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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: 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–FC)

Dear Acting Administrator Slavitt:

The physician and medical student members of the American Medical Association (AMA) thank you for allowing continued discussion and comment on the regulations to implement the new Quality Payment Program (QPP) that establishes two Medicare payment tracks: the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). Together MIPS and APMs have the potential to shape the future of healthcare quality and drive innovation for both physicians and patients. Given the importance of the QPP, we remain committed to working with the Centers for Medicare & Medicaid Services (CMS) to continue an open dialogue with the physician community to inform these programs as they develop. The following outlines our overarching views on the final QPP rule.

Improvements included in the final rule

We thank CMS for many of the changes made in the final MACRA rule. We believe the agency adopted numerous improvements over the proposed rule that will help physicians transition to and successfully participate in MIPS and APMs. Importantly, by adopting a "pick-your-pace" approach, CMS recognizes that physicians are at different stages of readiness, and those reporting for the first time face significant challenges. We therefore strongly support the final rule's approach that allows physicians to avoid a negative payment adjustment when they show an effort to participate by submitting some relevant data. This flexible solution also encourages participation by those in more advanced practices, creating incentives to report additional data and encouraging all practices to work at the pace that best meets the needs of their patients and practices.

In addition, the final rule alleviates the time crunch that many physicians were facing in trying to adopt significant practice changes by January 1, 2017. CMS' adjustment of the performance period will allow more practices to understand the QPP requirements and make informed decisions on how best to participate and improve care for patients. We further support the final rule's effort to reduce reporting

burden by decreasing the number of required measures in the quality, Advancing Care Information (ACI) and Improvement Activities (IA) sections of MIPS as well as the data completeness requirements that would have created perverse incentives for reporting data through registries.

We also applaud CMS for recognizing that components of the QPP will require additional work and refinement. In particular, we agree that the cost component of MIPS should not initially be scored until improvements are achieved and that certain measures, including global, population-based, and episode-based measures, need further modification.

Lastly, we believe the final rule adopts significant improvements to APMs. We support defining financial risk based on revenues rather than total cost of care, decreasing the benchmark spending requirements, and broadening models that can be certified as medical homes. We also support the additional credit awarded to MIPS APMs in the IA category and support CMS' efforts to work towards establishing an ACO Track 1+. These steps will help entities to seek out new payment and delivery models that can transform our healthcare system and encourage more practices to enter into innovative arrangements that benefit patients at a lower cost. **We encourage CMS to not only finalize these aspects of the program but find ways to maintain these parts of the rule in future program years.**

Transition period

In the final rule, CMS notes that, "[w]e envision that it will take a few years to reach a steady state in the program, and we therefore anticipate a ramp-up process and gradual transition with less financial risk for clinicians in at least the *first two years*."[1] The AMA strongly agrees with this sentiment given the QPP is not merely a combination of previous reporting programs but includes new requirements, deadlines, and components that will need to be understood by physicians and their practices. Furthermore, we fully agree that this transition will require at least a *two year period* and note that the MACRA statute, in several places, anticipates a multi-year transition period. For example, for the first two years of the program, the statute creates a "special rule" for the performance threshold as well as more specific thresholds for the components of MIPS.[2]

While acknowledging the need for a multi-year transition period, the final rule only adopts accommodations for 2017. Although helpful, we believe a more realistic transition period will require additional time, and urge CMS to engage in a more measured ramp up to the full QPP requirements. We fear that physician commitment to the program will be short lived if they do not have a sufficient glide path and are unaware of future year requirements. In addition, we believe a longer transition period is in keeping with concerns about reducing regulatory burden—a key driving point in the enactment of MACRA and a significant goal of the next Administration.

Furthermore, we fully believe that CMS will also benefit from a longer transition period. As discussed in more detail below, there are several components of the QPP program that require additional work by the agency. In particular, CMS still needs to fix methodological issues and test new measures and tools, especially with respect to risk adjustment, attribution, reliability standards, virtual groups, episode groups

[1] CMS. Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician- Focused Payment Models (hereinafter MACRA Final Rule). 81 Fed. Reg. 77008, 77010 (Nov. 4, 2016) (emphasis added).
[2] MACRA Pub. L. 114-110 § 101(c)(1) & (5) (2015).

and patient relationship codes. The final rule also needs additional clarification, including more detail on how to complete each of the IAs, publication of the performance thresholds, and greater information about MIPS scoring. Lastly, both the agency and physicians would benefit from further education about MIPS and APMs once the first year of the QPP is complete, allowing feedback and time for physicians to make changes so that they can improve in the following year. **CMS should therefore use the flexibility provided in the MACRA statute to create a longer transition period that, at a minimum, includes accommodations in 2018.**

Assistance to small, rural, and specialty practices

CMS took significant steps to alleviate the burden MIPS and APMs may have on certain practices by increasing the low-volume threshold and thereby exempting practices with less than $30,000 in Medicare Part B allowed charges OR 100 or fewer Medicare patients per year. We greatly appreciate this change and believe that it will provide substantial relief to many practices and help avoid negative impacts on patient access to care.

We note, however, that the QPP is a new program with many uncertainties, and that the full effect of the program will not be known until practices begin adopting and meeting reporting and other program requirements. **Consequently, we urge CMS to continue to monitor the QPP's effect on small, rural and other unique practices and to provide additional exemptions for these groups to ensure the success of the program and encourage continued participation.** In particular, we urge CMS to publish data on how the QPP has affected patient access to care and whether certain specialties or sites of service are penalized more than others. Such data, broken down by area, specialty, size, and other relevant factors, is needed so that all can evaluate the QPP and provide additional recommendations for the program in future years.

In addition, we believe that the final rule creates complexity through its inconsistent treatment of the low-volume threshold compared to other excluded categories. For example, all other excluded categories (i.e., new Medicare enrolled clinicians, Qualifying APM Participants (QPs) and partial QPs are determined at the individual NPI level while the low-volume threshold exclusion is determined at the tax identification number/National Provider Identifier (TIN/NPI) level for individual reporting and the TIN level for group reporting. Consequently, unlike the other exempt categories, a low-volume eligible clinician who reports through a group will incur the MIPS payment adjustment. If CMS maintains that the low-volume exclusion be treated differently under group reporting, then we urge the agency to establish a separate low-volume threshold for groups (as was done for non-patient facing providers). For example, CMS could exclude a group if more than 50 percent of its MIPS eligible clinicians meet the low-volume threshold.

We also note that CMS has made accommodations for small practices in only some of the MIPS components, and notably excluded additional assistance in the ACI category beyond having this component re-weighted. This is especially problematic since the ACI category requires physicians to adopt expensive new technology and utilizes a performance score that will require small practices to compete against much larger and more sophisticated entities. **We therefore ask that CMS seek to include additional accommodations for smaller practices in all components of the QPP.**

Finally, CMS needs to focus on implementing virtual groups to assist small practices. In our November 17 comment letter on CMS' Request for Information (RFI), we noted that smaller practices

will need time to learn about virtual groups, reducing the initial administrative burden on CMS and escalating the need for the agency to develop and disseminate information about this option. We strongly urge CMS to act on forming these groups as soon as possible. Without this assistance, we believe small practices may face even greater challenges when attempting to move into the MIPS program structure. When developing virtual groups, CMS should offer significant flexibility—there should be no initial, annual, or other limits placed on the maximum number of groups approved each year or the required geographic proximity. Furthermore, there should be no requirement that all clinicians within a virtual group be within the same specialty. We refer CMS to our RFI comments for more details on these proposals

Ultimate goal of the QPP

In the final rule CMS outlines six strategic objectives for the QPP, including the goal of maximizing participation. To achieve this end, we urge CMS to design a scoring system that is fair, reliable, and minimizes the number of losers, especially in early years. If the QPP becomes viewed as a penalty program, we do not believe that physicians will actively want to participate.

Furthermore, if the program is arbitrary or fails to meet the different needs of specialties and practices, physicians are unlikely to consider the QPP as beneficial or relevant. For example, CMS should not accept measures or methods with low reliability in an effort to "increase participation" as we believe the opposite will occur. Likewise, if CMS wants to encourage voluntary reporting from physicians that would normally be excluded from MIPS (e.g., low-volume threshold, new to Medicare, etc.) it would make sense to allow these individuals to earn a MIPS incentive if they meet the program requirements. Overall, CMS should focus on ways to not only encourage participation but success in the QPP.

The following outlines our principle recommendations on the final QPP rule:

MIPS:

- The AMA strongly supports the workable solution CMS created for the first year of the MIPS program by establishing "pick-your-pace" reporting for the 2017 performance period. We urge CMS to continue its use for at least 2018 to ensure an appropriate transition to MIPS.

- Physicians remain confused about the MIPS composite score and need simplified explanations of how the scoring translates into penalties or bonuses. In addition, CMS should provide additional data on how the performance threshold will be calculated in future performance years.

