPCI for addiction medicine by 24%. ***These significant and anomalous changes to the IPCI would have a substantial impact on non-facility practice expense payments for affected specialties and appears to be the result of distortions created with the development of an E/M IPCI.*** It is not at all intuitive or clear why practice payments for unrelated procedural services like injections should decline as a result of CMS's E/M proposals. The FAH believes that this is an extremely undesirable but unintended consequence of the proposed office E/M code collapse proposal and strongly opposes adoption of this proposal.

Prolonged E/M Services (GPRO1)

CMS proposes creating a new add-on G-code (GPRO1) that would be payable when the typical E/M visit time has been exceeded by 30 minutes. As CMS notes, the "'first hour' time threshold in the descriptor for CPT code 99354 is difficult to meet and is an impediment to billing [CPT codes 99354 and 99355]." 83 Fed. Reg. at 35,844. In fact, when CMS first established the RVU for CPT code 99354 in the CY 1994 PFS final rule, it said, "We consider a period of up to 15 minutes beyond the typical time to be included in the base visit." 58 Fed. Reg. at 63,675. At present, however, there is no payable code for a prolonged E/M visit that exceeds the typical time of the base E/M visit by more than 15 minutes but does not exceed the 30-minute threshold required for CPT code 99354. Proposed HCPCS code GPRO1 would address this gap

and remove the incentive for a physician to schedule a separately payable follow-up visit in lieu of a prolonged the E/M visit. ***Because HCPCS code GPRO1 is a well-considered coding change that addresses an existing gap in the reimbursement for prolonged E/M services and is wholly severable from the coding collapse proposal, the FAH supports its adoption for CY 2019.***

In the context of the current E/M code collapse proposal, however, the criteria for the prolonged services G-code is unclear. The E/M code collapse would suggest that the prolonged E/M services code would be appropriate whenever an E/M visit exceeds by 30 minutes the total time established for payment of the single, new rate for E/M visits levels 2 through 5. CMS suggested that the total time for the collapsed E/M visit codes might be 38 minutes for a new patient or 31 minutes for an established patient, based upon the weighted average of intra-service times across the current E/M visit utilization. 83 Fed. Reg. 35,837. Alternatively, the total time might be set at the current intra-service time for a Level 2 E/M visit (*i.e.*, 20 minutes for a new patient and 10 minutes for an existing patient), consistent with CMS' proposal to only require documentation that is associated with the current level 2 E/M visit code, 83 Fed. Reg. 35,853. ***Ultimately, because the E/M code collapse proposal is flawed and disruptive, the FAH urges CMS to adopt GPRO1 and to maintain the current E/M coding and payment structure for CY 2019 while working with the panel of experts convened by the AMA and other stakeholders to develop an alternative proposal for implementation in CY 2020.***

II.J. Teaching Physician Documentation Requirements for Evaluation and Management Services

In the Proposed Rule, CMS proposes to modify the regulations related to medical record documentation of a teaching physician's participation in the review and direction of services performed by residents in teaching settings. Specifically, CMS proposes that notes in the medical record made by a physician, resident, or nurse may be used to demonstrate the presence and involvement of a teaching physician during the provision of evaluation and management services. **The FAH supports this proposal. Allowing another physician, a resident, or a nurse to perform this documentation rather than requiring the teaching physician to do so will reduce the documentation burden on the teaching physician and prevent unnecessary duplicative notations in the record.**

II.M. Therapy Services

Of the proposed policies included in the Therapy Services section, CMS proposes to end the requirements for the reporting and documentation of functional limitation G-codes and severity modifiers for outpatient therapy claims with dates of service on and after January 1, 2019.

We agree with CMS's analysis indicating that continuing to collect more years of functional reporting data will not yield additional information useful to future analyses and that continuing to require this information to be reported results in unnecessary burden for providers. We appreciate CMS's proposal to remove this requirement and urge CMS to finalize the proposal to delete the functional limitation HCPCS G-codes and to eliminate the reporting requirement effective for dates of service after December 31, 2018.

II.N. Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments

CMS proposes to reduce payment for certain Part B drugs when average sales price (ASP) data is unavailable and when WAC data is used for reimbursement, per the statute, until ASP data becomes available. Under current regulation, for drugs when ASP price data is unavailable during the first quarter of sales, the Part B payment is determined as the WAC plus an add-on percentage of 6 percent. CMS proposes to reduce the add-on payment for these drugs to 3 percent. **The FAH opposes CMS’s proposal to reduce reimbursement for these drugs.**

The current formula for reimbursing this special set of Part B drugs at WAC plus 6 percent is appropriate and is working and there is little to no evidence that physicians are making prescribing decisions to maximize reimbursement. The current formula accounts for both provider acquisition costs and the additional costs associated with the complexity of Part B drugs including shipping fees, administration, and complicated storage and handling requirements.

In addition, the proposed reduction of the add-on payment to 3 percent is arbitrary and based on data analysis from third-party sources and not a review conducted by CMS.

III.A. Clinical Laboratory Fee Schedule

Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory

The FAH strongly supports CMS’s reasoning in the Proposed Rule that Congress intended to “effectively exclude hospital laboratories as applicable laboratories, which was apparent from the statutory language, in particular, the majority of Medicare revenues threshold criterion in section 1834A(a)(2) of the Act.” **As such, the FAH does not support the suggested alternative approaches to defining applicable laboratory.**

In regard to the suggested alternative approach of using form CMS-1450 bill type 14x to determine majority of Medicare revenues, we are in agreement with the CMS analysis of the four areas of concerns raised by CMS and urge CMS to not make any changes to implement use of bill type 14x in determining applicable laboratories. We also agree with CMS that the continued use of NPI to identify a laboratory that would be considered an applicable laboratory is more appropriate than converting to use of Clinical Laboratory Improvements Amendments (CLIA) certificate instead. Use of the CLIA certificate or bill type 14x would be administratively burdensome for hospitals and would likely require many hospital laboratories to report data which was not the Congressional intent.

III.D. 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 a clinician would consult a clinical decision support mechanism (CDSM) prior to ordering advanced diagnostic imaging. The legislation directs 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.

The AUC program was originally slated to begin January 2017, but, in the CY 2018 PFS Final Rule, CMS delayed the implementation date for ordering clinicians to consult with specified AUC – and for furnishing clinicians to submit claims-based documentation – until January 1, 2020. The FAH appreciates CMS’s recognition of the complexity of implementing the AUC program by undertaking a phased-in implementation. **As the FAH stated in previous comments, our members generally support the use of AUC. However, they remain concerned about the ability of providers to implement the changes required under the current schedule, the continued complexity of AUC implementation, and its potential impact on patient care.** In order to maintain the focus of the program on the goal of helping clinicians with decision-making – rather than producing a “check-the-box” exercise – the FAH offers the below comments and suggested improvements.

Applicable Settings

Independent Diagnostic Testing Facilities

The FAH supports the addition of independent diagnostic testing facilities (IDTFs) to the list of providers subject to the AUC program, as they are significant providers of advanced imaging services.

Emergency Departments

The FAH urges CMS to revise the applicable setting criteria to ensure beneficiaries receive timely services in emergency situations and reduce the burden on Emergency Departments (EDs) that provide a large proportion of care and stabilization for exempted emergency medical conditions. Specifically, 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. Clinicians do not always know whether a patient is truly emergent upon initial presentation and should focus on stabilization and treatment of emergency medical conditions – not whether the patient meets the AUC emergency exclusion. In addition, 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. To this end, ordering clinicians should not be subject to hindsight evaluation on a claim-by-claim basis of their determination that an emergency medical condition exists. A blanket exclusion of EDs from the AUC requirements would alleviate these concerns and ensure focus remains on patient care. In the alternative, if CMS does not exclude EDs from the AUC requirements altogether, then CMS should broadly define a subset of ED services that would not be subject to the AUC process.

Consultations by Ordering Professionals

The FAH appreciates and supports CMS’s proposal to allow auxiliary clinical staff under the direction of the ordering professional to perform AUC consultations via CDSMs.

This proposal appropriately acknowledges responsible delegation of work without compromising the ordering professional's ultimate responsibility. **In addition, the FAH urges CMS to allow non-clinical staff under the direction of the ordering professional to perform AUC consultations via CDSMs.** The FAH believes an expansion of this policy to include non-clinical staff is also an appropriate delegation of work while maintaining the ordering professional's responsibility for the completion and reporting of the AUC consultation.

Reporting AUC Consultation Information

In the Proposed Rule, CMS proposes to require that AUC consultation information be reported on both the furnishing professional's claim and the facility's claim to receive payment for the service. While CMS characterizes this as a clarification of the previously finalized regulations to better reflect the statutory language, this is a significant change and one that is not necessitated by statute. This new requirement would require duplicate reporting of AUC consultation information for two parts (technical and professional) of the same imaging service. Such duplication is unnecessary when the necessary information will be on the ordering professional's claim – a claim document upon which it is significantly easier to record the requested information. The CMS-1500 form used by most ordering professionals is much more flexible than the UB-04 form used by hospital outpatient departments; for example, the UB-04 form does not contain space to report the ordering physician or the full AUC consultation information.

Given these concerns, the FAH believes that AUC consultation information should only be reported on the furnishing professional's claim, not the facility claim. At a minimum, CMS should consider an approach under which a facility would only need to confirm that the AUC consultation was completed as part of its workflow; the facility would not be required to include the detailed information required on the furnishing professional's claim form.

In addition to the burden of reporting the AUC consultation information, CMS's policy of denying payment to the furnishing professional and/or facility penalizes those providers 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, does not properly record that consultation, or does not communicate the results to the furnishing providers in a timely manner.** For example, the furnishing provider could note "Not Applicable" on the claim in the case of non-compliance by the ordering clinician. This mechanism is essential to ensure that beneficiaries receive necessary, timely services.

Finally, the FAH urges CMS to focus its efforts on interoperability improvements that could make communication between ordering professionals and furnishing providers and facilities less burdensome. In its current state, communication between the electronic health records (EHRs) of ordering professionals and furnishing professionals and facilities are not automated, forcing professionals and facilities to piece together expensive and time-consuming workarounds to meet the AUC consultation requirements. The mandated communications

required by this policy between ordering and furnishing professionals and facilities will remain complex until interoperability improvements are addressed.

