AMERICAN OSTEOPATHIC ASSOCIATION

142 E. Ontario St., Chicago, IL 60611-2864 ph (312) 202-8000 | (800) 621-1773 | www.osteopathic.org

June 27, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Slavitt:

On behalf of the American Osteopathic Association (AOA) and the more than 123,000 osteopathic physicians and osteopathic medical students we represent, thank you for the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) *Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models* proposed rule (CMS-5517-P).[1]

The osteopathic profession strongly supported passage of the Medicare Access and CHIP Reauthorization Act (MACRA), and remains optimistic as we move towards a system that aligns well with the osteopathic philosophy of care – treating the whole person with a strong focus on prevention, wellness, and quality. During the law's development, the AOA was especially supportive of MACRA's focus on the value of care provided over volume. CMS is in a position to favorably shape the implementation of MACRA, and we are pleased to provide the following comments to CMS as it undertakes this effort.

Our comments focus on three basic principles which we believe will serve to enhance the delivery of high-quality patient care:

1) The system must be patient-centered;
2) The system must be practice-driven and provide the appropriate flexibility for physicians throughout to make decisions; and
3) The system must be simplified.

Executive Summary

Flexibility

We support the rule's flexibility for eligible clinicians.

- Voluntary MIPS reporting and aligned payment adjustments for partial qualifying APM participants.
- Inclusion of non-patient-facing clinicians as MIPS eligible clinicians only to the extent that measures meaningfully reflect their work. We support CMS' proposal to include telehealth services as patient-facing encounters.

[1] 42 CFR Parts 414 and 495

- Exclusion of eligible clinicians who fall below the low-volume threshold from MIPS. We add that CMS' low volume threshold is too restrictive and support expanding it to 150 patients.
- Exclusion of new Medicare-enrolled eligible clinicians from reporting to MIPS. We ask CMS to allow these clinicians to voluntarily report to MIPS, and still receive feedback for their initial year, to ease transition into the program.

Timeline

The current proposed schedule sets the performance period beginning January 1, 2017 and lasting for the duration of the 2017 calendar year—with payments for that period being applied in 2019. With a final rule not expected until September, 2016 at the earliest, physicians are significantly limited in time to prepare for MIPS. As such, we urge CMS to set the performance period for 2017 to begin July 1 and end on December 31, 2017. We would also urge CMS to use the first 6 months of 2017 to set a baseline for the performance period in the latter half of the year.

Legacy Programs

We applaud CMS for efforts to develop new programs to meet the requirements of MACRA statute. Newly developed programs, such as the Clinical Practice Improvement Activity (CPIA) performance category and scoring, are well constructed. This is in contrast to programs which CMS has designed based on legacy programs, such as the Advancing Care Information (ACI) performance category on meaningful use (MU). These updated programs are now more complex and burdensome, and represent only marginal improvements, if any, on the original programs.

Patient-Centered Medical Homes

We disagree with CMS' overly narrow interpretation of the ability for PCMHs to qualify as an Advanced APM, and also do not believe the proposed rule meets Congress' intent that qualify medical homes without bearing more than nominal financial risk. We urge CMS to establish a deeming program or process to enable practices enrolled in medical home programs run by states (including state Medicaid programs), other non-Medicare payers, and employers as being deemed to have met criteria "comparable to medical homes expanded under section 1115A(c)".

Small Practices and Virtual Groups

Solo and small practices represent a significant portion of care providers across the country, and downward financial pressure on these practice models is a threat to their ability to continue to provide patient care to Medicare beneficiaries. The lack of pathways to establish virtual groups for the 2017 performance period exacerbates this effect. We urge the expeditious development of a pathway for eligible clinicians to form virtual groups. As well, while we support leveraging existing reporting technologies such as registries, Qualified Clinical Data Registries (QCDRs), and electronic health records (EHRs) to transmit measure information to CMS, these technologies remain out of reach for many small practices. We are therefore disappointed that under the NPRM, this option is restricted to groups of 25 clinicians or larger.

Quality Performance Category

We are supportive of CMS' reduction in measures from the 9 required under the Physician Quality Reporting System (PQRS) to the 6 measures required in MIPS' quality performance category. Yet we have strong concerns with the proposed percentage of patients required to be reported on for this category. 80 and 90 percent of patients (depending on submission mechanism) is an unnecessarily high threshold, and is a significant increase from the 50 percent threshold CMS set for PQRS in previous years.

Clinical Practice Improvement Activity (CPIA) Performance Category
We applaud CMS for the design of this performance category. It is clean, simple, and easy to understand; it also allows clinicians to directly get credit for activities they are executing to benefit long-term patient care and enhance population-level health management. We greatly appreciate the lowered scoring thresholds for small, rural, or geographic HPSA eligible clinicians, and appreciate CMS providing this special consideration. We ask CMS to add recognition of Osteopathic Continuous Certification to the CPIAs, as currently only Maintenance of Certification is recognized.

Advancing Care Information (ACI) Performance Category
Many, if not most, of the facets of the Meaningful Use/EHR Incentive program in Medicare that have been so problematic for eligible professionals are perpetuated in this proposed rule, and we strongly encourage CMS to reconsider this approach.

Advanced Alternative Payment Models
We strongly urge CMS to reconsider the application of Advanced APM criteria to align more closely with what we see as Congressional intent, and provide more flexibility for the inclusion of APMs into the Advanced APM program. Utilizing strict criteria, CMS has identified only six models that it anticipates would qualify as Advanced APMs for the 2017 performance year. We also support an expeditious review process of models by CMS that enables new models and additional slots to become available.

Terminology
We urge CMS to reconsider some of the new terminology it appears to have set in the proposed rule, as we are concerned it will be very confusing and misleading for clinicians. From ACI performance category scores to ACI performance scores, a Quality performance category and a Quality Payment Program, and Advanced APMs while statute uses Eligible APM, the terms throughout will very likely be problematic if finalized. We recommend alternatives throughout our comments.

Our specific comments on the proposed rule follow in the pages below in greater depth.

Specific Comments on Proposals

Section Links

1. Meaningful Use Prevention of Information Blocking and Surveillance Demonstrations[2]

Surveillance Demonstrations

Real world use of health information technology (HIT) systems dictate that a multitude of software, hardware, and connectivity types must facilitate the transfer of data. These conditions are different than laboratory settings in which the equipment is initially tested. As such, we appreciate the Office of the National Coordinator for Health IT (ONC)'s continued efforts to evaluate equipment in the field to ensure certified electronic health record technology (CEHRT) is able to fully execute its promised functionality. However, we have strong concerns that participation in randomized surveillance, which had been voluntary for providers under ONC's 2015 Edition Final Rule, is now proposed to be made mandatory, both for MACRA's ACI category, and for remaining Meaningful

[2] Id. pg. 36-47

Use programs (such as the Medicaid EHR Incentive Program, and hospitals in the Medicare program).

Physicians are just one stakeholder in the HIT interoperability arena. While we agree that physicians must share in some of the responsibility, we stress that the burden of ONC's national goals on interoperability should not be placed disproportionately on their shoulders. While the MACRA legislation calls for widespread interoperability by the end of 2018, that provision only calls for the Secretary to issue a report to Congress at the end of 2019 with recommendations, if that objective was not achieved. We therefore believe the proposed requirement that providers must attest they will cooperate with CEHRT surveillance is against statutory intent.

With that being said, we would encourage providers to participate in CEHRT surveillance, and feel that a large majority would be very willing to do so, as it is an effective way of ensuring the very vendor products they are required to invest in will meet their expectations. We therefore propose that CMS incentivize voluntary participation in surveillance by providing clinicians that do so with an automatic half credit toward their ACI performance score (i.e. 25 percent of their total ACI category score). CMS sets precedent for such a mechanism in this very proposed rule, where it proposes that eligible clinicians who participate in a CPIA study to examine their clinical quality workflows and data capture would receive full credit (60 points) for the CPIA category. The impact on a particular clinician of participation in an EHR surveillance encounter in terms of intrusiveness, practice interruption, and time usage is almost identical to that encountered by a clinician in the CPIA study, and therefore should be approached in a similar manner.

We caution that surveillance efforts should be carried out so as to avoid placing undue burden on physicians and their staff. For instance, Office of the National Coordinator Authorized Certification Bodies (ONC-ACBs) must schedule appointments with physicians at least 30 days in advance. In addition, appointments should be flexible in timing, including hours before or after normal business hours, or on weekends, to allow physicians to meet the requirements of the oversight program without detracting from patient care. Finally, should an ONC-ACB handle matters inappropriately, physicians must have recourse with ONC and CMS to file a formal complaint, and during the time in which the complaint is reviewed and addressed by ONC and CMS, that ONC-ACB would not be permitted by to continue surveillance of that physician's or practice's systems. These parameters are suggested in addition to those described in the proposed rule regarding the methods used to select locations, sampling methodologies of providers, and the exclusion of certain locations.

Information Blocking

The AOA supports an open interoperability platform for health care delivery, in order for clinical information systems to capture and share quality, outcome, and cost data for the purposes of defining the "value" based model of care. As well, the AOA has signed the HHS' Interoperability Pledge that includes a commitment to not block electronic health information (defined as knowingly and unreasonably interfering with information sharing). We therefore agree that the proposed attestation requirements are appropriate, specifically: 1) no willful action to limit interoperability of EHRs, 2) implementation of practices to ensure connectivity and exchange of information, and 3) responsiveness to requests to retrieve health information from patients and providers.

2. MIPS Eligible Clinicians[3]

We agree with the proposed definition of MIPS eligible clinician including the exclusion of low-volume threshold eligible clinicians, qualifying APM participants, and partial qualifying APM participants. In particular, we support voluntary MIPS reporting and aligned payment adjustments for partial qualifying APM participants.

Non-patient-facing eligible clinicians

Non-patient-facing clinicians should be included as MIPS eligible clinicians to the extent that measures meaningfully reflect their work. This entails that these clinicians will likely have fewer and different measures than patient-facing clinicians. As a result, we support appropriate reweighting of performance categories if a minimum number of measures within that category cannot be meaningfully reported. We support the threshold of 25 or fewer patient-facing encounters in a performance period of one year as the definition of 'non-patient-facing clinician'. Further, activities that are not patient facing should be identified by CPT code so that clinicians can appropriately assess themselves in relation to this definition. We support CMS' proposal to include telehealth services as patient-facing encounters. These services represent both synchronous and asynchronous telemedicine in which the clinician and patient may be engaged in activity that is substantively similar to patient-facing activity.

Rural Health Centers and Federally Qualified Health Centers

We recognize that variations in billing may complicate MIPS participation and tracking. For providers in rural health centers (RHCs) and federally qualified health centers (FQHCs) with all-inclusive payment methodology, we urge CMS to consider alternatives for which clinicians in RHCs and FQHCs using all-inclusive payment methodology may receive incentive payments for improved health care. The intent of MIPS is to drive fee-for-service payments from volume- to value-based incentives, and this goal should be worked toward by all.

3. MIPS Eligible Clinician Identifiers[4]

We support the use of the taxpayer identification number (TIN) and national provider identifier (NPI) to identify eligible clinicians. For groups, a TIN with more than two associated NPIs who have assigned their billing rights to the TIN is appropriate.

For individuals, the use of both TIN and NPI is appropriate to identify the individual. We note that this TIN/NPI identifier can change if a MIPS eligible clinician changes practices or if a group merges with another in a performance period. In these cases, we suggest that the NPI would be consistent and can be tracked to determine a second TIN/NPI. For a performance period in which the eligible clinician switches identifiers, both identifiers should be used to track the eligible clinician.

4. Exclusions from MIPS[5]

Newly Medicare-enrolled eligible clinicians

CMS offers that new Medicare-enrolled eligible clinicians are inclusive of professionals who first become Medicare-enrolled and who have not previously submitted Medicare claims, either as an individual, or group. We appreciate that such clinicians who do not complete a full performance period in their initial year will not receive a payment adjustment in the corresponding payment period. However, we request that CMS consider ways to support these transitioning physicians to

[3] Id. pg. 48-60
[4] Id. pg. 60-65
[5] Id. pg. 65-68

deliver high quality care in Medicare. As such, we offer that any such eligible clinician should be able to voluntarily report to MIPS, and still receive feedback for that year. If they are part of a group, the scores for all MIPS categories and the composite performance score of that group should also be shared with the eligible clinician. If they are not, their results can be compared to a similar cohort of physicians in their particular practice settings. We also request clarification on how providers returning to Medicare after an absence would be considered under this definition, given they would have previously billed Medicare, but are new to the program under MIPS.

Partially Qualifying APMs
We agree with the proposal that qualifying APM participants are excluded from MIPS and that partially qualifying APM participants may select to participate in MIPS reporting and payment adjustments, but are not required to do so.

Low Volume Threshold
Participants below the low-volume threshold represent a distinct cohort of providers who should be excluded from MIPS. We are concerned about the proposed definition of low-volume threshold as less than or equal to $10,000 in charges and care for 100 or fewer Medicare Part B beneficiaries. According to CMS' estimates, this would include 225,615 eligible clinicians.[6] As we previously suggested in our response to the MACRA RFI, an eligible provider with either fewer than 150 established Medicare patients or fewer than 30 reported Episode Treatment Groups (ETGs) in a year should be considered as having met a low-volume threshold. We urge CMS to reconsider the threshold.

To determine an appropriate volume of Medicare patients, we offer that for a primary care provider, fewer than 150 established patients would be an appropriate threshold. To differentiate these patients from those that are not established patients, billing codes that relate to primary care services should have been used by the provider to Medicare at least one time in a 365-day period of time.

To determine an appropriate volume of services to Medicare patients, we offer that for a primary care provider, fewer than 30 ETGs per year would be an appropriate threshold. Specialists may have fewer or different ETGs associated with their eligible providers for this purpose. In summary, an eligible provider with either fewer than 150 established Medicare patients in a year, or fewer than 30 reported ETGs in a year should be considered as having met a low-volume threshold.

We also encourage CMS to be transparent and communicate with physicians about their status as it relates to the low-volume threshold per CMS data, and should there be any discrepancies between the physician's records and CMS data, the physician should have the opportunity to clarify information or question CMS. Lack of opportunity to do this may leave some physicians with an unanticipated volume threshold status and potential inability to comply with MIPS due to lack of preparation for the volume status assigned by CMS.

Providers who in previous years have met the low-volume threshold may be unprepared to participate in MIPS, so CMS should immediately notify them of their status as it reaches within 20 percent below or above of the low-volume threshold. This will allow these clinicians to align their practices with their requirement to participate in MIPS. As well, this would permit the provider to either seek further clarification from CMS in a timely manner before reporting requirements are due, or to invest in the infrastructure and resources needed to meet the MIPS reporting requirements.

---

[6] Id. pg. 663

Additionally, we believe CMS should review and possibly update this low-volume threshold after the first performance period to evaluate the impact on practices.

5. Group and Virtual Group Reporting in MIPS[7]

Identifiers
We agree that a group can be defined as two or more NPIs that have their Medicare billing rights assigned to a single TIN. The group should self-identify in advance of the performance period for the MIPS payment year. Regarding the criterion that the group must stay a unit for the duration of the performance year, we agree, but suggest that extenuating circumstances may prohibit this in all cases. For instance, one of the NPIs in the TIN may move to another practice or TIN in the middle of a performance year. We appreciate CMS' clarification that the TIN would aggregate performance data and report the aggregate to CMS in order to be assessed as a group across all four MIPS performance categories.

Registration
Regarding registration, we appreciate CMS' suggestion that requirements for groups reporting through third parties will not have an additional registration step directly with CMS. For groups reporting via Consumer Assessment of Healthcare Providers and Systems (CAHPS) or the CMS Web Interface, we understand that CMS cannot identify groups using the submitted data and that separate registration will be necessary. In either registration pathway, we suggest that CMS must have a transparent process in which the group is contacted to verify their status and offered the opportunity to address any inaccuracies. We believe that the June 30 registration deadline in advance of the next 12-month performance period is appropriate. However, we question how groups can be addressed in the initial performance period in 2017, as the rule is finalized after June 30, 2016. We therefore suggest December 1, 2016 as a registration deadline for the first performance period.