- For both the quality and cost categories of MIPS, the AMA urges CMS to focus on improving methodological shortcomings, especially with respect to risk adjustment and measure reliability. While some measures within these categories are being refined, CMS should lengthen the phase-in for the cost measure performance category and reduce the reporting requirements under quality.

- Under the ACI category, CMS should focus on proposals for more relevant measures and remove the pass-fail scoring component to avoid unfairly penalizing physicians. CMS should also ensure its policies related to the use of certified electronic health record technology are responsive to the availability of new versions and the real-world needs of physicians and patients.

- CMS' proposals for the IA category are generally very flexible and provide reduced reporting requirements for small, rural, and non-patient facing physicians. The AMA supports this approach and urges CMS not to add complexity to the IA scoring or attestation process in future program years.

APMs:

- The AMA strongly supports the significant changes that were made in the final rule to improve the financial risk standards for Advanced APMs, including: allowing APM entities to limit risk to eight percent of their Medicare revenues; simplifying the definition of risk; and, under the benchmark spending alternative, reducing minimum risk from four to three percent of the APM's benchmark.

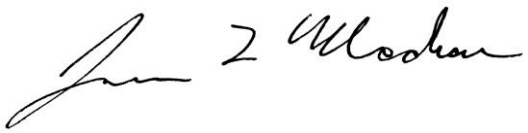
- CMS states its intention to increase the revenue-based nominal amount standard beginning in 2019 to as much as 15 percent of revenues. The AMA strongly urges CMS to preserve stability and predictability for APMs by maintaining the eight percent revenue standard for 2019 and at least three additional years.

- CMS should establish the same financial risk requirements for Other Payer Advanced APMs that it has set for Medicare Advanced APMs in order to facilitate the development of multi-payer models. The need to manage multiple and conflicting requirements from different payers is a disincentive to broader physician participation in APMs and can reduce their ability to improve quality and reduce spending.

- The AMA continues to strongly oppose requiring medical homes with more than 50 clinicians to meet a different set of financial risk requirements, and also urges CMS to allow specialty medical homes to meet the same risk standards as primary care medical homes. Medicare policies should provide a welcoming environment for the development of specialty models.

The attachment to this letter provides more detail on each of these recommendations, including the reasoning behind these suggested changes. We look forward to working with you on achieving a successful implementation of this important program. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD

Merit-Based Incentive Payment System

MIPS scoring & feedback

The AMA strongly supports the flexible performance threshold that CMS has set for the 2017 transition year, which will allow physicians to adjust to the new program and avoid being penalized in 2019. In particular, we appreciate that CMS has clearly and simply outlined what physicians must do in 2017 to avoid a penalty. This simplicity, however, is lost once the program moves beyond the transition year. MIPS scoring becomes increasingly more opaque and confusing, and we believe few physicians will understand their score or know what must be done in future years to succeed.

Contributing to this lack of clarity are several factors. The final rule does not fully detail the methodology and deadlines CMS will use to calculate final scores and how financial adjustments will be determined. To date, CMS has also focused its educational efforts on the components of MIPS but left out detail on how physicians will be scored. CMS should work with the AMA and other physician representatives to further evaluate the data and determine the best way to set the performance threshold in future years. Finally, additional analysis is needed before CMS proposes measuring improvement in the MIPS program.

Overview scoring issues:

- **Reduce complexity and provide physician education**

The methodology CMS finalized to calculate a physician's final score is extremely complex. While we understand that many of the scoring details are specified in statute, CMS should provide guidance that makes the final scores as clear and simplistic as possible. To achieve this, CMS should explain, through examples, what is generally required to earn an incentive vs. a penalty and what is required to earn the maximum incentive, as was included in this final rule. CMS should create specialty specific examples of how physicians can achieve an incentive payment or avoid a penalty. These examples should be included in educational webinars and in CMS' QPP tool. While we understand that performance varies, providing some insight through real life cases or trends can better inform physicians. We worry that CMS will instead in the future just publish a "threshold number" that does little to assist physicians in improving their performance. Where possible, CMS should follow the precedent it set for the 2017 reporting year and provide clear rules that physicians can follow to ensure they will avoid a MIPS penalty.

Transparency will be extremely important in teaching physicians about their score. CMS should make all data available as early as possible prior to the performance year so that physicians and the organizations that represent them can evaluate results, advocate for needed changes in methodology, and help their physician members improve their performance. We also encourage CMS to run simulations to help physicians understand how they may perform in a given program year. In particular, CMS could provide guideposts of what might be expected to earn an incentive or highlight ways that will maximize performance (e.g., such as focusing on the quality component given that it has the highest percentage of the MIPS composite score).

CMS also should identify and publish the areas that are the most challenging for physicians once it calculates the final scores. In the past, CMS provided break-downs of performance on specific measures, which allowed physicians to see where there were unique challenges. **We urge CMS to provide similar detail on the different MIPS components as well as the individual measures so that physicians can evaluate themselves against others participating in the program and find areas where they need improvement.** The information also must be published on a timely basis. The current precedent under Physician Quality Reporting System (PQRS) is unacceptable—publication of the PQRS Experience

Report is provided two years after the close of the reporting period. Without timely detail on specific measures it is extremely difficult to plan and educate physicians on improvements.

While CMS should work to reduce complexity of calculating physicians' final scores, it is unlikely that the methodology will be extremely simple. Therefore, CMS should also immediately begin providing education to physicians on how their final scores will be calculated, including hosting workshops and webinars to provide specific examples of how final scores will be determined. This information has been absent from the webinars and presentations that CMS has conducted for physicians to date. Ideally, many of these presentations would be coordinated with individual medical specialties so that scoring issues and examples specific to their members could be highlighted.

- **Address methodological shortcomings**

Risk Adjustment: The AMA remains concerned that the risk adjustment models for several of the measures (e.g., All-cause Hospital Readmissions, total cost of care, Medicare Spending per Beneficiary) do not adequately address the ongoing concerns around socio-demographic factors (SDS). CMS points to the work of the National Quality Forum (NQF) and an upcoming Assistant Secretary for Planning and Evaluation (ASPE) report as potential activities that will inform this issue. We, however, do not believe that the NQF SDS trial period will meet CMS' needs in addressing this question. Most of the measures in this trial period are limited in the type of factors tested and the underlying data. We believe that the impact that SDS plays in these measures has not been evaluated adequately due to these limitations. Indeed, NQF staff recently indicated that the findings that most SDS factors do not contribute significantly to the outcome may be due to the limited availability of the necessary data and not indicative of the true impact SDS may have on a physician's or hospital's performance.

Research is emerging that demonstrates the need to examine the potential impact that SDS factors, such as community supports, play. For example, a recent study examined the density of pharmacies in Oregon and the role this access within the community may play on hospital readmissions. Researchers found that the density of pharmacies in an area was directly linked to the number of readmissions to a hospital.[1] These types of factors have not yet been included in the SDS analyses presented to NQF.

Because of these ongoing concerns with the lack of robust data sets, the AMA urges CMS to identify new data sources to enable adequate analyses of these potentially contributing factors. Without the inclusion of SDS factors in the models, there may be potential negative consequences on physicians that impact their reimbursement and misrepresent their performance to patients.

Measure Reliability: It is unclear to the AMA why CMS continues to include measures in MIPS for which reliability is questionable and will very likely misrepresent physician performance. For example, CMS considers a reliability score of 0.4 an acceptable threshold for the episode-based cost measures. In this instance, for those physicians whose performance score yields a reliability result of 0.4, there is a 60 percent chance that this score is inaccurate and true performance could be higher or lower. We believe that measures with such low reliability results should not be considered acceptable by CMS for public reporting or for determining payment adjustments.

In addition, the minimum reliability threshold used for measures in MIPS varies depending on the measure. As discussed above, the episode-based cost measures use a minimum reliability score of 0.4. In

[1] Bissonnette S, Geores LM, Lee SDH. Pharmacy density in rural and urban communities in the state of Oregon and the association with hospital readmission rates. J American Pharm Assoc. Published online August 1, 2016. http://dx.doi.org/10.1016/j.japh.2016.05.008).

this same final rule, CMS points out that the group size was increased for the hospital-wide All-cause Readmission measure in an effort to improve on the reliability score, which was 0.56 for physician groups of 10 or more and a minimum sample size of 200 patients. The AMA is also aware that a different threshold was used for measures that would be publicly reported on Physician Compare in 2016; specifically, measures were considered unreliable if the 25th percentile of the reliability scores fell below 0.90. While we appreciate CMS' attempt to improve reliability, we see no reason why the same level reliability should not be required across the different measures and for different intended uses (i.e., public reporting, payment adjustments).