Claims-Based Reporting

The FAH encourages CMS to further consider alternatives to the use of G-codes and modifiers to capture AUC consultation information on claims. As discussed in detail above, CMS has added a level of complexity and burden to the AUC program by requiring facilities to report AUC consultation information for the advanced imaging services they furnish. At a minimum, any plan to use G-Codes and modifiers should be acknowledged as temporary, and CMS should work to simplify the billing compliance required under the AUC program. **In addition, CMS could improve the consultation and reporting process for professionals by requiring that the CDSMs provide the necessary billing codes and modifiers to the professionals consulting the AUC. This would significantly ease the burden on providers of converting the AUC results for billing and reporting purposes.**

Significant Hardship Exceptions

The FAH welcomes efforts to simplify the terms of the significant hardship exceptions under the Proposed Rule. We suggest, however, that CMS further simplify the process and remove burdens for providers when a significant hardship arises – particularly for providers, such as hospitals, at the forefront in responding to disasters.

In the Proposed Rule, CMS states, “the AUC program is a real-time program with a need for real-time significant hardship exceptions.”⁴ CMS proposes that in the event of a significant hardship, like a natural disaster, the ordering professional attest to the significant hardship and support such attestation with documentation. The ordering professional then “would communicate that information, along with the AUC consultation information, to the furnishing professional with the order and it would be reflected on the furnishing professional’s and furnishing facility’s claim by appending a HCPCS modifier.”⁵

While the FAH appreciates CMS’s desire to assist professionals and facilities in the event of a disaster, the type of communication and coordination suggested in this proposal does not reflect how real-time providers would or could respond under such circumstances. **During a disaster, hospital and ordering professionals will appropriately focus on the care of the patient first, not on AUC consultation criteria or hardship exception codes. Thus, to the extent possible, significant hardship exceptions should be self-implementing and not require the ordering professional to respond with an exception code on a claim-by-claim basis.**

Implementation Timing

The FAH supports a measured approach to implementation that fully considers the AUC program’s impact on ordering, billing, and payment systems. While the FAH continues to

⁴ 83 Fed. Reg. 35870 (July 27, 2018).

⁵ *Id.*

support a voluntary period of implementation, the current period is too short. **The voluntary period should be followed by a longer test period that can take full measure of the system, including testing of the CDSM systems using real claims and test submissions similar to testing for the switch from ICD-9 to ICD-10. Additionally, while the FAH supported the delayed implementation of January 1, 2020 in the CY 2018 Final Rule, our members now believe that more time is needed to implement the program.** Specifically, while CMS is proposing to use G-codes and modifiers to capture AUC consultation information on claims, the Agency has provided no details on precisely how these will be used. The development of these codes and modifiers will take time and then professionals and facilities will need additional time to add them to their systems, develop workflows, and appropriately train clinical and billing staff. Sixteen months is simply not enough time in which to accomplish these complicated tasks.

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

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

Certification Requirements

One such proposal would require Medicaid eligible professionals to use technology certified to the 2015 Edition to demonstrate promoting interoperability in 2019. Similar to our comments in response to proposed changes to the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category, even large health systems will have difficulty completing timely upgrades to the 2015 Edition, let alone clinician groups and individual clinicians. While CMS notes in the Proposed Rule that, “As of the beginning of the first quarter of CY 2018, ONC confirmed that at least 66 percent of MIPS eligible clinicians have 2015 Edition CEHRT available based on previous Medicare and Medicaid EHR Incentive Programs attestation data,”⁶ the FAH again stresses that available is not the same as delivered and implemented.

eCOM Reporting Period for 2019

In the Proposed Rule, CMS proposes to require electronic Clinical quality measure (eCQM) reporting for the full calendar year, which will require that all Electronic Health Records (EHR) are upgraded to 2015 Edition CEHRT prior to the start of the 2019 calendar year. As the FAH has previously noted, the changes required to upgrade to 2015 Edition CEHRT can take up to 15-18 months to implement, making it difficult for some eligible professionals to meet a 90-day reporting period, let alone a full-year reporting requirement.

This proposal is also out of step with proposals for Medicare eligible clinicians participating in MIPS, as well as for eligible hospitals and Critical Access Hospitals (CAH). MIPS eligible clinicians can complete their reporting for the Quality performance category via the Web Interface option or using a registry, which do not require 2015 Edition CEHRT. And, as

⁶ 83 Fed. Reg. 35913 (July 27, 2018).

proposed, MIPS eligible clinicians would be subject to a 90-day reporting period for the Promoting Interoperability performance category, meaning they could choose a reporting period later in 2019 to allow them the necessary time to finish upgrading to 2015 Edition CEHRT. In addition, in the FY19 IPPS Final Rule, CMS stated “Hospitals are not required to have their EHRs certified to the 2015 Edition CEHRT standards for the full calendar year; certification should be obtained prior to the end of the eCQM reporting period to meet program requirements (for example, before December 31, 2019 for the CY 2019 reporting period).”⁷

In order to align the requirements for Medicare eligible clinicians with those of MIPS eligible clinicians and eligible hospitals and CAHs, the FAH recommends that CMS instead finalize either a 90-day reporting period or one calendar quarter of the clinician’s choice or indicate that eligible professionals are not required to have their EHR certified to the 2015 Edition CEHRT standards for the full calendar year as long as it is obtained prior to the end of the eCQM reporting period.

Measure Thresholds

CMS proposes to maintain the reporting thresholds for the View, Download, or Transmit measure and the Secure Electronic Messaging measure at 5 percent for 2019 and subsequent years due to feedback that these measures are significant barriers to demonstrating meaningful use, particularly for eligible clinicians in rural and underserved areas.

Again, this proposal is out of alignment with the requirements for MIPS eligible clinicians. In the Proposed Rule, CMS proposes to remove the View, Download, or Transmit measure for MIPS eligible clinicians, stating that the measure “has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.”⁸ CMS goes on to say that consistent stakeholder feedback indicates “ongoing concern with measures which require patient action for successful submission.”⁹ CMS also proposes to remove the Secure Messaging Measure for similarly-stated reasons.

If CMS finalizes the removal of these and other measures in the Coordination of Care Through Patient Engagement objective for MIPS eligible clinicians, CMS should also remove the measures from the Medicaid Promoting Interoperability Program. The burdens CMS notes with regard to MIPS eligible clinicians are applicable to Medicaid eligible clinicians as well – and likely even greater given that “Medicaid populations that are at the greatest risk have lower levels of internet access, internet literacy and health literacy than the general population.”¹⁰ In addition, it should not be burdensome to the states to remove measures from the Medicaid Promoting Interoperability program in their attestation portals.

⁷ 83 Fed. Reg. 41606 (August 17, 2018).

⁸ 83 Fed. Reg. 35929 (July 27, 2018).

⁹ *Id.*

¹⁰ *Id.* at 35873.

III.F. Medicare Shared Savings Program Quality Measures

Proposed changes to the CMS Web Interface and claims-based quality measure sets

CMS is proposing to reduce the total number of measures in the Medicare Shared Savings Program (MSSP) quality measure set with the intention to reduce the burden on Accountable Care Organizations (ACO) and their participating suppliers. The FAH commends CMS for its proposed application of the Meaningful Measures initiative to the MSSP. Reducing the number of quality measures addresses our previously expressed concerns about the burden of managing many measures.

The FAH supports CMS's proposed removal of the claims-based quality measures which have a high degree of redundancy with other existing measures:

- ACO-35-Skilled Nursing Facility 30-Day All-Cause Readmission Measures.
- ACO-36-All-Cause Unplanned Admissions for Patients with Diabetes.
- ACO-37-All-Cause Unplanned Admission for Patients with Heart Failure.

The FAH support CMS's proposed removal of the claims-based quality measure which results in low denominator rates under the MSSP and as such is not a valuable reflection of the beneficiaries cared for under the ACO:

- ACO-44-Use of Imaging Studies for Low Back Pain

The FAH supports CMS's proposal to align with changes made to the CMS Web Interface measures under the Quality Payment Program (QPP) and agree that it would not be beneficial to propose CMS Web interface measures for ACO quality reporting separately. Consistent with CMS's policy of adopting changes to the CMS Web Interface Measures through rulemaking for the QPP, the FAH supports removal of the requirement to report the following measures for MSSP starting with performance year 2019:

- ACO-12 (NQF #0097) Medication Reconciliation Post-Discharge.
- ACO-13 (NQF #0101) Falls: Screening for Future Fall Risk.
- ACO-15 (NQF #0043) Pneumonia Vaccination Status for Older Adults.
- ACO-16 (NQF #0421) Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up.
- ACO-41 (NQF #0055) Diabetes: Eye Exam.
- ACO-30 (NQF #0068) Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic.

Additionally, the FAH supports the proposal to add the following measure to the CMS Web Interface for purposes of the QPP pending the extension of the intended change to performance year 2020:

- ACO-47 (NQF #0101) Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

In evaluating operational readiness to implement the new measure, FAH members have discovered that their EHRs are unable to capture the data required for the new measure. **In order to provide time for clinicians, groups, and facilities to work with their EHR vendors to update their systems and train staff, the FAH recommends that CMS maintain the current Falls: Screening for Future Risk measure in 2019 and delay inclusion of the new measure until 2020.**

III.G. Physician Self-Referral Law

The FAH believes that the changes proposed by CMS will be helpful in addressing “actual or perceived differences” between current CMS regulations pertaining to the physician self-referral law (Stark Law) and Section 50404 of the *Bipartisan Budget Act of 2018* (BBA of 2018). Such clarifications will provide greater assurances for our members when navigating the complexities of the Stark Law. Specifically, the FAH commends the following CMS proposals:

Special Rule on Compensation Arrangements, 42 C.F.R. § 411.354(e)

The FAH supports CMS’s proposal to set forth in regulation its “collection of documents” guidance, as previously addressed in its CY 2016 PFS final rule with comment period. By establishing, in regulation, that the Stark Law writing requirement for certain compensation arrangement exceptions may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, the FAH believes CMS will eliminate potential ambiguity between the statute and its regulations.

Special Rule for Certain Arrangements Involving Temporary Noncompliance with Signature Requirements, 42 C.F.R. §411.353(g)

Current CMS regulations provide entities and physicians with flexibility, once every three years with respect to the same physician, to the extent certain compensation arrangements are not timely signed by the parties. The Bipartisan Budget Act (BBA) of 2018, while it codified this CMS “late signature” rule, also provided that it: (1) was not limited to specific compensation arrangement exceptions; and (2) entities were not limited in their use of the rule to only once every three years with respect to the same physician. The FAH supports CMS’ proposal to update the “late signature” regulations to mirror that of the BBA of 2018. We also appreciate CMS’s clarification that such revisions to the “late signature” rule became effective as of February 9, 2018, the effective date of the BBA of 2018.

