

June 24, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
P.O. Box 8013
Baltimore, MD 21244-8013

File Code: CMS-5517-P

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Mr. Slavitt:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the issues discussed in the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (hereafter referred to as the MACRA Proposed Rule or Proposed Rule), published in the May 9, 2016, Federal Register.

HFMA is a professional organization of more than 40,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with the numerous rules and regulations that govern the industry.

Introduction

HFMA would like to commend CMS for its thorough analysis and discussion of the myriad Medicare physician reimbursement decisions addressed in the MACRA Proposed Rule. We appreciate CMS's thoughtful consideration of feedback solicited from stakeholders prior to drafting the Proposed Rule. As an organization, HFMA fully supports the transition to outcomes-based payment. Our members see this as crucial to efforts to improve the value of care delivered. To help our members successfully lead their organizations through this complex transition, we continue to publish the best practices of leading organizations through our Value Project research.¹

¹ http://www.hfma.org/valueproject/



In general, our members are deeply concerned about the timeline against which CMS is attempting to implement MACRA. The final rule will be available in the fall. This leaves practices little time to analyze the final rule, determine whether or not to pursue participation an Advanced APM (AAPM), and implement necessary processes to ensure compliance with new requirements. HFMA realizes CMS is being held to a statutory timeline. However, we advocate for a one year delay of the MIPs and APM Incentive Payment provisions. Given the sheer scale of the changes contemplated to physician payments by MACRA the potential for unforeseen adverse consequences on both patients and providers is significant. If a one year delay is not possible, HFMA encourages CMS to use whatever statutory flexibility it has at its disposal to delay implementation or phase in certain facets.

Beyond general concerns about the short implementation time frame coupled with the high risk of unintended adverse consequences, our members have specific concerns and questions regarding the proposals related to the:

- Merit-Based Incentive Program (MIPS)
 - o MIPS Participation Option for Hospital-Based Physicians
 - o Lack of Risk Adjustment for Socioeconomic Factors That Impact Measure Performance
 - Quality Measures
 - Clinical Practice Improvement Activities
 - o Resource Use Measurement
 - MIPS Low-Volume Threshold and Other Exclusion Criteria
 - o Timing of When a Practice Is Notified of Qualifying for an Exclusion from MIPS
 - o Insufficient Provisions for Targeted Review of MIPS Adjustments
 - o Data Validation and Auditing
- Advanced Alternative Payment Model Incentive
 - Insufficient Number of AAPMs
 - Exclusion of Bundled Payment Models from AAPM List
 - Medical Home Exclusion from AAPM Incentive Payment for Large Practices
 - Percentage of Physicians Required to Use a Certified Electronic Health Record (CEHR)
- Other Paver AAPM
 - o Documentation That an Other Payer AAPM Meets the Necessary Risk Requirements
- Other Issues
 - Lack of Discussion of Necessary Changes to the Fraud and Abuse Regulations

Below please find specific comments on the items listed above.

Merit-Based Incentive Program (MIPS)

1) <u>MIPS Participation Option for Hospital-Based Physicians</u>: The MACRA legislation includes a provision that allows CMS to develop a MIPS participation option for hospital-based physicians to use their hospital's quality and resource use measures in MIPS. HFMA strongly supports this provision as it would allow for the alignment of hospital and physician economic incentives by bringing MIPS in line with value-based payment mechanisms for hospitals (hospital value-based



purchasing [HVBP], hospital readmissions reduction program [HRRP], and hospital-acquired conditions program [HAC]).

In response to CMS's request for comments on how it might implement a process for hospitals and physicians to designate themselves for this participation option, HFMA suggests that CMS use active membership on a hospital's medical staff or proof of an employment contract that is effective for the measurement period as evidence of an existing relationship. HFMA believes that claims data elements could then provide proof of a sufficient relationship between hospitals and physicians for the physician to participate under this option. HFMA recommends that CMS use specific claims data elements such as inpatient and hospital outpatient department place-of-service codes as evidence.

2) <u>Lack of Risk Adjustment for Socioeconomic Factors That Impact Measure Performance</u>: CMS needs to ensure that both quality measures—particularly outcomes measures—and resource use measures are appropriately risk adjusted to account for factors beyond a provider's control. While the current set of measures is risk adjusted to reflect disease burden, results from the 2015 Value Modifier (performance period CY13) indicate that the existing mechanisms may be insufficient. Of the 106 groups that elected the "qualitytiering" method, the 14 groups that received an upward payment adjustment had the lowest average CMS Hierarchical Condition Category (CMS-HCC) score (1.02) while the 11 groups subject to a downward payment adjustment had the highest average CMS-HCC score (1.38).² Even though the sample size is small, CMS points to this relationship as a discussion item for its evaluation of its 2015 experience with the Value Modifier. HFMA strongly recommends that CMS develop refinements to the CMS-HCC risk adjustment mechanism to allow it to smooth out differences unrelated to physician performance.

In addition to refining the CMS-HCC mechanism to better adjust for differences in disease burden across patient populations and other confounding factors, HFMA believes CMS needs to implement a mechanism to account for differences in socioeconomic factors across patient populations. It has been long established that a range of social factors, such as education level, access to transportation, income level, available social support network, and access to fresh foods, have a significant impact on clinical outcomes. A recent literature review conducted by the National Academy of Medicine documents evidence of this impact on a variety of outcome measures, such as readmissions, total cost of care, and patient experience of care.

