September 10, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5522-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1693-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program proposed rule, published in the Federal Register on July 27, 2018.

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to also educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI’s Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI is committed to helping physicians adapt to and succeed under the Medicare program, especially the Quality Payment Program (QPP). To that end, over the past year PAI has been engaging with physicians and practices in-the-field in both one-on-one and group discussions. These discussions have helped identify current challenges and opportunities for improvement for both the QPP as well
as other value-based programs. Through these discussions, we have been able to identify the resources, modifications to the current program, and/or assistance that might be most useful to physicians and practices to address existing barriers and gaps. A complete summary of our findings from the in-field engagement is attached to this comment letter *(Addendum A).*

The input received from the in-field engagement has been informing the ongoing work of PAI’s QPP educational activities. PAI launched and continues to update a comprehensive, free educational initiative to guide physicians at every stage of readiness to succeed under the QPP and other value-based payment programs. These resources are available at [www.physiciansadvocacyinstitute.org](http://www.physiciansadvocacyinstitute.org). PAI welcomes the opportunity to partner with the Agency and HHS to help educate physicians to succeed under the program.

**Overview**

PAI is committed to advancing policies that protect the ability of patients to receive high-quality care and is supportive of the goals of the QPP of reducing costs and improving outcomes and the quality of care for patients. PAI commends the Agency for continuing to build in additional flexibilities and transition policies that help ease the burden of participation in the QPP for physicians. We are pleased to see that many of the proposed changes provide greater flexibility for physicians, incentivize participation of small practices, and reward quality improvement over time. However, PAI has concerns about several proposals that may unintentionally put some patients, physicians, and practices at a disadvantage, as well as with other proposals that lack clarity and increase the complexity of the program.

Furthermore, PAI believes that frequent changes throughout the program year and annually through the rule-making process create additional complexity and confusion. Physician practices are devoting a significant amount of time and resources trying to understand the QPP, which takes focus away from patient care. Ongoing changes to program terminology, requirements, and other characteristics make it difficult for physicians and practices to prepare for participation and anticipate their goals and performance. PAI urges the Agency to maintain the consistency of policies over time and make the program more predictable. Continuity in the program would allow physicians and practices to have a general idea of how they can make changes in their practices to increase their overall performance scores and payment adjustments.

Additionally, PAI would like to stress the broader importance of and need to rely on empirical data from the program to support any changes that could have a substantial impact on physicians’ reimbursement. Physicians need greater assurance that the data supporting any program changes is verified, accurate, and validated. They also benefit from program data and transparency that can help them have confidence they will not be at risk for greater potential losses.

In this letter, we provide comments in response to several proposals and questions posed in the proposed rule, including the following:

- Evaluation and Management (E/M) Coding and Documentation
- Merit-based incentive payment system (MIPS) participation eligibility and determination period
• MIPS low-volume thresholds
• MIPS submission mechanisms
• MIPS performance category weights, requirements, and scoring
• MIPS group reporting options
• MIPS performance threshold and bonuses
• MIPS social risk factors
• Medicare advanced alternative payment models (APMs) and Other Payer APMs
• Public Reporting on Physician Compare

Our comments are based upon the advocacy priorities of PAI as they relate to the QPP, which are to simplify the program and reduce physician burden, make the program translatable across specialties and settings, more predictable, accessible, and relevant to positive patient impact and related to everyday practice. PAI is committed to advancing these priorities to ensure physicians are afforded opportunities to successfully participate in the QPP, and to continue providing and be rewarded for their high-quality patient care.

Specifically, we would urge the Agency to:

• Implement burden reductions for E/M documentation guidelines and requirements but urge the Agency against tying them to any reduction in payments for E/M services.
• Avoid making drastic changes finalizing drastic changes to MIPS submission mechanisms and its categories (including scoring and reporting requirements/options) that would require substantial retraining for physicians and other eligible clinicians.
• Maintain the weight on the cost category at 10% and refrain from applying the new episode-based measures until further development and testing is conducted.
• We encourage the Agency to continue to engage with stakeholders and work closely on the development of cost category measures that more accurately assess the utilization of health care services and appropriately attribute costs.
• Refrain from reporting QPP data on Physician Compare until there is more predictability, continuity, consistency, and decreased complexity in the program.

Evaluation and Management (E/M) Coding and Documentation

E/M Documentation Requirements

There are currently five levels of codes for new and established patients for the office or other outpatient setting. The Agency recognizes that the current documentation requirements for E/M guidelines are outdated and aims to reduce physician burden by simplifying the documentation requirements through several proposals.

• CMS is proposing to remove the current requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office.
• Additionally, rather than requiring a full reiteration of all components of patient history for each visit, CMS is proposing to allow physicians to simply note what has changed since a patient's last visit or on pertinent items that have not changed from the patient’s last visit.
• CMS is also proposing to allow physicians to use either: 1) 1995 or 1997 E/M Guidelines; 2) medical decision making (MDM); or 3) time as a basis to determine the appropriate level of E/M visit.
Lastly, recognizing the increasing complexities with treating Medicare patients, CMS is proposing to eliminate the policy that prevents same or multiple physicians in the same specialty and practice from billing same-day visits.