Indefinite Holdover, 42 C.F.R. §411.357(a)(7), (b)(6), and (d)(1)(vii)

Lastly, the FAH agrees with CMS that the statutory changes made in the BBA of 2018 pertaining to the permissibility of “indefinite” holdovers for lease and personal service arrangements do not require regulatory revisions. As CMS stated, such provisions in the BBA of 2018 effectively mirror the existing regulatory language and do not change existing CMS rules permitting the indefinite holdover of lease and personal services arrangements, provided: (1) the arrangement has remained on the same terms as the previous arrangement; and (2) is within fair market value for the duration of the holdover period.

The FAH appreciates CMS’s proposals and effort to clarify certain aspects of the Stark Law. The FAH believes the proposed clarifying language will support our members’ continued compliance efforts.

III.H. CY2019 Updates to the Quality Payment Program

The *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) established a new framework for physician payment focused on value. The CMS QPP includes two payment pathways: the MIPS and the Alternative Payment Model (APM) Incentive program. CMS has implemented the QPP gradually in an effort to reduce burden, provide flexible participation options, and allow clinicians to spend less time on regulatory requirements and more time with patients. The transition period over the first two years of the program has been beneficial for our members as they strive to understand and implement the QPP.

FAH members are engaged in a variety of relationships with their physician partners so that both the MIPS and APM payment pathways have already had implications for our members, 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, as well as minimal return on investment to date.
- Independent physicians affiliated with FAH member facilities have sought expanded EHR access and functionality from those facilities to support MIPS performance data collection needed by those physicians.
- Some FAH members and their medical staffs have come together, or are considering partnerships, 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. Our comments focus on those issues our members continue to encounter in developing successful programs for FAH facilities and their clinicians.

General Comments

Continued Education Needed

As CMS has continued the implementation of the QPP, the FAH and its members appreciate the opportunities that have been afforded to participate in some of the educational efforts related to the program. FAH members have been able to provide substantive, timely, and responsive input to improve the CMS QPP website through product user-testing that enhances system and program accessibility, readability, and responsiveness, as well as providing feedback on the QPP website. These efforts have facilitated the development of a website that is more user friendly and intuitive to those accessing it from the participant side. We thank CMS for permitting FAH members to participate and ask that this level of cooperation continues in elements of the QPP that expand beyond the website alone. Our members are able to provide CMS with real life experience of the QPP and are willing to communicate these experiences and related suggestions to CMS throughout the program year.

Of note, although CMS has included an Improvement Activity (IA) that rewards physicians for participation in the website development (Participation in User Testing of the Quality Payment Program Website), this activity is of minimal utility to those who provide much of the actual feedback. As physicians do not typically use the website or submit attestations it would be beneficial if the IA was extended to include their representatives, as their delegated staff commonly perform these activities on their behalf.

Timely Feedback

The FAH commends CMS's efforts related to the development of the predictive tool used for the QPP. Eligible clinicians are able to access preliminary scoring within the MIPS program as data is submitted. The website has become much more user friendly, and the FAH encourages CMS to continue its development of communication tools that support such timely communication to eligible clinicians. Although the tool is immensely helpful for those participating in MIPS, the FAH suggests that CMS include a disclaimer for those clinicians participating in a MIPS APM that the same scoring model does not apply to them. As CMS continues to develop this tool, the FAH believes that a predictive total score model (minus cost) would be a very beneficial addition to those participating in MIPS.

Consistent Terminology

In previous comments, the FAH asked that CMS be sensitive to the challenge changes in terminology pose for clinicians before making additional changes. In the proposed rule, CMS has once again proposed terminology changes with the goal of making the terminology more precise. Specifically, CMS has proposed new terms to more accurately reflect how clinicians and vendors interact with MIPS- such as Collection type, Submitter type, and Submission type. This seems to have stemmed from possible confusion expressed to CMS over its use previously of "submission mechanism" to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted (e.g., eCQMs reported via EHR) and to the entities submitting such data (e.g., third party intermediaries on behalf of MIPS

eligible clinicians and groups). Although the FAH had not previously identified this as an issue to address, our members do not object to the proposed revisions. We do ask, however, that CMS strive to maintain consistency of terminology for the QPP to the greatest extent possible to facilitate understanding of the program by clinicians.

Merit-Based Incentive-Payment System

Low-Volume Threshold

For the third performance year, CMS has again proposed a low-volume threshold that would exclude a larger number of clinicians and groups from MIPS participation than in the first two years of the program. As with the 2018 performance year, the 2019 performance year will exclude individual clinicians and groups based on their Medicare Part B allowed charges and the number of Part B-enrolled Medicare beneficiaries to whom they provide services. Additionally, as of January 1, 2018 – and reflecting statutory changes in the *BBA of 2018* – the exclusionary criteria are based on “covered professional services” rather than “items and services.” Thus, for the 2019 performance period, CMS proposes to exclude individual clinicians or groups that have Medicare Part B allowed charges for covered professional services less than or equal to \$90,000 or that provide covered professional services for 200 or fewer Part B-enrolled Medicare beneficiaries. CMS also proposes to exclude clinicians or groups that provide 200 or fewer covered professional services to Part-B enrolled Medicare beneficiaries. CMS estimates that approximately 872,574 clinicians will be excluded from MIPS in the 2019 performance year (88,000 excluded because they are below all three low volume thresholds; 482,574 excluded unless they opt-in or submit as part of a group; and 302,000 clinicians excluded due to non-eligible specialty, newly enrolled, or QP status).¹¹

The FAH supported the flexibility the low-volume threshold provided to small practices in the 2018 performance period. However, the more expansive low-volume threshold has also impacted the clinicians remaining in MIPS. **With the exclusion of a significant number of eligible clinicians, the positive payment adjustments for those clinicians and groups who successfully participate in MIPS have been extremely low – far below the costs associated with participating in the program.** Even clinicians and groups that have achieved the high-performance threshold and were therefore eligible for the exceptional performance bonus received total positive payments well-below their expectations and costs expended related to the program.¹²

For the 2019 performance period, the statutory changes under the *BBA of 2018* (as well as the proposed Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration) will further reduce the number of MIPS-participating clinicians. CMS once again 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.¹³ This is the same estimate as the 2018 performance period/2020 payment year. Due to the budget neutrality

¹¹ 83 Fed. Reg. 35704, 36060 (July 27, 2018) (*see* Table 96).

¹² FAH members report that even exceptionally-performing clinicians received only a 1-2 percent payment adjustment for the 2017 performance year.

¹³ 83 Fed. Reg. 36066 (July 27, 2018) (*see* Table 98).

requirement of MIPS, the larger number of positive payment adjustment eligible clinicians will continue to have a very small pool of funds for this component of the program.

Ongoing low MIPS participation is detrimental to both health care improvement activities, as well as to those clinicians who are participating in the program. We are already beginning to see a two-tiered system among Medicare clinicians: those clinicians moving forward with MIPS; and those clinicians actively avoiding inclusion in MIPS or with only limited participation. **Thus, while the FAH supports CMS's efforts to offer flexibility to low-volume clinicians and groups during the initial years of MIPS, the FAH also encourages CMS to adjust the low-volume threshold to include more clinicians over time. Specifically, within the next year, CMS should decrease the low-volume threshold to that of the 2017 performance year (i.e., less than or equal to \$30,000 in Part B allowed charges; or 100 or fewer Part B-enrolled Medicare beneficiaries).**

Low-Volume Opt-In

Starting with the 2019 performance period, CMS is proposing to allow those clinicians below the low-volume threshold the opportunity to opt-into MIPS participation. Clinicians and groups would be permitted to opt-into MIPS if they meet or exceed one or two, but not all three, of the low-volume threshold determinations.

Even in their limited experience with the program thus far, FAH members have found that many clinicians excluded due to the low-volume threshold are prepared and would proactively choose to participate in MIPS if given the opportunity. Without the ability to participate in MIPS, these practices will remain subject to frozen payment updates in future 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. **The FAH supports CMS's proposal to allow clinicians and groups with the resources and interest to opt-into MIPS participation for a performance year and further encourages CMS to expand this policy. Specifically, CMS should permit clinicians and groups to opt-into MIPS participation even if they are below all three of the low-volume threshold parameters beginning in the 2019 performance year.**

Eligible Clinicians

CMS has proposed expanding the definition of MIPS eligible clinician over several payment years. Beginning with the 2021 MIPS payment year, CMS proposes expansion of the definition to include: physical therapist, occupational therapist, clinical social worker, and clinical psychologist; and a group that includes such clinicians. **The FAH supports this expansion as it will permit these additional clinicians to contribute to the success of MIPS participation and to realize the benefits of their efforts.** We also believe that reducing the promoting interoperability performance category to zero percent for the first two years is appropriate to facilitate the transition of these clinicians.

Additional clinician types in the definition of a MIPS eligible clinician beginning with the 2021 MIPS payment year are proposed to include: qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals. This proposal is based on an analysis that CMS will have to complete in the intervening time period to determine if each applicable eligible clinician type would have at least six MIPS quality measures available to them after CMS removes certain quality measures, as proposed. Even if those measures are finalized for removal, CMS believes that these additional clinician types will have sufficient measures available to them. **The FAH supports expanding the definition of eligible clinician, as it will contribute a larger eligible clinician pool.** We do question the utility of adding nurse midwives to the eligible clinician definition as they treat so few Medicare beneficiaries. It seems highly unlikely that these clinicians will exceed the low-volume threshold such that it may not be beneficial to expand the definition to include them.

While the FAH generally supports the inclusion of additional clinician types in the definition of a MIPS eligible clinician, we disagree with the requirement that all eligible clinicians or groups must submit hardship exceptions by December 31st of the performance year. Instead, the FAH recommends that CMS extend the hardship exceptions deadline until July 1 following the performance year (i.e., July 1, 2019 for the 2018 performance period) so that clinicians and groups can gather full-year data to effectively determine hardship eligibility.

Determination Periods

As the MIPS program continues to evolve and CMS learns from participants and processes the feedback received, some alterations in the administration of MIPS would make participation easier for clinicians. One such proposed change included in this rule is the alignment of the determination periods. Currently, MIPS uses various determination periods to identify certain MIPS eligible clinicians for consideration for certain applicable policies. CMS's proposal to consolidate several of these policies into a single MIPS determination period that would be used for purposes of the low-volume threshold and to identify MIPS eligible clinicians as non-patient facing, a small practice, hospital-based, and ASC-based, as applicable. The FAH supports this change and appreciates the added ease of administration this will offer.