Virtual Groups
MACRA statute outlines that MIPS eligible clinicians or groups of 10 or less MIPS eligible clinicians may elect to form a virtual group with others from the same two cohorts. Like the non-virtual group, the virtual group would be identified in advance of the performance period, which would be twelve months based on a calendar year. This structure would provide an opportunity for solo and small practices to share resources and economies of scale to meet the resource-intensive reporting required under MACRA. However, CMS has outlined that though the first MIPS performance period will begin in 2017, virtual groups would not be implemented until 2018. We are disappointed that further details as to how virtual groups may be developed even after this delay are unavailable at this time. We urge CMS to actively engage with physicians associations in order to expeditiously develop an actionable pathway to ensure robust virtual groups can be developed in advance of 2018. If virtual groups are to mirror non-virtual groups, the registration deadline for virtual groups would be by June 1, 2017. As such, we note the limited time in which virtual groups must be developed and urge CMS to assign a team to work with physician associations to address this need.

As CMS considers advancing virtual groups, we offer that virtual groups should allow for providers to establish relationships that not only enable them to maximize MIPS reporting, but also build on that to consider innovative ways to enhance care. In addition, virtual groups offer a foundation of relationships between providers that may enable them to explore other ways of improving care

[7] Id. pg. 68-74

delivery including 1) enhancing the quality of their care from sharing best practices, and 2) considering other ways of working together such as developing a new APM model.

CMS should consider guardrails, rather than strict limitations in setting parameters for virtual group formation. For example, relying only on a geographic approach (within a certain distance of each other) would be unfair to providers in rural areas who would have fewer potential virtual group members to choose from, if any, if CMS used distance to limit virtual groups. This is in contrast to providers in urban areas who would have a multitude of options within the radius of the same mileage. In addition, we would advise not restricting only by specialty. Physicians in a multi-specialty "brick and mortar" practice are able to report in MIPS as a group, so virtual groups should be able to form cross-specialty as well. Providers will be voluntarily self-selecting into virtual groups, and will naturally group together in ways that are appropriate to their particular situation—whether it is because they are in the same specialty, or because they are in different specialties that complement each other and frequently share patients.

6. MIPS Performance Period[8]

2017 Performance Period
We understand that the performance period for 2019 payment is proposed to begin on January 1, 2017 and last for the duration of the 2017 calendar year. However, we offer that this schedule strongly limits the time physicians have to prepare for MIPS, especially given that a final rule will likely not be released until late September, 2016.

We offer that CMS should consider 2017 benchmark options for MACRA programs based on MACRA data, not data from legacy programs. We expand upon alternate approaches to benchmarks in the MIPS Composite Performance Score section of these comments. However, should CMS decide to pursue benchmarks for any MIPS program, we urge CMS to develop separate benchmarks for solo, small group, and larger group practices so that eligible clinicians are compared to similar cohorts. This approach is especially important due to the lack of virtual groups in 2017, which disproportionately impacts options for eligible clinicians in solo and small practices.

For 2018, we support that 2017 data is used to develop a baseline. The performance period would be from January, 1-December 31, 2018. Data can be reported as often as quarterly, but at least once per year by March 31, 2019. CMS should prepare and distribute quarterly feedback reports to eligible clinicians.

Performance Periods in the Future
More generally, we support utilizing a calendar year as the performance year for the payment year that begins two calendar years after the performance year. We appreciate CMS' proposal to explore shorter performance periods in upcoming years. We agree that a shorter performance period can limit burden on eligible clinicians reporting in MIPS. However, we caution that some practices experience varied volume based on their geographies, specialties, and nature of the patients they treat. For example, practices in northern regions such as Alaska, may note decreased volume in the winter months and spikes in the summer months. Other practices, such as those based near ski facilities, may have spikes in volume during the winter and relatively light volume in the summer. Given these types of variations, an appropriate shorter performance period may be challenging to

[8] Id. pg. 75-79

identify in a manner that also aligns with CMS' need to gather data, determine appropriate thresholds, and assign payment differentials.

Claims Deadlines
Regarding the collection and processing of claims information for a performance year, we support the alternative that utilizes claims processed within 60 days after 2017 for 2017 services within the performance year. We caution that the alternative presented by CMS that deals with the processing of claims within 90 days, may be problematic from two perspectives. First, claims processing delays are outside of the physician's control and present uncertainty. Second, in order to meet proposed deadlines, physicians benefit from certainty about the data in advance of 90 days. We do not believe the elimination of any unprocessed claims 90 days after the end of the year will skew the data presented or substantively limit the volume of data reported by the eligible provider.

Less Than a Year of Performance Data
We agree that physicians with less than twelve months of performance data, such as when switching practices or taking longer-term leave, should report for the time they do have, and be assessed on it should there be sufficient sample sizes. Those with insufficient sample sizes due to the shorter time period will not be scored on those measures and activities, and as CMS notes, will not be scored on any measures for which the sample sizes are too low.

7. MIPS Category Measures and Activities[9]

Submission Mechanisms
Regarding submission of performance data, we greatly appreciate CMS allowing providers to use a different submission method per category. This provides flexibility and allows providers to leverage those resources they have—for example, a physician who is part of a specialty registry could have that qualified registry submit his Quality data on his behalf, use his EHR to submit his data for the ACI category, and manually attest for his CPIAs. We also applaud CMS for being flexible in cases where a provider submits data for a single category through two mechanisms, by scoring both submissions and using the higher score.

We support CMS and ONC to require health IT vendors to have the capability to submit data for all MIPS performance categories as CMS proposes. As noted, being able to use a single mechanism for submission will greatly reduce administrative burden on providers. Providers already face an overwhelming number of health IT products and options, and requiring this capability by vendors could reduce the number of expensive upgrades and add-ons they would need to invest in.

However, we question CMS' proposal to limit the use of CAHPS and CMS Web Interface for reporting to only groups of 25 providers or more. We envisioned the CMS Web Interface as a resource that would be available to all eligible providers. This would ensure that a single portal is available across geographies, practice types, and resource levels of providers. Small and solo practices of less than 25 providers are the very ones who could most benefit from the option to use the CMS Web Interface, since they are often unable to invest in the more sophisticated health IT systems that can facilitate reporting. They are unfairly locked out from it under this proposal. CMS' approach to the CMS Web Interface seems to be based on its use in previous programs, rather than its potential to facilitate the goals of MIPS for all eligible clinicians.

[9] Id. pg. 79-89

We appreciate CMS' intent to incentivize reporting via CEHRT including QCDR, qualified registry, CMS Web Interface, or other CEHRT by an awarding a bonus point in Quality for doing so. However, we caution that the availability of some new measures to limited reporting mechanisms, such as certain quality measures reportable only through QCDRs, is a disincentive to the use of other CEHRT that CMS may want to incentivize. In addition to being confusing, the varied availability of measures based on which reporting technology is used reinforces the effect of differentials in resources between providers. This creates a less level playing field for eligible clinicians.

Submission Deadlines
We agree that data submission deadlines should occur after the close of the performance period, to dovetail with claims and workflow processes commonly used by eligible clinicians. A data submission period of January 1 through and inclusive of March 31 would accommodate both policy options that CMS raised in regard to the claims included in a performance year. However, we note that the March 31 end date provides less time to review data after a 90-day claims processing deadline. For this additional reason, the 60-day processing deadline we supported earlier in these comments would better dovetail with a March 31 terminal date. We oppose shorter reporting timeframes for eligible clinicians using CMS Web Interface or any other reporting mechanisms. These divergences create complexity in the MIPS system. We do not support a closer reporting date after the close of the performance and claims inclusion periods. Eligible clinicians require this time to review the reported data.

We support quarterly or semi-annual data submission periods as options available to eligible clinicians so that clinicians may report up to quarterly, but must report a minimum of one time per year. This flexibility will allow eligible clinicians of varied practices to meet MIPS requirements with less burden, such as that of maintaining data sets throughout the year. After each quarterly reporting period, eligible clinicians should have the opportunity to review the data and escalate any concerns to CMS to be rectified. We further support a quarterly report by CMS for each eligible clinician that details their progress. The document will allow clinicians who report more frequently than one time per year with a tool to measure progress and include learnings in clinical practice and workflow.

8. Quality Performance Category[10]

Terminology
The term Quality Payment Program is not included in the MACRA statute, and is not fully defined in the proposed rule (only used throughout). We would recommend CMS use a different term to encompass the entire new payment system under MACRA (i.e. MIPS and APMs). Given that there is a Quality Performance Category under MIPS, using the term "Quality" as well for the all-encompassing program will be confusing for clinicians.

Contribution to the Composite Performance Score (CPS)
CMS proposes that the Quality category will count for 50 percent of the MIPS composite performance score (CPS) for the 2019 payment year. In 2020, this will decrease to 45 percent, and then in 2021 and future years, the percentage will be 30 percent. We support this proposed approach to weighting.

Submission Criteria

[10] Id. pg. 90-130

Eligible clinicians and groups submitting via all mechanisms except CMS Web Interface, CAHPS, and CMS-approved survey vendors, must report at least 6 measures, including one cross-cutting measure (if patient-facing), and at least one outcome measure. If an applicable outcome measure is not available, eligible clinicians or groups would report another high priority measure in lieu of the outcome measure. Overall, we are supportive of the reduction in measures from the 9 required under PQRS. We note that the alternative proposal CMS puts forth that allows clinicians to report on 6 measures, including one cross-cutting measure, and one high-priority measure (rather than just an outcome measure), is preferred. It increases the options for measure selection, and provides greater flexibility. Depending on which of these approaches CMS chooses to finalize, we suggest adding a table of just the high-priority or outcome measures for easier reference for clinicians. Currently, one must cross-reference measure types considered high priority under the proposed rule (appropriate use, patient safety, efficiency, patient experience, and care coordination measures), and then refer back to Table A to pick them out.

We also support the proposed approach to allow clinicians to choose their 6 measures to report from either a full list of MIPS measures, or from a specialty-specific measure set. Having the full list of measures sorted by specialty will facilitate clinician selection, and reduce administrative burden. As well, it reduces uncertainty for a clinician on whether a measure doesn't exist to report to, based on their specialty, or if they just missed one in the list of over 300 measures--the measure set already encompasses that limitation. We would propose for those specialty sets that don't have at least one outcome measure, for it to be clearly marked as such, and then note which measures in the set would qualify to meet the required as the high-priority alternative. This will further enhance the benefits of the specialty measure sets.

Given the above complications, we strongly support CMS' noted intention to develop a validation process to review and validate which measures an eligible clinician or group can report on, based on factors such as their specialty and sample size. We would suggest a simple web interface that clinicians could query to receive this information.

Measure Types

We agree with CMS that outcome measures "are more valuable than clinical process measures and are instrumental to improving the quality of care patients receive." Outcomes are the endpoint of processes, care coordination, patient safety, and patient experience, and therefore are the ultimate measures. Yet we caution CMS against simply increasing the required number of outcome measures each year. Currently, only roughly 120 out of over 1,900 available measures are outcome-based. In order for more outcomes measures to be utilized and incorporated into the Quality Performance Program (QPP), more must be developed. One standard approach to outcomes measure development is the Outcomes Measures Hierarchy model advocated by Dr. Michael E. Porter at Harvard[11]. We urge CMS to only increase the required number of outcomes measures when sufficient additional outcome measures have been developed and validated to ensure clinicians can choose those most meaningful to their practice.

We agree that patient safety and care coordination measures are more relevant than clinical process measures for improving patient care. However, we oppose CMS' suggestion that it will increase the required number of patient experience measures for the Quality category in future rulemaking. Physicians should not face payment penalties based on elements of care outside of the physician practice's control. Such surveys often depend on patient perception rather than on the actual care

[11] N Engl J Med 2010; 363:2477-2481

received, and can be easily influenced by external factors such as poor weather, or unexpected traffic on the way to the physician's office. As well, the recent scrutiny on opioid prescribing practices and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) questions on pain have revealed underlying pressures on physicians such surveys create to accommodate their patients through treatment approaches that may not be medically optimal.

We support CMS' proposal to closely examine recommendations from HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) on risk adjustment for socioeconomic status (SES) and potentially incorporate them in future rulemaking. There is already wide acceptance of the need to risk adjust outcome performance measures to account for differences in patient health status and clinical factors present at the start of care. However, SES may also influence patient outcomes. We therefore support adjusting measures in MACRA for SES to improve the relevance and accuracy of performance results. Doing so will ensure that physicians will not be penalized for serving populations that may require more intensive interventions, and thereby increase access to care for these individuals.

More broadly, we support risk stratification of other measures as soon as feasible to ensure that eligible clinicians serving higher need patients are not penalized. We support CMS' goals of increasingly incorporating population-based measures as they are determined to be relevant and meaningful, but we caution that these measures especially must be risk stratified and attribution methods do not disadvantage any cohorts of eligible clinicians.

We caution against measures of overuse or underuse which, as CMS notes, are based on differing metrics of appropriate use levels. Divergent opinions within the literature and medical practices demonstrate insufficient evidence for a measure on that topic.

Submission Criteria for Groups Reporting via CMS Web Interface
For groups reporting via CMS Web Interface, groups of 25 or more eligible clinicians populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample. If there are less than 248 Medicare beneficiaries, the group must report on 100 percent of beneficiaries. All measures in the set are required for reporting; the omission of any measures will be considered zero performance for that measure. As a result, groups with insufficient measures should not report via the CMS Web Interface. This policy limits the use of the CMS Web Interface by setting high thresholds for successful use of this technology. We oppose this approach.

Performance Criteria for Groups Reporting via CAHPS
For groups reporting via CAHPS, groups of 2 or more eligible clinicians can voluntarily participate in the CAHPS for MIPS survey and have the data reported on its behalf by a CMS-approved survey vendor to meet MIPS requirements for the one cross-cutting and/or patient experience measure. Five additional measures are required to meet MIPS' six measure threshold. CMS proposes that the survey would be administered from November to February of the reporting year. We caution that this period does not align with either the performance period (January 1-December 31) or the reporting period (January 1-March 31), and thus creates additional confusion within the MIPS program. We do not believe CAHPS for MIPS should be mandatory for any group. We further question CMS' proposal to expand CAHPS for MIPS beneficiary samples to those covered by other payers. This additional volume would increase burden on eligible clinicians.

Data Completeness Criteria

We have strong concerns with the proposed percentage of patients required to be reported on for the Quality category. 80 and 90 percent of patients (depending on submission mechanism) is an unnecessarily high threshold, and is a significant increase from the 50 percent threshold CMS set for PQRS in previous years. Transitioning to MACRA in 2017 will be an enormous undertaking for clinicians, and already encompasses many significant changes. We therefore strongly urge CMS to preserve that threshold of 50 percent for the 2017 performance period to allow clinicians time to adjust. Thereafter, any increases to this threshold should be incremental and phased in over multiple years, with no single annual increase larger than 10 percent.

Furthermore, we strongly oppose a differential threshold that is based on data submission mechanism. CMS proposes that MIPS eligible clinicians or groups reporting via QCDRs, qualified registries, or EHRs must report on 90 percent of patients meeting the denominator, regardless of payer, while individual MIPS eligible clinicians using Part B claims as the submission method must report on 80 percent of only Medicare Part B patients. Overall, having varied thresholds of data or cohorts of patients based on reporting mechanism complicates the MIPS program and creates confusion for physicians. As well, both the lower threshold and restriction of the denominator to only Medicare Part B patients for the claims submission mechanism create a strong perverse disincentive against submission via QCDR, CEHRT, or qualified registries. These are the very methods CMS itself notes earlier in the proposed rule that it is encouraging clinicians to use to submit their data.

We oppose requirement of all-payer data at this time for any submission mechanism. This additional data would add to the volume of data reported by eligible clinicians, and represents an unprecedented change in Medicare reporting. Inclusion of all-payer data should be voluntary, and data should be stratified to ensure Medicare beneficiaries and other patients are appropriately identified. Given the statute provides that "analysis of the quality performance category *may* include quality measure data from other payers..." (emphasis ours), we believe having all-payer data reporting as voluntary will remain in line with statutory intent. We also note that neither the Resource Use nor the ACI performance categories require any all-payer data—given CMS' stated desire to streamline and harmonize reporting under MACRA, we therefore strongly urge reporting all-payer data to be made voluntary for the Quality performance category.