PAI supports these proposals for reducing physician reporting burden and commends the Agency for recognizing the need to eliminate unnecessary “check-the-box” requirements. These proposals simplify the documentation requirements and refocus physician attention on medical decision-making and patient-centered care. However, PAI urges the Agency against tying burden reductions for E/M documentation guidelines and requirements to any reduction in payments for E/M services.

E/M Payment Collapse
As a second component of its E/M coding and documentation burden reduction efforts, CMS is proposing to collapse the payments for levels 2-5 of both new and established patient office visit codes (i.e., 99202-99205 and 99212-99215). CMS is maintaining the code levels—and expects physicians to continue using those levels to bill for E/M services—but is proposing to establish a single payment rate for levels 2-5. Correspondingly, CMS is proposing that practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam and/or MDM, except when using time to document the service. As the Agency notes, this policy would result in a reduced payment for some physicians and specialties, and as a result, is also proposing to create “add-on” codes to offset these reductions.

While PAI appreciates that the Agency is aiming to reduce physician burden, we do not support these proposals for collapsing the E/M payment levels to a single rate with add-on codes. Medicare patients often require variable levels of care due to their complexities and needs and physicians tailor their office visits for those patients. We are concerned that a collapsed payment rate may create access-to-care issues and have other negative, unintended consequences for Medicare patients, especially for high-cost, complex patients who may have several chronic conditions. Furthermore, we believe this proposal significantly devalues physician decision-making and work and advances a payment structure that is not accurate, fair, nor adequate. PAI encourages the Agency to seek further input and work collaboratively with physicians and other clinicians to analyze the existing E/M codes and determine what changes are necessary and appropriate.

Merit-based Incentive Payment System (MIPS) Participation Eligibility and Determination Period

MIPS Eligible Clinicians
For the 2017 and 2018 performance years, CMS defined eligible clinicians (ECs) to include physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. CMS has noted in the past that it expects to expand the definition of ECs to include additional clinicians. Beginning with the 2019 performance year, CMS is proposing to expand the definition of ECs to also include physical therapists, occupational therapists, clinical social workers, and clinical psychologists (as defined by the Secretary), and any group that includes all such clinicians.
PAI does not have concerns with the new proposed definition. However, PAI believes that CMS should work with the expansion group to ensure they are well-educated on the QPP participation requirements and the importance of participation to their broader cohort of clinicians.

**MIPS Determination Period**
Similar to the current policy, beginning with the 2019 MIPS performance year/2021 payment adjustment year, CMS is proposing a 24-month MIPS determination period that would include a two-segment analysis of claims data to determine whether physicians must participate in MIPS. The two segments would consist of the following: an initial 12-month segment beginning October 1 two years prior to the applicable performance period and ending on September 30 the year preceding the applicable performance period, with a 30-day claims run-out (e.g., for the 2019 performance year this segment would be October 1, 2017 – September 30, 2018); and a second 12-month segment beginning on October 1 of the year preceding the applicable performance year and ending on September 30 of the performance year (e.g., for the 2019 performance year this segment would be October 1, 2018 – September 30, 2019).

While PAI understands the logic behind the use of the proposed two segments, it believes, the second segment could lead to confusion and uncertainty about participation status. Many physicians and practices have expressed frustration over not knowing definitively whether they are required to participate in MIPS or not. This policy with a notification decision made during the performance year can result in physicians participating in MIPS throughout the year only to find out that they are exempt. PAI requests that the second segment have an end date and notification date, which both occur prior to the start of the performance year, regardless of the length of the segment. This will allow physicians and practices to better prepare for participation beginning January 1 of the applicable performance year.

**MIPS Low-Volume Threshold**
The low-volume threshold excludes physicians and other clinicians (individuals and groups) from MIPS participation if they fall below established thresholds based on allowed charges or patient panel size. For the 2017 performance period, the low-volume threshold was less than or equal to $30,000 in Medicare Part B allowed charges or providing care to 100 or fewer Medicare Part B patients. For 2018 performance period, the low-volume threshold was increased to less than or equal to $90,000 in Medicare Part B charges or providing care to 200 or fewer Medicare Part B patients.

The Bipartisan Budget Act of 2018 required that beginning with the 2019 performance year/2021 payment adjustment year, the low-volume threshold include a third criterion based on the number of covered professional services provided under the PFS. Thus, CMS is proposing that ECs and groups may be excluded if they meet one of the following three criterion: 1) Have ≤ $90,000 in Part B allowed charges; OR 2) Provide care to ≤ 200 beneficiaries, OR 3) Provide ≤ 200 covered professional services under the PFS. Additionally, CMS is proposing to allow, groups, virtual groups, and APM Entities to opt-in to MIPS participation if they meet or exceed one or two of the above criteria.