Scoring Thresholds

CMS has also proposed updates to the scoring thresholds for both performance and exceptional performance. The FAH believes that those clinicians who have engaged in MIPS and put forth the effort and resources to participate fully should be recognized. **As such, the FAH supports the proposal to increase the performance threshold to 30 points. The FAH believes this proposal is a meaningful increase in the threshold, while still being achievable for participating clinicians.** This increase to the threshold level needed to achieve at least a neutral payment adjustment and avoid a negative payment adjustment will hopefully contribute to a larger pool of funds for positive payment adjustments under the required budget neutrality standard required by MIPS. More MIPS eligible clinicians below the performance threshold translates into an increased opportunity for MIPS eligible clinicians above the threshold to receive a greater percentage increase in their payment adjustment.

In the same vein, the increase to the threshold for the additional bonus for exceptional performance is a welcome change to those clinicians already performing at a high level under MIPS. These clinicians have invested time and resources to implement elements of MIPS and have already demonstrated success under the MIPS performance standards. Unfortunately, these clinicians have not received the anticipated recognition under the existing additional bonus. With the increase in the threshold to 80 points for the exceptional performance bonus, the pool of clinicians who achieve this level will likely be reduced. Although the FAH would support an increase to the pool of funds available for the exceptional performance bonus, we realize that CMS is limited by statutory constraints and support efforts to limit the number of clinicians among whom the pool of funds is divided. The FAH does encourage CMS, however, to create a steeper scale for awarding the exceptional performance bonus to better reward truly exceptional performers who achieve scores of 90 or greater.

Virtual Groups

The option to participate in MIPS as a virtual group was implemented in the 2018 performance year. FAH members have struggled to participate in this option for a number of reasons, including the late publication of the final rule last year and the complexity of the coordination needed for virtual group formation and oversight. Though CMS continues to offer the virtual group options, the FAH is curious to hear what others' experience has been with virtual groups to date. Due to our understood low level of participation in virtual groups, the FAH questions the utility of offering this option and whether it is realistic. To that end, we ask that CMS poll those who have participated in virtual groups and then provide possible best practices and tips for those considering formation of a virtual group.

Without the full picture of how virtual groups operate and succeed 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 and this will likely continue to impact participation levels. 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 continue 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.

Subgroups/Split TINs

In the Proposed Rule, CMS discusses making an option available to groups that would allow a portion of a group to report as a separate sub-group on measures and activities that are more applicable to the sub-group and be assessed and scored accordingly based on the performance of the sub-group. CMS stated that, in future rulemaking, it intends to explore the

feasibility of establishing group-related policies that would permit participation in MIPS at a sub-group level and create such functionality through a new identifier. **The FAH continues to support consideration of subgroups within Taxpayer Identification Numbers (TIN) for purposes of MIPS participation.**

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.**

In order to recognize those subgroups within TINs that work together to achieve goals under MIPS, the FAH believes a form of separate identification for these groups is appropriate. We support adding 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 2019 MIPS performance period and future performance periods to add more flexibility for clinicians and groups to be assessed in the context of the facilities at which they work. **As noted in previous comments, the FAH supports CMS's facility-based MIPS reporting accommodations for hospital-based clinicians and groups.** Allowing hospital-based clinicians and groups to utilize hospital quality measures, specifically those measures from the Hospital Value-Based Purchasing (VBP) Program, for the MIPS quality category simplifies participation in the quality category and 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 previously expressed support for the 75 percent threshold to determine whether a clinician or group is facility-based and supports CMS's proposal to include on-campus outpatient hospital (POS code 22) (in addition to inpatient hospital eligible (POS code 21) and emergency department (POS code 23) to the eligible settings for that determination. The 75 percent threshold as an appropriate measure in identifying those clinicians or groups who provide their covered professional services in a facility and contribute to the quality measures of the facility in which they practice. And the inclusion of the on-campus

outpatient hospital setting will appropriately capture observation services and increase the number of eligible facility-based clinicians. **The FAH also supports CMS’s proposal not only to automatically apply the facility-based scoring method to eligible clinicians, but also to allow those clinicians to submit their own MIPS data and be scored as an individual.** 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 enabling those clinicians or groups who are eligible for facility-based measurement to receive the benefit of such calculation without a formal opt-in process. While there are no submission requirements for individual clinicians in facility-based measurement, we support CMS’s proposal that a group must submit data in the improvement activities or promoting interoperability performance categories in order to be measured as a group under facility-based measurement. If a group does not submit improvement activities or promoting interoperability measures, then the individual clinicians would not be scored as a group. The FAH believes that the facility-based analysis will benefit clinicians whose activities contribute to the facility in which they work rather than a group or individual basis.

CMS also expressed interest in adding additional facility types for facility-based measurement in future rulemaking.¹⁴ The FAH recognizes there are scoring issues that would need to be resolved in order to implement an expansion to other facility types, such as post-acute care providers, and encourages CMS to collaborate with clinicians and providers to determine how best to address these concerns.

Quality Performance Category

The FAH appreciates that CMS continues to reward clinician improvement in the Proposed Rule. The FAH further encourages CMS to extend such a reward mechanism to those clinicians who consistently achieve high quality performance.

- *Multiple Submission Mechanisms*

Our members appreciate that CMS permits individual MIPS eligible clinicians and groups to submit data on measures and activities, as applicable, via multiple data submission mechanisms (or submission types as the proposed definitions would identify them) for a single performance category (specifically, the quality, improvement activities, or promoting interoperability performance category). Our understanding remains 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.

¹⁴ *Id.* at 35956. “We do not propose to add additional facility types for facility-based measurement in this proposed rule, but we are interested in potentially expanding to other settings in future rulemaking.”

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 (QCDRs), 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. We request that CMS confirm our continued 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 / Measure Suppression*

The FAH appreciates that CMS continues to implement a four-year timeline for topped out measures to provide adequate notification to afford clinicians time to update their EHR systems. However, the FAH is concerned about CMS's proposal to suppress a measure without rulemaking, if during the performance period a measure is significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns. Suppression of measures and then altering the possible scoring resulting from implementing such measures does not acknowledge the effort and resources required to implement these measures and track them via EHRs. 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.** Because updates to EHR systems are complex and take time to implement, mid performance year changes to these measures cannot be activated immediately, and clinicians should be provided adequate

time to receive this information to implement changes that will support successful participation in MIPS without the applicable measure.

- *Web Interface Measures*

In the Proposed Rule, CMS proposes to reduce the number of CMS Web Interface measures and to align them with those required as part of the Shared Savings Program measure set. **The FAH commends CMS for its proposed application of the Meaningful Measures initiative to the CMS Web Interface and the Shared Savings Program and believes this will decrease provider burden associated with managing numerous measures.** The FAH is concerned, however, about CMS's proposal to remove the current *Falls: Screening for Future Risk* measure and replace it with *Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls*. In evaluating their operational readiness to implement the new measure, FAH members have discovered that their EHRs are unable to capture the data required for the new measure. **In order to provide time for clinicians, groups, and facilities to work with their EHR vendors to update their systems and train staff, the FAH recommends that CMS maintain the current *Falls: Screening for Future Risk* measure in 2019 and delay implementation of the new *Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls* measure until 2020.**

Cost Performance Category

The cost performance category was weighted at zero percent for the 2017 performance year and at 10 percent for the 2018 performance period, and CMS proposes to weight it at 15 percent for the 2019 performance period. **The FAH supports CMS's implementation of the Bipartisan Budget Act of 2018 provision providing additional scoring flexibility for this category through 2021 and urges CMS to maintain the cost performance category weight at 10 percent for the 2019 performance period.** Congress appropriately realized that clinicians and the Agency are still adapting to MIPS and that the flexibility will provide CMS and clinicians with additional time to prepare for an increase in weighing of the cost category in future years.

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 has previously stated it 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 but has yet to actually provide the level of detail available in QRURs available to eligible clinicians.

In addition to maintaining the category weight at 10 percent, the FAH urges CMS not to move forward with its proposal to add eight episode-based measures. As clinicians

are still in a transition period for MIPS, it would be a dramatic change to adjust from two global measures to adding eight episode-based measures. This becomes even more difficult to implement due to the lack of information available to clinicians regarding the two current global measures, let alone the lack of information and details regarding the episode-based measures. If CMS wants to move toward episode-based measures, the FAH suggests that pick one high-impact episode to test, solicit feedback on, and analyze. This will allow CMS time to continue to refine patient attribution models and determine how bundles affect the cost performance category before moving forward with a significant and not-well-understood change. Once CMS has appropriately developed and tested that one episode-based measure, it can then develop path forward for future performance years.

Promoting Interoperability Performance Category

In the Proposed Rule, CMS proposes many modifications to the requirements that MIPS eligible clinicians must meet to earn a score in the Promoting Interoperability performance category. The FAH appreciates that the proposals address concerns raised by the field about the feasibility of operationalizing current requirements, including maintaining the minimum 90-day reporting period and the removal of Stage 3 measures that hold clinicians responsible for the technology-related actions of their patients, such as view, download, and transmit. CMS also proposes to revamp the scoring of objectives and measures for the Promoting Interoperability performance category to align with policies finalized in the FY19 IPPS Final Rule.

- *Scoring Methodology*

The FAH understands CMS's desire to simplify the program and sees value in aligning requirements for eligible hospitals and CAHs with those for eligible clinicians. The current base plus bonus scoring requirements are complicated and often confusing for clinicians. Additionally, because the proposed methodology would make it nearly impossible to score the maximum points for the category, it will force a greater distribution among clinicians and, hopefully, appropriately reward those clinicians who have put forth the greatest effort. However, the changes in the Proposed Rule collectively represent the third major restructuring of the program in as many years, effectively negate the substantial investments clinicians have made to date, and will substantially impact clinicians' scores in this category. Each change to the program means clinicians, groups, and other providers must make corresponding time-consuming and costly changes to their electronic records systems and, most importantly, to clinician workflows.¹⁵ Constant workflow changes distract from patient care and increase clinician frustration with the very technology on which this performance category is based. Additionally, CMS estimates the median score for clinicians participating in the Promoting Interoperability performance category at 73 points (out of a possible 100), which translates to

¹⁵ 83 Fed. Reg. 41647 (August 17, 2018). CMS acknowledged these concerns in the FY19 IPPS Final Rule, stating "We acknowledge that changes we finalize to objectives and measures require additional time and resources for EHR developers, vendors and health care providers to perform necessary updates to CEHRT and workflows, as well as training of staff. We are committed to reducing burden as well as being responsive to the concerns of stakeholders in the Promoting Interoperability Programs and consider many factors prior to proposing changes to the requirements."

approximately 18 points (out of a possible 25) for the category overall. While the FAH appreciates CMS's efforts to estimate median performance, this estimate is based on 2016 program data, uses proxies for the CY 2019 proposed measures, and is meaningfully higher than FAH members have calculated using their internal data. Even based on CMS's generous proxy calculations, clinicians who scored well on this category in previous years – including those with perfect scores – are looking at a significant drop in overall points for the category under the proposed methodology. **The FAH urges CMS to carefully balance the desire for alignment across the Promoting Interoperability programs and a greater distribution of clinicians' scores with clinicians' capacity to absorb additional changes to the structure of the program.**

Should CMS move forward with the changes outlined in the Proposed Rule for CY 2019, the comments and suggestions offered below are similar to those the FAH provided in response to similar proposals in the FY19 IPPS Proposed Rule and are intended to support the goals of advancing interoperability and increasing the use of health information technology (HIT).