The AMA continues to believe that physician performance on any measure should not be used for payment or be publicly reported unless a reliability of 0.80 can be demonstrated. Statisticians and researchers generally believe coefficients at or above 0.80 are considered sufficiently reliable to make decisions about individuals based on their observed scores, although a higher value, perhaps 0.90, is preferred if the decisions have significant consequences.[2] Accordingly, CMS should not rely on profiling measures that have suboptimal reliability scores, recognizing that doing so could be misleading to patients and physicians.[3]

- **Improve measure comparison among physicians**

The scoring methodology that CMS finalized in the final rule does not make accurate comparisons to determine physicians' scores on measures in the quality, cost, and ACI categories. Specifically, measure benchmarks must be further stratified to ensure accurate comparison among physicians. CMS states that it does not believe differences in specialty, group size, and region create an inherent need for separate benchmarks. The AMA respectfully disagrees. Much of the variation associated with these factors cannot be avoided by physicians and should be reflected in measure benchmarks.

Some subspecialties consistently treat higher risk patients or patients who require more expensive drugs so that comparisons across all physicians who perform a particular procedure may not result in accurate cost or quality comparisons. Regional differences, such as state laws or socioeconomic factors, can also produce large and unavoidable cost differences. The type of site where physicians practice creates additional variations.

In a skilled nursing home, for example, a large number of the patients are likely to have significant comorbidities and advanced disease that make it essential to compare costs and quality for physicians in this setting only to that of other physicians treating a similar patient population in the same or a similar site of service. It should also be recognized that physicians often do not have the option of choosing between a more or less expensive site of service—because the patient's condition or the mix of providers in the community dictates where the care is provided. For example, certain procedures are almost always done in ambulatory surgical centers (ASC) in some regions of the country and in hospital outpatient departments in other areas. The choice is largely due to certificate of need laws that severely limit ASC formation and make selection of this less costly option impossible in some states. Physicians have no control over these variations and should not be penalized or rewarded because of them. **CMS must work**

[2] See e.g., Webb, Noreen, et al. Reliability Coefficients and Generalizability Theory. Handbook of Statistics, Vol. 26. 2006 Elsevier B.V. DOI: 10.1016/S0169-7161(06)26004-8. http://web.stanford.edu/dept/SUSE/SEAL/Reports_Papers/ReliabCoefsGTheoryHdbk.pdf ; Del, Siegle. Instrument Reliability. Educational Research Basics. University of Connecticut. Accessed 06/13/2016. http://researchbasics.education.uconn.edu/instrument_reliability/

[3] Adams, John, et al. Physician Cost Profiling – Reliability and Risk of Misclassification. N Engl J Med. 2010 March 18; 362(11): 1014–1021. doi:10.1056/NEJMsa0906323.

to further define and narrow its comparison of physicians on quality, cost, and ACI measures by subspecialty, geographic location, and site of service.

- **Increase flexibility**

CMS requests feedback on whether it should allow combined scoring on all measures submitted across multiple submission mechanisms within a performance category. The AMA supports allowing physicians to receive a combined score through multiple submission methods within a performance category in order to provide maximum flexibility to doctors. CMS should not develop different weights for different submission methods, which it mentions as one option in the final rule.

Setting the Performance Threshold:

As CMS notes in the final rule, the agency does not know how MIPS will impact small practices and solo physicians. Given this concern, CMS should set the lowest performance threshold possible until there is data on how physicians in various specialties and practice arrangements are performing under the QPP and necessary adjustments can be made.

The AMA believes there are several steps CMS could take to ensure a small number of physicians are penalized each payment year. It is difficult, however, to know the effects of different policy options without additional information from the agency. Below we describe ways CMS can ensure that the performance thresholds it develops are not overly burdensome for physicians. We also urge CMS to engage with the AMA and other medical organizations to determine how different methodologies for setting the performance threshold might affect the number of physicians who are able to succeed under the QPP.

- **Slowly increase the performance threshold**

The AMA strongly supports CMS setting the performance threshold for the 2017 performance year at three, an easily achievable level that will provide physicians time to educate themselves on the details of the QPP. The MACRA statute provides a "special rule for the initial two years" that allows CMS significant flexibility in establishing the performance threshold in 2017 and 2018, and illustrates Congress' intent that CMS should allow physicians time to familiarize themselves with the program while the performance threshold is set at a realistic level. Despite this statutory language, CMS states that it intends to increase the performance threshold in year two. We believe that this proposal disregards the statutory intent to provide a longer transition period. Furthermore, physicians, CMS, and vendors will all benefit from a longer transition period, and the agency should consider how stability in the program requirements will help physicians to become more familiar with MIPS and minimize administrative burden. **We urge CMS to set the performance threshold for 2018 at a similar level to 2017 that is easily achievable by physicians.** Establishing a low performance threshold for 2018 will continue to encourage early participation in the MIPS program, which will enable more robust engagement in the QPP over time.

- **Conduct additional analyses before calculating the performance threshold in year three and beyond**

Section 1848(q)(6)(D)(i) of the statute requires the performance threshold in year three and beyond to be equal to the mean or median of final scores from a prior period. The final rule does not provide information on how CMS plans to set the performance threshold in the future. The AMA believes that additional information and analysis are needed from CMS to determine the impact of choosing the mean

over the median. CMS should run and publish analyses that would provide information on how choosing the mean versus the median to set the performance threshold will affect the number of physicians who receive penalties and incentive payments as well as if choosing one over the other would disproportionately impact certain specialty, small practices, or sites of service.

The statute also states that CMS should use data from a prior period when setting the performance threshold. The AMA believes the choice of which clinicians to include in the calculation of data from prior performance periods could significantly impact the performance threshold. CMS also has not released any analyses or data on this issue, limiting our ability to provide guidance on this topic. One option to maintain a low performance threshold in 2019 may be to use the data from the 2017 performance year to set the 2019 performance threshold. Given that 2017 is a transition year, and many physicians will likely engage in reduced reporting as they transition to a new reporting program, using the 2017 performance period data to set the 2019 performance threshold may allow physicians to continue to familiarize themselves with the QPP. The AMA would appreciate the opportunity to engage further with CMS officials as they determine the performance thresholds in future program years.

In addition, we note that CMS intends to publish future performance thresholds on a web site prior to the performance period, rather than publishing via notice and comment rulemaking (although the methodology would be open for public comment). We urge CMS to allow physicians to still provide comment on the final numerical figures to ensure that the program retains full transparency.

- **Set the performance threshold as a range**

Initially, CMS' had proposed to set the 2017 benchmark at a level that would produce a 50-50 split between the number of physicians above and below the mark, thereby penalizing half of all physicians treating Medicare patients. We are grateful that this approach was not finalized. However, we are concerned that MACRA language tying the benchmarks to either the mean or median data point will lead CMS to resurrect their earlier proposal. In our view, setting a performance threshold with a predetermined 50 percent failure rate would have very negative consequences for a large number of physicians and jeopardize their continued ability to serve Medicare patients. The AMA believes the best course of action for the initial years of the QPP is to set the performance threshold at a level that confines penalties to a limited number of physicians who fall well outside the norm. **Therefore, we recommend initially setting a range of scores on either side of the performance threshold that would be considered "average" and not subjected to either penalties or bonuses.** This would likely lead to fewer penalties in the early years of the program.

Measuring Improvement:

Section 1848(q)(5)(D) states that "beginning with the second year of MIPS, if data sufficient to measure improvement are available, the final score methodology shall take into account improvement of the MIPS eligible clinician in calculating the performance score for the quality and cost performance categories and may take into account improvement for the improvement activities and advancing care information performance categories." CMS states in the final rule that it is not proposing an approach for scoring improvement at this time. While the AMA supports measuring improvement in addition to achievement, we caution that any measurement of improvement does not penalize physicians that may already score very high on all measures. These physicians should have the option to be scored on achievement only so they are not penalized for their previous high performance. We are encouraged that the three options to evaluate improvement that CMS discusses but does not finalize in the rule would try to account for this concern. **The AMA urges CMS to work with us and other stakeholders to engage in a dialogue about how to best score improvement in future years.**

Reweighting:

The final rule focuses predominantly on moving any missing category into the weight of the quality performance category. We believe this approach could overemphasize the quality component. **Instead, we recommend that CMS consider holding physicians harmless or scoring them as "average" for the categories that they cannot report on.** This will maintain the balance across categories without penalizing those who do not have applicable measures.

In the final rule, CMS contends that the MACRA statute permits re-weighting of the categories but does not permit assigning a score to judge a participant as "average." Yet, the statute specifically states that CMS can re-weight both the entire category or the individual measures and activities. We therefore believe that such re-weighting is permissible under the statute. Furthermore, this is supported by CMS' own proposal to assign a final score at the performance threshold to a MIPS eligible clinician who has only one performance category score, essentially holding these individuals harmless.

CMS could also increase the weight of the IA category to make up for the lack of quality or other measures. CMS itself states that "we envision that all MIPS eligible clinicians would have sufficient activities applicable and available and do not propose any scenario where a MIPS eligible clinician would not receive an IA performance category score." CMS should therefore leverage the breadth of the IA category when it needs to re-weight the MIPS components.