PAI supports maintaining the low-volume threshold and the addition of the third criterion. We believe that maintaining the low-volume threshold continues to help additional small and rural
physicians avoid a negative payment adjustment and not be subject to participating in a program that may be too burdensome for their practice. Additionally, PAI commends the Agency for offering an opt-in option for physicians and other ECs who meet or exceed at least one of the three criteria. We believe the voluntary opt-in allows some physicians and practices who may fall below the threshold, yet may be high-quality performers, to be able to participate in and contribute to the goals of the QPP. This option not only allows them to participate, but also provides them with an opportunity to be eligible to earn a positive payment adjustment.

PAI encourages the Agency to effectively communicate this policy with appropriate guidance so physicians and practices have a clear understanding of the process. Additionally, PAI stresses the need for further clarification on the application of the opt-in for virtual groups and APM entities, especially with application to individual ECs and groups that may be part of a larger virtual group or APM entity.

**MIPS Submission Mechanisms**

Beginning with the 2019 performance year, CMS is proposing to create new definitions categorizing the MIPS submission mechanisms. CMS is proposing the following five submission categories:

- **Direct** – transmission of data computer-to-computer interactions, for example, an API
- **Log in and upload** – upload and submission of data in CMS-specified form and manner
- **Login and attest** – manual attestation that certain measures and activities were performed in CMS-specified form and manner
- **Medicare Part B claims** – as currently defined, but proposing to limit this option for ECs in small practices
- **CMS Web Interface** – for CMS Web Interface measures, and expanding the option to groups of 16-24 ECs

CMS states it will continue to use administrative claims data for measure performance as applicable, for example, cost category measures. Additionally, CMS is proposing to allow multiple submission mechanisms for single measures as well as for measures reported by groups and virtual groups.

PAI understands the need for updating the terminology to be more reflective of the different technologies that can be used for submitting data for the MIPS categories, measures, and activities. However, as we discuss above, such edits though “minor” at the individual level can have a “major” impact at the aggregate level. Frequent changes in terminology and definitions, including the name change of the Promoting Interoperability category, create additional complexity and confusion in the program. While PAI understands these definitions, we oppose the changes to the terminology for the MIPS submission mechanism. PAI recommends that the Agency retain the current terms and definitions to allow for greater continuity and less disruption in the program.

PAI also recommends that the Agency not change the applicability of the CMS Web Interface option to groups of 16-24 ECs. This change may not be appropriate for the new proposed practices given the subset of measures currently available in the CMS Web Interface. Consequently, this may result in harm to some practices in the form of lower performance scores. We believe the Agency should
provide additional insight, a list of the proposed subset of measures, and rationale for this proposal prior to any adjustment.

PAI supports the proposal allowing the use of multiple submission mechanisms for measures. However, we request CMS to issue clarification that the use of multiple submission mechanisms is optional and not mandatory. PAI believes permitting the use of multiple submission mechanisms allows greater flexibility and would make it easier for some practices to meet reporting requirements. However, we do not believe multiple submission mechanisms should be required of ECs. This could impose additional reporting costs for EC’s. For example, an EC could elect to report the quality performance category measures using the claims submission mechanism but may only be able to report four applicable measures. The EC, then, should not be required to also contract with a vendor and incur additional costs and fees to report two additional measures to meet the six measures minimum for the quality performance category. The option of multiple submission mechanisms should offer ECs greater flexibility and options for participation, rather than be burdensome to them.

**MIPS Performance Categories**

*MIPS Performance Periods*

For the 2018 MIPS performance period, the Agency continued some of the transition year policies from the 2017 MIPS performance period. These included, maintaining a 90-day performance period for the Promoting Interoperability (formerly Advancing Care Information) and improvement activities performance categories. For the 2019 performance year, CMS is proposing to maintain these performance periods for these two categories and is proposing full calendar years for the quality and cost categories. CMS is seeking input on whether it should expand the cost category performance period from one year to two or more years in future rulemaking to better evaluate performance in the cost category measures.

PAI supports maintaining a 90-day performance period for the Promoting Interoperability and improvement activities performance categories. We recommend similar reporting periods for the quality and cost categories to promote alignment across the program.

The proposed two or more years performance period for the cost category could potentially also be an option. CMS could develop a pathway for practices to eventually have the option for a two-year performance period for the cost category, with safeguards in place to both invite and protect continued physician participation in the program. We believe the two-year period would allow for greater testing and collection of data to determine the appropriateness and validity of the proposed episode-based measures. However, additional clarifications would be necessary to provide insight as to how precisely the two or more years performance period for the cost category would operate and be implemented. For example, when and how would the cost category performance be accounted for in the MIPS final score, and how would it impact the payment adjustment? Thus, we encourage the Agency to provide additional details, impact analysis, and other information for stakeholder review and input prior to finalizing or moving forward with this proposal.
MIPS Category Weights
For the 2018 performance year, the quality category is weighted 50%, the Promoting Interoperability category is weighted 25%, the improvement activities category is weighed 15%, and the cost category is weighted 10% of the 2018 MIPS final score. For the 2019 performance period/2021 payment adjustment year, CMS is proposing the following category weights: quality 45%, Promoting Interoperability 25%, improvement activities 15%, and cost 15%. Additionally, the Agency is proposing to increase the weight of cost category by 5% each year until the required 30% weight is reached for the 2022 performance year/2024 payment adjustment year. CMS is proposing to maintain the current category reweighting policies.