- *Certification Requirements*

The Proposed Rule affirms that for the 2019 reporting year, MIPS eligible clinicians must use technology certified to the 2015 Edition in order to score in the Promoting Interoperability category. While the FAH understands CMS's desire to move to the 2015 Edition to advance interoperability, CMS is also proposing changes to the objectives and measures that would require numerous updates to current EHR systems. If the Proposed Rule is finalized, even providers and clinicians that have previously implemented the 2015 Edition will have limited time to work with vendors to make the significant modifications needed. These tight timelines are difficult for hospitals and large health systems, let alone for clinician practice groups and individual clinician offices. While CMS notes in the Proposed Rule that, "As of the beginning of the first quarter of CY 2018, ONC confirmed that at least 66 percent of MIPS eligible clinicians have 2015 Edition CEHRT available based on previous Medicare and Medicaid EHR Incentive Programs attestation data,"¹⁶ the FAH again stresses that available is not the same as delivered and implemented. Such changes can take up to 15-18 months to implement, making it difficult for some health care providers to meet even the 90-day reporting requirement.

- *Reporting Period for 2019*

The FAH thanks CMS for its proposal to maintain a minimum 90-day reporting period for the 2019 performance year. In light of the requirement to use the 2015 Edition only and the many other changes in meaningful use requirements proposed in the rule, we appreciate the flexibility provided in maintaining the 90-day reporting period for 2019. As noted above, the many changes in objectives and measures will require adjustments to EHR software that cannot be quickly implemented by vendors, so allowing clinicians to continue to choose a 90-day reporting period is essential.

¹⁶ 83 Fed. Reg. 35913 (July 27, 2018).

- *Proposed Program Measures*

The FAH thanks CMS for proposing to remove the View, Download, and Transmit and Patient-Generated Health Data measures. The removal of these measures is a relief to our members because clinicians should not be assessed on the extent to which patients choose to engage with their electronic health record, something over which clinicians have little to no control. The FAH appreciates CMS’s continued commitment to reevaluating measures on an ongoing basis to ensure they are achieving their intended outcome and offers additional recommendations regarding the proposed program measures below.

E-prescribing

The FAH supports continuation of the existing e-prescribing measure, although we request clarification that eligible clinicians continue to have the flexibility to include or exclude controlled substances from the measure calculation as long as they do so uniformly across patients and all available schedules and in accordance with applicable law. The FY19 IPPS Final Rule confirmed this flexibility for eligible hospitals and CAHs,¹⁷ and we want to ensure parity for eligible clinicians.

The Proposed Rule proposes to add two new measures involving opioids to this objective, first as voluntary measures with bonus points available in 2019, and then as mandatory measures in 2020. **The FAH supports initially introducing all new measures that CMS may propose to add as voluntary measures eligible for bonus points.** Regarding these specific measures, while the FAH supports the attention to measures involving opioids as an important topic area, **we do not believe that they are ready for implementation and instead recommend that CMS not finalize a mandatory implementation date for either of these measures until the specifications and operational aspects are more fully developed. Further, as discussed below, we recommend that the opioid treatment agreement measure not be implemented at all – not even voluntarily – at this time.**

One proposed new measure, “Query of Prescription Drug Monitoring Program (PDMP),” assesses the number of Schedule II opioid prescriptions for which CEHRT data are used to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. Our members cite current challenges associated with querying PDMPs, most notably the lack of integration of this feature into CEHRT. In addition, PDMPs maintain and exchange data differently, which poses problems when a provider must query multiple state PDMPs. **We urge CMS to work with the Office of the National Coordinator (ONC) to ensure interoperability between and among PDMPs, as this will improve the usefulness of PDMP queries to**

¹⁷ 83 Fed. Reg. 41648 (August 17, 2018). “Eligible hospitals and CAHs have the option to include or exclude controlled substances in the e-Prescribing measure denominator as long as they are treated uniformly across patients and all available schedules and in accordance with applicable law (80 FR 62834; 81 FR 77227).”

fight opioid addiction. Finally, the FAH urges CMS to confirm that the measure only requires queries of the PDMP at discharge.

The FAH does not believe the second proposed new measure, “Verify Opioid Treatment Agreement,” is appropriate for implementation – even voluntarily – in 2019. This measure would require eligible clinicians to identify whether the patient has an active signed opioid treatment agreement and incorporate it into the patient’s electronic medical record using CEHRT. While we understand and applaud the goal behind this proposal, the questions asked by CMS in the Proposed Rule underscore that no definition exists for such treatment agreements, and no processes exist for incorporating them into a medical record using CEHRT. As a result, clinicians will be burdened with attempting to locate and determine what qualifies as a treatment agreement, and the measure will produce information that is inconsistent and not useful to physicians in preventing and treating opioid addiction and abuse. Additionally, 2019 is too soon to implement this measure as none of the elements are clear, and vendors will need more than a few months to modify and incorporate it into CEHRT. **Instead, CMS could address the desire for this information by working with ONC and standards development organizations to establish a data class that would allow clinicians to exchange treatment agreement information as part of the Continuity of Care Document (CCD) or other routine data currently exchanged.** This would obviate the need for a separate action to track down and incorporate treatment agreements, reducing both clinician and patient burden. As to the latter, if clinicians are unable to locate and/or determine what constitutes a treatment agreement, they may resort to asking the patient to sign a new one, burdening the patient and leading to multiple, potentially conflicting documents.

Additionally, the FAH requests that CMS clarify that the term “electronically prescribed,” which is used in the denominators of the two proposed new measures, delineates prescriptions that are electronically documented within a patient’s medical record from those that are “electronically transmitted,” as referenced in the numerator of the current e-prescribing measure. We believe this distinction is appropriate and want to be sure this understanding is what CMS intends.

Health Information Exchange

The FAH generally supports the new combined measure proposed in this objective, “Support Electronic Referral Loops by Receiving and Incorporating Health Information,” as well as the exclusion that would apply to any clinician that could not implement the measure for the 2019 reporting period. This measure would build on and replace two measures previously adopted for Stage 3, and vendors will need sufficient time to make these features functional, and then clinicians will need time to implement them. Even if the medical record system is modified to provide eligible clinicians the ability to satisfy this measure, it would represent considerable effort for eligible clinicians to perform all the elements of reconciling medication, medication allergy, and current problem lists.

To address these operational concerns, the FAH suggests that CMS consider phasing in elements of this measure or scoring it in such a way that a clinician meeting some of the elements would receive points. For example, CMS could greatly reduce the provider burden associated with the proposed measure by requiring only that the medication, allergy, and problem information be in the record and available for clinician review. The audit logging capabilities of the EHR could be leveraged to show that a clinician reviewed the patient’s medications, allergies, and problem list rather than requiring that the provider formally “reconcile” the information by checking a box or providing a signature within the EHR. Alternatively, if CMS finalizes a requirement for a formal reconciliation action, the measure should initially focus only on medication and allergy reconciliation. If problem lists are later added to the measure, CMS should require only that these lists be incorporated into the record and available to the clinician rather than requiring problem list reconciliation.

The FAH also urges CMS to permit clinicians to be credited with providing shared access to the medical record in addition to sending and receiving information. The goal of the measure is for other clinicians and providers to view patient medical records, and this should include physicians located elsewhere across a health system or group who view the record without having to formally “send” and “receive” the information.

The FAH also seeks clarity on what information would increment in the numerator of the measure. Specifically, we request that CMS clarify that the reconciliation process can involve manual updates to the electronic record and not rely solely on information that is received electronically. This flexibility would be consistent with what CMS has indicated in past rulemaking and allow the receiving clinician to utilize both information received electronically and information received directly from the patient.

Provider to Patient Exchange

The FAH has deep concerns about the measure that would be renamed “Provide Patients Electronic Access to Their Health Information.” This measure requires eligible clinicians to ensure that the patient’s health information is available to them using any application of their choice that meets the API technical specifications. While we recognize the potential value of API functionality, it is new in the 2015 Edition, there are concerns about API readiness across stakeholders, and our members and their clinicians are only just beginning to test the API feature. Importantly, because applications are proprietary, this proposal would require clinicians to interact with a wide range of products with whom they have no relationship or agreement. Our members are very concerned about the security of APIs and various applications from multiple standpoints, including lack of security of patient data (e.g., smartphone applications are not generally subject to HIPAA), as well as making their electronic health records vulnerable to malware, hacking, and data mining. **Hospitals and clinicians must be empowered to protect their systems – and their patients’ HIPAA-covered protected health information – from unproven and potentially harmful applications and, as such,**

should not be considered “information blocking” for forgoing relationships with questionable applications.

In response to similar concerns expressed in response to the FY19 IPPS Proposed Rule, CMS stated, “It was not our intent to imply that eligible hospitals and CAHs and their technology suppliers would not be permitted to take reasonable steps to protect the privacy and security of their patients’ information. Such measures might include vetting application developers prior to allowing their applications to connect to the API functionality of the provider’s health IT.”¹⁸ While the FAH stands ready to work with CMS and the other agencies to help develop a trust framework for third party applications, it is unrealistic and burdensome to expect individual hospitals and/or clinicians to vet the security of third-party applications. It is also currently unrealistic and burdensome to expect individuals to understand the difference between HIPAA-covered entities, such as hospitals, and non-HIPAA-covered entities, such as most smartphone applications.

Thus, the FAH urges CMS to work with ONC to establish a trust framework for third party applications, including security standards, terms of use, and an overall validation process, as well as an agency-led (e.g., CMS, ONC, FTC) hotline for stakeholders to report inappropriate application security or data usage. In developing this framework, it is imperative that third party application developers be held accountable for any inappropriate use of patients’ health information and liable in the event of breach of such information. CMS, ONC, OCR, and FTC should also undertake a joint campaign to educate patients about the differences between HIPAA and non-HIPAA-covered entities, and how that may affect the ways in which their data is used, stored, and shared with others.