We also believe that CMS creates an overemphasis on the ACI category for MIPS APMs. For these entities that do not submit quality data through the CMS Web Interface, CMS plans that their ACI score will account for 75 percent of their total score. Again, we think this creates too much of an emphasis on a single category and limits the ability for a clinician to average performance across the different MIPS components. Since MIPS APMs report on quality measures, it makes sense to not ignore this component but to either work with MIPS APMs to identify alternative means for their participants to achieve a quality score or allow them to be scored at least as average.

Informal Review Process:

Section 1848(q)(13)(A) of the statute requires CMS to establish a process under which physicians may request an informal review of the calculation of the MIPS payment adjustment factor. CMS finalized a 60-day period for physicians to request a targeted review beginning on the day CMS makes the MIPS payment adjustment factors available to physicians. Given the numerous issues with Physician Quality Reporting System (PQRS) and Value Modifier informal review processes over the past several years, we have significant concerns that CMS has not finalized an improved process under MIPS.

In the past, many physicians have been denied the opportunity for an informal review without receiving an explanation as to why their requests for review were rejected. We urge CMS to improve communication between the agency and physicians and practices requesting informal reviews under the MIPS program going forward. **The majority of requests for an informal review should not be denied, and CMS should provide detailed feedback to physicians on each performance category and all individual measures whenever an informal review is conducted.**

CMS also notes that they will utilize the QPP Service Center, similar to the Help Desk under PQRS, to assist physicians in the informal review process. The Help Desk was often uninformed and unhelpful to physicians throughout the PQRS informal review process, frequently causing confusion and relaying inaccurate information. While providing additional staff to the new QPP Service Center, as CMS mentions in the rule, would be helpful, CMS must also work to better educate the Service Center staff on

how to actually assist physicians. In addition, Service Center staff should have a direct contact on the program team at CMS to which they can elevate issues as needed in order to better facilitate communication between CMS staff and Service Center staff.

Feedback:

In previous comment letters, we have highlighted problems with the lack of timely and actionable feedback and called for performance reports that provide more understandable information. To that end, we urge CMS to work with the physician community as it continues to refine physician reporting. We highlight two items CMS should include in the first round of MIPS reports that CMS will produce by July 1, 2017.

First, we urge CMS to retain its current Quality and Cost Reports (QRUR) practice of identifying the attributed beneficiaries (including their characteristics and resource use by category) for each cost measure. This information can assist physicians in delivering more efficient care.

Second, we urge CMS to ensure its identity management system allows reports to be accessed at both the group and the individual level even if physicians choose to participate in MIPS at the individual level. For example, if a group (as identified by one billing tax identification number [TIN]) of 30 physicians participates in MIPS at the individual level, in addition to permitting physicians to access their own reports individually, CMS should make it possible for one person to have access at the TIN level to pull all 30 individual reports. Moreover, CMS should also combine the 30 individuals under the TIN into one TIN level report with aggregated performance for each measure. This aggregation will facilitate physician understanding on how they would like to participate in MIPS in future years.

Quality

It is important that CMS develop achievable requirements within the quality performance category given the weight placed on this component. In year one of MIPS, quality is worth 60 percent of the final score and can be even greater for participants that have their score re-weighted. Consequently, successful participation will depend heavily on participants' ability to understand and meet the MIPS quality measures.

The AMA urges CMS to use lessons learned from PQRS when setting the MIPS quality performance category requirements. CMS should also maintain consistency and not ramp up quality requirements in 2018 or 2019, as there will likely be many new entrants to MIPS. It is hard for a practice to invest in resources and appropriately plan when requirements change on a yearly basis. CMS also runs the risk of a significant drop-off if requirements increase too drastically and practices do not see a return on investment. **We, therefore, urge CMS to maintain the quality reporting threshold at 50 percent in 2018 and not increase it to 60 percent.** As we have stated in our previous comment letters, CMS' goal should be to ensure participants can be successful in MIPS, especially in the early program years.

We do believe CMS has made some significant improvements to the quality category. In particular, the AMA supports protections to physicians who chose to report on new measures. A minimum floor promotes such measures because physicians are ensured that they will not be penalized by reporting on unfamiliar measures. While the final rule also simplifies reporting in the quality performance category, we note the following further improvements are needed.

- **Further reduce reporting requirements**

The AMA encourages CMS to further reduce the reporting requirements to ensure all physicians, regardless of specialty or practice size, have a fair chance at achieving the maximum amount of points in the quality performance category. A more appropriate number of required measures would be three or four. There are still many specialists and sub-specialists who are struggling to find six relevant measures to report on, such as physicians who treat patients in the nursing home, due to the variety of conditions and significant comorbidities that are found in this patient population. Measures that may appear clinically relevant are often inappropriate due to the severity of these patients and may jeopardize instead of improve care quality.

- **Eliminate the outcome measure requirement**

The AMA understands the importance of reporting on outcomes or high priority measures, but, as we highlighted in our MACRA RFI and proposed rule comments, there are still a number of methodological issues that must be addressed before requiring reporting on these measures. In addition, there is still an insufficient suite of outcome measures for physicians to choose from.

Infrastructure challenges may also prevent physicians from reporting on outcomes measures. For example, a physician may not have the appropriate data elements in his or her electronic health record (EHR). In addition, there may be interoperability issues that could interfere with the exchange of needed information or the ability to perform longitudinal tracking due to the lack of uniform patient identifiers.

We strongly encourage CMS to maintain flexibility by not requiring the use of any specific type of measures in the initial years of the program. **Instead, CMS should recognize the importance of these measures through bonus points rather than a mandate on all participants**. Removing the outcome measure requirement would ensure maximum potential achievement by all physicians regardless of specialty, sub-specialty, practice size, or patient population. It would also simplify the overall calculation for scoring quality.

- **Maintain the elimination of cross-cutting measures**

The AMA fully supports the elimination of the cross-cutting measure requirement. The proposed approach and list of measures outlined to meet the requirement did not sufficiently address the nuances in the MIPS reporting options and differences in how care is delivered. It also led to physicians being forced to pick a measure for the sake of reporting and turned attention away from higher priority care improvement areas.

In addition, the proposed cross-cutting measure requirement did not make sense for Qualified Clinical Data Registries (QCDRs) given the specialization of many QCDRs. If CMS proposes the requirement again in the future, it will severely limit the number of patients that can be captured within a QCDR, as we explained in our proposed rule comments. Similarly, many of the proposed cross-cutting measures were not directly related to physician specialties. Requiring physicians to address areas that may be outside of their scope of practice adds unnecessary burden and costs with little to no demonstrated value to patient care and improving outcomes. The measures that mandate some follow-up action are good examples of requirements that some specialties found difficult, if not impossible to report (e.g., emergency medicine). **Going forward, we urge CMS to maintain the elimination of the cross-cutting measure requirement.**

- **Provide a phase-out period for topped out measures**

The AMA continues to have concerns regarding CMS' strategy for removing measures, specifically the "topped out" methodology. CMS has already removed a significant number of measures under MIPS, and we reiterate that it is premature and short-sighted to remove additional measures considered "topped out" given that reporting rates within PQRS have historically been low and there remains a lack of relevant measures for specialists and sub-specialists.

The AMA does support the removal of measures when clinical evidence has changed, but we are concerned with the growing gap that has been created in the measure portfolio due to the number of quality measures removed over the last few years and the additional measures that are slated for removal in 2017**. At the very least, we recommend that if CMS seeks to remove a measure, it first identifies a replacement measure. Alternatively, CMS could set a minimum reporting rate before classifying a measure as "topped out," such as requiring 30 percent or 40 percent specialty reporting before considering removal.** Currently, the vast majority of specialty measures have less than a 10 percent reporting rate. Therefore, classifying a measure as "topped out" when there is such a small sample is questionable. It is currently impossible to know whether a high rate of reporting is representative of the practice of medicine or merely illustrative of physicians who are successful at the measure and no longer have a gap in care.

Furthermore, we once again urge CMS to provide a three-year phase out period for any new measures being proposed for removal to allow time for the submission of new measures. This is particularly important for measures included within QCDRs. As we have seen over the last two QCDR vetting periods, CMS has provided no advance warning to QCDR developers or physicians participating in a registry when a QCDR measure is removed. It takes time for a QCDR steward to develop the evidence base and new measure that are needed to replace the "topped out" measure.

- **Avoid limitations on QCDRs**

Since the passage of MACRA, CMS has routinely stated that it wants to encourage reporting through QCDRs given their robust nature and potential for advancing quality care. Specialties are currently spending millions of dollars to further develop QCDRs to allow physicians to receive more timely and relevant feedback and benchmark information. In addition, they enable physicians to report on quality measures that are robust, outcome oriented, and more applicable to a physician's patient population compared to traditional PQRS measures. We strongly support this view and appreciate CMS' growing acceptance of QCDRs in clinical care. To achieve this shared goal of greater QCDR participation, QCDRs need the flexibility to incorporate measures that are tailored to their participating specialties. We are therefore alarmed at recent actions by CMS that would severely limit this flexibility.