PAI is concerned about increasing the weight of cost category from 10% to 15%. The Agency is proposing new changes to the cost category measures and reporting requirements, that would, if finalized, be implemented for the first time in the 2019 performance year. The cost category is still evolving and being refined, and we strongly believe that this category weight and scoring should not change until more stability and continuity is introduced. Therefore, PAI recommends maintaining the 10% cost category weight and the 50% quality category weight until concerns with the cost category (discussed in greater detail below) are addressed.

MIPS Quality Category
The proposed rule contains several proposals related to the quality category measures and scoring for the 2019 performance year as well as potential changes for future years. PAI stresses, again, the need for consistency and predictability in MIPS. We strongly discourage the Agency from proposing and finalizing drastic changes that would require physicians and other ECs to re-learn the program requirements from scratch.

Quality Category Measures
The Agency is proposing changes to the removal of topped-out measures and non-high priority measures, and a new definition for high priority measures.

In the CY 2018 QPP final rule, the Agency finalized a policy for the removal of topped out measures for which overall performance by ECs is at or near 100%. CMS finalized a four-year phase-out timeline for removing topped out measures. As part of this timeline, if measures are topped out for at least two consecutive years, they will receive a maximum of seven points, and this policy was implemented beginning in 2018. Going forward, the Agency is proposing a new policy for “extremely” topped out measures (e.g., a measure with an average mean performance within the 98th to 100th percentile range). CMS is proposing that once a measure has reached extremely topped out status, the Agency may propose the measure for removal in the next rulemaking cycle, regardless of whether it is during the topped-out measure process finalized in previous rulemaking.

Additionally, CMS is proposing an incremental approach for removal of non-high priority process measures. This approach would, among other considerations, take into account the impact the removal of the measure would have for a specific specialty and whether the measure promotes positives outcomes in patients.
PAI opposes both proposals. PAI believes that the Agency should only propose a measure for removal during the official measure process to assist with predictability. Furthermore, we urge the Agency to reconsider its topped-out measures policies. There are already a limited set of measures applicable to many specialists and by removing topped-out measures, the options are further limited. Additionally, it does not necessarily follow that a topped-out measure no longer contributes to high-value care; those measures may still be valuable and necessary for patient care and processes and they should not be automatically eliminated without additional consideration. Furthermore, PAI does not believe that the Agency has provided a clear explanation of what the removal process for non-high priority measures entails beyond the broad considerations.

Beginning with the 2019 performance year, the Agency is also proposing to redefine a high priority measure to be an outcome (including intermediate-outcome and patient-reported measures), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. PAI supports the intent of the additional opioid-related quality measure; however, has some concerns that the measure may not meet the needs of patients. We believe CMS should continue working across agencies and with stakeholders to develop and present opioid-related measures to the physician community for comment prior to its inclusion in the set. Additionally, as the Agency develops these measures, it is important that the measures at the federal level align with state-level initiatives and programs. Many states have already initiated and implemented their own opioid-related initiatives; we are concerned that without alignment there is the potential for conflicts between federal and state requirements that could increase the burden of participation and compliance with MIPS.

**Quality Category Scoring**

CMS is proposing to maintain the three-point floor for each measure that can be reliably scored against a benchmark for the quality category. CMS is also proposing to maintain the minimum scoring for measures that do not meet the data-completeness criteria (minimum one point except small practices receive at least three), do not meet the case-minimum requirement (minimum three points), or do not have a benchmark (minimum three points). PAI supports this policy and encourages the Agency to move towards greater alignment and predictability by increasing the minimum number of points to three for all reported measures. However, we do not support the additional proposal beginning with the 2020 performance year to assign a score of zero points for measures that do not meet the data completeness criteria.

Additionally, the Agency is proposing to eliminate the bonus points for CMS Web Interface high-priority measures and is also proposing to eliminate the bonus points for end-to-end reporting of high-priority measures after the 2019 performance year. PAI does not support these proposals to eliminate bonus points and recommends the Agency gain additional experience and gather additional data on performance and reporting prior to making such changes in the program.

CMS is also seeking input on moving towards one of two new approaches for the quality category scoring methodology in future years. The two proposed approaches are:
Establishing a pre-determined denominator (e.g., 50 points) without requiring reporting of a minimum number of measures. Instead, measures would be classified based on a value tier (e.g., gold, silver, and bronze), and the value tier would determine the maximum points that could be earned for a measure.

Keeping the current requirement that a minimum of six measures be reported, with every measure worth up to 10 points, but changing the minimum number of points that can be earned based on the value tier the measure falls into (e.g., gold measures would receive at least 5 points instead of at least 3 points).