Given these uncertainties, the FAH recommends that, until there is more robust infrastructure to vet applications – or patients can access their data under the Draft Trusted Exchange Framework and Common Agreement (TEFCA) – CMS should allow clinicians to begin with an application of their choice instead of being required to interact with any application a patient may choose. This recommendation carefully balances patient access to data with clinicians’ need to protect their systems and patient health information. Additionally, as mentioned above, the FAH believes the infrastructure envisioned under the TEFCA could provide patients with the access to their medical records that CMS envisions. Specifically, clinicians could direct patients seeking their electronic health information to the Qualified Health Information Network (HIN) and ensure HINs are appropriately situated to respond to and fulfill these patient inquiries as a condition of becoming a Qualified HIN.

Public Health and Clinical Data Exchange

The FAH supports the proposal to reduce the number of public health measures on which eligible clinicians must report in the Public Health and Clinical Data Exchange objective. The FAH also appreciates the proposal to allow clinicians to report on any two

¹⁸ *Id.* at 41663.

measures in the category, and the same finalized policy in the FY19 IPPS Final Rule.¹⁹ As noted in the FAH’s comments regarding the FY19 IPPS Proposed Rule, syndromic surveillance is not available in some states, including California, and thus is not appropriate as a mandatory measure. In addition, we recommend that clinicians be eligible for bonus points (e.g., five points) for reporting on a third measure in this objective.

Participating in public health data exchange can be burdensome to multistate health systems and their affiliated clinicians because there is a lack of uniformity across states in formats and other features. Instituting uniformity across states would reduce these costs and administrative burden. In addition, as the Administration moves forward with developing the Draft TEFCA, CMS might consider using that infrastructure to enable Qualified HINs to report these data to states rather than individual providers and clinicians. And to help support development of APIs, CMS should offer bonus points to eligible clinicians and groups willing to participate in emerging standards pilots for API-based public health reporting.

In addition, the FAH would like to CMS to confirm that the proposed changes to this objective and associated measures do not prevent MIPS eligible clinicians from public health reporting through specialized registries, which is permitted under the CY18 QPP Final Rule. In that Final Rule, CMS stated, “In the proposed rule, we noted that we have split the Specialized Registry Reporting Measure that we adopted under the 2017 Advancing Care Information Transition Objectives and Measures into two separate measures, Public Health Registry Reporting and Clinical Data Registry Reporting, to better define the registries available for reporting. We proposed to allow MIPS eligible clinicians and groups to continue to count active engagement in electronic public health reporting with specialized registries. We proposed to allow these registries to be counted for purposes of reporting the Public Health Registry Reporting Measure or the Clinical Data Registry Reporting Measure beginning with the 2018 performance period.”²⁰ In the CY18 QPP Proposed Rule, CMS stated these proposals were meant “to continue to encourage those MIPS eligible clinicians who have already started down the path of reporting to a specialized registry to continue to engage in public health and clinical data registry reporting.”²¹ **As the proposed changes in the CY19 Physician Fee Schedule Proposed Rule do not specifically address this issue, the FAH reads the CY18 QPP Final Rule policy of permitting MIPS eligible clinicians and groups to report with specialized registries as still in effect. The FAH urges CMS to confirm this understanding the Final Rule.**

¹⁹ *Id.* at 41640. “As stated in section VIII.6.e. of the preamble of this final rule, we believe the Syndromic Surveillance Reporting measure should not be required as we understand some hospitals and local jurisdictions are not able to send and receive syndromic surveillance files. In addition, allowing eligible hospitals and CAHs to report on any two measures of their choice promotes flexibility in reporting and allows them to focus on the public health measures that are most relevant to them and their patient populations.”

²⁰ 82 Fed. Reg. 53674 (November 16, 2017).

²¹ 82 Fed. Reg. 30069-70 (June 30, 2017).

- *Physician Compare Reporting*

The FAH supports the proposal in the Proposed Rule to report clinician performance on the Promoting Interoperability category as “successful” on the Physician Compare website rather than reporting that performance as either “successful” or “high.”

- *Promoting Interoperability Program Future Direction*

The FAH appreciates CMS’s commitment to continually reevaluate the Promoting Interoperability performance category to reduce burden, advance interoperability, and promote innovative uses of HIT. As discussed above, the FAH is concerned with the continual changes to the Promoting Interoperability performance category and the corresponding costs, time, and effects on patient care. However, the FAH believes there are opportunities to improve the category and achieve operational efficiencies in the future, such as through permitting measures or activities to count across multiple MIPS performance categories. For example, the documentation of medications Quality category measure requires similar activities to the medication reconciliation Promoting Interoperability category measure. We encourage CMS to work with clinicians and providers to develop these opportunities.

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

The FAH supports CMS's proposal to continue bonuses for complex patients. Although CMS has proposed a bonus for small practices for the next performance year, the FAH encourages CMS to add this bonus to the overall score as it has in the past, rather than moving it to the quality performance category. The FAH also continues to support the development of a bonus for 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 providing bonuses in the MIPS final score calculation address such factors and circumstances to a certain degree.

- *Complex Patient Bonus*

The FAH supports a complex patient bonus to support eligible clinicians who take on patients with more intricate needs and ensure that caring for these patients does not negatively affect their overall final MIPS score. CMS proposes to continue the complex patient bonus for another year to support MIPS eligible clinicians who treat patients with risk factors, as well as to maintain consistency with the 2020 MIPS payment year and minimize confusion. The FAH agrees that the complex patient bonus is appropriate and beneficial and should be continued.

- *Bonus for Small Practices*

The FAH appreciates that CMS has acknowledged the challenges unique to clinicians in small group practices by continuing to provide a bonus for such practices. However, the FAH believes that it would be a mistake to move this bonus from the overall MIPS score to the quality performance category. If CMS implements this change, the impact will be a severe watering down of the positive effect intended by the small practice bonus. Adding three points to the quality performance category is really only worth 2.5 overall MIPS overall score points for a clinician whose quality category is weighted at 50 percent. **Rather, the FAH strongly encourages CMS to retain the policy of the first two years of the program and add five points to the overall MIPS score in recognitions of the cost and resource limitations small practices face.** In the alternative, the FAH suggests that, if CMS moves forward with only applying the bonus to the quality performance category, the bonus should be increased to six points. 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*

Although CMS offers support to small and rural practices by offering free and customized resources available within local communities, including direct, one-on-one support from the Small, Underserved, and Rural Support Initiative along with other no-cost technical assistance, the FAH believes more can be done to support the rural providers. **For many of the same reasons the FAH supports a bonus for small practices, the FAH once again 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.

Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

The FAH urges CMS to proceed cautiously in permitting MIPS eligible clinicians to use their participation in Medicare Advantage (MA) – without corresponding participation in a Medicare Option Advanced APM – toward exclusion from MIPS reporting and payment adjustment requirements. Such an approach is far outside the legislative text of *The Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), which specifically included MA under the Advanced Alternative Payment Model (Advanced APM) All-Payer Combination Option beginning in performance year 2019. CMS expressly noted this statutory construction in the CY 2018 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.”²²

The FAH is pleased to see that CMS agrees with our reading of the statute and is no longer considering payment amounts or patient counts under MA to be included in QP determination calculations under the Medicare Option. However, the FAH remains concerned that the MAQI Demonstration could further reduce the number of clinicians in the MIPS program. Under the statute, only those clinicians meeting the low-volume threshold or those meeting the QP threshold should be excluded from MIPS participation. And, as the statute, clearly states, even clinicians participating in MA must meet the criteria – including the Medicare Option criteria – of the All-Payer Combination Option starting with the corresponding 2019 performance period.

Thus, while CMS might have flexibility through its waiver and demonstration authorities, the FAH cautions against use of that flexibility, if it exists, in the face of such a clear statutory directive from Congress. MA plans have developed a myriad of contractual models and payment methods that can distribute a wide range of risk to providers and clinicians – from minimal to substantial. With each of these models, there is little corresponding evidence available to providers, beneficiaries, or even CMS as to how care delivery and outcomes are driven by each model’s level of risk and incentives. Should CMS move forward with permitting clinicians to use their MA participation to avoid participation in the Medicare Option and MIPS, the variety of incentives and relationships between plans, providers, and members under MA will make it difficult to differentiate between those health care providers and clinicians taking on sufficient levels of risk from those taking on minimal amounts of risk more substantively similar to a traditional fee-for-service like paradigm. The FAH believes Congress recognized these difficulties, and thus created a statutory direction under which MA would be treated the same as Other Payer Advanced APMs. **Given limited CMMI resources and the clear statutory directive from Congress, the FAH recommends that CMMI apply its resources to developing Advanced APMs under Medicare fee-for-service.**

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 not increasing the financial risk parameters through performance year 2024. However, the FAH remains concerned about several 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 penalty provisions.

²² 82 Fed. Reg. 30190 (June 30, 2017) and 81 Fed. Reg. 77473 (November 4, 2016).

Advanced APM Model Criteria

The FAH has previously expressed concerns about the limited number of models that meet the Advanced APM designation and the limited number of participating clinicians who can reach Qualifying APM Participant (QP) status. CMS estimates that only 160,000-215,000 clinicians will meet QP status for the 2021 payment year.²³ This is due to several factors, including the significant upfront investments required to participate in these arrangements, the significant financial risk requirements, and the patient count and payment amount threshold requirements. **The FAH appreciates that some of these requirements are driven by the enabling statute but encourages CMS to use its discretionary authority wherever possible to boost participation in Advanced APMs.** For example, the FAH appreciates that CMS exercised its authority to revise the Advanced APM definitions to allow more APMs to be designated as Advanced APMs, such as the Bundled Payments for Care Improvement Advanced (BPCI Advanced) and Comprehensive Care for Joint Replacement (CJR) models.

- *CEHRT Usage*

One of the criteria models must meet to be an Advanced APM includes the use of CEHRT by model participants. Specifically, Advanced APM Entities must require at least 50 percent of eligible clinicians to use CEHRT to document and communicate clinical care. In the Proposed Rule, CMS proposes to increase that threshold to 75 percent starting in performance year 2019 for the Medicare Option Advanced APMs and in performance year 2020 for the Other Payer Advanced APMs. The FAH disagrees with the proposed increase, as it will be an additional barrier to Advanced APM participation for clinicians and groups. The FAH appreciates that CMS wants to advance interoperability and the use of health information technology (HIT), but this must be balanced against CMS's goal of encouraging clinicians to move from MIPS to Advanced APMs. **Given that the number of clinicians meeting QP status is already quite low, this change would only further reduce the chances of meeting the threshold requirements.** In addition, as noted in response to the proposed changes to the MIPS Promoting Interoperability performance category, hospitals and health systems, clinician groups, and individual clinicians are still struggling to upgrade to 2015 Edition CEHRT. **The FAH recommends that CMS maintain the 50 percent threshold, particularly while these upgrades are ongoing, to encourage Advanced APM participation.**

CMS also proposes that, for Other Payer Advanced APMs, clinicians or payers must submit evidence of sufficient CEHRT usage when that usage is not explicitly required in the payment arrangement materials that must be submitted as part of the Advanced APM determination process. The FAH agrees with CMS that CEHRT usage is not always explicitly required in payment arrangement materials and appreciates the flexibility to offer other evidence of such usage. However, our members would appreciate further guidance on the form and content of the evidence, such as examples, to ensure their Advanced APM determinations are not delayed and/or rejected for insufficient evidence.