Specifically, we are troubled that, as part of its review and approval of QCDR measures for 2017, CMS required any QCDR that had measures similar to existing PQRS measures to drop the similar QCDR measure and adopt the PQRS measure(s). This requirement reduces the more sophisticated QCDR measures and moves QCDRs to a more basic and less meaningful traditional PQRS system.

QCDRs are successful in improving quality because physicians recognize that QCDR measures are meaningful to their profession and improve patient care, even though participation may cost in the hundreds to thousands of dollars. Yet, CMS, at the last minute, has forced QCDRs to drop many existing measures due to claims that the measures are "topped out." We understand the value in adopting new measures, but often the individual measures within a QCDR are designed to serve a greater improvement purpose and may not be "topped out" when evaluated on an aggregate rather than individual basis.

In some instances, CMS is also misinformed on the status of the "similar" QCDR measure and existing measure within the PQRS program. For example, CMS' consultant, Signature Consulting Group (SCG), informed one QCDR that its bowel prep measure had to be removed because it was similar to a PQRS measure, but the PQRS measure was actually never finalized. CMS' exclusion of this QCDR measure ignored the evidence gap and clinical need to incorporate the measure into the QCDR. Another QCDR was told that one of its measures was duplicative, but, in fact, the QCDR measure reflected an update to the evidence base and change in guideline recommendations, while the PQRS measure was relying on the old guideline recommendation and not following the latest evidence. **Thus, we urge CMS to ensure flexibility for QCDR measures by not requiring the use of any specific type of measures.**

- **Maintain the removal of the Acute and Chronic Composite Measures**

The AMA fully supports the elimination of the Acute and Chronic Composite Prevention Quality Indicators (PQI) measures from the calculation of MIPS score. We remain concerned with CMS' intent, as stated in the rule, to modify the existing PQI measures. These measures were developed for implementation and reporting at the metropolitan area or county level (per 100,000) and have been endorsed as such by the NQF with the exception of PQI 8 (Heart Failure), which is at the health plan/integrated delivery system level. Applying measures that are intended to be used at a different level of measurement is inappropriate.

While the AMA understands the need to measure and track the quality and costs associated with the health of a population, **we urge CMS to reconsider the current approach of implementing measures developed for one purpose into a different program or audience.** The MIPS program, with its various reporting requirements, already measures the health of a defined population for whom a physician provides continuous care. We expect and anticipate that a more holistic view of population health will be more evident as the number of specialty-specific measures continues to grow. These measures are implemented to measure the performance of a specific clinical condition and often for a specific specialty, which leads to measures that more accurately represent the patients seen by a physician or group and the quality of care provided. As a result, it is unclear why there is a need to adopt modified PQI measures.

- **Allow vetting of the All-Cause Readmission Measure**

The AMA continues to remain concerned that the All-Cause Hospital Readmission measure, which was developed for use at the hospital/acute care facility level, is now applied to groups of 16 or more clinicians with at least 200 cases. Applying measures that are intended to be used at a different level of measurement is inappropriate without sufficient testing and rigorous assessment of appropriate sample sizes and risk adjustment models. The information on the reliability rates achieved by group and patient sample size must be transparent. In addition, the risk adjustment approach must ensure appropriate representation of clinical and socio-demographic factors and be vetted by the physician community and others before widespread implementation.

We acknowledge that CMS completed some reliability analyses and published them in the CY 2015 Physician Fee Schedule Final Rule. We, however, do not believe that this analysis is sufficient. The largest groups included were groups with 10 or more eligible professionals, which yielded a reliability score of 0.56. While we assume that reliability increases with the new requirement of applying the measures only to groups of 16 or more eligible clinicians, we do not know whether the measure achieves a reliability level of 0.8 or higher when implemented with the more appropriate and statistically valid threshold or group size. Therefore, we strongly urge CMS to drop the use of the measure until it has been submitted to the NQF for endorsement review and allow for the physician community to vet the measure

and review testing results to ensure that it is appropriate as specified and risk-adjusted for use at the physician level.

We are also once again disappointed that CMS has not addressed the need for refinements to the risk-adjustment model for the All-Cause Hospital Readmission measure and the other administrative claims measures incorporated into MIPS. We refer CMS to our comments earlier in the document for our detailed concerns and recommendations.

- **Develop a transparent validation process**

The AMA urges CMS to develop a transparent validation process that allows for physician input to review and validate a physician's inability to report on the required number of quality measures. CMS states that they anticipate the validation process would function similarly to the Measure Applicability Validation (MAV) process. The AMA has previously shared our concerns with the MAV process, including the lack of clarity in how the MAV functions. CMS also states that they plan to use the cluster algorithms from the current MAV process under PQRS to identify which measures a MIPS clinician is able to report. These MAV clusters, however, were developed without sufficient input from medical specialties, and, as a result, physicians are often inappropriately held accountable for measures. In addition, it was often difficult for certain subspecialties to determine which measures they were required to report due to a lack of specificity within the MAV clusters. CMS should consult with the AMA and other physician stakeholders to determine whether existing clusters hold physicians accountable for measures unrelated to their practice. **We urge CMS to develop a more transparent validation process under the new MIPS program that will enable physicians to easily understand which measures they are required to report.**

- **Reinstate measures group reporting option**

The AMA urges CMS to reinstate measures group reporting as an option under the quality performance category. Allowing physicians to report on a measures group for a sampling of their patients is a less burdensome yet meaningful way for physicians to meet their quality reporting requirements. In addition, measure group reporting encourages the use of harder, more resource intensive outcome measures. This reporting option also provides smaller practices and individual physicians without an EHR a less costly and administratively burdensome reporting option.

Measure groups are designed to create an overall picture of patient care for a particular condition or set of services. The design of measures groups provides a holistic approach to evaluating quality and aligns with health policy experts' recommendations on how to design a relevant and value-driven MIPS program. For example, the cataract measures group addresses surgical complication rates, clinical outcomes, patient-reported outcomes, and patient satisfaction to provide a comprehensive picture of surgical care. The measures included in a measures group undergo a deliberate process with the intent of the measures group in mind. Often if a measure is intended as part of a measures group, it is cited as such as it undergoes the NQF evaluation so the consensus development process includes goals of the measure. Therefore, CMS should reinstate the measures group reporting option for physicians under the MIPS program. Maintaining all previous reporting options allows for maximum flexibility in the quality performance category of MIPS and the greatest number of pathways to success for physicians.

Cost

CMS finalized 12 cost measures (two per capita cost measures and 10 episode cost measures) and stipulated that cost will count for zero percent of the MIPS final score in 2017 (payment year 2019), 10

percent in 2018 (payment year 2020) and 30 percent in 2019 (payment year 2021) and thereafter. We support CMS' decision to make 2017 the transition year and not include performance on cost measures in the 2017 MIPS final score. Yet, we continue to have concerns with respect to this category of MIPS. The following outlines our additional feedback on this section of the final rule.

- **Lengthen the phase-in for cost measure performance**

We continue to oppose the use of the two per capita cost measures (Total Per Capita Spending and the Medicare Spending per Beneficiary measures (MSPB)) because they lack sufficient validity and reliability due to flawed retrospective patient attribution and inadequate risk adjustment for vulnerable patients. Also, although we believe that episode measures offer a promising alternative, further refinement of the episodes and attribution and risk adjustment methodologies is needed prior to widespread adoption. **To address these concerns, we urge CMS to modify its cost scoring approach starting in performance year 2018 to accommodate the implementation and transition to the new patient relationship categories, care episodes, and patient condition classifications required under MACRA.**

It is our expectation that any measures included in the program in future years will have to be re-specified to accommodate these additional factors. The new patient relationship categories will overhaul the current attribution approach, the patient condition classifications will allow for better risk adjustment to provide for fair comparisons among attributed patients, and the new care episode measures will need to be tested, evaluated, and modified to accommodate the new patient relationship categories and patient condition classifications. Thus, the usefulness of the experience that physicians gain with the current attribution, risk adjustment, and episode definitions will be minimal at best until each measure is re-specified.

Given these practical realities, CMS should use the discretion provided by Section 1848(q)(5)(F) of MACRA (Certain Flexibility for Weighting Performance Categories, Measures, and Activities) to continue to weigh the cost category as zero until CMS re-specifies the measures and provides physicians with at least one year of performance data using the re-specified measures.