PAI does not support this proposal and has several concerns with the new proposed methodologies. We believe they would increase the scoring complexity rather than simplify it. We do not believe that values should be arbitrarily assigned to measures as different measures may be more/less appropriate and considered high-value depending on patient needs. Thus, we support maintaining the current scoring methodology. However, PAI supports eliminating the minimum number of measures requirement, and we continue to believe new applicable measures across specialties and settings should be developed.

**MIPS Promoting Interoperability Category**

For the 2017 and 2018 performance years, the Promoting Interoperability category score is based on a three-prong approach that includes a base score, a performance score, and a bonus score. In the past, the Agency lauded this approach for the flexibility it provides practices and physicians, as well as its shift away from the Meaningful Use program’s all-or-nothing scoring approach. However, going forward, the Agency is proposing a new scoring methodology that would move away from this approach.

In its place, the Agency is proposing a smaller set of four objectives: e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange. The new proposed methodology would require ECs to report certain measures from each of the four objectives, and their score would be based on their performance in each measure. The scores of each measure would be added for a total combined score of up to 100 possible points. CMS is proposing an alternative scoring approach under which scoring would occur at the objective level, instead of individual-measure level. This alternative approach would require ECs to report on only one measure from each objective to earn a score for that objective. Lastly, the Agency is proposing to eliminate the bonus for completing certain improvement activities using certified electronic health record technology (CEHRT).

PAI does not support the new scoring methodology as it further adds to the complexity of the program and reduces a physician’s ability to participate. The proposed new scoring methodology eliminates the flexibility that is offered under the existing methodology—allowing physicians to report the objectives and measures that are most meaningful for their patients. PAI is concerned that the proposed objectives and measures are too limited. Additionally, many physicians have expressed concern that under the proposed methodology they may be unable to meet the minimum thresholds as many states have yet to implement and offer for reporting data exchange registries like those outlined in the objectives. PAI also opposes the proposal to eliminate the bonus points and continues to support bonuses for those improvement activities currently qualified for CEHRT reporting.
Physicians support health information exchange and interoperability, and the unimpeded flow of information for their patients. However, PAI does not believe that it is appropriate to apply pressure on physicians and other ECs and hold them accountable for ineffective exchange of information when the responsibility should be on vendors and their products. Physicians and patients have little influence on the speed with which these exchanges are implemented, and also have minimal influence on acceleration. Physicians are often unjustly penalized for reliance on vendors and trusting that their vendors will become certified, maintain their certification, and appropriately submit their data to CMS on their behalf. Many vendors have delayed their updates and continue charging practices exorbitant fees for these updates, even when they are delayed or not completed.

PAI continues to advocate for the need to hold vendors accountable for their compliance with program requirements. As we have recommended in the past, we encourage the Agency to consider developing a “Vendor Compare” that would publicly report vendor data, capabilities, and error rates, just as physicians and other ECs participating in the program are held accountable for their performance on Physician Compare.

**MIPS Cost Category**

Ten episode-based measures were previously finalized for the cost performance category that would be scored beginning with the 2018 performance period. However, in the CY 2018 QPP final rule, the Agency finalized a policy replacing the previous ten episode-based cost measures with new measures and basing the 2018 cost category score on performance only in the total per capita costs measure and the Medicare Spending Per Beneficiary (MSPB) measure. Beginning with the 2019 performance year, the Agency is proposing to add eight new episode-based measures. These measures are: Elective outpatient percutaneous coronary intervention; Knee arthroplasty; Revascularization for lower extremity chronic critical limb ischemia; Routine cataract removal with intraocular lens (IOL) implantation; Screening/surveillance colonoscopy; Intracranial hemorrhage or cerebral infarction; Simple pneumonia with hospitalization; and ST-elevation myocardial infarction (STEMI) with PCI.

The Agency is proposing to categorize the cost measures into two episode groups: acute inpatient medical condition episode-based measures and procedural episode-based measures. The case minimum and the attribution methodologies for the measures would be based on these two groups (i.e., the methodology would be the same for all measures within each type of episode group). These would be as follows:

- **Acute inpatient medical condition episode group** – attribution to each MIPS EC who bills inpatient E/M claim lines during trigger inpatient hospitalization under a TIN that renders at least 30% of inpatient E/M claim lines in that hospitalization. The case minimum would be 20 episodes.

- **Procedural episode group** – attribution to each MIPS EC who renders a trigger services as identified by HCPCS/CPT code. The case minimum would be 10 episodes.

PAI supports making changes and improvements to address issues that need to be resolved with the cost category, and we believe this is an opportunity for all stakeholders to further engage in and work closely on the development of cost category measures that more accurately assess the utilization of health care services and appropriately attribute costs.
PAI has several concerns with the proposed cost category episode-based measures. These concerns include:

- The proposed measures may create an unlevel playing field in this category amongst specialists.
- The minimum episode thresholds for the measures would not provide reliable, statistically valid data that could be used as performance indicators.
- The attribution methodology, as well as the measures and categories fail to take into account socio-economic factors and social determinants of health that have a great impact on utilization and costs.

PAI believes that these measures require additional testing and experience which can be accomplished through the MIPS cost category. We further believe these new episode-based measures should not be the basis for the cost category score, especially as many physicians and practices are still unfamiliar with the measures their specifications.