In prior Inpatient Prospective Payment System (IPPS) proposed rule comment letters, HFMA recommended that CMS use claims-level data to match zip codes on claims to existing Census Bureau poverty and education-level data as a mechanism to adjust hospital readmission rates for socioeconomic factors. HFMA's members believe that CMS should explore using a similar approach to risk adjust physician quality and resource use scores under MIPS. Failing to account for socioeconomic factors will likely further diminish access to care for individuals from

² 2015 Value-Based Payment Modifier Program Experience Report; Centers for Medicare & Medicaid Services; June 16, 2015



challenging economic circumstances as providers will be unwilling to locate practices in these areas or accept patients from them. Further, it will exacerbate healthcare disparities by inappropriately reducing resources for those providers who choose to practice in these areas.

3) <u>Quality Measures</u>: HFMA appreciates CMS's proposal to streamline the number of reported measures from nine to six measures. We support CMS's selection of measures from the sets developed as part of the Core Quality Measure Collaborative and encourage CMS to use all resources at its disposal to encourage other purchasers of health care to use these common sets of measures.

While this is a good start, much still needs to be done to reduce the unnecessary administrative burden physician practices face from reporting quality measures to multiple payers. A recent study of four physician specialties found that the average practice spends more than \$40,000 per year per physician reporting quality measures.³ This figure amounts to an estimated \$15.4 billion for these four specialties alone and represents a tremendous waste of resources that could otherwise be spent on patient care delivery. In light of this unnecessary resource use, we encourage CMS to build on these good first steps by using the recommendations of the National Academy of Medicine's 2015 *Vital Signs* report to identify the highest-priority measures for development and implementation in the MIPS. To ensure that all parts of the healthcare system—hospitals, physicians, the federal government, private payers, and others—are working in concert to address priority issues, the *Vital Signs* report recommends 15 "Core Measure" areas, with 39 associated priority measures. These areas represent the current best opportunities to drive better health and better care based on a comprehensive review of available literature.

Finally, in addition to better focusing measures on the core areas identified in the *Vital Signs* report, our members request that CMS make its long-term quality measurement strategy public and broadly publicize its availability. While CMS has stated its intention to move to more outcomes measures over time (which HFMA fully supports), our members need to better understand the path CMS intends to take to get there. This will allow providers to make efficient investments in the necessary infrastructure to support quality reporting and the analytical tools that drive quality improvement.

a. Reduce the Percentage of Patients Required to Be Reported Under Various Mechanisms: In the Proposed Rule, CMS significantly increases the percentage of patients that must be submitted under select mechanisms in order to be considered a successful MIPS participant. For both the qualified clinical data registry (QCDR) and qualified registry mechanisms, the requirement increases approximately 44 percent (from 50 percent of patients to which the measure applies in the 2016 Physician Quality Reporting System (PQRS)—2018 payment determination—to 90 percent in the 2017 MIPS performance periods—2019 payment determination).

³ http://content.healthaffairs.org/content/35/3/401.abstract



HFMA believes CMS provides insufficient justification for increasing the percentage of applicable patients that must be reported through the QCDR and qualified registry mechanisms. Therefore, in the Final Rule, CMS should reduce the percentage required to 50 percent for both mechanisms or provide a detailed justification for this significant increase.

- b. Requirement to Submit Data via QCDR, Qualified Registry, and EHR on All-Payer Basis: In the PQRS program, CMS has previously required data submitted via an electronic health record (EHR) or QCDR on an all-payer basis. The Proposed Rule now imposes this requirement on providers who choose to submit via a qualified registry. Under PQRS, HFMA strongly opposed the reporting of all-payer data via QCDR and EHR. We believe it is inappropriate to require the submission of all-payer data as a condition of receiving Medicare payment. Under MIPS, we believe it is equally inappropriate that performance on a set of all-payer measures would influence Medicare payment. In the short term, this requirement sets up a situation whereby some practices will experience "double jeopardy" or "double bonus," such that they are penalized or rewarded for the same performance twice. Further, collecting all-payer data will likely thwart CMS's long-term goals. In the 2017 IPPS Proposed Rule, CMS discusses attempting to create a value measure for select conditions for which CMS has both outcome and efficiency measures. HFMA assumes CMS will eventually attempt to do something similar for physicians. While most of the outcome measures currently contemplated are claims based, it is likely that future outcome measures may require data from registries or EHRs. If it's reported on an all-payer basis in the aggregate, the effort to match Medicare expenditures with the outcomes of related Medicare patients will be difficult. Therefore, HFMA requests that CMS only require providers to report data for Medicare fee-for-service patients under MIPS.
- 4) <u>Clinical Practice Improvement Activities (CPIAs)</u>: HFMA's members believe that several changes need to be made to the proposals related to qualifying for and scoring the CPIA component.
 - a. Increase the Size of the Practice That Qualifies as "Small" for CPIA: HFMAs members believe that CMS needs to increase the size of the practice considered small from 15 to 25 providers for purposes of the CPIA. We appreciate CMS's recognition that asking a practice of fewer than 16 providers to complete the myriad activities necessary to score the full 60 points necessary to achieve the highest potential score under CPIA is too burdensome. However, our members believe that, even for practices of up to 25 providers, achieving the full 60 points could be both administratively and financially burdensome. If left unchanged in the Final Rule, the size qualification will disadvantage mid-sized practices. If CMS does not believe it is appropriate to increase the practice size as recommended above, an alternative recommendation would be to decrease the maximum number of points a practice can achieve to 40.
 - b. <u>Allow APM Entities to Receive Full Credit</u>: Practices participating in an APM make significant investments in technology, analytics, and care coordination. Therefore, HFMA's members believe CMS should award any practice participating in an APM⁴ full CPIA points. Beyond

⁴ Payment models that would meet CMS's definition of "Category 3 or 4."



recognizing the investments described above, incorporating this improvement into the Final Rule will have the added benefit of incentivizing practices to participate in payment models that in many cases are experimental and largely unproven.