As well, it is unclear from the rule as written whether failure to meet the proposed data completeness threshold will result in failure of the entire Quality category, or of just that measure. The proposed rule states, "clinicians and groups who do not meet the proposed reporting criteria noted below would fail the quality component of MIPS." Our interpretation of this language would be that it clearly denotes a failure of the entire Quality performance category. Yet CMS officials at the May 23 Listening Session with physician associations in Washington, DC clarified that it would only mean failure for individual measures that do not meet completeness thresholds. We strongly oppose the first interpretation, and urge CMS to clarify that failure to meet a completeness threshold for a particular measure will only result in a failed score in the final rule for that measure.

We therefore propose that for the 2017 performance period, a 50 percent data completeness threshold should apply to each measure regardless of submission mechanism, and if it is not met for a measure, only that measure would be failed, not the whole of the category. In subsequent years, the threshold should not increase by more than 10 percent in a single year.

Non-Patient Facing Physicians
We are concerned that CMS' proposed definition of non-patient facing is too limited. MIPS eligible clinicians *or group*s with 25 or fewer patient facing encounters during a performance period are defined as 'non-patient-facing'. Our concern is that equating an individual and a group for the purposes of setting this threshold is an imbalance. Twenty-five or fewer is be an appropriate threshold for an individual, but is likely too low for a group, especially a large group. We encourage CMS to revisit this definition and consider a sliding scale threshold that increases for categories of increasing group size.

Application of Additional System Measures
We appreciate CMS' intent to use reliable measures for all cohorts of eligible clinicians. For eligible clinicians based in facility setting, we support the option for those clinicians to use their institution's performance rates as a proxy for their MIPS eligible clinician's quality and/or resource use scores. However, when calculating performance thresholds, CMS should stratify eligible clinicians to ensure that small, independent physicians are not compared to facility-based physicians who have adopted their institution's performance score as a proxy. Doing so would severely disadvantage smaller practices in meeting the MIPS performance threshold and result in cuts to their Medicare payment.

Selection of Quality Measures for Individual MIPS Eligible Clinicians and Groups
Regarding CMS' proposal to have measures available by November 1 the year in advance of the performance period, we tentatively support this date. We note that this will provide 60 days in advance of the beginning of a performance period to align workflow and reporting to the measure. Ideally, eligible clinicians would have more time to consider changes and alternatives, but we recognize that the development and evaluation of measures will require time earlier in the calendar year and we support leaving appropriate time for these activities. Regarding the measure submission deadline of June 1 two years in advance of the performance period in which the measure would be used, we suggest that the runway between measure proposal and approval be shortened where possible to allow measure developers to fill gaps in measures and update measures in a timely manner.

As the current volume of measures is a burden to providers and does not add value for patient care or to the health care system more broadly, we support the alignment and streamlining of measures across both public and private programs. In order to ensure a core set of measures is available for providers, we would prioritize cross-cutting measures such as care coordination. This quality domain as well as the domains of clinical care, safety, and population health and prevention be prioritized above other domains. Care coordination represents an investment in patient care for which better health outcomes generally result. It includes time with patients to engage with and educate them, time with other health care professionals or staff to collaborate and share information, and time without others present to deal with administrative issues, such as appropriate documentation, follow up, and planning. This investment of time and documentation can reduce duplication of provider services and tests, and also fortifies non-clinical collaboration including referrals to community services and follow up to learn if they were actually utilized by the referred patient. As coordinated care would limit or eliminate duplication of services, this approach would highlight resource efficiencies associated with this care model.

Topped Out Measures
We oppose the removal of topped out measures as defined by measures on which eligible clinicians perform well with little room for improvement. High performance on a particular measure, if aligned appropriately with the goal of improving quality, should be rewarded and more importantly

should be incentivized to maintain – this, after all, is the essence of improving patient care. While we understand that CMS seeks to incentivize continued growth, the continued increase of performance measures and thresholds, while tied to payment, creates an exhausting system in which eligible clinicians have little opportunity to consider innovative practices because they are instead continually meeting prescriptive thresholds. This system can be a disadvantage for patients and the health care system which can benefit from the innovative solutions developed by physicians, when they are provided with the opportunity and resources to make such changes. We urge CMS to ensure MIPS leaves room for innovation and organic growth, rather than meeting increasing prescriptive measures.

9. Resource Use Performance Category[12]

General Overview and Strategy
Measure reporting can pose a burden to eligible clinicians, so we appreciate CMS' intent to minimize reporting and utilize claims data to determine resource use without requiring any clinician intervention or involvement. For any measures attributed to an eligible clinician, we stress that the data associated with that measure should be available to the eligible clinician to review in advance of its use to determine performance. This will provide eligible clinicians with the opportunity to review the data and identify any potential issues in advance of its use in a MIPS score.

We agree with CMS' approach not to have a minimum number of measures to receive a score for resource use. We question equal weighting of resource use measures attributed to a clinician. We suggest that episodic measures reflect discrete care that is more appropriate for resource use comparisons and metrics than overarching resource use measures. We appreciate CMS' intent to also use broader resource use measures that are not specific to episodes, but we do not think these measures are meaningful or present an opportunity to reliably compare eligible clinicians' performance due to the varied nature of the services provided by eligible clinicians.

As well, we support CMS' recognition that all resource use measures should be risk-adjusted for geographic rate adjustments and beneficiary risk factors. In addition, we agree that a specialty adjustment should be applied to the total per capita cost measure.

Value Modifier Cost Measures Proposed for the MIPS Resources Use Performance Category
Regarding the use of legacy measures from the VM [total per capita cost, Medicare Spending per Beneficiary (MSPB), payment standardization, etc.], we appreciate CMS' intent to be comprehensive, but we are concerned that the selected measures still have issues which should not be carried over into the newly established MIPS program.

- For the MSPB, CMS proposes to use a minimum of 20 cases, alter the measure to remove specialty adjustment, and modify the cost ratio for the difference between observed and expected episode costs before assigning the measure to eligible clinicians as solo or group practices. CMS states that this approach will result in a low-moderate reliability score of 0.4. We reiterate our concerns with utilizing measures that lack robust reliability.
- For the total cost per capita measure, we appreciate CMS' analysis a minimum of 20 cases results in high-average reliability of this measure for both solo and group practices. However, we caution that even within these practice cohorts, variations in patient mix contribute to skewed results.

[12] Id. pg. 131-160

Attribution

We support CMS' proposal to allow evaluation of performance at the individual and group level, rather than just at the TIN level. Using a TIN/NPI combination will allow CMS to appropriately identify eligible clinicians. For clinicians reporting as a group, the TIN/NPI can be used for all cases attributed to that TIN. This approach will apply one methodology to individuals and groups and aid CMS in appropriately attributing contributions of eligible clinicians if changes occur during the performance period, such as their exit from the TIN.

We also support defining primary care by HCPCS/CPT codes: 99201-99215, 99304-99340, 99341-99350, G0402, G0438-G0439 as used in the VM along with the addition of new care management codes: 99495-99496 and 99490. We support the elimination of CPT codes 99304-99318 when the claim is used with POS 31 modifier that identifies services provided to patients in skilled nursing facilities which occur more frequently than primary care services defined in the code set without the POS 31 modifier. We support the proposal for attribution to primary care services based on beneficiary attribution and not by restricting specialties on an exclusion list.

Reliability

We appreciate CMS' intent to use reliable measures, but we are concerned with the proposed approach to use less reliable measures in an effort to broaden participation in the program. Given that these measures are a basis for resource use performance ratings and contributors to the MIPS score, we are concerned that the use of any measure that is not highly reliable is a disservice to eligible clinicians whose Medicare payments may be modified using MIPS incentive payments.

Episode-based Measures Proposed for the MIPS Resource Use Performance Category

Episodic resource use measures will be established for use for conditions and procedures that are high cost, have high variability in resource use, or are high impact conditions, and for which a minimum of 20 cases are met. We note the challenge in identifying an episode of care, which necessitates discrete beginning and end times, for some health care services. However, for services that can be included as an episode, we believe that this bundle provides a valuable lens through which care can be viewed and resource allocation compared. In addition, these episodes can be inclusive of care across settings including across Medicare Parts A and B. We encourage CMS to have a transparent and collaborative process with physician associations in developing these episode groups.

Episode-based Measures

For attribution of acute condition episodes, we question using a determination that a clinician billed at least 30 percent of the inpatient E&M visits during the patient's "trigger event" as the primary attribution mechanism. Rather than this retrospective approach, we urge CMS to consider a prospective approach utilizing the newly created patient relationship codes. For procedural episodes, we question which code is the trigger code for each episode, how that code was identified, and if physician associations informed that decision.

Additional System Measures

We support the exploration of measures that are inclusive of resource use across sites of service including Medicare Parts A and B. Additional resource use in the outpatient setting may result in lower resource use in the inpatient setting, and these measures may highlight areas in which additional outpatient resource use results in lower resource use elsewhere. In addition, we support considerations of how Medicare Part D costs can be included in a holistic, system-wide measure. However, theoretical ideals differ from actual application and we caution that such measures should

be thoroughly vetted through the availability of CMS data and methodologies that stakeholders can independently replicate and on which they can provide insight in advance of completing measure development. Finally, we suggest that such measures should be piloted in advance of broader use in MIPS.

10. Clinical Practice Improvement Activity (CPIA) Performance Category[13]

Contribution to Composite Score
In the 2017 performance year, CPIA will account for 15 percent of the MIPS score. Eligible clinicians may satisfy the CPIA requirement by selecting activities from Table H. In that first year, CPIA activities will be designated as yes/no, where "yes" indicates the activity was performed for a minimum of 90 days within the performance period.

We support the overall approach developed for this performance category, and applaud CMS for incorporating widespread stakeholder calls for a "menu" approach.

Patient-Centered Medical Homes
Under statute, MIPS eligible clinicians or groups that are a certified Patient-Centered Medical Home (PCMH) must be given the highest possible CPIA score. A PCMH will be eligible if it is a nationally recognized accredited patient-centered medical home, a Medicaid Medical Home Model, or a Medical Home Model. As well, NCQA Patient-Centered Specialty Recognition will also be eligible. CMS proposes that nationally recognized accredited PCMHs would be recognized if they are accredited by: National Committee for Quality Assurance (NCQA) PCMH recognition, the Accreditation Association for Ambulatory Health, the Joint Commission Designation, or the Utilization Review Accreditation Commission (URAC).

We strongly support CMS' approach in the proposed rule to provide PCMHs with full credit for the CPIA performance category, as was called for in statute. As well, we support the four listed organizations serving as recognized accrediting bodies. Yet we recommend that CMS broaden PCMH eligibility for full CPIA credit to specifically be inclusive of programs that have a demonstrated track record of support by non-Medicare payers, state Medicaid programs, employers, and/or others in a region or state. The programs to be included should be clearly articulated by CMS in advance, along with transparent criteria and methodology for the addition of new PCMH programs. To inform such efforts, we recommend that CMS look to the recommendations of the Patient-Centered Primary Care Collaborative (PCPCC) Accreditation Workgroup. The AOA is a founding member of the PCPCC, and its Board-approved Accreditation Workgroup recommendations include a set of guiding principles to improve medical home recognition processes overall, as well as more specific recommendations for accrediting organizations—whether nationally recognized accreditation program or by a state or non-Medicare payer program. CMS should investigate how it can assist in moving all types of recognition and accreditation programs toward true improvement and patient-centeredness as outlined by the Workgroup. As was noted in the recommendations:

> "PCMH recognition should ultimately be a "good housekeeping seal of approval" demonstrating achievement of the attributes (outcomes) ensuring consumer confidence in the practice and its clinicians. Recognized practices should be rewarded with increased payment or participation in other "preferred programs"."

[13] Id. pg. 161-186

Similarly, while we support those practices with NCQA Patient-Centered Specialty Recognition also qualifying, as noted in the proposed rule, we ask that CMS broaden this eligibility to include those practices that may be certified in some manner by other nationally recognized accreditation bodies or programs implemented by non-Medicare payers, state Medicaid programs, employers, and others in a region that may become available. Such comparable specialty practices would at minimum document to CMS that they provide at least four of the following:

i. Planned coordination of chronic and preventive care.
ii. Patient access and continuity of care.
iii. Risk-stratified care management.
iv. Coordination of care with primary care physicians and across the medical neighborhood.
v. Patient and caregiver engagement.
vi. Shared decision-making.
vii. Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

For a PCMH that is only a portion of a TIN, such as one practice site out of five sites under the same TIN, we support prorated credit for the entire TIN that is in proportion to the percentage of the TIN that is a PCMH. Therefore a PCMH in one out of five sites would receive 20 percent of the 100 percent PCMH credit for the CPIA score. Effectively the eligible providers in the other four sites within the TIN would need to demonstrate other CPIAs to enhance this score.

CPIA Data Submission Criteria

Submission Mechanisms

We support CMS' proposal to allow CPIA data submission by qualified registry, EHR, QCDR, CMS Web Interface, and attestation. We encourage CMS to allow for yes/no attestation, regardless of submission mechanism, beyond its currently proposed limitation of it to 2017.

Weighted Scoring

CMS proposes to weight CPIA activities as high or moderate depending on their alignment with programs such as Quality Innovation Network-Quality Improvement Organizations (QIN/QIO) and CPCI, and programs that require performance on multiple activities. As the PCMH is weighted as the highest score, we offer that it is a reasonable metric for the weighting of other measures. The PCMH rewards investments that benefit patient care by building and/or expanding capacity within the practice. These investments benefit patients in both the short and long terms. As such, we offer that CPIAs that build or expand capacity to provide care for patients and demonstrate both short term and long term benefit should be highly weighted. Alternatively, CPIAs that improve care in the short term only, without capacity building for the long term, should be weighted as moderate.

Submission Criteria

The highest potential score for the category is 100 percent, which can be achieved by getting 60 points through 1) being a PCMH, 2) being an APM and performing 30 points of other CPIA, or 3) performing a combination of CPIA that sum to 60 points with highly rated CPIAs at 20 points, and medium rated ones at 10 points. For eligible clinicians in small practices (15 or fewer clinicians) or rural areas or geographic HPSAs, a 100 percent score can be achieved with just two CPIA activities (either medium or high) and a 50 percent score can be achieved with one CPIA activity (either medium or high).

We support the proposed approach to give 50 percent credit (30 points) for MIPS eligible clinicians or groups participating in an APM, based on their participation alone, allowing them to make up the other 30 points through reporting on an additional two or three CPIAs.

Finally, CMS notes that many of these criteria are for the first year only. We strongly support the proposed approach for this first year, but would urge the agency to continue this approach (including the 90-day reporting period) in subsequent years. The design of this performance category is clean, simple, and easy to understand; it also allows clinicians to directly get credit for activities they are doing to benefit long-term patient care and enhance population-level efforts. This is a marked and welcome contrast to the legacy reporting programs, which physicians have long complained only encourage "check-box medicine".

Special Consideration for Small, Rural, or Health Professional Shortage Areas Practices

We greatly appreciate the lowered scoring thresholds for small, rural, or geographic HPSA eligible clinicians, and applaud CMS for providing this special consideration.

CPIA Subcategories

We support the subcategories used in the proposed rule, and the addition of both emergency preparedness and integration of behavioral health in primary care. We strongly support the inclusion of this latter subcategory which will reward providers who integrate behavioral health with primary care. We suggest CMS consider a similar subcategory for primary care and dental health. Though Medicare does not cover dental care for its beneficiaries, Medicare beneficiaries do benefit from appropriate dental health services. Given the lack of Medicare coverage for dental health, a primary care physician may be the first to assess a dental health issue that requires a dental specialist to resolve. Primary care physicians who make such assessments, provide appropriate referrals, co-locate their practices with dental health services, or train with dental professionals to better evaluate their patients' oral health, should be recognized for this effort.