These concerns about the new episode-based measures also reinforce our reservations about increasing the weight placed on the cost category until more testing and evaluation of the measures can be performed. If the performance of ECs does not vary greatly on the other categories used in MIPS, variation in their cost category score could have significant effects on their overall performance measure – even with a relatively low weight. Moreover, the proposed change from 10% to 15% weight may seem modest but represents a 50% increase in the impact of the cost measure on the overall score. Depending on how the Agency accounts for changes in the distribution of scores, the cost measure could have an outsized impact on the distribution of overall scores and payment adjustments.

We also reiterate our past concerns with the total per capita cost and MSPB measures, which are also not applicable to many physicians or practices. PAI believes the cost category needs to be further evaluated as there are many concerns with attribution and risk-adjustment issues that need to be resolved with the cost category overall. We encourage the Agency to continue to engage with stakeholders and work closely on the development of cost category measures that more accurately assess the utilization of health care services and appropriately attribute costs.

**MIPS Group Reporting Options**

Currently, physicians in a practice can report either at the individual level, group level (practice Tax Identification Number (TIN) level), as part of a MIPS APM entity, or as part of a virtual group.

**Virtual Group Eligibility Determination and Election Process**

CMS is proposing to establish a virtual group eligibility determination period which will be a 12-month assessment period beginning October 1 two years prior to the performance period and end on September 30 one year preceding the performance period, with a 30-day claims run out (e.g., for 2019 performance year, this will be October 1, 2017 - September 30, 2018). CMS is also proposing to transition to a web-based system for the virtual groups election process.
PAI supports the alignment of this eligibility period and election process via the QPP portal with similar policies for other participation options, as it provides for more predictability and consistency across the program.

**Group Application of MIPS Adjustment**
Under current policies, payment adjustments for TIN-level group reporting are applied to all NPI/TINs associated with that TIN. However, since physicians may change practices and other modifications may be made, the Agency is proposing further clarification to the NPI/TINs that group level adjustments would apply to. The Agency is proposing that, beginning with the 2019 performance year/2021 payment adjustment year, it will apply the TIN-level group adjustment to NPIs who bill under the TIN during the following 15-month window: October 1 of the year prior the performance year through the end of the performance year (e.g., for the 2021 payment adjustment year this would be the October 1, 2018 – December 31, 2019).

PAI believes additional clarity and guidance is needed on this proposed policy so it does not add a new level of confusion and complexity to the program. CMS should provide examples of how this policy would be applied in different scenarios, for example, if a physician joins or leaves a practice mid-year. Additionally, the Agency should also consider the implications of these policies on physician employment and how they may negatively impact physicians’ abilities to switch between practices based on their past MIPS performance scores and adjustments that might follow them going forward.

**Sub-Group Reporting Option**
For group TIN level reporting, all physicians and other ECs in a practice are evaluated at the aggregate level on the same measures and activities, regardless of specialties or patient mixes. For future years, CMS is considering implementing sub-group options and is seeking comments in response to the following questions: whether and how sub-groups should be treated as separate from the primary group?; Whether the sub-group’s data should be aggregated with or treated distinctly from the primary group?; and low-burden solutions for identification of a sub-group.

PAI supports the creation of a sub-group option. We believe that the Agency should proceed on this path in a transparent manner to best address the operational challenges. This could potentially be a valuable option for multidisciplinary groups, as well as groups that span across geographic/regional areas. Specifically, we suggest the following for consideration as this option is being developed and refined:

- Sub-group options be consistent with specialization categories as reflected in the National Plan and Provider Enumeration System (NPPES) as well as the specialty measure sets.
- Grouping by specialty that is treated separate from the primary group.
- Allowing for an option for the sub-groups data to be treated as part of or separately from the primary group, and similarly for their final scores and payment adjustments.
- Allowing for registration of and reporting by sub-groups through the QPP portal.
MIPS Performance Threshold and Bonuses

MIPS Performance Threshold
The MIPS final score and related payment adjustment for ECs and groups is determined based on their performance compared to a MIPS performance threshold. Currently, the 2018 performance threshold is set at 15 points, and the exceptional bonus threshold is set at 70 points. CMS is proposing to increase the performance threshold from 15 points to 30 points and increasing the exceptional performance threshold from 70 points to 80 points for the 2019 performance year. Additionally, CMS is seeking input on the approach for establish the performance threshold for 2022 performance / 2024 payment adjustment year and beyond.

PAI recommends a more gradual increase in the performance threshold. For example, a maximum five-point increase to the threshold each year could be reasonable. Additionally, PAI does not recommend increasing the exceptional performance threshold until additional insight is gained on how many MIPS participants by practice size have been able to meet/exceed the 70-point threshold.

PAI also emphasizes the importance of sharing feedback reports on a timely and continuous basis so that practices have adequate time to not only make improvements for the remainder of a current performance period, but also for the subsequent performance period to improve their overall MIPS performance scores.