- c. <u>Request for Clarification</u>: HFMA's members ask CMS to clarify whether or not the specialist physicians in a multispecialty integrated group practice where all of the primary care physicians in the group are patient-centered medical home (PCMH) certified by a nationally recognized organization would also receive the full score on the CPIA measure. On the basis of the Proposed Rule, our members believe that under this scenario the specialists in the practice would receive full score but would greatly appreciate clarity on the issue.
- 5) <u>Resource Use Performance Measurement</u>: HFMA's members believe that the current construction of the resource use performance measure is suboptimal relative to the goal of helping providers identify and act on opportunities to reduce the overall cost of care. CMS can better empower providers by taking the following steps:
 - a. <u>Use Data from CY15 as the Baseline Period</u>: CMS proposes not to use a baseline period to score the resource use performance measure. Instead, it proposes to use data from CY17—the performance period—to derive benchmarks. This action violates a core tenet of designing pay-for-performance programs identified by the Agency for Healthcare Research and Quality. Providers need to know their benchmarks in advance so they know what is expected of them. HFMA strongly recommends that CMS, similar to its approach to quality measures, use data from four years prior (e.g. 2015 for 2019) to set benchmarks for resource use performance measures. Similar to the recently finalized MSSP benchmarking rule, HFMA believes that CMS should use a regional factor to trend resource use measures so they can be compared to the performance period. Our members are generally supportive of the recent MSSP Final Rule's approach. Beyond the benefit of providing physicians with a known benchmark prior to the performance period, using this method to trend data forward will help practices become familiar with a key component of CMS's most prevalent accountable care organization (ACO) model, the MSSP.
 - b. Provide Physicians and MIPS-Eligible Clinicians with More Frequent Resource Use Feedback Reports: Currently, providers receive updated Quality and Resource Utilization Reports (QRUR) biannually. Given the significant lag time between the performance period and availability of the QRUR, the data's potential to guide performance improvement is reduced. Our members report difficulty in engaging providers with the data because of the lack of recency. HFMAs members strongly believe that CMS should provide resource use reports to providers on a rolling quarterly basis. More frequent data will both better engage providers and allow for mid-course adjustments to help them improve their resource use scores during the actual performance period.

⁵ For specific comments related to the trending proposal, see HFMA's comment letter, available at http://www.hfma.org/Content.aspx?id=47402. While most recommendations were specific to the MSSP program and the timing of the phase-in, these suggestions may have merit for the broader population of physicians.



c. Expand the Type of Data Available to Providers: In addition to increasing the frequency of resource use reporting, HFMA's members request that CMS provide additional data to support performance improvement efforts. First, while the QRUR provides some ability to drill down into the data, the reports only provide patient-level expenditure data at the aggregate level compared to national benchmarks. It would be extremely helpful to have CMS provide patient-level claims data for each resource use performance measure so providers can understand specific care pathways and referral patterns that drive unnecessary expenditure. HFMA asks that CMS provide physician practices files similar to what are provided to hospitals for the Medicare Spend Per Beneficiary measure that is part of Hospital Value-Based Purchasing. While not all practices will be able to manipulate these data to identify outlier cases, those that have this capability would find these data extremely beneficial.

Second, CMS should make available reports to providers on their high-utilization patients in as close to real time as possible. We believe this reporting will be possible once CMS is able to implement the patient relationship codes required by MACRA. The reports should be delivered to providers who have identified themselves as having a continuing care relationship with a high-utilization patient. This information will allow the provider most responsible for the patient to intervene faster and develop a care management plan designed both to reduce the total cost of care, by providing the necessary preventative care and coordination services, and to ensure that care is provided in the appropriate site of service. More importantly, the availability of these data will lead to better outcomes for the patient as they will likely help physicians reduce avoidable acute utilization. Until the reports described above become available, HFMA's members ask that CMS provide physician practices with reports similar (both in terms of detail and frequency) to what is provided to hospitals as a result of the Hospital Readmissions Reduction Program.

MIPS Low-Volume Threshold and Other Exclusion Criteria: While CMS states in the proposed rule MACRA and the MIPS program will simplify participation in a range of Medicare physician payfor-reporting and pay-for-performance programs (PQRS, Value Modifier, and EHR incentive payment), HFMA's members are concerned it may have the opposite effect. Although the Proposed Rule reduces the number of measures under the quality component of MIPS by three (which HFMA strongly supports), the program adds a component (CPIA) that eligible professionals must report. Further supporting this concern, 822,810⁶ eligible professionals participated in PQRS in 2014, but CMS in the Proposed Rule estimates that between 687,000 and 746,000 professionals will receive a MIPS score, with an additional 29,613 reporting data but not receiving a score due to an insufficient number of cases to meet the necessary volume thresholds. Despite the decrease in the number of eligible professionals participating, the incremental cost and total number of hours necessary to comply are estimated by CMS to increase by \$127 million and 2.5 million hours annually relative to the existing mandatory programs.

Given the relatively low participation rate of small practices, HFMA is concerned that the reporting burden will increase the barrier to participation. As a result, these practices will

⁶ 2014 Reporting Experience Including Trends (2007-2015) Physician Quality Reporting System; CMS; April 2016

disproportionately be subject to downward payment adjustments because they cannot afford the administrative overhead necessary to participate. On the basis of data from the 2014 reporting year, only 62 percent⁷ of all eligible professionals participated in PQRS reporting. However, rates of participation vary widely in terms of practice size, as shown in Table I below.