CMS also could test and refine these new measurement tools and potentially jump-start their adoption by encouraging their use starting in 2018. Details could vary but the goal would be to hold physicians harmless in the cost category through 2020 while at the same time awarding bonus points to physicians who comply with any new requirements to implement the tools. For example, CMS could continue to assign a zero weight to this category through 2020 while also awarding bonus points to physicians who comply with any new requirements to implement the tools. This would encourage wider use of the new tools and facilitate evaluation and improvements in the measures and methodologies CMS employs for comparing physician resource use.

The AMA strongly believes that CMS and its contractor(s) need more time to evaluate, refine, replace and expand the 10 episode measures included in this final rule and to incorporate the new patient relationship and patient condition identifiers into its cost measurement methodology. We recognize that MACRA called for the creation of "episode groups and patient condition groups," which account for a target of an estimated half of expenditures under parts A and B (with such target increasing over time as appropriate). We do not think that this language should be read as requiring the rushed development and implementation of new episode measures that have not been adequately vetted or tested. We note that the target covers both episodes and patient conditions and could be met by some combination of the two. In addition, MACRA language laying out the "methodology for resource use analysis," essentially calls for the use of episodes and patient conditions that have passed critical muster through several levels of

physician review. It further indicates that the "Secretary shall" use care episodes and patient conditions "as the Secretary determines appropriate."

In addition, physicians should have adequate time to understand how these tools work in practice before CMS uses performance on the re-specified measures to determine a physician's MIPS cost score. **Physicians should have the opportunity to review their cost scores based on at least one full year of performance using the new measures before they are used in the MIPS final score to adjust payment. In addition, in future years, CMS should apply the policy of assigning a minimum number of points to new cost measures as well as new quality measures.** We expect that performance year 2021 will be the first year in which fully-refined measures using these new patient condition and patient relationship categories could be counted in the MIPS cost score. We arrived at this timetable given the following assumptions:

- 2018 – CMS and physicians begin to use the new measurement tools.
- 2019 and 2020 – CMS re-specifies its cost measures and provides feedback to physicians so that CMS and physicians gain experience with how these tools affect their cost measure performance.
- 2021 – Earliest possible performance year in which the new codes will be used for scoring purposes.

In short, until performance year 2021, the MIPS cost scoring methodology (or weighting of the cost performance category) should be adjusted to hold physicians harmless under the existing flawed risk adjustment/attribution methodologies. CMS also could revise its cost scoring approach for performance years 2018 to 2020 to encourage uptake and testing of the new measures and patient condition and patient relationship categories so that resource use measurement proceeds on a firm analytical ground.

- **Remove the two administrative claims measures**

CMS's decision to retain the two administrative claims measures (the total per capital cost and the MSPB measures) is likely to undermine physician acceptance of MIPS and its promise of more efficient care.

Individual physician's share of patient costs is a small fraction of the total per capita cost, especially as many Medicare beneficiaries have multiple health problems and, in most cases, obtain services from multiple physicians, health care providers, and facilities. Traditional Medicare rules allow beneficiaries to seek services from any physician. It is not a managed care network. Even if an individual physician is efficient, the overall spending for the patient's care may be higher because of the number and types of physicians that the patient uses. And, given the weaknesses in CMS' retrospective attribution methodology, in many cases physicians are attributed the spending for services that they did not provide while others are not attributed spending for any of the services they provided. Both errors undermine physician buy-in of these measures because they do not reflect how care is ordered and provided.

The MSPB measure, which was developed for hospital use, is not well-equipped to measure physicians, especially for costs that are not within the physician's control. CMS data shows that most variation in measure performance is due to differences in post-acute care costs that the attributed physician, in most cases, does not control.

We also believe that the changes CMS has made to the MSPB measure in this rule will reduce, rather than enhance, its reliability and further undermine its credibility in the physician community. As noted in our comments on the proposed rule, the AMA is opposed to elimination of the specialty adjustment and the reduction in the minimum case size from 125 to 20. CMS has made several changes regarding case size and specialty adjustment of this measure without sufficiently detailing the underlying analysis.

Although we appreciate the minimum case size increase to 35 rather than 20, we urge CMS to be more transparent about the reasoning for and the data underlying it policies changes. A first step in this direction is to provide additional data analysis as part of its annual experience reporting. See below for further discussion on improved data analysis.

The current risk adjustment methodologies for these measures also do not appropriately level the playing field for those variations in spending associated with patients who have higher needs, are lower income, and/or are in challenging populations. As acknowledged by CMS, the total per capita cost measure is risk adjusted on the basis of clinical conditions before the performance period but is not updated during the year to capture more relevant risk information. In addition, an as-yet-to-be-released report by the Office of the ASPE on socio-economic factors could dramatically affect CMS' current risk adjustment methodology. Given the attribution errors and the lack of appropriate risk adjustment, the AMA strongly believes that CMS should remove these measures from the MIPS cost category.

- **Remove Part B drug cost from the measure calculations**

The AMA also urges CMS to refine its methodology by eliminating the cost of Part B drugs in the overall calculation of physician costs. Physicians who administer these life-changing drugs face a greater than average risk of Medicare payment penalties due to the lack of appropriate risk adjustment and inadequate adjustment for specialty differences. Including these costs could lead to erroneous comparisons of physicians and could unjustly penalize certain QPP participants. Likewise, we urge CMS to reconfirm that it will not apply the MIPS payment adjustment factor (MIPS final score) to the cost of Part B drugs, but rather only to the services paid under the Medicare Physician Fee Schedule.

- **Improve attribution for acute episodes**

CMS has finalized an attribution method that attributes an acute condition episode to physicians that bill at least 30 percent of inpatient evaluation and management (E&M) visits during the initial treatment because they "are likely to have been responsible for the oversight of care for the patient during the episode." CMS also indicated there could be multiple attributions if two or three physicians meet the 30 percent threshold.

This multiple attribution policy counters the basic idea behind episode costs. Episode cost measures help ensure that physicians are accountable for the costs they control. **If there is an episode of care for which more than one physician is responsible, CMS should develop a way to divide the costs of care among physicians in proportion to the amount of care they provided and/or controlled within the episode.** This way, individual physicians are only held accountable for the services and costs they can control. At a minimum, CMS should provide analyses of "likelihood" that there is multiple attribution and reasons behind it prior to adopting a multiple attribution policy. For more detail, see the data analysis discussion below.

- **Examine how incentives are affected when the same costs are attributed to multiple unaffiliated physicians**

The overlapping costs used to construct the 12 MIPS cost measures and the different attribution rules are likely to provide conflicting signals for physicians and frustrate CMS' goals to deliver more efficient care. The use of total per capita cost measures incorporates the same costs used to construct the MSPB measure and the 10 episode cost measures. A patient's total cost could be attributed to one physician, a subset of those costs could be included in the MSPB and attributed to another physician(s), and another subset of total costs could be attributed to multiple physicians for the 10 episode cost measures. Our concern is that

the various attribution methods could provide mixed signals to physicians as to who is actually in charge of delivering efficient care. This problem is exacerbated by the fact that many of these clinicians may be unaffiliated and thus there is no real way for physicians to actually coordinate. The delay in providing physicians with lists of attributed patients also stifles real-time coordination.

We believe the extent of the problem is likely to vary with the number of measures in a physician's MIPS cost score. We urge CMS to include information about the extent of this overlap in its annual experience reporting. For more detail, see the data analysis discussion below.

- **Increase the reliability threshold for cost measures**

As noted earlier, we continue to disagree with CMS' policy to set a low 0.4 reliability standard for each cost measure. If a physician's cost measure has a reliability of only 0.4, it means that differences in the cost scores of two physicians are more likely due to random or unadjusted-for difference in the physician's patients than to systematic differences in the physician's resource use. Moreover, this very low standard for payment contrasts starkly with the high 0.9 reliability standard that CMS is using to report physician measure performance on Physician Compare. **We urge CMS to reconsider this decision and to raise the minimum reliability threshold to at least 0.8.**

We are concerned that, in a desire to increase the number of physicians who can be scored on MIPS measures, CMS intends to adopt measures that will create serious access issues for Medicare's sickest beneficiaries. Several contractor reports on experience with existing measures have shown that they are more likely to penalize physicians who treat the sickest Medicare patients. Retaining these measures and continuing to apply such a modest reliability standard to future measures will only exacerbate these problems. If CMS insists on retaining a lower reliability threshold, a number of steps must be taken to limit the damage that could be caused by such a risky MIPS cost measure.

First, no payment penalties based on such low reliability measures should be applied unless there is evidence that a particular practice has consistently scored well below other similar practices over an extended period of time. In addition, CMS should treat individual physicians fairly if their individual cost measure performance falls below the minimum reliability standard. Specifically, we urge CMS to adopt a two-part test before including a cost measure in a physician's cost score. **A physician should meet the minimum case threshold and, after meeting the threshold, the physician's measure performance should meet CMS's minimum reliability threshold.** In other words, the minimum case size is a necessary but not sufficient condition to include a measure in a physician cost score. The individual physician's cost measure performance should exceed the minimum reliability threshold, and, if the physician's performance on a measure does not meet the reliability threshold, CMS should not include it in the physician's cost category score.