Small Practice Bonus
Beginning with the 2018 MIPS performance period, the Agency finalized a policy to provide a bonus to ECs or groups in a small practice. Small practices are defined as 15 or fewer clinicians, and they have five bonus points added to their MIPS final score if the EC or group submits data on at least one performance category for the 2018 performance period. The Agency is proposing to continue the small practice bonus for 2019; however, this bonus would be added to the quality category as opposed to the overall MIPS final score.

PAI urges the Agency to continue the small practice bonus as currently finalized and applied. The bonus helps "level the playing field" for small practices and allows them to earn a positive payment adjustment. Alternatively, if the Agency insists on shifting the application of the bonus to the category level, ECs and practices should have the option to have the bonus points added to a category of their choice rather than the Agency’s choice.

Complex Patient Bonus
To protect access and the quality of care for complex patients and to avoid placing ECs at a potential disadvantage for caring for complex patients, the Agency added a complex patient bonus for the 2018 MIPS performance period. Complex patients are defined as those with high medical risk. The Agency is proposing to continue the complex patient bonus as currently finalized. PAI supports the continuation of this bonus without modifications.

MIPS Social Risk Factors
CMS would like to begin incorporating social risk factors into MIPS performance and scoring. The Agency is seeking feedback on which social risk factors provide the most valuable information, as
well as the methodology for accounting for differences in outcomes based on these disparities and differences in social risk factors.

PAI strongly supports the Agency’s desire to account for social risk factors as required by statute and to gain understanding how they can impact outcomes and performance. It is essential that MIPS and the QPP account for varying patient populations and disparities. One approach would be adopting risk adjustment factors that take into consideration social determinants of health as well as socioeconomic status and barriers. Risk factors the Agency should investigate include: patient demographics, race, ethnicity, health status, severity of illness, disability, comorbidities, income poverty level; as well as housing status, caregiver needs and ability, transportation, language services, among others.

It is our understanding that over the years the Agency has cited multiple studies and papers on social determinants of health, and that the Agency has access to significant social risk factor data on Medicare patients. The Agency should utilize this wealth of information to inform the adoption of social risk factors into the QPP and MIPS. For example, the Agency could consider establishing HIPAA compliant cohorts that allow a “Risk Adjustment Factor (RAF)” type measure to be applied to patient populations. PAI believes the opportunity is ripe now to act on those needs as those are the patients that can often benefit most from focused and value-based care.

**Medicare Advanced Alternative Payment Models (APMs) and Other Payer APMs**

CMS is proposing to maintain some of the policies currently finalized for Medicare and Other Payer Advanced APMs, while proposing new policies that provide additional clarification and others that increase the threshold for qualifying as an Advanced APM under the QPP.

**Advanced APM and Other APM Determination Criteria**

Currently, both Medicare and Other Payer Advanced APMs must meet certain criteria to be qualified as an Advanced APM under the QPP. Generally, the criteria require that the APM require participants to: bear certain level of risks, use CEHRT, and to report measures that are comparable to those in MIPS.

**Nominal Amount Standard**

CMS is proposing to maintain the eight percent nominal amount standard for the QP performance periods through 2024. PAI reaffirms our past comments on the need to lower the nominal amount standard for small and rural practices. A lower standard should apply to both practices that are participants in a Medicare Advanced APM as well as those that join larger APM entities to participate in a Medicare Advanced APM. The current nominal risk standard is too high for small group practices and ECs – as it far exceeds their typical profit margins and financial reserves and thus often deters them from participating in an APM. To entice small groups, PAI recommends starting with fairly low nominal amount standards and gradually increasing them as small groups get comfortable taking on more risk – similar to the approach being taken under the Medical Home Model.
**Measures Criterion**

CMS is proposing to amend the Advanced APM quality criterion so that at least one quality measure in the Advanced APM must be on the MIPS final list, be endorsed by a consensus-based entity, or otherwise be determined to be evidence-based, reliable, and valid by CMS to considered MIPS-comparable. CMS is proposing similar criteria for at least one outcome measure in the Advanced APM.

PAI appreciates this clarification; however, as we discuss in greater detail above under the MIPS quality category section, we urge the Agency against making independent determinations about the appropriateness and value of certain measures over other measures.

**CEHRT Criterion**

Beginning with 2019, CMS is proposing that to be an Advanced APM, the APM must require at least 75% of ECs to use CEHRT. CMS is proposing a similar increase for Other Payer Advanced APMs beginning with 2020.

While PAI supports the adoption of EHRs, PAI is concerned that the CEHRT requirement for Advanced APMs is restrictive. This requirement prevents practices and physicians from adopting and utilizing technology that is better suited for their practices and patients, especially under a given APM’s care model. Thus, we recommend that the Agency consider adopting more flexibility for the EHR adoption requirement, rather than specifying that it must be CEHRT, that may have certain capabilities and functionalities that are not applicable to or appropriate for different practices and patients.