The AOA agrees that reducing health disparities is a national priority, and is a key focus of our organization. Regarding the proposed new subcategory for Achieving Health Equity, we have concerns with a system that rewards a provider to a greater degree because of the gender, race, religion, or other such identifying information of their patients, over which they as a physician have no control. However, we do support additional rewards to providers who serve in underserved areas as they tend to treat more complex patients including persons with behavioral health conditions, disabilities, racial and ethnic minorities, and sexual and gender minorities. We also support additional rewards to those providers who successfully manage health care for those patients regardless of geography.

We strongly support CMS' proposed additional categories for future consideration, Promoting Health Equity and Continuity, and Social and Community Involvement. We are in fact disappointed that CMS did not include them in this first year. Promoting Health Equity and Continuity would support access to care for all Americans, whether it is through Medicare, Medicaid, or Marketplaces. In addition, providers may undertake other activities to contribute to health care equity that could fall into these categories. These may include volunteering as part of medical missions, free clinics, etc., or having available equipment and accommodations for patients with disabilities. Social and community involvement recognizes non-clinical factors impact patient health. We suggest that it be explicitly inclusive of at least two components: 1) continuity of care through the social and community service systems, which includes appropriate referrals for support, and 2) integrated care

with the social and community service systems, which includes follow-up with the appropriate agencies to gather information helpful in treating the patient.

CPIA Inventory[14]

We are pleased at the breadth of activities included in the inventory, and support the vast majority of them as proposed, with the following exceptions:

- Activity - Participation in Maintenance of Certification Part IV: DOs board-certified by the AOA (rather than the American Board of Medical Specialties) are not eligible to participate in Maintenance of Certification (MOC). Rather, the AOA requires them to participate in Osteopathic Continuous Certification (OCC), a parallel process with equally rigorous requirements. The parallel section to MOC Part IV is Osteopathic Continuous Certification Component 4 - Practice Performance Assessment and Improvement. This component requires DOs to engage in continuous quality improvement through comparison of personal practice performance measured against national standards for their medical specialty.

  Earlier this year, CMS added AOA Board Certification data to Physician Compare (previously only holding ABMS data), allowing consumers to more accurately determine if a DO is in fact board certified. We therefore strongly urge that the CPIA in question either be amended to add Osteopathic Continuous Certification Part 4, or that an additional new CPIA for OCC Component 4 be added, allowing physicians to choose between them as appropriate.

  We propose the following description be used for them, "Participation in Osteopathic Continuous Certification Component 4 for improving professional practice by engaging in continuous quality improvement through comparison of personal practice performance measured against national standards for his or her medical specialty,"

- Activity – Use of telehealth services and analysis of data for quality improvement: we recommend adding an additional CPIA that pertains to these activities when provided to those in Rural Health Clinics (RHC), Indian Health Service (IHS) locations, or Federally Qualified Health Centers. We recommend this added CPIA be weighted as High.

- We recommend the addition of a new CPIA supporting performance improvement continuing medical education (CME) in recognition of the importance of, and the osteopathic profession's commitment to, lifelong learning.

- We recommend the following CPIAs be reweighted from Medium to High, in order to acknowledge their potential to greatly improve care and benefit patients, while also requiring a higher intensity of resources from clinicians to achieve:
  - Modified: Use of Telehealth services... (see above)
  - Participating in a Rural Health Clinic, Indian Health Service, or FQHC in ongoing engagement activities...
  - Participation in CMMI models such as Million Hearts Campaign
  - Access to an enhanced patient portal that provides up to date information…
  - Engage patients, family and caregivers in developing a plan of care and prioritizing their goals for action, documented in CEHRT
  - Incorporate evidence-based techniques to promote self-management into usual care

[14] Table H

- Completion of training and obtaining an approved waiver for provision of medication -assisted treatment of opioid use disorders using buprenorphine.
- Build the analytic capability required to manage total cost of care for the practice population
- Major depressive disorder: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions

CMS Study on CPIA and Measurement
We support CMS' proposal to conduct a study on CPIAs to inform this program as it is implemented. Further, we support awarding study participants with full credit for the CPIA category for their participation. We urge CMS to select an appropriate sample of eligible clinicians from both rural and non-rural settings, solo, small, and larger practices, inclusive of primary and specialty care, representative of varied philosophies of medicine including osteopathic and allopathic medicine, and inclusive of all types of providers who are eligible clinicians, in order to inform this study in a robust and comprehensive manner.

Stakeholder Engagement
We offer that consideration of additional CPIAs for inclusion should be a transparent process into which stakeholder feedback is invited. Further, we believe that stakeholders should be formally invited to nominate CPIA activities and their justification in an annual call for measures in advance of rulemaking. Decisions on new CPIAs should be completed in a timely manner and published in advance of the performance year.

11. Advancing Care Information Performance Category[15]
Overall, we are disappointed with the proposed approach to this category under MIPS. Many, if not most, of the facets of the Meaningful Use/EHR Incentive program in Medicare that have been so problematic for eligible professionals are perpetuated in this proposed rule. We are therefore very disappointed that CMS has approached this opportunity by clinging to the previous, problematic program design, and we strongly encourage it to reconsider this approach.

Our concerns with this performance category center on several areas. The first is its complexity. That the ACI section is the longest in the proposed rule of the four MIPS performance categories (almost *double* the next longest, Quality) aptly demonstrates that instead of streamlining the meaningful use program, as CMS had stated it would on numerous occasions, ACI is now greatly more complex. Both the scoring of performance, and terminology used throughout the category, are far too complicated and confusing for the average clinician to fully understand and be able to excel under.

Future Considerations
CMS notes in the proposed rule that it will continue to increase the stringency of the program as directed under the HITECH statute[16]. We caution CMS that the current approach under the EHR Incentive Program for increasing stringency has yielded little success, especially with the "all or none" scoring approach. Therefore, while we support CMS' proposal to in future years of ACI compare eligible clinicians' performance to their previous years or to a cohort of similar eligible clinicians (rather than to the universe of other eligible clinicians) in order to credit improvement, we urge reasonable and incremental increased thresholds for the overall category.

[15] Id. pg. 187-247
[16] 1868(o)(2)(A)

CMS seeks feedback on a use case approach to measuring meaningful EHR use, rather than a measure-based approach. We support such an approach, and urge CMS to quickly bring it into reality. Scoring clinicians on how they actually use health IT to improve patient care would make this performance category significantly more meaningful, and more importantly, could transform how EHR systems themselves are designed.

We would argue that the measure-based approach used to date is largely responsible for the current state of EHR systems with poor usability that do not integrate into a physician's normal workflow. These systems were designed *to* the measures, and not to how physicians actually work, in order to meet certification criteria. Therefore, a use case approach that measures how physicians actually work could lead to EHR systems designed for how physicians actually work. CMS notes that the technology and measurement for such a program is currently unavailable—we therefore would argue that the measure-based approach proposed in the rule should be significantly scaled back for the time being, so that resources in CMS and ONC can be devoted to developing and transitioning to the new use case approach.

We therefore note that we oppose the entire approach for the ACI performance category proposed in the rule. But short of such a drastic overhaul in the limited time that remains before MACRA's first performance year goes into effect, we offer the following specific comments.

Clinical Quality Measurement
We are pleased CMS followed statutory intent under MACRA to treat MIPS eligible clinicians as satisfying the Clinical Quality Measures (CQM) reporting requirement under the HITECH Act, and thereby have removed these duplicative measures as necessary to demonstrating meaningful use.

Performance Period Definition for ACI Performance Category
We do not agree with CMS' proposed mandatory 12-month reporting period for this category. As CMS notes in the proposed rule, it delayed finalizing such a reporting period previously under the EHR Incentive Program for 2015 based on feedback from many stakeholders and clinicians. Little has changed in the interim to justify now moving to require a twelve-month reporting period.

Further, CMS notes it has proposed to do so for the ACI performance category and in doing so "…the performance period for the advancing care information performance category would be the same as the performance periods for the other performance categories as indicated in section II.E.4." Yet CPIAs must only be attested to for 90 days. We therefore would argue that allowing a 90-day reporting period *as an option* under ACI for clinicians is still in alignment with the rest of the MIPS categories. We propose that clinicians under ACI for at minimum 2017 and 2018 should be allowed to choose whether to report to a 90-day period, or twelve months. This would allow clinicians who use third party intermediaries, such as registries and QCDRs, to submit for the calendar year if simpler for them, while giving others who do not currently have access to such systems a shorter reporting period and the needed flexibility it can bring.

ACI Performance Category Data Submission and Collection
Definition of Meaningful EHR User and Certification Requirements
We appreciate CMS providing flexibility and giving providers the option to use 2014 or 2015 edition CEHRT for 2017, which will give providers a longer period of time to update to the 2015 edition of CEHRT before the ACI reporting period in 2018.

That said, given the previous issues with CEHRT availability, we do have some concern that 2015 edition CEHRT could be delayed and would not be widely available for EPs by the designated timeframe. Final 2015 CEHRT requirements were released in December of 2015, and we understand that a typical timeframe for vendors to develop a system is between 18 and 24 months. However, this does not factor in additional modifications vendors will likely need to now make in order for the systems to meet new MACRA functions; these won't be finalized until this fall. We therefore are concerned vendors will not have sufficient time to adequately develop their products, achieve their certification requirements, and have their EHR products tested in real-world settings and ready for the market in advance enough of 2018. We must keep in mind that clinicians need considerable time to compare, select, purchase, install, and transition to a new system, so ideally they would need 2015 CEHRT widely available for purchase by June 2017.

We therefore recommend that CMS closely monitor the availability of 2015 CEHRT on the market in the early part of 2017, and should widespread availability not be achieved by July, 2017, we call on CMS to delay the 2015 CEHRT requirement beyond 2018.

Method of Data Submission

We appreciate the options provided to report data include EHRs, QCDRs, registries, and CMS Web Interface, as we support flexibility and options for eligible clinicians to report data. CMS notes that some QCDRs and registries may not be ready by 2017 to allow for such submissions, but we agree that having this mechanism as an option will support early adopters. We ask CMS to provide further details on the form and manner for data submission as soon as possible.

Group Reporting

We support CMS' proposal to allow clinicians the option to report as individuals, or as a group. Group reporting was not previously possible in the EHR Incentive Program, and could significantly reduce administrative burden. For groups, we support reporting by TIN/NPI in which data is aggregated into the TIN for the purposes of scoring the group. We urge CMS to adopt similar reporting and aggregation across MIPS categories to streamline the program and avoid complexity.

Reporting Requirements and Scoring Methodology

We strongly urge CMS to reconsider the proposed scoring methodology. We first note that just the terminology for this category is confusing--under the proposal, there would now be 1) a MIPS composite score; 2) an ACI performance category score; 3) an ACI performance score; and 3) an ACI base score. Given how very similar "ACI performance category score" and "ACI performance score" are as terms, we would minimum urge CMS to rethink calling it an "ACI performance score," and instead rename it to something like the "ACI graduated score". The base score can remain named as is under this new construct we are recommending.

Base Score

We question the need for a Base Score component in determining a clinician's final ACI performance category score. Beyond requiring clinicians to meet the Protecting Patient Health Information objective (which we support), achievement of the full 50 percent credit for this portion of the ACI category's score seems to simply require submitting a numerator and denominator (or yes/no statement) for each of the same measures included in the ACI performance score, without thresholds to achieve.

We would instead propose that the base and performance portions of the ACI score be combined into one. Short of that, we would support the primary proposal over the alternate proposal for the

base score, in order to minimize the number of required measures. As well, we support the modified measures for the base score proposed for 2017 only, for those clinicians who are unable to upgrade or purchase 2015 CEHRT by then. As noted earlier in our comments, clinicians will face significant barriers to obtaining 2015 CEHRT for 2017.

Performance Score

On its own, we support the graduated scoring approach for the performance score portion—we have long called for allowing clinicians to receive "partial credit" for achieving aspects of meaningful use, and the proposed scoring methodology does allow for that.

As noted above, though, we do not agree with having a base + performance score approach to scoring for the ACI category. We would instead recommend an approach as follows that is comprised of a single score for the category:

- 11 measures are scored
- Each measure can receive up to 10 possible points
    - E.g. a performance rate of 85 percent on a given measure would yield 8.5 points towards the entire ACI score.
    - ePrescribing, Protecting Patient Health Information, and Immunization Registry Reporting measures can retain a Yes/No, 0 or 10 points approach
- The points across all 11 measures are totaled
- A 20 point constant is added to that total for a final percentage (as is provided through the base score, since that has a total of 50 points but only encompasses three measures of 10 points each).
    - As with the proposed rule approach, the total can be up to 130 percent. Anything above 100 percent is scored at 100.
- The final percentage is then applied to the 25 points allocated for the advancing care information performance category and incorporated into the MIPS CPS (as proposed in the rule).

An example follows:

Objectives	Protect Patient Health Information	ePrescribing	Patient Electronic Access		Coordination of Care Through Patient Engagement			Health Information Exchange			Public Health
Measures	"	"	Patient Access	Pt-Specific Education	VDT	Secure Messaging	Pt-Generated Health Data	Pt Care Record Exchange	Request/ accept Pt Care Record	Clinical Info Reconciliation	Immunization Registry Reporting
Score	100%	100%	65%	75%	35%	40%	20%	60%	60%	80%	100%
% Points Earned	10	10	6.5	7.5	3.5	4	2	6	6	8	10
Added Constant	20 points										
Total	**73.5 + 20 = 93.5%**										

Entering in the same scores we use here in our example into the base + performance score methodology proposed by CMS in the rule will yield the equivalent final score (with the 20 point constant added). These equivalencies hold regardless of scores used, so we note that our recommended scoring approach is no more or less rigorous than that proposed by CMS, but will be simpler for clinicians to understand.

Measures

Regardless of scoring approach used, we do not agree with most of the measure set chosen for ACI in this proposed rule, nor with their thresholds. When the Stage 3 EHR Incentive Program was first released, clinicians were almost unanimous in our opposition to the measures included and overall approach. Recent estimates note that less than 15 percent of physicians have achieved Stage 2 of meaningful use. We therefore question why CMS would then carry over many of the same measures, only with the much higher thresholds set for Stage 3, into MACRA given these significant challenges.

As well, two of the measures proposed for the Performance Score require 2015 Edition CEHRT (Patient-Generated Health Data, and Patient Access, due to API requirement), which as noted above, many clinicians will not have in 2017. CMS has stated that for those clinicians with 2014 Edition CEHRT in 2017, they will only report on modified stage 2 measures. Yet this leaves them with a zero score for two measures, leaving them at an unfair disadvantage—especially since CMS itself implemented regulation that 2015 Edition CEHRT will not be required in 2017. Our specific comments on the ACI measures are as follows:

Objective – Protect Patient Health Information

Measure: Conduct or review a security risk analysis, implement security updates, and correct deficiencies.

The AOA supports this objective and measure. We believe additional educational efforts are necessary to ensure that physicians are properly informed and well-equipped to protect electronic patient information.

Objective – Electronic Prescribing

Measure: Eligible clinicians must generate and transmit permissible prescriptions electronically.

The AOA supports this objective and measure, and appreciates that the 80 percent threshold for this measure that was in Stage 3 has been reduced to a Yes/No approach.

Objective: Patient Electronic Access

Patient Access Measure: For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's certified EHR technology.

We appreciate CMS reducing the threshold for this measure from the Stage 3 final rule of 80 percent of patients, to a single patient. We note; however, that this continues the "all or none" scoring that we had hoped to move away from. We would also request clarification on how CMS plans to define "timely". In the Stage 3 final rule, this was set at 24 hours, which we opposed. We instead support a 4-day timeframe.

Regarding the API requirement, we note that in the Stage 3 final rule, CMS had noted this as an alternative, not a requirement, for the measure. Given that API technology is still new, we urge CMS

to keep this as an option under ACI, in order to allow clinicians time to upgrade their EHRs to enable this functionality.

Patient-Specific Education Measure: The MIPS eligible clinician must use clinically relevant information from certified EHR technology to identify patient-specific educational resources and provide electronic access to those materials to at least one unique patient seen by the MIPS eligible clinician.

- Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from certified EHR technology during the performance period.

While we appreciate any move away from an "all or none" scoring approach, we have concerns with setting the score to directly correlate to the percentage of patients the clinician is able to provide these resources to. With the denominator set at all patients seen by the clinician during the performance period, it will make it very difficult, if not impossible, for a clinician to achieve a high score on this measure. The measures specifies "clinically relevant information" identified from the CEHRT. There will be instances where information relevant to the patient's condition is not available. Or, in the case of a wellness visit, even appropriate. We therefore recommend instead that for this measure, the percentage calculated be multiplied by a coefficient of 2 to achieve the final score. Should this number be greater than 100, it will be reduced down to 100 for scoring purposes.

Objective: Coordination of Care Through Patient Engagement

View, Download, Transmit (VDT) Measure: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician. An MIPS eligible clinician may meet the measure by either—(1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's certified EHR technology; or (3) a combination of (1) and (2).

- Denominator: The number of unique patients seen by the MIPS eligible clinician during the performance period
- Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the performance period.

While we appreciate any move away from an "all or none" scoring approach, we have very strong concerns with setting the score to directly correlate to the percentage of patients, especially for such a challenging measure that relies almost entirely on patient actions and access to technology that is completely out of the clinician's control. The physician cannot control whether the patient accesses her record, sends a message, or submits her own data. Physicians should not feel pressure to make patients review their records if the patient is not inclined to do so. Patient portals are expensive and under-utilized by patients, who often find that the portals are difficult to navigate and feel they are of limited or no value. Even the added option of the patient accessing it through an API will not mitigate the challenging nature of this measure—

API technology is still nascent, and there has been limited development of apps that can successfully link with a clinician's EHR.

We therefore recommend that CMS either 1) set this measure threshold to "at least one unique patient", *or* 2) multiply the percentage calculated in the current proposed approach by a coefficient of 4.

Secure Messaging Measure and Patient-Generated Health Data Measure: For both of these measures, while we appreciate a lower threshold of "at least one unique patient", we again reiterate that this continues the "all or none" approach under the EHR Incentive Program. We would recommend instead that a percentage of patients be calculated under the proposed numerator and denominator, and then multiplied by a coefficient of 5, in acknowledgement of the challenging nature of these two measures.

As noted on the VDT measure, all of this is entirely outside of the clinician's control, and therefore we oppose performance being tied to the actions of their patients.

Objective: Health Information Exchange

Patient Care Record Exchange Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider—(1) creates a summary of care record using certified EHR technology; and (2) electronically exchanges the summary of care record.

- Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.
- Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

To ensure that physicians can successfully achieve the objective's measures is dependent on several factors outside the physician's control which include: readiness of the health care infrastructure, adoption of interoperability standards, interoperability of EHRs in real-world settings, and radical improvement in secure email exchange within the next year. To date, usable electronic exchange of data with others continues to be problematic - EHRs largely still do not talk to each other. CMS should focus its efforts on improving interoperability rather than moving more data.

Should CMS still keep this measure, we would propose for a scoring approach that the percentage be multiplied by a coefficient of 2 to achieve the final score. Should this number be greater than 100, it will be reduced down to 100 for scoring purposes.

Additional Considerations

We support reweighting the ACI Performance Category to zero for hospital-based MIPS eligible clinicians, as well as those facing extreme circumstances, lack of face-to-face encounters, or lack of control over the availability of CEHRT, as outlined in the proposed rule.

Medicaid Data

Regarding the mandatory reporting of data from Medicaid EHR Incentive Programs to Medicare ACI, we oppose this proposal. The additional volume of data tracking and reporting would pose a burden for eligible clinicians providing services to vulnerable populations. It does not make sense to require them to report their Medicaid data for the ACI performance category through the MIPS

submission methods, *and* being required to also separately demonstrate meaningful use in their state's Medicaid EHR Incentive Program in order to earn a Medicaid incentive payment. MACRA was meant to streamline reporting burdens on clinicians, and this would do anything but. We suggest that further consideration of this proposal be deferred for at least two years to provide eligible clinicians with time to meet the requirements of ACI with their Medicare cases before additional volume is considered.

12. MIPS APMs Scoring[17]

We seek clarity on the terminology CMS uses here. The proposed rule uses the term "MIPS APMs" 122 times, yet CMS staff at the May 23 Listening Session with physician associations in Washington, DC insisted that "there's no such thing as a MIPS APM". Regardless, we reiterate our comment that the terminology in MACRA surrounding APMs is unclear and inconsistent.

Challenges
CMS proposes that all eligible clinicians, including those in APMs, must report on MIPS in 2017. We understand CMS' rationale for this proposal in that eligible clinicians do not have guarantees that the will qualify as Advanced APMs for the purposes of 2019 payments under MACRA. However, we caution that CMS' approach to include these eligible clinicians under MIPS in 2017 presents several challenges.

First, eligible clinicians who participate in APMs are likely differently resourced and have made more substantial progress on the move to value-based care than eligible clinicians in other practice models. As such, the integration of data from MIPS APMs, to those in MIPS but not in an APM, will skew the universe of reported data to the side of better performance. This will impact CMS' threshold for 2019 payments to eligible clinicians who are not MIPS APMs. The effect will be that eligible clinicians not in MIPS APMs will have a higher threshold to meet in order to qualify for a bonus, and are more likely to receive a negative payment update. We therefore suggest that 2017 data from eligible clinicians in MIPS APMs should not be included with data from eligible clinicians who are not in MIPS APMs for the purposes of setting thresholds for 2019 payments. Instead, CMS can separately aggregate this data and use it for MIPS APM eligible clinicians' performance measurement.

In addition, as CMS notes, MIPS APMs have varied structures, incentives, and metrics that do not entirely align with MIPS categories and measures. As such, forcing MIPS reporting on MIPS APMs represents a drain on their resources while not being reflective of their work and model of care. CMS' attempt to correct for the disjoint between MIPS metrics and MIPS APMs by revaluing MIPS categories for MSSP, NextGen, and other models exacerbates imbalances with MIPS data previously described. For MSSP and NextGen, CMS proposes to eliminate the resource use category and reweight the other categories to 50 percent for quality, 20 percent for CPIA, and 30 percent for ACI. For other MIPS APMs, CMS proposes to also eliminate the quality category and redistribute the weight to CPIA for 25 percent and ACI to 75 percent.

We are concerned with this approach because it is complex and presents an imbalance in the MIPS program. First, should an eligible clinician in a MIPS APM indeed fully qualify as an Advanced APM under MACRA, the incentive payment would be 5 percent and not be based on MIPS metrics. In these cases, the reweighting should not affect eligible clinicians' payments. In the case that a MIPS

[17] Id. pg. 248-288

APM eligible clinician does not meet the criteria as a fully qualified Advanced APM, their incentive payments under MIPS would be heavily skewed to categories other than resource use. In addition, for non-MSSP or NextGen MIPS APMs, their performance is proposed to be based on just two categories with the overwhelming majority within ACI. This is a gross imbalance of reweighting, and given the significant challenges around meaningful use, could serve a significant perverse disincentive to clinicians entering into an APM. We do not think it was the intent of MACRA that any one category under MIPS should so fully dominate the MIPS performance score. We support that eligible clinicians in a MIPS APM are assessed as a group in a similar attribution manner to other eligible clinicians in groups under MIPS.

Methodology
CMS also proposes a scoring methodology[18] in which MIPS APMs scores are weighted by the size of their TIN as a portion of the APM entity. We question the rationale behind this method. Instead, we support that for any MIPS APM, the data would be aggregated at the APM Entity level and performance would be based on the group level. This would result in scores that more accurately reflect the contribution of eligible clinicians in MIPS APMs, which have little to do with the performance of unrelated eligible clinicians in the same model. We support feedback to eligible clinicians in MIPS APMs at the APM Entity level, the group level, and the individual level.

13. MIPS Composite Scoring Methodology[19]

Minimum Volume
To ensure robust benchmarks, we support that there should be a minimum of 20 eligible clinicians reporting on a measure in the same cohort, in the same baseline period for that measure to be validated. For 2017, those cohorts should include at minimum, eligible clinicians in MIPS APMs and eligible clinicians not in MIPS APMs. In addition, we support a minimum number of cases to be reported for each measure to be validated. We support 20 cases per eligible clinician as a minimum for this metric. The combination of these two metrics will ensure a minimum universe of 400 points of data for each measure used. For any measure that falls short of these data validity requirements, we support that for any eligible clinicians reporting 20 or more cases of the measure, the measure should count to any minimums required for that performance category, but a score for that measure should not be calculated due to insufficient data across all eligible clinicians.

Variation in Benchmarks
CMS suggests that benchmarks for a single measure would vary based on the submission mechanism used to report the measure. As we previously stated, we oppose the added complexity of varying the availability of measures for reporting based on the submission mechanism. We add that we also oppose the varying benchmarks based on the submission mechanism. These differentials create unnecessary complexity in MIPS.

Quality - Alternatives
We are concerned with CMS' approach to scoring the quality performance category of MIPS. Instead we offer an alternate approach that simplifies the program, empowers eligible clinicians to track their own progress, and eases the burden on CMS. CMS' proposed methodology uses a benchmark for each measure that is divided into deciles, each associated with a percentage and number of points. This system is complex and nearly impossible to replicate by individual eligible

[18] Id. pg. 268
[19] Id. pg. 289-357

clinicians using their own data to monitor their progress. We believe that the methodology should be transparent and simple enough that eligible clinicians can independently validate their scores. As such, the methodology employed to generate a score for the quality performance category should be streamlined.

We offer that for any measure, an eligible clinician will have a score of numerator over denominator, which can also be represented as a percentage. As eligible clinicians will report 6 quality measures, 6 related percentages would be generated from that data. We support that the score for the quality performance category can be the simple mean of those 6 quality measure scores. If fewer than 6 measures are reported without sufficient data (minimum of 20 cases), the eligible provider would receive a score of 0 for that measure.

As CMS discusses intent to minimize certain measures (such as topped out measures) and support others (such as outcome measures), we offer that measures can be weighted according to the following rubric: disincentivized or topped out measures at 0.75, high priority measures or use of CEHRT to report at 1.50, and all other measures at 1.0. We do not support weighting measures in the initial year of MIPS, but would support weights in future years as the program is established. Methodologically, the appropriate weight would be applied to each measure by multiplying the percentage by that weight in advance of determining the mean of the 6 measures.

This approach to determining the quality performance score will negate the need for benchmarks for the purposes of scoring quality performance. For the purposes of providing feedback to eligible clinicians, we support CMS' analysis of the data reported for each quality measure to determine deciles associated with percentages for each measure for the universe of eligible clinicians, those reporting in groups, those reporting in similar geographies, and those from rural or underserved areas. This feedback will allow eligible clinicians to view their performance on each measure in the context of similar cohorts of eligible clinicians. However, this feedback would not affect the eligible clinician's score. In addition to the achievement benchmarks identified earlier, the feedback report can also provide improvement scores for each eligible clinician, year over year. As improvement benchmarks require history with the program, we understand that these scores will be unavailable in 2017, but support efforts to identify these tools in future years.

Quality – Additional Comments

Should CMS decide to proceed with the proposed scoring methodology for quality, we offer further suggestions to strengthen the program. In particular, CMS proposes to create a benchmark for each measure based on a timeframe two years previous to the performance year. This allows CMS to publish benchmarks in advance of the performance year. We appreciate CMS' efforts to make this information available to eligible clinicians in advance of the performance year. However, for the initial years of MIPS implementation, we question the validity of setting a baseline using pre-MACRA data and have concerns with using multiple methodologies for developing baselines. For instance, CMS proposes to use 2015 data as a baseline to develop benchmarks for the quality category, while using performance period data to develop benchmarks for the resource use category. Rather, we support the use of a single baseline period for all categories, should benchmarks be used.

We question CMS' proposal to exclude measures reported with a 0 percent performance rate in data sets used to determine performance thresholds. If CMS can validate that the data were submitted in error, such that the eligible clinician in question successfully reported 6 other quality measures as an example, then we support removing the data as erroneous. However, if CMS is unable to discount the datum in this manner, it should be included in the aggregate to determine performance

thresholds. By not including the data in question, CMS will skew the data set towards a higher performance threshold that may be inappropriate for the reporting eligible clinicians.

We appreciate CMS' proposals to reward improvement in quality. Regarding Option 1, we admire the flexibility built into the system that would award the greater of the improvement or achievement scores, but we are concerned that the methodology may be difficult to implement by CMS and to replicate by eligible clinicians seeking to independently validate their scores. Regarding Option 2, we are also concerned with the complex methodology used. We do not think Option 3 has merits above Options 1 and 2. We refer CMS to our proposal for improvement to be recognized in all performance categories as discussed earlier.

Resource Use
We support the development of benchmarks based on the performance year as proposed by CMS for the reasons stated in the proposed rule. We urge CMS to consider publishing a tentative benchmark for the performance year by June 1 which can be used to inform eligible clinicians. A final benchmark can be published by January 31 based on the previous calendar year performance period. We support CMS' proposal to calculate the resource use score including the aggregation of data divided into deciles to which a range of percentages is tied. We urge CMS to stratify data by cohorts of eligible clinicians and provide feedback reports with analyses that identify opportunities and challenges for eligible clinicians.

CPIA
We support weighing more resource intensive CPIA at a higher rate than other CPIA and further support CMS' methodology to do that. We agree with the scoring of the CPIA performance category as referenced in our earlier comments and reflected in CMS' proposed rule.

Advancing Care Information
We oppose the structure and score calculation of the ACI performance category in the proposed rule. We refer CMS to our earlier comments which outline an alternative proposal and rationale for our concerns.

Improvement
We support the use of improvement benchmarks to reward eligible clinicians who continue to make progress in any performance category. For any performance category, percentage improvement over the previous year can be recognized as an additional half portion bonus in the score for that category. For example, if an eligible clinician scores 66 percent on quality in year 1 and 72 percent on quality in year two, the differential of 6 percentage points can be added as a 3 percentage point bonus in year two, bringing the final quality score to 75 percent.

Composite Performance Score
We support the proposed methodology to calculate the MIPS composite performance score (CPS) by summing the weighted values of the performance scores for each category. Regarding the weights of the performance scores, we appreciate CMS' effort to implement the regulation per the statute. This means that performance categories for 2019 payment are weighted with 50 percent for quality, 10 percent for resource use, 15 percent for CPIA, and 25 percent for ACI. This heavily weights the quality category. We are pleased that CMS plans to limit the weight of the quality category in future years. We encourage CMS to consider rebalancing weights in future years to raise the value of CPIA, which represents direct activity by eligible clinicians to improve capacity and access to care.

For eligible clinicians exempt from one or more performance categories due to low volume of cases, lack of measures, lack of face-to-face time with patients, alternative practice models, or other reasons, performance categories will need to be reweighted to redistribute weight from zeroed out categories across other categories. As we mentioned earlier, this rebalancing as proposed by CMS has skewed effects for some eligible providers. For instance, eligible providers in MIPS APMs that are not MSSP or NextGen would have 75 percent of their total score in ACI.

We urge CMS to consider alternatives that would limit the weight of any category to no more than 50 percent. In another example, eligible clinicians without resource use or ACI, but with at least three quality measures would have the weights of resource use or ACI attributed to the quality performance category. We support the alternative CMS proposes to this policy which would evenly redistribute the weight across all categories, not just the quality category. Further, we support CMS in designing MIPS scoring to avoid basing the CPS on a single category like CPIA for some eligible clinicians, as such as program would undermine the intent of broad evaluation under MIPS.

14. MIPS Payment Adjustment[20]

Payment Adjustment based on Composite Performance Score and Identifier
We support using the TIN/NPI for the purposes of identifying appropriate MIPS payment adjustments for each eligible clinician, regardless of if they report as a group or individual. Eligible clinicians who report as a group would have the same adjustment factor. Likewise, eligible clinicians in a MIPS APM, all eligible clinicians in an APM Entity would have the same adjustment factor.