- **Work with the physician community to develop episode cost measures**

Development of episodes that are fair, relevant, and credible will require assistance at all stages of the process from clinicians with an in-depth understanding of the conditions and/or procedures involved. The AMA and medical specialty societies therefore have greatly appreciated the opportunity for involvement in the latest effort to identify, develop, and refine measures. We are concerned that due to time and resource constraints, the opportunity for physician input into episode development has been inadequate.

We recognize the enormous challenges CMS faces to develop the episodes on the timetable required by MACRA. Notwithstanding these deadlines, the process can be enhanced given the many misfires so far. Greater physician input, and recognition of that input by CMS and its contractor, could go a long way to

aid in the development of the care episodes and tamp down perceptions of bias. For example, CMS and its contractor could provide formal responses to new measures that physician specialties develop. Getting clinical expert panels involved earlier and providing them with greater decision-making authority and longer opportunities to assess and react to contractor proposals would also improve the process. The revised timeline that we have proposed would create more realistic contractor deadlines and workloads as well as facilitate the kind of collaborative process that would assist in the development, uptake, acceptability, and actionability of the new care episodes.

- **Provide improved policy experience reporting**

We urge CMS to be more transparent about the effects of its MIPS payment policies and the reasons for future policy changes. CMS has a model for this increased transparency – the 2012 QRUR Experience Report and the 2015 Value Modifier Program Experience Report (which reviewed the 2013 QRURs). These reports discuss the program results and, especially in the case of the QRUR report, include more detailed information on the outcomes of attribution and risk adjustment policies as well as the statistical properties of the program measures. Public release of this foundational information will help gain physician acceptability as these polices affect a greater and greater share of payment moving forward. **We urge CMS to update these reports based on 2015 data and annually thereafter.**

In addition, CMS could use the 2015 QRUR and Supplemental QRUR data to examine the following issues that could help the physician community and others understand how its policies work in practice:

(1) Overlap of cost measures. Our concern is to make sure physician incentives are aligned. If the MIPS cost score sends conflicting signals, then the program will not achieve CMS' goals. To this end, the following data would be helpful to understand these incentives.

- **Frequency:** What is the maximum number of measures that any physician has? What is the mean and median? What percentage of practices has no measures that meet minimum case threshold? How often is a physician attributed the same costs via one, two, or more cost measures?

- **Physician Characteristics:** How is the number of measures and overlap between them affected by specialty, site of service, geographic region, type of service, Hierarchical Condition Categories (HCC) scores, and socioeconomic differences of attributed patients?

- **Patient Characteristics:** How often is a patient attributed to different physicians through different cost measures? Are there differences in locations, sites of service, geographic region, HCC score, age, or other characteristics that are meaningful?

(2) Attribution of episode measures. CMS finalized a multiple attribution rule for the acute episodes. The following information would be helpful to understand the impact of this policy.

- **Frequency:** How often is an episode attributed to different physicians? Which episodes were most likely to have multiple attributions? What percentage of the affected physicians were in the same practice or on the staff of the same hospital (i.e., were there realistic opportunities for collaborative decision-making)?

- **Physician Characteristics:** Are there differences in physician specialty, type of service, sites of service, billing TIN, geographic region, or others that make multiple attribution more or less likely?

- **Patient Characteristics:** Are there differences in patient locations, HCC score, age, etc., that make multiple attribution more or less likely?

(3) Impact of Other Methodological Decisions.

- What is the impact of setting a 0.4 percent reliability standard rather than a 0.8 percent reliability standard on the number of physicians with at least one attributed cost measure and the number subject to each of the individual measures? How does the lack of any adjustment for site of service affect physician cost profiles? How do average scores for physicians providing services in a hospital outpatient department compare with scores for office-based physicians in the same specialty and region? How do average costs for surgery in an ambulatory surgical center compare to costs for the same surgery in a hospital outpatient department? Is there a significant increase in average costs associated with patients in skilled nursing homes and those who are living in the community? How do geography and potentially certificate of need laws affect site of service?

Advancing Care Information

With the passage of MACRA, physicians were hopeful that MIPS would fundamentally change the Meaningful Use (MU) program to implement a truly flexible approach to EHRs. The final rule, however, disappoints as it maintains components that were some of the largest pain points for physicians. In particular, the program continues to include a pass-fail approach and fails to pave a path forward to new measures and innovative uses of the technology. Accordingly, we urge CMS to continue to seek changes to the ACI component. Claiming that the program cannot progress because of EHR limitations only further solidifies the problems with these systems. We therefore ask that CMS make the following changes in order to push technology in a more innovative direction.

- **Develop a plan for new ACI measures**

As the AMA noted in our comments on the MACRA proposed rule, the ACI category adopts the same flawed Stage 3 measures opposed by the majority of physician societies. In particular, patient engagement measures are a source of frustration for many physicians who do not have control over patient activity at home, and who have noted that the Medicare population is not always comfortable interacting with their physician online. Unfortunately, the final rule does not create a path forward and away from these measures, and physicians will continue to be penalized for activity that is out of their control.

In every other MIPS category, CMS has defined a way for stakeholders to propose new measures or activities to include in future years; yet, this opportunity is completely missing from the ACI category. This is especially surprising given that the ACI category is premised on innovation and harnessing new ways to use technology—it should have the most flexibility to incorporate new activities. **We ask that CMS implement a call for new ACI measures that is similar to the proposal for developing new IAs.** Such a call for new measures should focus on improving usability, emphasizing how vendors can implement user-centered design principles, improving user experience, and reducing cognitive workload. Absent new measures, EHR developers will continue to rely on existing requirements as a roadmap for product design, hindering usability and limiting the relevance of the technology to different practices and patients.

CMS' publication of a plan to develop new measures will signal that the ACI category is intended to be flexible and that new technology and other care innovations will be incorporated in the future. It also provides consistency across the different MIPS categories.

- **Allow the use of 2014 edition certified electronic health records technology (CEHRT) past 2017**

We appreciate CMS' recognition that physicians will need time to transition their technology from 2014 edition to 2015 edition CEHRT and note that the agency will monitor the availability of 2015 edition technology. We remain concerned, however, that 2015 edition technology will not be ready and available to all physicians and specialties by 2018. In particular, small and rural practices may face barriers in updating or adopting the new version within the tight timeframe required by CMS. In addition, vendors should be focusing on incorporating the new MIPS measures, including quality measures which will have a full-year performance period in 2018, to ensure physicians can report through these tools.

Consequently, CMS should allow physicians to continue to use the 2014 edition, or a combination of technology, until it confirms that the 2015 edition is readily available and equipped to facilitate physician reporting on all MIPS measures.

- **Simplify ACI scoring**

The AMA believes the ACI scoring system, which creates performance and base scores, remains extremely complex and creates significant barriers to achieving CMS' goals of a simplified program. We feel that physicians will be confused during the first years of the program and may inadvertently fail the entire ACI category because of the retained pass-fail approach of the base score. CMS is no longer tied by the MU statute to create mandatory measures. **We therefore believe the base score should allow for partial credit.**

We do, however, agree that the base score represents the foundation of the ACI category, requiring physicians to initially attest to a measure. **To first ensure that MIPS eligible clinicians are focused on and working to fulfill the base score requirements before moving on to the performance score, CMS should assign a higher weight to the base score (e.g., 75 points).** We emphasize that greater weighting of the base score should only occur if CMS moves away from the pass-fail approach to scoring this section, as described above. We do not support a greater base score weight if CMS maintains the pass-fail scoring approach.

Similarly, we believe the performance score should also be changed to account for improvement and new measures. As described in our proposed rule comments, **CMS should measure a participant's first full year of performance and, in the following year, award full credit for each measure on which they improve by at least one percentage point.** For example, a physician first reports in 2017 that she meets the secure messaging requirement for five percent of her patients. In 2018, the physician meets the secure messaging requirement for 10 percent of her patients. In 2019, the physician again shows improvement and provides secure messaging for 11 percent of her patients. Under our proposal, the physician is showing improvement and would earn the full 10 points for the 2018 and 2019 reporting periods. This scoring process creates an incentive for physicians to try to improve their performance from year to year and also may guard against any potential bias in favor of groups with more sophisticated resources.

Similarly, as new ACI measures are developed and implemented, we urge CMS to provide a safety net for physicians reporting on such measures for the first time. This should mirror CMS' approach to new quality measures, creating a floor or hold harmless provision for new ACI measure performance. This approach will streamline differences across the different MIPS categories and will encourage physicians to try out innovative uses of technology without facing potential penalties.

- **Increase opportunities for bonus percentage points**

The AMA strongly supports CMS' inclusion of bonus ACI percentage points in the final rule and applauds CMS for recognizing that physicians should be rewarded for using health information technology (health IT) to accomplish IAs. This approach helps physicians earn credit for the use of health IT not simply for measurement's sake, but also as part of an activity that improves clinical outcomes and patient care. We strongly urge CMS to continue with this approach so that physicians will regard health IT as a useful tool that they can leverage to accomplish patient care goals.