Table I: Participation Rates in PQRS by Practice Size⁸

	Solo	2-10	11-24	25-50	51-99	100-199	200+
Participation	25%	51%	60%	66%	68%	72%	85%
Rate							

These rates of participation appear to mirror CMS's estimate of MIPS results in the first year of the program. This analysis factors in CMS's current exclusion policy. Table II below shows CMS's projection of the net impact by practice size (net of exceptional performance payment adjustment, as it sunsets after 2024).

<u>Table II: Projected Net Payment Impact by Practice Size</u> (\$, millions, net of exceptional performance payments)⁹

Practice Size	Solo	2 - 9	10 - 24	25 - 99	100+	Total
Negative Pmt Adjustments	-300	-279	-101	-95	-57	-832
Positive Pmt Adjustments						
Net of Exceptional						
Performance Pmt	65	182	103	147	335	832
Net Pmt Impact	-235	-97	2	52	278	0

On the basis of PQRS participation rates, the Proposed Rule appears to penalize smaller practices. However, the penalty is largely not based on projected performance on quality and resources use measures but is assessed because smaller practices cannot afford the overhead to even participate. HFMA believes that this penalty is unfair and could lead to a reduction in access to services for Medicare beneficiaries in some areas.

In an attempt to avoid penalizing small practices because of limited financial resources, the rule proposes to exclude eligible clinicians with less than \$10,000 in allowable charges and fewer than 100 Medicare patients. Publicly available data are insufficient to model PQRS participation rates at various combinations of Medicare panel size and Part B revenue. However, in its PQRS participation report, CMS provides data on participation rates for each factor independently, as shown in tables III and IV below.

Table III: Participation Rates in PQRS by Part B Revenue 10

⁷ 2014 Reporting Experience Including Trends (2007-2015) Physician Quality Reporting System; CMS; April 2016

⁸ Table A5: Participation and Incentive Eligibility by Eligible Professional Characteristics (2014); 2014 Reporting Experience Including Trends (2007-2015) Physician Quality Reporting System; CMS; April 2016; HFMA Analysis

⁹ Table 64, Proposed Rule; HFMA Analysis

¹⁰ Table A5: Participation and Incentive Eligibility by Eligible Professional Characteristics (2014); 2014 Reporting Experience Including Trends (2007-2015) Physician Quality Reporting System; CMS; April 2016; HFMA Analysis



Part B Revenue	< \$2,500	\$2,501 - \$10,000	\$10,001 - \$40,000	\$40,001 - \$100,000	> \$100,000
% Eligible Professionals					
Participating in PQRS	47%	51%	63%	74%	76%

Table IV: Participation Rates in PQRS by Medicare Panel Size 11

Medicare Panel Size	1-25	26-100	101-200	201+	Unknown
% Eligible Professionals					
Participating in PQRS	40%	60%	70%	77%	96%

HFMA's members believe that the low-volume threshold exclusion for practice size needs to be altered to protect smaller practices that cannot afford the administrative overhead necessary to participate in MIPS. We encourage CMS to consider modifying the exclusion threshold so that a provider need only meet one of the criteria (either Medicare panel size or Part B revenue) to be exempt. If CMS chooses to loosen the criteria, HFMA believes it may be possible to use a lower threshold for panel size. Even if CMS chooses to allow either/or criteria, HFMA believes that CMS will need to increase the dollar threshold. However, considering the lack of publicly available data, we are unable to recommend specific thresholds for both.

If CMS does not see fit to make the recommended changes to the low-volume threshold for participation, HFMA believes that CMS needs to work with the Office of Inspector General (OIG) to expand the safe harbors available for physicians who wish to align with larger multispecialty practices or health systems to gain access to the administrative systems necessary to participate in MIPS. Specific recommendations are included later in this comment letter.

Finally, as discussed below in the section on AAPMs, HFMA's members believe that Track 1 MSSPs should be considered an AAPM. Similar to other AAPMs, if an entity participating in Track 1 of the MSSP meets either of the volume requirements to qualify (or partially qualify) as an AAPM participant, HFMA believes that it should have the option to not report data for any of the MIPS categories.

7) Timing of When a Practice Is Notified of Qualifying for an Exclusion from MIPS: The Proposed Rule as currently written sets up a scenario where a provider who attempts to qualify for the APM exclusion from MIPS (either as a qualifying participant [QP] or as a partially qualifying participant [PQP]) could instead suffer the maximum downward MIPS adjustment for not reporting the necessary data. The rule proposes to notify providers of whether or not they met the revenue or patient volume criteria necessary to qualify as a QP or PQP months after the MIPS reporting deadlines. While possible submission deadlines vary, the Proposed Rule requires providers to submit quality measures by March 31 of the year following the performance period. CMS proposes to notify providers of their QP or PQP status by no earlier than "summer" following the performance period.

¹¹ Table A5: Participation and Incentive Eligibility by Eligible Professional Characteristics (2014); 2014 Reporting Experience Including Trends (2007-2015) Physician Quality Reporting System; CMS; April 2016; HFMA Analysis



Given the potential for a provider to inadvertently incur the maximum MIPS downward adjustment, the only prudent action for it to take is to submit all required data. This action negates one potential benefit of being a QP or PQP, avoidance of duplicative reporting for both MIPS and the APM. **HFMA strongly believes that this outcome was not intended by Congress.** Further, the duplication will waste resources, contributing to the increasing cost of health care.

HFMA recommends that CMS take one of the following steps to rectify this situation. First, CMS should provide a grace reporting period for those providers who elect to opt out of MIPS as a QP or PQP but fail to meet the volume requirements. While this option might delay CMS's ability to calculate the correct payment year adjustment, it could apply the adjustment retrospectively. The second option, which HFMA favors, is for CMS to base its QP or PQP determination on payment or patient volume data from a prior year using the APM's attribution methodology. This option will give providers the administrative certainty they require for planning while eliminating the need to possibly adjust a large volume of claims subsequent to the initial payment.