For eligible clinicians who transition out of a group or APM during the performance period, and as such, has part of the year in one group or APM and the other part of the year as an individual, or in another group or APM, we support calculating the MIPS performance score for each reporting situation. This score would be weighted by the percentage of the performance period in which reporting was performed in that setting. Of the two resulting scores, the eligible clinician would be assigned the higher one. If an eligible clinician does not have a CPS assigned to their TIN/NPI, and is outside the low volume or other exclusions with their TIN having a score, the TIN score can be used to determine the eligible clinician's CPS.

For groups or MIPS APMs who lose an eligible clinician during the performance period, that eligible clinician's data should be included in the data used to determine the performance score for the group. If an eligible clinician joins a group or MIPS APM in the middle of a performance period, we support that the eligible clinician should identify with the group or MIPS APM within 30 days of joining and all data from that provider during the performance period should contribute to the performance score.

Performance Thresholds
In determining performance thresholds, we urge CMS to base the threshold for 2017 performance on post-MACRA data. We understand the limitations of the statute in this regard, but are concerned that data from previous years are not reflective of the MIPS program. In addition, as pre-MACRA data would not be available two years in advance of the threshold for 2018 performance, we urge a similar solution. We support having performance thresholds announced in advance of performance years in future years, but for the first two years we urge CMS to identify a performance threshold using 2017 data for both 2017 and 2018.

[20] Id. pg. 357-373

In determining performance in relation to the threshold, we support that half of clinicians would fall below the threshold and half would fall above the threshold. This approach is preferred to the 1.0 scaling factor or minimum number of points to be considered for a bonus. For exceptional performance, we appreciate that a performance threshold cannot be determined for actual performance scores using pre-MACRA data. However, as we stated, we are concerned about the use of pre-MACRA data for MIPS. Our proposal to use 2017 data for the performance threshold would also support a method to use actual scores, rather than possible scores, to support the exceptional performance bonus. Regarding the proposed upper 25 percentile threshold for the performance bonus, if funding for the exceptional performance bonus permits, we offer that the threshold should not be less than the 25 percentile, but may be greater than that figure. This would boost bonuses to more high performing physicians. Given CMS' interpretation of the statute, the upper limit of the bonus would be up to 10 percent additional to the adjustment factor. For the first year, we can provisionally support the 0.5 percent starting point for the exceptional performance bonus.

Regarding the application of the adjustment factor to performance thresholds, we are concerned that the system will exacerbate distortions between well-resourced and less-resourced practices. We urge CMS to evaluate the application of MIPS to ensure that less resourced practices, especially small practices and those in rural and underserved areas, have a reasonable chance to achieve a bonus. In the MIPS system as proposed, these practices face a steeper curve to meet thresholds and achieve a bonus. As such, they disproportionately represent practices that would receive a negative payment adjustment. We are concerned that cutting resources from already under-resourced practices will result in less access to care for vulnerable patients. We urge CMS to commit to a MIPS program in which any eligible clinician can succeed with reasonable effort.

15. MIPS Composite Performance Score Review and Correction[21]

Progress Review and Feedback Reports

We support eligible clinicians' ability to review their identifier information, reported data for measures, resulting performance scores for MIPS categories, and CPS. We support quarterly feedback from CMS to eligible clinicians on these metrics including analysis of trends and projected performance for the performance period at the same trend. Should an eligible clinician's information demonstrate that continued performance at the same rate would likely position them below the performance threshold, CMS should also include insight about what shortcomings the eligible clinician should address to result in favorable performance for the performance period. We understand that CMS intends to provide feedback on annual basis for the first year of MIPS. We urge CMS to consider quarterly feedback starting in 2017. This can be accomplished by inviting eligible clinicians to report data as often as quarterly, but no less often that once per year. Information from the feedback report should include all performance categories and will be invaluable to eligible clinicians as they align their practices with the MIPS program. When a feedback report is available, the eligible clinician should be contacted by email with a link to the CMS web-based portal where they can access the information.

We support additional resources for eligible clinicians to receive feedback on their progress such as embedded technology in registries and EHRs that can inform progress. We encourage CMS to coordinate with vendors to develop these technologies. In addition, we believe that standardized methodologies and reports, regardless of source, are vital. We encourage CMS to ensure vendors

[21] Id. pg. 374-388

have necessary specifications to align their products with CMS methodologies and report structures. To develop performance feedback templates, we encourage CMS to work with eligible clinicians and their professional associations to inform this effort. These templates must be user friendly, simple, and informative, and as such, should be informed by the audiences who would use them.

Targeted Review
We support the availability of targeted review at the request of eligible clinicians. We appreciate CMS' suggestion that longer than 60 days after the close of the performance period may be helpful. We support a longer period of a minimum 90 days for this purpose. Regarding CMS' decision on if targeted review is warranted, we urge increased transparency on the criteria used and timeliness of that decision. We also urge CMS to include an appeals process by which eligible clinicians can formally seek redress. As part of this process, we urge a 30 calendar day period in which eligible clinicians supply information to contractors, starting the date of the receipt of the contractor's request for information.

Data Validation and Auditing
We appreciate CMS' need to validate data and to selectively use audits to ensure appropriate reporting under this program. We urge CMS to lengthen the data sharing response requirements to 30 days after a request is made to the eligible clinician. In addition, we urge CMS to ensure that audits do not pose a burden on eligible clinicians. Finally, we urge CMS to identify the methodology used to select eligible clinicians for audits.

16. Third Party Data Submission[22]

We support that third parties would be authorized by eligible clinicians to submit data on their behalf. These third parties may include QCDRs, qualified registries, or health IT vendors. We urge strong standards on the products used for this reporting to ensure they meet MIPS program requirements, are capable of sharing information with CMS information technology systems, and demonstrate ability to accurately report data on eligible clinicians. Should any third party fall short of these guarantees, we support a probationary period by which they are given an opportunity to correct issues. Should an eligible clinician have signed up for a third party product or service that was unable to accurately submit data, the eligible clinician should not be penalized. Eligible providers should be notified if their third party vendor is in a probationary period and the reason for the probation. Regarding auditing third party intermediaries, we question whether retention of 10 years of data is necessary and encourage CMS to consider an alternate threshold.

17. Public Reporting on Physician Compare[23]

We commend CMS for its efforts to improve the quality and usefulness of the information provided on the Physician Compare website. Public reporting of performance data should be implemented gradually and carefully to ensure the data are accurate and presented in a format and context that is easy to understand, meaningful, and actionable. However, we are concerned that Physician Compare has unresolved issues and that adding MIPS data to this platform may exacerbate them.

We caution CMS that reported MIPS data for any eligible clinician does not constitute a basis for rating that provider's clinical care quality. Clinical care quality is best measured over time, not as a

[22] Id. pg. 388-425
[23] Id. pg. 426-439

snapshot in a single performance period. Any public ranking of providers, or use of MIPS benchmarks on Physician Compare, may be misleading for the user of the information. As such, if CMS chooses to pursue this effort, it should educate users about the methodology, relevance, and context of the information presented. In addition, we oppose any performance indicators of 'low' based on performance in one or more performance categories.

Regarding review, we support a 60 day preview period and urge CMS to increase to this figure from the proposed 30 days in the rule. Thirty days does not provide physicians with adequate time to review their data, identify errors, and gather the evidence needed to refute any errors.

Above all, the information on Physician Compare must be presented to consumers in a format and content that is easy to understand and meaningful, and provides the proper context from which users can draw accurate conclusions.

18. Overview of Incentives for Participation in Advanced APMs[24]

Terms and Definitions
We disagree with CMS' rationale[25] for introducing the term *Advanced APM* in the proposed rule. We question the need for this added terminology, and suggest instead using Q*ualifying APM,* or in keeping with statute, *Eligible APM,* as either would be more clear. If the former, it would also better align with the term *Qualifying APM Participant (QP)* used both in statute and the rule to reference those clinicians in a model who are eligible for the 5 percent payment in 2019-2024.

To add further confusion, throughout the proposed rule CMS refers to the term *Advanced APM* as if it were used in statute, even describing specific instances of it when citing statute. For example, when discussing eligibility of Physician Focused Payment Models (PFPMs), the proposed rule states, "Section 1833(z)(3)(C) and (D) of the Act makes a clear distinction between APMs and Advanced APMs and we do not believe the statutory requirements for Advanced APMs can or should be waived for proposed PFPMs."[26] This is a disingenuous mischaracterization of that section of statute; section 1833(z)(3)(C) and (D) instead *only* make a clear distinction between an Alternative Payment Model (C) and an Eligible Alternative Payment Entity (D).

The proposed rule also uses the term *MIPS APMs* on numerous occasions, yet CMS staff at the May 23 Listening Session with physician associations in Washington, DC stated that, "there's no such thing as a MIPS APM." It may be simpler to reference these as *Non-Qualifying APMs* under the construct we propose above.

Advanced APMs
In MACRA statute, an APM is any of the following: (i) a model under section 1115A (other than a health care innovation award); (ii) the Shared Savings Program under section 1899; (iii) a demonstration under section 1866C; or (iv) a demonstration required by Federal law. CMS proposes narrowing the parameters of this last point of "demonstration required by Federal law" by adding three additional criteria[27]:

1) The demonstration must be compulsory under the statute, not just a provision of statute that gives the agency authority, but one that requires the agency to undertake a demonstration;

[24] Id. pg. 440-499
[25] Id. pg. 448
[26] Id. pg. 610
[27] Id. pg. 453

2) There must be some "demonstration" thesis that is being evaluated; and
3) The demonstration must require that there are entities participating in the demonstration under an agreement with CMS or under a statute or regulation.

We disagree with CMS' proposal to narrow this eligibility requirement at all, and emphasize that it would significantly contravene statutory intent. Further, we do not understand how CMS chose the first and third of the additional criteria—why should a demonstration be required to be compulsory under the statute creating it? The third criteria seems circular, in that it calls for the demonstration "required by federal law" to require that entities participating in the demonstration to do so under a statute or regulation (if not under an agreement with CMS). We do acknowledge some value in the second criteria that a demonstration should have a thesis being evaluated, as that is a demonstration program's fundamental purpose.

Advanced APM Determination

We support CMS' proposal to identify and notify the public of those APMs (including specific tracks or options) that would be considered Advanced APMs for a QP Performance Period. Posting this notification prior to the beginning of the first QP Performance Period, and then updating it on an ad hoc rolling basis (but no less than annually) will help clinicians plan for the upcoming year and beyond. We also support CMS' proposal for notification of APMs that will qualify as Other Payer Advanced APMs.

Advanced APM Criteria

MACRA statute describes an "eligible alternative payment entity"[28] as **an entity** that:

1) Participates in an APM that requires participants in such model to use certified EHR technology; and,
2) Participates in an APM that provides for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS; and,
3) Bears financial risk for monetary losses under such alternative payment model that are in excess of an nominal amount; *or*, be a Medical Home Model expanded under section 1115A(c) of the Act.

In the proposed rule, CMS instead mischaracterizes the third attribute as an APM that (emphasis ours) "(a) requires its participating Advanced APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount...or (b) is a Medical Home Model expanded under section 1115A(c) of the Act.[29]" We would argue that CMS is moving away from statutory intent by interpreting that the alternative payment *model* must require its participants to bear financial risk above a nominal amount. Rather, the statute actually says that *an entity* in a model (not the model itself) must simply bear financial risk in excess of a nominal amount for losses that might occur under the APM. Note that unlike the first two provisions, there is no "Participates in an APM" qualifier for the third, and therefore it refers directly to the entity and not the model. We believe CMS' revisionist criteria significantly narrows eligibility to be an Advanced APM, and, as noted, is not in line with statutory intent. **We would urge the agency to reconsider this rather misleading interpretation**.

[28] 1833(z)(3)(D)
[29] Id. pg. 460

Use of Certified EHR Technology

We support CMS' proposal to define CEHRT for Advanced APM qualification the same as it is defined under MIPS. Given that most clinicians will not know if they are Qualifying APM Participants and therefore exempt from MIPS until well into their performance period, it only makes sense to align these definitions.

However, we oppose CMS requiring an APM to set a threshold for the number of eligible clinicians in an Advanced APM entity that must use CEHRT. We believe this goes beyond statutory intent, as MACRA only stated that the model "requires participants in such model to use certified EHR technology,"[30] rather than "requires [all] participants in such model to use CEHRT." We especially oppose raising the 50 percent threshold to 75 percent beginning in the second QP Performance Period. CMS itself acknowledges that clinicians will be expected to upgrade from 2014 Edition CEHRT to 2015 Edition CEHRT for use in 2018, making this second performance period an especially challenging time for use of CEHRT.

CMS also invites comment on whether it should consider higher thresholds for APMs that target clinicians with higher-than-average CEHRT adoption, such as PCMHs, and lower thresholds for APMs that target clinicians with lower-than-average adoption, such as specialty-focused APMs. Unless the specialty-focused APMs in such a scenario consist only of non-patient-facing clinicians, we do not understand why CMS would consider lower thresholds for such models. Additionally, having higher thresholds for models such as the PCMH is unfairly penalizing participants in the model, and could serve as a perverse disincentive for participation.

Comparable Quality Measures

We agree with CMS that a measure framework for requiring comparable quality measures in an Advanced APM should give the APM flexibility to determine which measures are most appropriate for an Advanced APM entity for the purpose of linking those measures to payment under the model. As well, we support the five options CMS proposes that an Advanced APM must require that at least one of be tied to payment.

Financial Risk

CMS proposes a financial risk criterion for Advanced APMs that would apply to the design of the APM financial risk arrangement between CMS and the participating APM Entity. We reference again our previous comment that we believe this interpretation of financial risk applying to the model rather than the entity is outside of statutory intent.

That being said, we support that CMS' proposal does not impose any additional performance criteria related to bearing financial risk. An APM Entity should not need to actually achieve savings or other metrics for success under an APM in order to meet the MACRA statute's "more than nominal financial risk" criterion.

Bearing Financial Risk for Monetary Losses

Overall, we support CMS' proposed approach for generally applicable financial risk standards for Advanced APMs to include provisions that allow CMS to withhold payment, reduce payment rates, or require the APM Entity to owe payments to CMS if the entity's actual expenditures exceed its expected expenditures. We agree that this is in line with statutory intent that Advanced APM Entities must bear financial risk for "monetary losses", rather than be able to simply have bonus

[30] 1833(z)(3)(D)(i)(I)

payments reduced. As well, we agree that financial risk for monetary losses under an APM must be tied to performance under the model as opposed to indirect losses related to financial investments APM Entities may make.

Risk in Medical Home Models

For Medical Home Models, CMS proposes unique financial risk standards, in recognition of the fact that many medical homes to date have had little experience in taking on financial risk. We support CMS's proposal for these models to allow a performance-based forfeiture of part or all of a payment under an APM to be considered a monetary loss—rather than only allowing withholds or reduced payments as is required for other Advanced APMs.

We support accommodating these models with a lower financial risk standard, but we oppose CMS limiting these lowered standards only to medical home entities with 50 eligible clinicians at the entity's owner organization level beginning in 2018. While we could support a lowered financial risk criterion being limited to smaller medical homes, we do not think it should be measured at the level of the entity's parent organization, as this will significantly limit the number of medical homes that can qualify. Rather, we urge CMS to set this limit at the entity level. As well, we disagree with CMS' approach to only institute the size limit in the second performance year (2018). This could lead to scenarios of medical homes qualifying in year one, and then suddenly no longer being able to qualify in year two. It would leave the medical home at the end of 2017 either needing to reduce the number of clinicians it or its parent organization has (which is unrealistic), or to suddenly transition to a new Medical Home model (should one even exist) that meets the higher risk standard of other Advanced APMs.

Finally, we also oppose CMS' alternative option to establish this size limitation based on the number of eligible clinicians in the Medical Home Model, rather than on the number of eligible clinicians in the APM Entity's organization. This proposal would modify the Medical Home Model definition so that an APM could only be considered a Medical Home Model if no more than 10 percent of eligible clinicians (or, alternatively, 10 percent of APM Entities) in the APM are part of parent organizations with more than 50 eligible clinicians. We do not feel this alternate approach addresses our concerns with these size limitations overall.