²³ 83 Fed. Reg. 36058 (July 27, 2018).

- *Financial Risk Definitions*

The FAH welcomes CMS’s proposal not to raise the revenue-based nominal risk threshold through performance period 2024, as this will provide some stability for clinicians and groups participating in – or entering into – APMs. As noted in previous comments, however, the FAH remains concerned that the financial risk criterion for Advanced APM designation is excessively strict and sharply limits eligibility. 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. With the Advanced APM bonus only available for six years (2019-2024), there is a narrow window for CMS to use the MACRA-established incentive payments to encourage providers to move into these models. **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 also noted in 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. CMS recognized the burden imposed by such costs in its Advanced Payment ACO Model under the MSSP. Although that model is no longer active, CMS should use the lessons learned from it to reliably measure upfront costs in other APM models. **The FAH again strongly recommends that CMS explore options to capture upfront APM infrastructure costs in its risk framework for APMs.**

In addition, CMS seeks comment on potentially raising the revenue-based nominal risk threshold and the expenditure-based nominal risk standard in performance year 2025. **Given the continuing concerns regarding the financial risk requirements for Advanced APMs, the FAH urges CMS not to finalize any proposals related to performance year 2025 at this time.**

Other-Payer Advanced APM Multi-Year Determinations

CMS proposes to revise the process for determining whether Other Payer models meet the Advanced APM criteria. Starting with performance year 2020, CMS proposes that, once it makes an initial determination that an Other Payer model meets the Advanced APM criteria, only Advanced APM criteria-related changes would need to be submitted annually. If there are no submitted changes, CMS would extend the Advanced APM determination for up to five years or until the end of the contracted arrangement, whichever comes first. The FAH urges CMS to finalize this proposal to reduce the burden associated with the current information submission process and better align the determination process with the multi-year contracts employed by these models.

QP Participant Determinations

The FAH appreciates CMS's continuation of the three "snapshot" periods for Medicare QP participant determinations for each performance year (March 31st, June 30th, and August 31st). **In addition, the FAH supports CMS's proposal to make QP determinations at the TIN level in addition to the current individual clinician and APM Entity levels and to base QP determinations on the higher of these calculations.** This will simplify the determination process for both CMS and participating clinicians and entities.

The FAH is deeply troubled, however, by the increases in the patient count and payment amount thresholds clinicians must meet in order to meet QP status. For the 2019 and 2020 payment years, the thresholds for the Medicare Option are 20 percent for the patient count threshold and 25 percent for the payment amount threshold. For the 2021 and 2022 payment years, the thresholds for the Medicare Option increase to 35 percent for patient count and 50 percent for payment amount. Starting with the 2023 payment year, the Medicare Option thresholds increase to 50 percent for patient count and 75 percent for payment amount. For the All-Payer Combination Option, the thresholds for the 2021 and 2022 payment years are 35 percent (with a 20 percent Medicare Option minimum) for the patient amount threshold and 50 percent (with a 25 percent Medicare Option minimum) for the payment amount threshold.²⁴ Starting with the 2023 payment year, the All-Payer thresholds increase to 50 percent (with a 20 percent Medicare Option minimum) for patient count and 75 percent (with a 25 percent Medicare Option minimum) for payment amount.

The FAH strongly disagrees with these increases, as even current QPs will have trouble maintaining that status as the patient count and payment amount thresholds increase over time. The FAH recognizes the statutory construction of these thresholds and encourages CMS to use the full extent of its statutory discretion and waiver authority to address these concerns.

Post-Acute Care

As noted in previous comments, the FAH encourages CMS to consider the provision of services by post-acute care (PAC) providers and how those providers can participate in the development of APMs. **The FAH has recommended in the past and recommends here that CMS develop and test a voluntary CMMI bundling program that includes inpatient rehabilitation facilities (IRFs).** This bundling program would not be derived from the IRF prospective payment system (PPS), but instead would permit IRFs to assume the risk of caring for certain patients over a defined period of time and with sufficient regulatory relief, such as rescinding the 60 Percent Rule and 3-Hour Therapy Rule.

Regulatory relief under the 60 Percent Rule and 3-Hour Rule is 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

²⁴ *Id.* at 35994. *See* Table 57.

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 distinct 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.

Need for APM Regulatory Waiver and Exception/Safe-Harbor

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 (AKS), and certain civil monetary penalties (CMPs) stand as an impediment. A legal safe zone is needed that cuts across these fraud and abuse laws and allows full APM participation.

The FAH urges CMS to put aside its current case-specific approach to bundled payment fraud and abuse waivers and work with the Office of Inspector General (OIG) to develop a single, overarching waiver for CMS-led APM arrangements applicable to the Stark Law, AKS, and relevant CMPs. Additionally, the FAH urges CMS and OIG to implement a Stark Law exception and AKS safe harbor to provide parity to non-CMS-led APMs, such as commercial payer arrangements. This would encourage financial relationships that incentivize collaboration in delivering health care, while rewarding efficiencies and improving care. The FAH submitted comments to CMS specifically addressing these concerns on August 24, 2018 in response to the Request for Information Regarding the Physician Self-Referral Law (issued on June 25, 2018). We encourage CMS to consider those comments in the continued implementation and development of the QPP.

IV.A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

CMS is seeking feedback in the Proposed Rule on how it could advance the electronic exchange of information in support of care transitions among providers using: Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care Facilities. Specifically, CMS is considering revising these to require providers to electronically perform a variety of activities, including: transfer of medically necessary information from a hospital to another facility upon a patient transfer or discharge; transfer of discharge information from a hospital to a community provider, if possible; and providing patients access to certain information via electronic means, if requested, including directing that information to a third-party application.

The FAH has long supported efforts to achieve comprehensive interoperability and data liquidity – the free flow of meaningful, actionable information that supports and enhances patient care within and across settings. As the largest purchasers and consumers of HIT, hospitals and health systems – and their employed and affiliated clinicians – have a vested interest in data flow to improve patient care, workflow efficiencies and clinician satisfaction, population health and payment models, and research. **However, the FAH does not support the proposed revision of the CoPs, CfCs, and RfPs related to interoperability and the exchange of health information.** The current ecosystem is simply not mature enough to facilitate the movement of this information, as evidenced by the obstacles that currently prevent seamless information exchange and would make it exceedingly difficult for hospitals and other providers to comply with the requirements. The FAH appreciates CMS’s acknowledgement of this in the Proposed Rule, noting that, “While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.”²⁵

These obstacles are amplified in the patient discharge and transfer arenas because post-acute providers and behavioral health providers were ineligible for the EHR Incentive Programs under the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, which have been instrumental in enabling acute care hospitals to achieve so much of the potential that EHRs specifically and HIT generally offer. As such, post-acute providers and behavioral health providers have not been able to adopt HIT to the extent of hospitals and CAHs. Thus, were CMS to move forward with revisions to the CoPs, CfCs, and RfPs, hospitals and CAHs would be unable to meet these requirements because of the lack of providers available to accept that information electronically. And, for post-acute care and behavioral health providers, it would be unfair, and tantamount to an unfunded mandate, to require that these providers adopt and maintain expensive EHRs and other HIT through CoPs, CfCs, and RfPs when they receive no corresponding financial assistance to do so.

²⁵ 83 Fed. Reg. 36006-36007 (July 27, 2018).

The lack of providers in a position to accept this information electronically raises questions regarding how providers would be deemed in compliance with such requirements. How would providers prove during a survey process that they are “interoperable?” Would they need to send information to other providers electronically? Ensure those providers ultimately received the information? Receive information from other providers? And/or receive information and incorporate it into an actionable format in the EHR? These are just a sampling of the multitude of questions that would arise in determining compliance – and many of them would hinge not on the individual provider’s action, but the actions of HIT vendors and other providers over whom the hospital and clinicians have virtually no control. For example, a hospital may be able to send the information electronically, but the receiving hospital or post-acute care provider is unable to accept it. Or, a provider may be unable to incorporate the information it receives into its EHR in a format acceptable to the surveyors due to the limitations of the EHR itself, for example, the misaligned standards, semantics, and specifications that currently hinder data flow and useable data across vendor platforms. Additionally, the CoPs, CfCs, and RfPs are infrequently updated relative to the annual Medicare payment rules and rules related to the Promoting Interoperability Programs. As such, it is possible that the proposed revisions to these requirements could quickly become outdated and hinder future HIT-related innovation, in many cases even before they are finalized.

Failure to comply with CoPs, CfCs, or RfPs, carries serious penalties for health care providers, including the potential inability to treat Medicare and Medicaid beneficiaries. Such penalties also have profound consequences for patients as well, as they may lose the ability to receive treatment in their communities. **Imposing these penalties on providers and patients in the face of an immature health information ecosystem – and the significant implementation issues raised above – would only restrict rather than facilitate patients’ access to care and information exchange.**

The FAH appreciates CMS’s focus on interoperability and shares CMS’s frustrations regarding the lack of actionable, accessible electronic information, as well as the desire to accelerate an interoperable health system that improves the safety and quality of care, enables innovations, and achieves the best possible outcomes for patients. **To continue to address these concerns, the FAH recommends that CMS permit the numerous public and private initiatives in this area, some of which are nascent, time to mature and advance our shared goals. CMS and ONC should also continue to work to improve the capabilities of EHRs and other HIT, including: simplifying information exchange across HIT vendor platforms; identifying patients across vendor platforms; and simplifying clinician workflow related to sending, receiving, incorporating, and utilizing information.** As CMS states in the Proposed Rule, there are “several important initiatives that will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information.”²⁶ These initiatives include the Trusted Exchange Framework and Common Agreement (TEFCA), which is still in draft form; the revamped and refocused Promoting Interoperability Program, which was

²⁶ *Id.* at 36007.

recently proposed; the Prevention of Information Blocking Attestation;²⁷ and the MyHealthEData initiative, which was announced earlier this year, among others. There are also private-sector led efforts underway to advance other components of the interoperability puzzle, such as plug-and-play interoperability among devices and systems.²⁸ The FAH provided feedback on these and other initiatives and looks forward to continuing to work with CMS, ONC, and other private-sector partners to realize the promise of HIT to improve our nation's health care system.