8) <u>Insufficient Provisions for Targeted Review of MIPS Adjustments</u>: CMS proposes a targeted review process under which a clinician may seek review of the MIPS adjustment factors. CMS says that a clinician may seek a targeted review if he or she believes that the measures or activities submitted to CMS contain errors or data quality issues or believes that CMS made errors in calculating the performance scores. Other circumstances may also lead to a targeted review request.

CMS proposes the following regarding the targeted review process:

- An eligible clinician may request a targeted review within 60 days (or a longer period specified by CMS) after the close of the data submission period. All requests for targeted review must be submitted by July 31 after the close of the data submission period or by a later date specified in guidance.
- o CMS will first respond with a decision as to whether a targeted review is warranted.
- No hearing process will be included, as this process is informal and the statute does not require a formal appeals process.
- If CMS requests additional information to assist in the review, the supporting
 information must be received within 10 calendar days of the request.
 Nonresponsiveness to the request for additional information will result in the closure of
 that targeted review request, although another review request may be submitted if the
 submission deadline has not passed.
- Decisions based on the targeted review will be final, and no further review or appeal will occur.

Finally, CMS states that the statute (1848(q)(13(B)) prohibits administrative and judicial review of the methodologies used to calculate performances and determination of the MIPS adjustment factor, the establishment of performance standards and performance periods, and identification of measures and activities specified for a performance category.



Given that there is no administrative and judicial review of the methodologies used to calculate performance and payment determination related to MIPS, HFMA's members believe the proposed targeted review process is wholly insufficient. HFMA appreciates the initial period of "at least 60 days" that CMS proposes. However, HFMA believes that, similar to the Hospital Readmissions Reduction Program and other Medicare pay-for-performance or penalty programs, eligible providers should have the opportunity to review the data once the preliminary MIPS scores and payment impacts have been calculated. Therefore, HFMA requests that CMS make preliminary MIPS adjustment factors and the underlying performance scores available as part of the annual proposed physician fee schedule rule. Given the administrative complexity of reviewing the results, we ask that CMS give providers an additional 60-day window once these factors are available to request a targeted review and related corrections.

Additionally, given the absence of a formal appeals process, HFMA's members believe CMS should not have the ability to deny requests for targeted review. Otherwise, we are deeply concerned that providers will suffer significant reductions in their Medicare reimbursement as a result of the administrative complexity of the program, not poor clinical quality or the inefficient provision of care.

Finally, HFMA believes that the 10 days CMS proposes to give providers to respond to requests for additional documentation is too narrow a time frame. Again, given the limited administrative staff that many small practices have and the potential volume of material that CMS could request, we believe it is appropriate to allow providers more time to respond. Additionally, while we do not believe this would happen, this narrow of a window creates a situation whereby CMS or its contractors could reduce the volume of targeted reviews by overwhelming practices with requests for additional data. HFMA's members believe that CMS should expand the response window to 30 days to prevent practices from being inadvertently penalized and remove the possibility that additional data requests will be inappropriately used by contractors as a tool to "manage" their workload.

CMS states that "other circumstances may also lead to a targeted review request." **HFMA** requests that CMS, through the notice and comment process, work with providers to define what other circumstances would merit a targeted review.

- 9) <u>Data Validation and Auditing</u>: CMS proposes to selectively audit eligible clinicians on a yearly basis. An eligible clinician or group selected for audit must:
 - o Provide all data as requested to CMS (or its contractor) within 10 business days or an alternate time frame that is agreed to by CMS and the clinician. Data would be submitted via e-mail, facsimile, or an electronic method via a secure website maintained by CMS.
 - Provide substantive, primary source documents as requested. This documentation may include copies of claims, medical records for applicable patients, or other resources used in the data calculations for MIPS measures, objectives, and activities. Primary source documentation also may include verification of records for Medicare and non-Medicare beneficiaries.

CMS notes that it would limit each such data validation and audit request to the minimum data necessary to conduct validation.



HFMA's members general support CMS's program integrity efforts. However, we have significant concerns about the dearth of detail included in the Proposed Rule about how CMS will audit and validate data. HFMA's members request that CMS, through the process of proposed notice and comment, address the following questions:

- o How will the contractors who perform these audits be compensated?
- How will audit samples be chosen?
- How frequently will a provider be eligible to be audited if he or she was audited in a prior period?
- o How does CMS intend to define "the minimum data necessary to conduct validation"?
- Will providers who are reporting in MIPS and an alternative payment model be subject to duplicative audits?

Additionally, CMS proposes to allow providers only 10 days to respond to audit requests. **HFMA's members request that CMS allow providers 45 days to respond to audit requests.** This is the same time frame that CMS uses in other programs. Otherwise, we are concerned that the 10-day turnaround time will be disruptive to smaller practices that do not have the administrative staff to manage and respond to these requests.

Advanced Alternative Payment Model Incentive

1) <u>Insufficient Number of Advanced APMs (AAPMs)</u>: CMS proposes a limited list of AAPMs, which includes only the MSSP Tracks 2 and 3, Next Generation ACO, Comprehensive ESRD (end-stage renal disease) Care Model, Comprehensive Primary Care Plus, and Oncology Care Model. HFMA strongly disagrees with CMS's decision to exclude the Track 1 MSSP model from the AAPM list on the basis of CMS's interpretation that this model does not meet the nominal risk requirement.