Nominal Amount of Financial Risk

We agree with CMS' proposal to measure three types of risk to determine if the nominal amount standard is met: marginal risk of at least 30 percent of losses in excess of expected expenditures, minimum loss rate of no greater than 4 percent of expected expenditures, and total potential risk of at least 4 percent of expected expenditures. Setting total potential risk at 4 percent is sensible, as it is still lower than the 5 percent payment QPs in Advanced APM Entities will receive, thereby justifying the investments and business risks they must take on to participate. As well, it is at the same amount of the maximum penalty a clinician in MIPS can receive in the first payment year, thereby also reducing the risk of a clinician trying for the Advanced APM track over MIPS. Under worst-case scenarios in either track, he or she would bear equivalent losses.

For Medical Home Models not deemed as "expanded", we support a lowered risk criteria. As proposed, Medical Home Models would set the total annual amount that an Entity potentially owes CMS or foregoes under the model to 2.5 percent of its total Medicare Parts A and B revenue for 2017. We appreciate CMS' consideration of lower financial risk for Medical Home Models than for other APMs. We oppose, though, CMS increasing that amount to 3 percent in 2018, 4 percent in 2019, and 5 percent in 2020 or later. The total risk for other Alternative Payment models does not

increase by year, and therefore we urge CMS to keep the risk standard for Medical Home Models not deemed as "expanded" at 2.5 percent in subsequent years.

Capitation

We agree that full capitation risk arrangements would meet the Advanced APM financial risk criteria.

Medical Home Expanded under Section 1115A(c) of the Act

CMS writes in the proposed rule that "Section 1833(z)(3)(D)(ii)(II) of the Act states that an Advanced APM must either meet the financial risk criterion or be a Medical Home **Model** expanded under section 1115A(c) of the Act."[31] That is in fact *not* what Section 1833(z)(D)(ii)(II) states. Instead, that provision merely defines an Eligible Alternative Payment Entity as (emphasis throughout ours) "**an entity** that—

(i) participates in an alternative payment **model** that—

(I) Requires participants in such model to use certified EHR technology; 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)."[32]

Only provision (i) sets any parameters for **the model** itself under which the entity must operate to be eligible. Provision (ii), meanwhile, only refers to **the entity**.

We therefore strongly disagree with CMS' assertion in the proposed rule that "…the expanded Medical Home **Model** criterion cannot [be] met unless a Medical Home **Model** has been expanded under section 1115A(c). Merely satisfying expansion criteria would not be sufficient to meet this Advanced APM criterion."[33] We believe that CMS's interpretation of PCMH eligibility (or lack thereof) is overly narrow, and significantly contradicts Congressional intent. A reasonable reading and interpretation of the statute demonstrates instead that congressional intent was for CMS to allow a medical home to qualify as an [advanced] APM, without bearing more than nominal financial risk; if it is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c). This language is even included in the discussion of the all-payer option that begins in 2021 (which is when other payer payments can be counted toward the threshold to determine if one is a qualifying APM participant), making it clear that the intent of the law is to incentivize medical homes that are aligned with Medicare initiatives.

In order to determine a medical home's eligibility to be an Advanced APM, we instead propose CMS establish a deeming program or process to enable practices enrolled in medical home programs run by states (including state Medicaid programs), other non-Medicare payers, and employers as being deemed to have met criteria "comparable to medical homes expanded under section 1115A (c)". A deemed PCMH program is one that:

- has a demonstrated multi-year track record of support by non-Medicare payers, state Medicaid programs, employers, and/or others in a region or state;

[31] Id. pg. 499
[32] Section 1833(z)(D)
[33] Id. pg. 500

- shares data with participating practices to assist them in improving quality and lowering costs;
- provides financial support such as risk-adjusted prospective per enrollee payments for care coordination to the practices and/or other types of support to such practices; and
- submits sufficient data to the Secretary that the deemed program, based on the experience of the patient populations served by the program, can be expected to:
    - reduce Medicare spending without reducing the quality of care; or
    - improve the quality of patient care without increasing Medicare spending.

The PCMH practice in a deemed program would need to provide patient-centered care to Medicare beneficiaries, as well as the other patient populations served by the deemed program, consistent with the requirements that are outlined for the Medical Home Model in the proposed rule.

- The PCMH practice in a deemed program would qualify as a Medical Home Model that is an advanced APM, without having to bear more than nominal financial risk (per both the intent of the law)—and therefore the participating practices in that program would be eligible to be qualifying participants (QPs) and not be part of the MIPS program, but rather would receive the 5 percent bonus payment on their Medicare fee-for-service payments, should their Medicare Part B payments meet the required threshold.
    - Per the statute in 2019 and 2020, at least 25 percent of the payments to the APM participant must come from Medicare Part B in order for that clinician to be determined to be a qualifying participant.
    - This threshold to be a qualifying APM participant would then broaden to include payments from the other payers, starting in 2021.
- This deeming process can use the five comprehensive primary care functions as its criteria, along the lines of how the Agency is expected to be able to expand the Comprehensive Primary Care Initiative (CPCI) program. Newly deemed programs would not be eligible for the additional financial support that CPCI provides (i.e., care management fees and shared savings) provided by Medicare; however, they would still be able to receive any additional payment incentives being provided by the other payers and also the 5 percent bonus payment on Medicare fee-for-service reimbursements over the course of time that those bonuses are available.

Regardless of how PCMH eligibility for Advanced APM status is eventually determined, CMS should immediately initiate advanced planning to develop an expansion approach for the CPCI program. This expansion should take place nationally with regard to Medicare payments to those practices that apply, attest to the five comprehensive primary care functions, and demonstrate ability to meet the milestones over the course of a given timeframe that is clearly articulated in advance. Other payers should be actively invited to apply to collaborate with Medicare; however, the expansion of this program should NOT be dependent upon additional payer participation. Practices should be fully informed in advance of finalizing their agreements with CMS to participate as to whether or not their other regional payers are participating.

PCMHs are proven models developed in line with the Joint Principles of the PCMH supported by the AOA, the American Academy of Family Physicians, and the American College of Physicians. Consensus and evidence has continued to build around the PCMH's value in achieving improved care and better health at lower costs. More than 90 health plans, 43 state Medicaid programs, multiple federal agencies, and thousands of clinical practices of varied sizes have adopted this model. Eligible clinicians are currently practicing in demonstrated models like the PCMH. By CMS

choosing to apply overly strict criteria to the Advanced APM program, these eligible clinicians will be separated from their peers in Advanced APMs and forced into MIPS. We urge CMS to rethink its overall proposed approach to determining PCMH eligibility for Advanced APM status.

Application of Advanced APM Criteria

Utilizing the previously outlined criteria, CMS has identified only six models that it anticipates would qualify as Advanced APMs for the 2017 Performance Year:

1. Comprehensive ESRD Care LDO Arrangement (CEC)
2. Comprehensive Primary Care Plus (CPC+)
3. Medicare Shared Savings Track 2 (MSSP2)
4. Medicare Shared Savings Track 3 (MSSP3)
5. Next Generation ACO Model (NextGen)
6. Oncology Care Model two-sided risk arrangement (OCM)

As noted, we feel CMS has gone beyond statutory intent in narrowly defining parameters for APMs to qualify as advanced, and we are concerned that these models represent an undersupply of slots for eligible clinicians. There are only thirteen CEC organizations; CPC+ will only accept a maximum of 5,000 practices; only six MSSP2, sixteen SSP3, and eighteen NextGen ACOs are currently in operation; and 100 practices operate as OCMs.

The proposed rule notes that this list is not precluded from change, based on changes made to the proposed criteria in the final rule in response to public comments, modifications to current APM design, or announcement of new APMs before the performance period. We therefore strongly urge CMS to reconsider the application of Advanced APM criteria and provide more flexibility for the inclusion of APMs into the Advanced APM program. CMS' proposed scope for the Advanced APM program has substantially limited the number of available slots in which eligible clinicians can participate, and drastically undermines HHS' stated goal of moving providers into APMs, which is highly problematic to the intent of MACRA.

19. Qualifying APM Participant (QP) and Partial QP Determination[34]

QP Status

We support CMS' interpretation of statute that for the purposes of QP Threshold calculations, payments "through" an Advanced APM Entity mean "payments made by CMS for services furnished to attributed beneficiaries, who are the beneficiaries for whose costs and quality of care an Advanced APM Entity is responsible under the Advanced APM."[35]

We appreciate and support CMS' proposal that it will perform QP/Partial QP threshold calculation using both a patient count method and a payment amount method, and then use the calculation that is more favorable to the group of eligible clinicians in the Advanced APM Entity. This will provide added flexibility, and will maximize opportunities for entities and individuals clearly engaged in delivering value-based care to have a favorable QP status determination.

We agree with CMS' proposal to conduct QP determination sequentially beginning in 2021 so that the Medicare Option is applied before the All-Payer Combination Option; the All-Payer Combination Option is then only applied when a group's Medicare threshold is below that required

[34] Id. pg. 503-524
[35] Id. pg. 505

for Medicare Option alone, but above the lower Medicare threshold in the All-Payer Combination Option. We agree that this sequential approach will streamline the analytic and operational requirements for making QP determinations.

QP Performance Period

We agree with CMS' proposal to align the QP Performance Period with the MIPS Performance Period, both to reduce confusion for eligible clinicians in either program, and to allow time for CMS to communicate an eligible clinician's status in the Advanced APM program throughout the process.

Group Determination and Lists[36]

CMS proposes that an eligible clinician's QP status for a given payment year would be based on a collective evaluation of a group consisting of all eligible clinicians participating in an Advanced APM Entity. Each eligible clinician would have to be listed on December 31 of the QP Performance Period as part of an Advanced APM Entity that, through the collective calculation of all its eligible clinicians, meets the QP Payment Amount or Patient Count Threshold. QP status would apply to the individual eligible clinician's NPI across all of the TINs to which he or she reassigned the right to receive Medicare payment, not solely to the billing TIN affiliated with the Advanced APM Entity.

We agree with this approach to make QP determination at the group level, both for the sake of simplicity and to minimize administrative burden for clinicians, APM Entities, and CMS. CMS acknowledges that this could lead to some eligible clinicians becoming QPs when they would not have met the QP Threshold individually (a "free-rider" scenario) or, conversely, some eligible clinicians not becoming QPs within an Advanced APM Entity when they might have qualified individually (a dilution scenario). We therefore urge CMS to evaluate QP determinations (whether through a sampling method, or otherwise) after each of the first three performance years to calculate the frequency of either of these scenarios, and if either is too high, adjust the QP determination methodology accordingly.

CMS proposes that where a Participation List can be used to identify eligible clinicians in an APM Entity, that this list automatically be considered for QP Determination. Yet at times there may be no Participation List of eligible clinicians, such as when an Advanced APM Entity only has a list of entities affiliated with and supporting the Entity in its Advanced APM participation. Instead, the Entity may have a list of eligible clinicians with contractual relationships with it based at least in part on supporting the Entity's quality or cost goals under the Advanced APM. CMS then proposes to use this Affiliated Practitioners List for QP determination. Should both lists exist, CMS proposes to only use the Participant List to determine the eligible clinicians. Yet CMS notes that "We also believe that although the relationship an Affiliated Practitioner has with an Advanced APM Entity is less direct than an eligible clinician on a Practitioner List, the contractual relationship the Affiliated Practitioner has with the Advanced APM Entity is sufficient for an Affiliated Practitioner can become a QP based on their support of the Advanced APM Entity."[37] We therefore would recommend that when both lists exist, they be reconciled to ensure the broader group of eligible clinicians will be able to receive APM Incentive Payments. This will ensure that even eligible clinicians with a less direct relationship with the Advanced APM Entity are incentivized to participate in the Advanced APM.

[36] Id. pg. 515-517
[37] Id. pg. 517

Timing of Group Identification for Eligible Clinicians

CMS proposes to use a "snapshot", point in time, assessment to identify eligible clinicians on December 31 of each QP Performance Period. Under this method, any eligible clinicians on a Participant or Affiliate Practitioners List on December 31 would be assessed together for the purposes of QP determination. We agree with CMS that certain APMs allow for changes in participation (either adding or dropping participants from the APM Entity), so therefore an earlier point in time may not be an accurate assessment. However, we have concerns with using a single day at the end of the year. What if an eligible clinician actively participated in Advanced APM Entity throughout the year, and significantly contributed to its provision of value-based care, but then changed practices on December 23? He or she should still be credited for participation. Conversely, an eligible clinician who relocated across the country and only joined the group on December 28 should not receive credit. We therefore recommend that CMS use a range of time rather than a snapshot approach for QP determination. Furthermore, we would recommend that clinicians who were on a list for 6 months or more should qualify.

Partial QP Election to Report to MIPS[38]

MACRA excludes from the definition of MIPS eligible clinician an eligible clinician who is a Partial QP for a year. However, an eligible clinician who is a Partial QP for a year and reports on applicable measures and activities as required under the MIPS is considered to be a MIPS eligible clinician for the year. To carry out these provisions, CMS proposes to require that each Advanced APM Entity must make an election each year on behalf of all of its identified participating eligible clinicians on whether to report under MIPS in the event that the eligible clinicians participating in the Advanced APM Entity are determined as a group to be Partial QPs for a year.

We have concerns with this approach, and recommend instead that individual eligible clinicians should make the Partial QP MIPS reporting election. Eligible clinicians in an APM Entity who are unsure of whether the Entity will achieve QP status may prefer not to report in MIPS as a group, or the group that they would choose to report to MIPS together may not align directly with the APM Entity (such as a small practice that is part of an ACO).

20. Qualifying APM Participant Determination: Medicare Option[39]

We support the procedure CMS proposes to use to calculate a Threshold Score for an Advanced APM Entity, which would allow for both patient count and payment amount methods. As well, we support the Threshold Score being calculated by dividing a numerator (aggregating all payments for Medicare Part B covered professional services furnished by the eligible clinicians in the Advanced APM Entity to attributed beneficiaries during the QP Performance Period) by a denominator (aggregate of all payments for Medicare Part B covered professional services furnished by the eligible clinicians in the Advanced APM Entity to attribution-eligible beneficiaries during the QP).

We agree that limiting the denominator to only attribution-eligible beneficiaries will ensure entities are not penalized for furnishing services to beneficiaries who could not possibly be in the numerator. This will ensure greater access to care for patients who may not have Medicare as a primary payer.

---

[38] Id. pg. 520-522
[39] Id. pg. 524-544

We similarly support the formula proposed for calculating a Threshold Score using the patient count method.

Finally, we commend CMS for proposing to calculate the Threshold Score under both methods, and assigning QP status using the more advantageous of the Advanced APM Entity's two scores.

21. Combination of All-Payer and Medicare Payment Threshold Option[40]

Medicaid Medical Home Models
We support the elements that CMS proposes a Medicaid Medical Home Model must at minimum have in order to qualify as a Medicaid APM to then determine if it meets the criteria to be an Other Payer Advanced APM.

Use of Certified EHR Technology
CMS proposes to define use of CEHRT in order for an Other Payer APM to qualify as advanced similarly to how it proposed it for an Advanced APM. However, it sets an even higher threshold for participants in an Other Payer Advanced APM entity to be required to use CEHRT, at 75 percent. As with the Medicare Advanced APM definition, we oppose setting such a threshold for Other Payer Advanced APMs.

Unlike the Advanced APM definition in statute, which "requires participants in such model to use certified EHR technology," MACRA defines the requirement for Other Payer Advanced APMs as "payments must be made under arrangements in which certified EHR technology is used."[41] Again, we believe setting a threshold is against statutory intent in both cases, but is even more so for the Other Payer APM. Requiring certified EHR to be used under the arrangements in no way justifies CMS requiring Other Payer Advanced APMs to set a CEHRT threshold at 75 percent of eligible clinicians participating in an Entity under its model.

Bearing Financial Risk for Monetary Losses
Advanced APM Standard
We support the financial risk standards being set similarly for Other Payer Advanced APMs as they were for Advanced APMs that are Medicare-only. This will simplify the process, and reduce confusion for eligible clinicians, since, as CMS notes earlier in the proposed rule, they will be assessed sequentially to see if they qualify for a 5 percent bonus through either of these options.