**Qualifying Advanced APM Participant (QP) Determinations**

Currently, CMS utilizes three snapshot dates for QP determinations under the Advanced APM pathway of the QPP. CMS is proposing that for each of the three determination dates, it will allow for a claims run-out of 60 days before calculating the scores. This is an effort to have the determinations completed approximately three months after the end of that determination date. PAI supports the Agency's efforts to notify ECs of their QP determinations as soon as possible. We encourage the Agency to consider ways that also effectively communicate this information on a timely basis rather than burdening physicians with constantly checking the QP look-up portal to see that this information is available. Additionally, PAI supports bilateral opportunities for correction of errors or delays in reporting by either an APM entity or the Agency. We believe greater communication and transparency is necessary for this process.

For All-Payer QP determinations, the Agency is proposing to add a third option for QP determinations. Under this third option, when all clinicians have reassigned billing under a TIN that participates in a single entity APM, the QP determination may be made at the TIN level. This would only be permitted where the entire TIN has met the Medicare threshold for the All-Payer Combination Option. PAI continues to support proposals which enable more physicians and other ECs to receive QP/PQ credit for their participation in both Medicare and Other Payer Advanced APMs.

Lastly, for ECs who may be PQs and considered to also be part of a virtual group, the Agency is providing additional clarification on their QPP participation options. The Agency is proposing to clarify that ECs determined to be Partial QPs and are in a virtual group will not have their actual MIPS...
reporting activity used to determine whether the EC is participating in MIPS. The EC would need to make an explicit election to opt-in or opt-out of MIPS participation. PAI supports this option for PQs and not automatically defaulting them into the program and being subject to the payment adjustment unless they take affirmative actions to explicitly participate.

Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration
The Agency recently announced a MAQI demonstration designed to test whether excluding MIPS ECs who “sufficiently” participate in payment arrangements with Medicare Advantage (MA) Organizations (MAOs) from MIPS reporting and payment adjustment would increase or maintain participation in those payment arrangements. The Agency is seeking input on the design of this demonstration, including the appropriate waivers that would help support this.

PAI supports this demonstration and exclusion of ECs who are already participating in value-based payment arrangements. In the past, PAI has urged the Agency to support physician contracts with MA plans that meet the risk, quality and CEHRT requirements to be counted as Medicare Advanced APMs. PAI believes this demonstration is a step in the right direction. However, we have concerns about potential perverse incentives and uneven bargaining power that may result from this demonstration.

This initiative may drive more physicians to enter into risk-based arrangements with MAOs (in order to be exempt from MIPS altogether). However, those physicians may not be fully equipped or armed with an understanding of the different types of arrangements and how they could impact their practices. Moreover, the number of MAOs that are offered in an area and the number of competing insurers varies widely across the country—which could put physicians in areas with limited competition among MAOs at a disadvantage.

While we are supportive of overall direction of the demonstration, additional focus should also be provided on equipping and helping physicians and practices better understand their options under Medicare, MA, and other value-based payment arrangements.

Other Payer APMs
Beginning with the 2019 performance period, ECs and groups will have the opportunity to have their participation in non-Medicare, Other Payer Advanced APMs count towards their QPP participation for the QP/Partial QP (PQ) determinations. Beginning with the 2019 performance period, CMS previously finalized two different processes—a Payer Initiated and an EC Initiated Submission of Information and Data processes—for the Other Payer Advanced APM determination and All-Payer Combination determination. CMS is proposing to maintain the annual submission process for both processes, with a few modifications.

PAI continues to encourage the Agency to implement a strong mechanism in place to begin negotiations with APM Entities well in advance of any modifications impacting this expected exchange of information during the submission process. This would ensure that there are appropriate safeguards in place during the submission process that would protect physicians and other ECs from issues that may arise from data exchange and communications between the APM
Entities and CMS, which could prevent them from receiving credit for participating in Other Payer Advanced APMs.

**Public Reporting on Physician Compare**

For some time, CMS has stated that it will be publicly reporting final scores, performance categories, and aggregate information on Physician Compare. PAI supports transparency and publicly reporting data; however, we do not believe that there is valid or reliable data that should be posted on Physician Compare at this time. The first two years of the program have been “transition years,” resulting in different levels of participation by physicians and practices. Thus, we believe any data from these first two years, and including year 3, could be misleading, and would not be fully contextualized. Therefore, reporting should be tested and rolled out when reliable and only after there has been stability in the QPP. Until the concerns voiced throughout this comment letter regarding predictability, continuity, consistency, and decreased complexity are addressed, we do not believe that it would be appropriate or even helpful to publicly report QPP participation data on Physician Compare. We strongly urge the Agency against proceeding with this proposal.

**Conclusion**

Overall, PAI supports CMS’s efforts to streamline and reduce unnecessary burdens placed on physician practices and continuing transition year policies for the third MIPS performance period. PAI and the medical associations represented on the PAI Board of Directors continue to welcome the opportunity to work with the Agency to further implement and advance the QPP in a meaningful and impactful way. If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI’s Executive Vice President and CEO, at k2strategiesllc@gmail.com.

Sincerely,

Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute

Enclosures: PAI Executive Summary – In-Field Engagement Discussions