An American Hospital Association analysis estimates start-up costs of \$11.6 million for a small ACO and \$26.1 million for a medium ACO. Further, our members who are employed by ACOs state that annual ongoing costs related to the ACO run into the millions of dollars on average. However, CMS in the Proposed Rule classifies the risk providers are exposing themselves to as normal business risk.

HFMA strongly rejects that assertion for multiple reasons. First, the MSSP model is unproven and imperfect (as evidenced by CMS's recently finalized rule to revise the benchmarking methodology). In reviewing results from the second performance year, the 86 ACOs that achieved shared savings had a benchmark that was significantly higher (\$10,489) than the 89 ACOs that did not achieve sharable savings (\$10,000) or the 152 ACOs whose expenditures exceeded the benchmark (\$9,577). Some relationship appears to be present between having a higher starting benchmark and the ability to achieve sharable savings that is independent of participating provider efforts. Additionally, HFMA would like to point out that the 89 providers who generated savings for CMS but were unable to share in those

¹² http://healthaffairs.org/blog/wp-content/uploads/4482230 Introcaso table revised.jpg



savings due to the minimum savings rate (MSR) received no return on their investment despite achieving the desired outcome for their business partner, CMS. It is unclear if the amended Final Rule will create a level playing field for all MSSPs or if current inequities will persist. Therefore, it is HFMA's contention that providers who agree to participate in Track 1 expose themselves to a significant amount of policy risk. It is still highly uncertain whether the MSSP contract terms will produce a "level-playing field" for all ACOs or CMS will have to further adjust the benchmark.

Beyond the risk MSSP participants expose themselves to due to the untried nature of the program's rules, the ACO business model itself is unproven. MSSP Track 1 participants are committed to providing higher-quality health care and aggressively managing the total cost of care. However, no incentive is in place for Medicare beneficiaries to receive care at an ACO instead of a delivery system still wedded to pure fee-for-service. Therefore, Track 1 participants are making significant investments in ACO infrastructure that will reduce unnecessary utilization (and thus their fee-for-service revenue) without the Medicare program taking steps to encourage more patients to be attributed to and receive necessary services from MSSP participants.

Finally, given that the benchmarks (as revised by the Final Rule) will still reset after every contract period, the opportunity for MSSP participants to achieve savings decreases over time as unnecessary or inefficient care is removed from the system. MSSP participants over time face the risk of having a smaller pool of achievable savings that can be used to cover the initial investments in ACO infrastructure and the significant ongoing costs.

HFMA strongly believes that Track 1 MSSP participants should qualify for the AAPM incentive payment assuming they meet one of the volume criteria. If CMS refuses to acknowledge in the Final Rule that the risk these organizations are exposed to is different in kind and nature than normal business risk, HFMA recommends the following alternative. For Track 1 MSSP participants, HFMA recommends that CMS hold any AAPM incentive payments in an escrow account until the ACO transitions to Track 2 or another qualifying AAPM. Once the ACO has finished its first AAPM agreement period, it should receive any AAPM incentive payments with interest related to years when the entity was in Track 1. This compromise will ensure that Track 1 ACOs receive some reimbursement for their infrastructure investments that ultimately will generate significant savings for the Medicare program. Further, unlike the current risk/reward profile for Track 2 and other AAPMs, the compromise will provide a meaningful incentive for these ACOs to continue with the MSSP or similar programs once they have termed out of Track 1.

Further, HFMA believes that any model in which CMS takes a direct discount off of fee-for-service payments (e.g., Comprehensive Care for Joint Replacement [CJR] discount), regardless of whether or not it meets the "nominal risk" criteria outlined in the Proposed Rule, should qualify for the AAPM incentive payment. Under these models, CMS is guaranteed savings while participating providers are at risk to generate sufficient savings to recoup the investments necessary to participate.



As CMS looks to develop new AAPMs, HFMA's members strongly encourages it to look to adapt models currently used by other payers for Medicare fee-for-service.

2) Exclusion of Bundled Payment Models from AAPM List: HFMA is deeply concerned by the dearth of specialist payment models that qualify as AAPMs. As the rule is constructed, we believe that CMS is missing a significant opportunity to engage specialists in AAPMs. The Proposed Rule states that the Bundled Payments for Care Improvement (BPCI) and CJR programs, as currently designed, do not meet the statutory criteria. As CMS interprets the MACRA statute, neither BPCI nor CJR meets the requirement that a payment model "requires participants in such model to use certified EHR technology (as defined in subsection (o)(4))." Additionally, BPCI does not qualify, as it does not "provide for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i)."

Regarding the certified EHR technology (CEHRT) requirement, HFMA believes that CMS is taking an unnecessarily narrow interpretation of the statute as it relates to both BPCI and CJR. Both payment models use historical Medicare Parts A and B payments trended forward to set a target price per episode. Providers involved in the episode (both participating and nonparticipating) receive fee-for-service payments for the services they provide during the episode. At the end of the performance year, the participating provider is held accountable for financial outcomes via a reconciliation.

Physicians and hospitals that participate in Medicare fee-for-service are required to be "meaningful users" of CEHRT. A hospital that is not a meaningful user of CEHRT will have its annual market basket update significantly reduced, thereby reducing payments to the hospital. A similar penalty exists for physicians. In 2016, those who fail to attest to meaningful use of CEHRT will have their Part B payments reduced by 2 percent. Moving forward under MACRA, a physician practice that is not a meaningful user of CEHRT will be penalized under the MIPS system.