Similarly, we support the financial risk standard for a Medicaid Medical Home Model aligning with those set for Medical Home Models to qualify as Advanced APMs. Yet as we did for those Medical Home Models, we oppose Medicaid Medical Home Models' lowered financial risk standards only applying to those with 50 or fewer eligible clinicians in the organization through which the APM Entity is owned. While we could support a lowered financial risk criterion being limited to smaller medical homes, we do not think it should be measured at the level of the entity's parent organization, as this will significantly limit the number of medical homes that can qualify. Rather, in line with Medicare medical homes we urge CMS to set this limit at the entity level.

[40] Id. pg. 544-580
[41] Section 1833(z)(2)(C)(iii)(II)

Nominal Risk Standard

As with the nominal risk standard CMS proposes for Advanced APMs, we support a similar nominal risk standard being set for Other Payer Advanced APMs, at an MLR of 4 percent, a marginal risk of 30 percent, and a total potential risk of 4 percent of Other Payer expected expenditures.

We do oppose setting the same standard for Medicaid APMs as the rule proposes. As CMS itself notes in the proposed rule, "we recognize that Medicaid practitioners may be less able to bear substantial financial risk because they are generally reimbursed at lower payment rates, and they serve low-income populations and those with significant health disparities."[42] We therefore recommend that the total potential risk for Medicaid APMs that are not Medicaid Medical Home Models be set at 3 percent.

For Medicaid Medical Home Models, CMS proposes to set the nominal risk standard as the minimum total annual amount that an entity must potentially owe or forego to be considered an Other Payer Advanced APM at 4 percent of its total revenue under the payer in 2019, and then 5 percent in 2020 and beyond. We note these amounts for 2019 and 2020 align with those set for Medical Home Models for those years, but we opposed the increases in those risk percentages by year, and called for it to remain at 2.5 percent after 2017. We therefore urge CMS to set the total nominal risk standard for Medicaid Medical Homes in 2019, 2020, and beyond at 2.5 percent.

Calculation of All-Payer Combination Option Threshold Score[43]

CMS proposes that APM Entities and/or clinicians must submit the information needed to make QP Determinations using the All-Payer Combination Option, and that this information must include (1) the payment amounts and/or number of patients furnished any service through each Other Payer Advanced APM for each payer; and (2) the sum of their total payment amounts and/or number of patients furnished any service from each payer. CMS then notes that it will ask each payer to attest to the accuracy of all of this submitted information, and if the payer does not do so, the data will not be assessed under the All-Payer Option.

We have concerns with this submission proposal, as it requires clinicians or APM Entities themselves to submit a significant volume of information, requiring significant time to compile, that may not be easily separated from the stored data of their other patients in Medicare. Furthermore, if payers are going to be asked to attest to the information's accuracy, we propose that CMS simply request the information to begin with from the payer. Doing so will reduce burdens on clinicians, and eliminate the need for an attestation step by the payer since they are directly supplying the information and can therefore rely on its accuracy.

Regardless of which entity compiles the data, we strongly oppose CMS' alternative proposal to address the scope and intensity of audits to verify the submitted data. Audit contractors in Medicare are already far too aggressive in their practices, and subject many physicians in Medicare to time-consuming and expensive audits that are often overturned anyway. Increasing their scope and intensity under this proposal would in no way benefit the program.

Excluded Payments[44]

We seek clarification on CMS' proposal with regard to excluded payments in determining threshold scores. The proposed rule states, "We propose that title XIX payments or patients would be

[42] Id. pg. 563
[43] Id. pg. 568-569
[44] Id. pg. 570-571

excluded in the numerator and denominator for the QP determination unless: (1) a state has at least one Medicaid Medical Home Model or Medicaid APM in operation that is determined to be an Other Payer Advanced APM; and (2) the relevant Advanced APM Entity is eligible to participate in at least one of such Other Payer Advanced APMs during the QP Performance Period, regardless of whether the Advanced APM Entity actually participates in such Other Payer Advanced APMs. We have concerns with CMS' proposal to include any Title XIX payments or patients in the numerator and denominator for QP determination when a state has at least one Medicaid Medical Home Model or APM determined to be Advanced, and the relevant Advanced APM Entity is just *eligible* to participate in it, regardless of whether the Entity *actually* participates in it. Simply because an Advanced APM Entity may be eligible to participate in that Advanced Medicaid APM or Medical Home, does not mean that it is necessarily appropriate. There could be many instances where an Advanced Medicaid APM may not be a good fit for a particular eligible entity to participate in, especially if they are already participating in others. CMS notes that it will exclude such payments or patients from the numerator and denominator when the Entity is *not* eligible, to avoid unduly disadvantaging potential QPs by inflating denominators based on circumstances beyond their control.

Payment Amount Method[45]
CMS proposes that the numerator for calculating the All-Payer Threshold Score would be the aggregate of all payments from all other payers, to the Advanced APM Entity's eligible clinicians—or the eligible clinician in the event of an individual eligible clinician assessment—under the terms of all Other Payer Advanced APMs during the QP Performance Period.

The denominator would be the aggregate of all payments from all other payers, to the Advanced APM Entity's eligible clinicians—or the eligible clinician in the event of an individual eligible clinician assessment—during the QP Performance Period.

We support this proposed approach to calculating the All-Payer Threshold Score.

Patient Count Method[46]
As with the Medicare Option, we support CMS only counting unique patients when calculating an All-Payer Threshold Score using the Patient Count method, and allowing multiple eligible clinicians to count the same patient, as long as they are not in the same Advanced APM Entity.

We support the proposed method of calculating the Threshold Score. This would be done by dividing a numerator of: [the number of unique patients to whom eligible clinicians in the Advanced APM Entity furnish services that are included in the measures of aggregate expenditures used under the terms of all of their Other Payer Advanced APMs during the QP Performance Period, plus the patient count numerator for Advanced APMs], by the denominator of: [the number of unique patients to whom eligible clinicians in the Advanced APM Entity furnish services under all non-excluded payers during the QP Performance Period].

Submission of Information for Assessment under the All-Payer Combination Threshold Option
As with the Medicare Option, we oppose requiring eligible clinicians or the APM entity to be the parties to submit payment information such as revenue amounts for services provided through the arrangement, and patient counts. This is a significant volume of information, requiring significant

[45] Id. pg. 572-573
[46] Id. pg. 575-576

time to compile, that may not be easily separated from the stored data of their other patients in other payer arrangements. We propose that CMS simply request the information to begin with from the payer, as this will ensure accuracy of the information and reduce administrative burdens for APM Entities and clinicians.

We support CMS' proposal to make early Other Advanced APM determinations if sufficient information is submitted at least 60 days before the beginning of a QP Performance Period, and directly communicate those determinations to participating APM Entities and eligible clinicians rather than through public notice. We ask that CMS make it clear in these communications that this initial determination is, as noted in the proposed rule, considered final for the QP Performance Period based on the information submitted, and is only subject to review and revision if new information is submitted based on a change in the Other Payer APM.

APM Incentive Payment

Incentive Payment Base Period

We support using a full calendar year to calculate the estimated aggregate payment amount for the year preceding the QP payment year that will serve as the basis for the incentive payment, as CMS proposes. We agree that partial-year data for a forecasting approach could be unduly impacted by seasonal fluctuations and other variations that could lead to inaccurate estimates and potentially disadvantage some eligible clinicians. As well, we support limiting claims run-out to three months, rather than six months, in order to expedite incentive payments.

We believe that 6 months after the end of the incentive payment base year is a reasonable time-frame for paying out incentive payments. However, we oppose CMS' proposal to not set a specific deadline midway through the payment year because doing so would "pose operational risks in the event that 6 months is impracticable in a given year for reasons that CMS cannot predict."[47] We all have internal processes and timeframes that can be impacted by unpredictable events, yet deadlines are still set.

Treatment of Payment Adjustments in Calculating the Amount of APM Incentive Payment

We support CMS's proposal to exclude the MIPS, VM, MU and PQRS payment adjustments when calculating the estimated aggregate payment amount for covered professional services upon which to base the APM Incentive Payment amount. As noted in the rule, statute bases the APM Incentive Payment on the estimated aggregate payment amounts for "such" covered professional services for the preceding year.

Treatment of Payments for Services Paid on a Basis Other than FFS[48]

We have concerns with CMS' proposal to exclude financial risk payments such as shared savings payments or net reconciliation payments when calculating the estimated aggregate payment amount. These payments are part of an APM's payment model, and therefore should be included.

As well, we have strong concerns with CMS' proposal to only determine on a case-by-case basis whether certain supplemental service payments (such as a PBPM for care management) will be considered in lieu of covered services reimbursed under the physician fee schedule (PFS), and therefore included for purposes of calculating the estimated aggregate payment amount. Care management and other such supplemental services play a valuable role in providing high value care

[47] Id. pg. 584
[48] Id. pg. 588-589

in an APM. Therefore, subjecting them to a complicated case-by-case determination that CMS will make, and then publically announce, is unnecessary and could pose a disincentive to high quality, advanced care.

Payment of the APM Incentive Payment

We oppose CMS' proposal that for eligible clinicians who are QPs, the APM Incentive Payment will be made to the TIN that is affiliated with the Advanced APM Entity through which the eligible clinician met the threshold during the QP Performance Period. It is unclear how individual eligible clinicians could be ensured that they would receive their correct portion of a payment from the TIN. As well, we believe this goes against statutory intent. MACRA stated (emphasis ours), "...there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part of the preceding year."[49] Therefore, under statute the APM Incentive Payment must be made to the QP, not the TIN.

We would instead recommend that CMS make separate payments for each TIN/NPI combination associated with the individual eligible clinician's APM Incentive Payment, as it does with PQRS. CMS itself notes in this section of the rule that the CMS-maintained participation list of eligible clinicians for the Advanced APM entity would allow it to track the APM Entity/TIN/NPI identifiers for each individual eligible clinician[50]. Therefore, individual payments should be easy to calculate and direct to them.

22. Physician-Focused Payment Models[51]

Physician-focused payment models (PFPMs) should place the physician as the 1) lead of a care team, 2) the central node of coordinated patient care, and 3) the decision-maker in how resources will be used to deliver care to patients and how resources will be invested to ensure continued success. Furthermore, these models should reward physicians for high quality and/or improvements in care over which they have influence.

PFPMs should be patient-centered. As such, if the patient population served is broad and has varied needs, the model must incorporate multiple areas of specialty or providers who practice care across a spectrum of illness. Overall, the criteria should be consistent with primary care models, and these specialty models should include communication with the patient's primary care provider to ensure care is coordinated. We continue to believe that a strong health care delivery system is built on a strong primary care infrastructure.

We appreciate the Physician-Focused Payment Model Technical Advisory Committee (PTAC)'s role in collaboration with CMS to identify opportunities to include APMs as Advanced APMs under MACRA. As CMS considers APMs, we note that significant financial investment is required to transition practices to alternative payment models. In addition, these models require additional investment to maintain. This investment represents risk to the physician and/or group practice. Smaller practices and those in under-resourced regions are poorly positioned to take this level of risk, and often have insufficient resources to even consider taking any risk. In contrast, the vulnerable patient populations served by these practices stand to benefit most from advanced care models that place value over volume. We offer that this gap in need should be a priority area for CMS.

---

[49] Section 1833(z)(1)(A)
[50] Id. pg. 597
[51] Id. pg. 603-623

More generally, CMS should ensure that models are appropriately incentivizing physicians to make investments in new models of care, and that these models of care can be successfully implemented across practices of varied resource access. Models that can only be implemented by the highest-resourced cohort of practices will be unavailable to the majority of physicians, who treat most of our nation's Medicare beneficiaries.

We also caution CMS against focusing on PFPMs that solve issues in payment policy that have not been addressed in other CMS programs, because a new PFPM may provide an opportunity to develop a better approach than those in current CMS programs. While we believe gap analysis is important to formulate inclusive policies, so is inclusiveness across primary and specialty care. In addition, PFPMs should not focus solely on filling gaps, but also on improving upon existing care models. Any policy that focuses only on gaps will risk stagnation in other areas.

Stakeholders' ability to suggest appropriate APMs would be bolstered by the availability of free data from CMS that can inform practice patterns and services to Medicare beneficiaries. This information will aid stakeholders in the development of models that are reflective of current trends and needs from a macro level. This information, coupled with micro level insight from stakeholders, will lead to robust models.

Unfortunately as currently designed, Advanced APMs recognized under MACRA are too limited in number. In addition, these limitations extend to available slots for eligible clinicians to practice in these models. As the volume of Advanced APM slots is lower than the demand for them, we support an expeditious review process of models by CMS that enables new models and additional slots to become available. For proven models, such as the PCMH, we urge CMS to initiate this process now. For models with less demonstrated impact, we support a process that will sufficient time for CMS to consider PTAC's recommendations as well as collaborate with stakeholders in seeking clarification as necessary.

23. Burden and Impact Analysis[52]

We have strong concerns with the overall administrative burden that participating in MACRA will place on physicians. While MACRA has great potential to streamline current reporting programs and reduce administrative burdens, as proposed it in fact could likely be more complicated and time-consuming to comply with. We are especially concerned with the burden that the incredibly complex ACI Performance Category will pose on participating clinicians. We disagree with CMS that "ACI performance category data will not be submitted separately by MIPS eligible clinicians in most cases as was required under the Medicare EHR Incentive Program."[53] Simply because group reporting is now allowed for ACI when it wasn't for the EHR Incentive Program, does not mean that all clinicians will suddenly be able to transition to group reporting.

Lastly, we disagree with the Information Collection Requirement (ICR) regarding burden estimates that CMS presents in the proposed rule for the ACI Performance Category. CMS estimates the total burden hours for ACI to be 4 hours. The Quality Performance Category, on the other hand, was estimated to range between 7.22 hours to 18 hours, depending on submission mechanism. As well, CPIA submission is considerably simpler than ACI, requiring only a simple Yes/No attestation for

[52] Id. pg. 624-653
[53] Id. pg. 644

items in the CPIA inventory, and is estimated at 3 hours. It is extremely difficult to believe, then, that ACI would only be an hour longer to complete, at 4 hours.

We cannot express strongly enough our concern that MIPS does not provide adequate incentives for eligible clinicians to provide services in solo and small practices. In many areas of this country, solo and small practices represent the majority of available care for patients. The financial pressure on eligible clinicians in these practice models, as a result of MIPS, is a threat to their ability to continue to provide patient care to Medicare beneficiaries.

One reason for this negative pressure on solo and small practices results from CMS' inaction to establish pathways for virtual groups for the 2017 performance year. Virtual groups were included in MACRA statute to provide a pathway for eligible clinicians, especially solo and small practices to meet MIPS requirements. By implementing MIPS without this program, CMS is approaching lift off without appropriate landing gear. We advise that CMS' analysis is illustrative of the effect of a piecemeal implementation plan which will have negative consequences for eligible clinicians and the patients they serve.

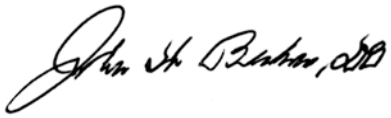
Conclusion

As the MACRA legislation was being developed in Congress, policymakers turned to physician associations at every step for feedback on improvements and to ensure an aligned approach to its development and passage. Since its passage, we have been pleased that CMS has maintained this approach by providing numerous opportunities for physician associations such as the AOA to provide input into MACRA implementation efforts. We hope that CMS will continue in this collaborative spirit by thoughtfully considering, as well as accepting, our recommendations.

Please do not hesitate to call on the AOA for insight as you develop this plan. To do so, or for additional information, please contact Ray Quintero, Senior Vice President for Public Policy, at rquintero@osteopathic.org, or (202) 349-8753.

The AOA and the osteopathic medical profession look forward to working collaboratively with CMS to implement this new payment system in a manner that benefits our patients and is both flexible and simple for our physicians to continue providing high-quality patient-centered care.

Sincerely,



John W. Becher, DO
President