IV.B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

The FAH is supportive of efforts to ensure that consumers have clear, accessible, and actionable information concerning their cost-sharing obligations, but is concerned that CMS is considering avenues for providing this information that focus exclusively on hospitals when payers—insurers, group health plans, Medicare, Medicare Advantage organizations, and others—are best suited to provide actionable coverage and cost-sharing information for all providers and suppliers involved in an episode of care.

CMS should give careful consideration to the best method and data needed to provide patients with the information required to understand potential cost-sharing obligations. Requiring hospitals to disclose competitively sensitive information, including average or median contracted rates or discounts, would not enable patients to better understand their potential financial liability for services or to accurately compare their likely cost-sharing exposure between hospitals. A patient's cost-sharing obligation is determined based on benefits and coverage under her plan, the plan's provider network and cost-sharing structure, and the plan's specific negotiated rates with each provider and supplier involved in an episode of care. As a result, average or median contracted rates or discounts do not help patients to accurately compare their potential financial liability for an episode of care. In fact, by consulting with her plan, a patient might discover that her actual projected financial liability for an episode of care would be lower at a hospital with "higher" average or median contracted rates. Meanwhile, disclosing information concerning contracted rates or discounts would ultimately be counterproductive to a competitive marketplace. Economists and antitrust enforcers have recognized that the disclosure of negotiated provider network rates could lead to inflation of prices by discouraging private negotiations that can result in lower prices for some buyers. In fact, the Department of Justice and Federal Trade Commission's antitrust safety zone for pricing surveys requires that the source data be at least three months old. Department of Justice and Federal Trade Commission, Statement on Provider Participation in Exchanges of Price and Cost Information (Aug. 1996).

²⁷ Eligible hospitals, eligible professionals, and CAHs participating in the Promoting Interoperability Programs must attest to the Prevention of Information Blocking Attestation. *The Medicare and Medicaid EHR Incentive Programs Prevention of Information Blocking Attestation Fact Sheet*, October 2017, available at:

https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR_InformationBlockingFact-Sheet20171106.pdf.

²⁸ Center for Medical Interoperability, *Fact Sheet*, available at: <http://medicalinteroperability.org/wp-content/uploads/2017/01/CMI-Overview-Jan2017.pdf>.

Payers, on the other hand, can provide clear, accurate and actionable cost-sharing information to members and beneficiaries without jeopardizing price-based competition among providers. Payers are uniquely qualified to provide patients with precise information concerning any limitations on their coverage, the scope of patient cost-sharing obligations (including out-of-pocket spending limits, deductibles, coinsurances, and any reference-based pricing strategies used by the plan), any network tiering used by the plan, and the applicable allowed amount for each provider or supplier involved in an episode of care. CMS's Office of the Actuary estimates that approximately 90 percent of individuals will have health coverage in 2019 (an uninsured rate of 9.6 percent). 83 Fed. Reg. at 20,392. Thus, for the vast majority of patients, payers are in the best position to provide the most relevant information. Payers understand the full range of benefits under a patient's applicable health coverage and cost-sharing obligations and, because an episode of care typically involves multiple providers and suppliers, the payer is the only entity that is capable of providing a patient with an accurate and actionable estimate of their potential financial exposure for the entire episode of care.²⁹ Seeking this information from each provider and supplier involved in an episode of care is not only inefficient, but it is also error-prone because the cost-sharing picture is fragmented among the providers and suppliers and may not accurately reflect the details of the patient's coverage.

With regard to the small minority of patients that are uninsured, hospitals and other providers may be the preferred source of pricing information, but it is the FAH's belief that uninsured patients are best served by receiving individualized information through a provider's financial counselors. Most uninsured patients receive substantially discounted or even free care under a hospital's charity care policy or receive other generous discounts that limit their financial obligations. Moreover, a sizeable number of uninsured patients are actually eligible for free or subsidized health coverage. By meeting with a hospital's financial counselor, these individuals can access individualized and actionable pricing information and make informed choices concerning their medical care. Overemphasizing a hospital's typical or average rates, discounts, or charges, on the other hand, may dissuade individuals that may be entitled to free or low-cost care from speaking with a financial counselor and, in some circumstances, may cause an individual to forego needed care.

For these reasons, the FAH believes requiring hospitals to publish median contracted rates or discounts or to provide an estimate of the patient's out-of-pocket costs before furnishing a service is not an appropriate avenue to address concerns about transparency. Hospitals will always provide patients with assistance in understanding their obligations and with available programs and policies such as eligibility for charity care and discounts. But as stated earlier, it is far more appropriate for covered individuals to receive cost-sharing estimates from the applicable payer, whereas uninsured individuals should consult with the provider's financial counselor to obtain an individualized assessment of her eligibility for charity care, discounts, or free or subsidized health coverage. Along similar lines, the FAH believes that information concerning "what Medicare pays" for a service is not a useful reference point and does not help

²⁹ This is also true with regard to Medigap coverage. CMS asked who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care. 88 Fed. Reg. at 20549. Responsibility to provide this information should fall on the Medigap plan itself, which is the entity in a position to provide enrollees with accurate and actionable information regarding their cost-sharing obligations for an entire episode of care.

patients to understand their potential financial liability. Medicare rates are not negotiated in arm's-length transactions and provide little to no information about the rates negotiated with or established by other payers, let alone the cost-sharing obligation borne by the patient. In addition, the provision of Medicare-specific pricing information by providers would likely create confusion among patients who are either not enrolled in Medicare or who receive their Medicare benefits through a Medicare Advantage plan that pays a different, negotiated rate. However, should CMS desire for patients to have that information, it is in the best position to provide it.

The FAH also opposes any effort to expand section 2718(e) of the Public Health Service Act (PHSA) to require disclosure of median rates, discounts, or competitively sensitive information. Section 2718(e) requires each hospital to establish, update, and make public “a list of the hospital’s standard *charges* for items and services provided by the hospital” (emphasis added). Critically, Congress chose to use the word “charges” in lieu of “price,” “rate,” “cost,” or any other similar term. CMS should not ignore Congress’ clear intent to address dissemination of charge information by redefining “standard charges” as rate information, discounts, or other pricing information that is simply unrelated to charges.

Finally, the FAH opposes the creation of a federal enforcement mechanism for section 2718(e) of the Public Health Service Act. Based on the plain text of the Public Health Service Act, Congress declined to provide *any* penalties or enforcement authority with regard to section 2718(e). In addition, the enforcement provisions for Part A of title XXVII of the Public Health Service Act, which apply only to health insurers, emphasize the overriding importance of state-level enforcement of insurance market requirements. States are far better suited than CMS to experiment with price transparency measures and to enforce these measures as appropriate under their general police powers. Meanwhile, Congress specifically did not grant CMS statutory authority to enforce the requirement that hospitals publish their standard charges.

The FAH supports CMS’s goal of ensuring that patients have access to clear, accurate, and actionable cost-sharing information, and urges CMS to pursue this goal through payer-side regulations. Hospitals are simply not the appropriate entity to be tasked with interpreting and explaining a patient’s cost-sharing obligations under a particular plan. Payers, on the other hand, are in a position to offer this important information. As such, the publication of average or median hospital rates or discounts as some sort of proxy for an individual’s cost-sharing obligations would be misleading to individual consumers, contrary to Congress’s express direction that hospitals publish information on standard “charges,” and counterproductive to a competitive marketplace for hospital services.

Related to ensuring patients have access to clear, accurate, and actionable cost-sharing information is the opportunity for CMS to take action to negate negative outcomes from instances where consumers are subject to a “surprise bill” when they receive services in an in-network hospital, but some of those services are delivered by an out-of-network physician. This is another example of how consumers may not have accurate information from their insurance plan about in-network providers and are not adequately protected against unexpected out-of-pocket costs. CMS finalized a policy in the Final Notice of Benefit and Payment Parameters for 2017 to address surprise bills to consumers. Under this policy, beginning in 2018, Qualified Health Plans (QHP) sold on the Marketplace must count the cost-sharing amount associated with

an essential health benefit provided by an out-of-network provider in an in-network facility (e.g., hospital) toward an enrollee’s annual cost-sharing limit. This requirement does not apply if the QHP provides written notice to the beneficiary (a non-customized form letter would suffice) that the provider might be out-of-network and the beneficiary could be subject to additional cost-sharing obligations. The QHP has the longer of 48 hours prior to the service or the time in which the plan would typically respond to a prior authorization request to provide the notice.

Unfortunately, the CMS policy falls short of the mark as it provides more protection for plans than it does for consumers. It is reasonable to assume that QHPs will routinely issue the form letter, in which case the consumer remains exposed to the additional cost-sharing, while the plan keeps the consumer that much further away from reaching the annual cost-sharing limit, the point at which the plan becomes fully responsible for the cost of care. **Instead, the FAH continues to recommend that CMS adopt the surprise billing section of the National Association of Insurance Commissioners’ (NAIC) Health Benefit Plan Network Access and Adequacy Model Act (Model Act) as a more robust way to address the issue of surprise billing.** The FAH believes this policy provides real protection for patients by providing an important measure of transparency combined with reasonable protections of patients’ financial interests. In addition, the NAIC provision strikes the right balance between the roles and responsibilities of hospitals, providers, and plans in situations in which a patient seeks care at an in-network hospital and may be treated by a provider who is not covered by the patient’s plan.

Under the NAIC’s Model Act, if a patient receives emergency treatment from an out-of-network provider (e.g., anesthesiologist, pathologist, radiologist) at an in-network facility, the patient’s out-of-pocket costs would be limited to those of an in-network provider. If the billed amount from the out-of-network provider is at least \$500 more than the allowed amount under the patient’s plan, the proposal offers a mediation process between the out-of-network physician and the insurance company when they cannot agree on a payment amount – essentially holding the patient harmless. Additionally, before any non-emergency treatment is scheduled, the Model Act would require the in-network hospital to provide the patient a written notice stating, among other items, that the patient might be treated by a provider who the patient’s plan determines is out-of-network, as well as a range of what the charges could be for such treatment. The notice also would include a statement telling the patient that she can obtain from her plan a list of providers who are covered by her plan, and request treatment from one.

Finally, for information to be meaningful, accessible, and actionable, it must be readily available for all types of consumers. Health plans should use effective and innovative communication methods and convey the information as simply and directly as possible. Insurers should continually communicate price and other information in multiple ways using a variety of methods to be most effective and have the broadest reach.

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 cursive script, appearing to read "Andrew M. [unclear]". The signature is written in black ink and is positioned below the word "Sincerely,".