Both CJR and BPCI are built on Medicare Parts A and B fee-for-service payments. As described above, both Parts A and B fee-for-service payments have a meaningful use requirement embedded in them as a result of the downward payment adjustment for providers who do not meet the requirements. Given these two facts, HFMA's members believe that both the CJR and BPCI payment models inherently have a CEHRT requirement incorporated in them, as they are based on Medicare fee-for-service payments, so it is not necessary to specifically state such a requirement in the model rules for BPCI or CJR. Therefore, in order for CJR and BPCI to meet the MACRA statute's CEHRT requirement, HFMA recommends that CMS require providers participating in the CJR and BPCI programs report data for the advancing care information (ACI) MIPS performance category.

If CMS, in the Final Rule, persists in its overly narrow interpretation of the MACRA statute, HFMA believes that it should allow providers currently participating in CJR or BPCI Models 2 or 3 the opportunity to alter their participating agreements with the Center for Medicare & Medicaid Innovation (CMMI) so that both programs will meet the CEHRT requirement.



HFMA also believes that CMMI needs to offer participants in BPCI Models 2 and 3 the opportunity to remediate the lack "payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i)." HFMA recommends that CMMI allow participating providers to modify their participation agreements so that they incorporate payment based on quality measures. HFMA believes the use of quality measures in CJR is an acceptable model that could be replicated in other episodes with relevant measures.

Additionally, if the results from early adopters of the BPCI program allow CMS to certify one or more of the episodes and continue offering them, HFMA believes that CMS should offer two participation options for physicians. One option should incorporate the quality-based payment modifications necessary to qualify as an AAPM; the other should not. This differentiation will allow CMS to understand the impact of quality-based payment on both cost and quality outcomes.

Assuming that BPCI and CJR will eventually qualify as an AAPM, HFMA believes that CMS needs to develop a way to identify individual physicians who are employed by an episode initiator (e.g., hospital, post-acute care facility) and involved in the bundle for purposes of the AAPM incentive payment. HFMA strongly recommends that the episode initiator provide CMS with a list of employed physicians who are involved with the bundle for purposes of qualifying for the AAPM incentive payment. The timing of the provision of the list could coincide with the deadlines that CMS has discussed in the Proposed Rule relative to identifying eligible providers for assignment to an APM entity.

Finally, HFMA asks CMS to clarify whether or not an eligible provider who is collaborating with an episode initiator (be it a hospital, a post-acute care facility, or another group practice) can qualify as an Advanced Alternative Payment Entity for purposes of AAPM incentive payment. HFMA strongly believes providers who sign a "collaborator agreement" or "participation agreement" that meets the AAPM requirements in MACRA and achieve the volume thresholds should be eligible for the AAPM incentive payment. If CMS fails to permit collaborators/participators in arrangements that meet the nominal-risk, quality-based payment, and CEHRT requirements, it will have missed a significant opportunity to align incentives with providers across the care continuum. HFMA recommends that the episode initiator submit a separate list of collaborators (or participants). With the list of collaborators/participants, episode initiators should also submit the related collaborator/participant agreements to CMS so that it can verify that the nominal-risk criteria are met.

3) Medical Home Exclusion from the AAPM Incentive Payment for Large Practices: CMS proposes that, beginning in the second QP performance period (proposed to be 2018), the medical home model financial risk standard and nominal amount standard, described in section II.F.4.b.(4) of the Proposed Rule, would only apply to APM Entities that participate in medical home models and have 50 or fewer eligible clinicians in the organization through which the APM Entity is owned and operated.



HFMA's members have interpreted this to mean that, for organizations with 51 or more clinicians, participating in a medical home model will not qualify them for the AAPM incentive payment unless the medical home model in which they are participating meets the "generally applicable financial risk and nominal amount standards" as defined in the Proposed Rule.

HFMA asks CMS to confirm that this interpretation is correct.

Assuming the interpretation of the proposal above is correct, HFMA believes that CMS is adding words to the MACRA statute that do not exist. The section of the law that defines an Eligible Alternative Payment Entity states the following (emphasis added):

(D) ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—The term 'eligible alternative payment entity' means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (o)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i); and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; **or**

(II) is a medical home expanded under section 1115A(c).

Nothing in the excerpted section above (or other sections of the law that pertain to how a provider or a practice may qualify for the AAPM incentive payment) explicitly or implicitly excludes a physician group from qualifying for the AAPM Incentive payment under the expanded medical home pathway if the number of eligible clinicians in the practice or parent organization exceeds a maximum size. Given this, HFMA strongly recommends that CMS remove the medical home maximum organization size requirement in the Final Rule.

HFMA believes that Congress included the medical home pathway out of recognition that some practices, regardless of size, will be unable to bear downside risk during the period that the AAPM incentive payments are available. First, all of the CMS and CMMI models that qualify for the AAPM incentive payment are new and relatively unproven. The methodology used to determine their benchmarks is still likely subject to significant revisions that could negatively impact performance. As discussed above, many executives are unwilling to expose their organizations to this policy risk and the related potential for arbitrary losses inherent in these models as CMS refines the benchmarking methodology.

Further, HFMA's members believe that organization size speaks to a necessary but not sufficient component to bearing risk. While practice size, as CMS alludes to in the Proposed Rule, may suggest that an organization has the financial wherewithal to bear some degree of risk, it does not correspond to the organization's ability to actually manage that risk. HFMA, through its

¹³ Total risk: minimum of 4 percent of APM spending target, marginal risk minimum 30 percent spending above APM target for which the Advanced APM Entity is responsible, maximum 4 percent of the amount by which spending can exceed the APM benchmark before the Advanced APM Entity has responsibility for losses



Value Project research, has defined the core capabilities ¹⁴ our members believe are necessary to manage risk. Given the considerable investments in personnel and infrastructure required to develop the capabilities, HFMA's members believe that Congress intended the medical home pathway to be a mechanism to help practices fund investments in these capabilities so they will be prepared for payment models that require significant two-sided risk.

Finally, HFMA's members believe that CMS's choice of 51 or more eligible clinicians as the maximum sufficient size of an organization required to successfully bear risk is arbitrary. We are unaware of any peer-reviewed studies or data that suggest this breakpoint. If CMS insists on finalizing the arbitrary number in the Final Rule, HFMA's members request that CMS make all of the data and analysis that CMS used to select this number publicly available.

4) Percentage of Physicians Required to Use a Certified Electronic Health Record (CEHRT): The rule proposes an aggressive increase in the percentage of physicians using CEHRT in order for an AAPM Entity to qualify for the AAPM incentive payment. During the first performance period (CY17), 50 percent of eligible clinicians must meet the CEHRT requirements. For the following performance period (CY18), that threshold increases to 75 percent. HFMA's members fully support the use of CEHRT, as they believe that these investments will eventually lead to higherquality, lower-cost care and a reduction in administrative expense. However, we are concerned about the aggressive ramp-up of the percentage requirement proposed. Given the incentives in MACRA, we believe that many of the remaining community-based independent physician practices may seek to join clinically integrated networks to gain access to CEHRT and the administrative infrastructure necessary to support the reporting requirements contemplated in the Proposed Rule. Our members are concerned that, given the potential for the rapid integration of a large number of small physician practices at once, it may be difficult to bring the newly added practices up to the current CEHRT standards in a short period of time. As CMS is well aware, this activity requires considerable time and resources. Therefore, HFMA recommends that CMS decrease the slope of the ramp by increasing it to 75 percent in five percentage point increments over five years.

Other Payer Advanced Alternative Payment Model

1) <u>Documentation That an Other Payer AAPM Meets the Necessary Risk Requirements</u>: CMS in the Proposed Rule requests comments on the type of documentation it needs to request in order to validate that an "Other Payer AAPM" meets the necessary risk requirements for the AAPM incentive payment. HFMA believes that it is unnecessary and inappropriate for CMS to require providers to submit the entirety of a contract with another payer—especially the section with the negotiated fee schedule or payment rates.

HFMA's members have suggested that they would be hesitant to participate under the Other APM method if they were required to submit managed care contracts in their entirety, given that these are considered trade secrets by both the provider and the health plan that are parties to a contract. Beyond the proprietary nature of the managed care contract, if CMS elects to review the entire managed care contract, it will create a significant and unnecessary

¹⁴ http://www.hfma.org/ValueProject/Phase1/



administrative burden for itself. Given the number of contracts CMS will need to evaluate, choosing to review the entire managed care contract will significantly delay the determination for those providers attempting to qualify for the AAPM incentive payment under the Other Payer AAPM methodology.

Finally, CMS proposes "to the extent permitted by federal law, it would maintain confidentiality of certain information that the Advanced APM Entities and/or eligible clinicians submit regarding Other Payer Advanced APM status in order to avoid dissemination of potentially sensitive contractual information or trade secrets." HFMA appreciates CMS's disclosure.

However, our members request that CMS in the Final Rule provide a full discussion of what federal law may compel it to make public and under what circumstances. Unless providers have a clear understanding of what CMS may be compelled to disclose, they are unlikely to participate in an Other Payer AAPM given the perceived risk of an inadvertent disclosure of contracting terms between a health plan and a provider.

Other Issues

<u>Necessary Changes to Fraud and Abuse Laws to Support Provider Alignment</u>: HFMA is deeply disappointed that the Proposed Rule does not mention any efforts on CMS's part to work with the OIG to create the necessary safe harbors from the existing antiquated fraud and abuse regulatory regime.

By tying a portion of most physicians' Medicare payments to performance on specified metrics and encouraging physician participation in APMs, MACRA marks another step in the healthcare field's movement to a value-based paradigm from a volume-based approach. To achieve the efficiencies and care improvement goals of the new payment models, hospitals, physicians, and other healthcare providers must break out of the silos of the past and work as teams. Of increasing importance is the ability to align performance objectives and financial incentives among providers across the care continuum.

To do that, a legal safe zone for those efforts is needed that cuts across the fraud and abuse laws—specifically, the physician self-referral (Stark) law, anti-kickback statute, and certain civil monetary penalties (CMPs). In our view, these laws are not suited to the new models. The statutes and their complex regulatory framework are designed to keep hospitals and physicians apart—the antithesis of the new models.

HFMA believes that a single, broad exception that cuts across the Stark law, the anti-kickback statute, and relevant CMPs for financial relationships designed to foster collaboration in the delivery of health care and to incentivize and reward efficiencies and improvements in care is necessary. We recommend that the exception be created under the anti-kickback statute and arrangements protected under the exception be deemed compliant with the Stark law and relevant CMPs. HFMA asks that CMS work with the OIG where it sees opportunity within the existing statute to create this exemption, and with Congress where statutory adjustments are necessary to update the existing fraud and abuse framework to allow providers the full range of actions necessary to respond to the economic incentives embedded in the MACRA legislation. We are concerned that failure to do so will negatively impact smaller practices. It will also increase employment of independent and small group



practices by hospitals and large multispecialty practices that would otherwise want to remain independent.

HFMA looks forward to any opportunity to provide assistance or comments to support CMS's efforts to refine and improve the MACRA Proposed Rule. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS, and advisory groups.

We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,

Joseph J. Fifer, FHFMA, CPA

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President and Chief Executive Officer

Healthcare Financial Management Association

About HFMA

HFMA is the nation's leading membership organization for more than 40,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms, and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant, and consultant.

HFMA is a nonpartisan professional practice organization. As part of its education, information, and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices, and standards.