In response to CMS' request for comment on this integration, we suggest that CMS extend bonus percentage points to physicians who utilize CEHRT functionality as they undertake IAs. For example, the Beneficiary Engagement IA subcategory suggests the use of evidence-based decision aids to support shared decision-making. The AMA believes that if a physician chooses to utilize Clinical Decision Support (CDS) tools to help with this activity, he or she should also receive credit under the ACI category, even though CDS is not a required ACI measure. Similarly, the Patient Safety and Practice Assessment IA subcategory includes the use of tools that assist specialists in tracking specific measures that are meaningful to their practice. The AMA believes that an EHR's Export and Application Access—Data Category CEHRT function could assist in accomplishing this IA, and that the physician should receive credit for using technology in the ACI category as well. To this end, we have included suggestions for additional IA/ACI bonus point scenarios utilizing both ACI measures and CEHRT functions in a chart that follows.

The AMA is also very supportive of CMS' efforts to reward physicians with MIPS bonus points for participating in registries. Registries have the ability to provide more timely and actionable information back to physicians and are important components in measuring quality. However, while some registries support end-to-end electronic reporting, many registries still rely on both automated and manual data entry. Most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection. **We therefore ask CMS to reward physicians for utilizing registries and not mandate end-to-end electronic reporting.**

Furthermore, we remain concerned that due to data blocking actions by some EHR vendors, many physicians will miss out on the EHR-registry bonus points. Data blocking is routinely being identified and tends to be expressed through: 1) EHR vendors levying excessive fees to connect a physician's EHR to a registry; or 2) EHR vendors citing technical limitations or outright refusing to connect to a registry.[4] While ONC has created a number of certification criteria addressing quality measurement, at this time, there are no methods available for physicians to incentivize or persuade EHR vendors to develop reasonable solutions to registry interoperability. **CMS must work with medical societies and vendors to identify ways to continue to reward physicians for registry participation and develop a process to limit registry blocking in the near term.**

- **Significant hardship application-based exemptions should be multi-year**

The final rule states that MIPS eligible clinicians unable to report on sufficient ACI measures must submit annual applications to have CMS reweight their ACI scores to zero. This places an unnecessary burden on physicians whose circumstances will not change from year-to-year. We request that CMS reconsider its decision to require physicians to apply for the hardship exemption on an annual basis, or at a minimum, make the application a "check-the-box" form if the physician's circumstances have not changed from the prior year.

[4] Tahir, Darius. "Specialty societies say EHR vendors are blocking their registry work." *Politico.* October 28, 2016. Accessed December, 2016 from: http://www.politico.com/story/2016/10/specialty-societies-say-ehr-vendors-are-blocking-their-registry-work-230444

- **Allow physicians who report on MU to receive ACI credit**

The MU/ACI program has now been divided depending on if you have Medicare or Medicaid patients or if you work in a physician office versus a hospital setting. Few physicians will understand the different requirements and may end up reporting twice. **CMS should therefore allow reporting on MU to count for ACI and vice versa.** At a minimum, CMS should work towards aligning the two programs wherever possible.

- **Remove the application requirement for new MU participants transitioning to MIPS in 2017**

In its 2017 Outpatient Prospective Payment System final rule, CMS stated that MIPS eligible clinicians who would be new to the MU program in 2017 and are transitioning to MIPS in 2017 must apply for a significant hardship exception from the 2018 payment adjustment. CMS specified that physicians must submit an application that includes information demonstrating their eligibility for this hardship exception, as well as an explanation of why, based on their particular circumstances, participating in both MU and reporting under the ACI category in 2017 would result in a significant hardship. The AMA reiterates its stance that this hardship application requirement is unnecessary and overly burdensome on physicians. **Instead, when a physician who has not previously participated in MU submits data for the ACI performance category, he or she should automatically be granted a hardship exemption from the MU payment adjustment in 2018.** Reporting similar measures for two separate programs, with two separate requirements, and through two separate attestation methods is clearly extremely onerous. CMS should not require physicians to use valuable time and resources to provide an explanation regarding why participating in both programs simultaneously would create a significant burden.

Table: Additional Improvement Activities Eligible for the Advancing Care Information Performance Category Bonus

Improvement Activity: Subcategory	Activity	Improvement Activity: Weight	Related Advancing Care Information Measure(s) or CEHRT Function (CF)
Expanded Practice Access	Collection of patient experience and satisfaction data on access to care and development of an improvement plan, such as outlining steps for improving communications with patients to help understanding of urgent access needs.	Medium	Secure Messaging Patient-Generated Data
Population Management	Implementation of regular reviews of targeted patient population needs which includes access to reports that show unique characteristics of eligible professional's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources.	Medium	Data Export (CF)
Care Coordination	Timely communication of test results defined as timely identification of abnormal test results with timely follow-up.	Medium	Secure Messaging Patient Access
Care Coordination	Establish standard operations to manage transitions of care that could include one or more of the following: Establish formalized lines of communication with local settings in which empaneled patients receive care to ensure documented flow of information and seamless transitions in care; and/or Partner with community or hospital-based transitional care services.	Medium	Send Summary of Care Request/Accept Summary of Care Clinical Information Reconciliation
Care Coordination	Establish effective care coordination and active referral management that could include one or more of the following: Establish care coordination agreements with frequently used consultants that set expectations for documented flow of information and MIPS eligible clinician or MIPS eligible clinician group expectations between settings. Provide patients with information that sets their expectations consistently with the care coordination agreements; Track patients referred to specialist through the entire process; and/or	Medium	Send Summary of Care Request/Accept Summary of Care Clinical Information Reconciliation

Improvement Activity: Subcategory	Activity	Improvement Activity: Weight	Related Advancing Care Information Measure(s) or CEHRT Function (CF)
	Systematically integrate information from referrals into the plan of care.		
Beneficiary Engagement	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.	High	Secure Messaging Patient-Generated Health Data
Beneficiary Engagement	Use evidence-based decision aids to support shared decision-making.	Medium	Clinical Decision Support (CF) Patient-Specific Education
Beneficiary Engagement	Regularly assess the patient experience of care through surveys, advisory councils, and/or other mechanisms.	Medium	Secure Messaging
Beneficiary Engagement	Engage patients and families to guide improvement in the system of care.	Medium	Secure Messaging Patient Access
Beneficiary Engagement	Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or How's My Health).	Medium	Patient Access Patient-Specific Education
Beneficiary Engagement	Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community.	Medium	Patient-Specific Education
Beneficiary Engagement	Provide a pre-visit development of a shared visit agenda with the patient.	Medium	Patient Access Secure Messaging Patient-Generated Health Data
Beneficiary Engagement	Provide coaching between visits with follow-up on care plan and goals.	Medium	Patient Access Secure Messaging Patient-Generated Health Data
Patient Safety and Practice Assessment	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of the Surgical Risk Calculator.	Medium	Export (CF) Application Access – Data Category (CF)
Patient Safety and Practice Assessment	Build the analytic capability required to manage total cost of care for the practice population that could include one or more of the following:	Medium	Export (CF)

Improvement Activity: Subcategory	Activity	Improvement Activity: Weight	Related Advancing Care Information Measure(s) or CEHRT Function (CF)
	Train appropriate staff on interpretation of cost and utilization information; and/or Use available data regularly to analyze opportunities to reduce cost through improved care.		
Patient Safety and Practice Assessment	Measure and improve quality at the practice and panel level that could include one or more of the following: Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel); and/or Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.	Medium	Export (CF)
Patient Safety and Practice Assessment	Implementation of fall screening and assessment programs to identify patients at risk for falls and address modifiable risk factors (e.g., clinical decision support/prompts in the electronic health record that help manage the use of medications, such as benzodiazepines, that increase fall risk).	Medium	Clinical Decision Support (CF) Clinical Information Reconciliation
Integrated Behavioral and Mental Health	Diabetes screening for people with schizophrenia or Medium Behavioral and bipolar disease who are using antipsychotic Mental Health medication.	Medium	Clinical Decision Support (CF) Clinical Information Reconciliation
Integrated Behavioral and Mental Health	Tobacco use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including tobacco use screening and cessation interventions (refer to NQF #0028) for patients with co-occurring conditions of behavioral or mental health and at risk factors for tobacco dependence.	Medium	Clinical Decision Support (CF)
Integrated Behavioral and Mental Health	Unhealthy alcohol use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including screening and brief counseling (refer to NQF #2152) for patients with co-occurring conditions of behavioral or mental health	Medium	Clinical Decision Support (CF)

Improvement Activity: Subcategory	Activity	Improvement Activity: Weight	Related Advancing Care Information Measure(s) or CEHRT Function (CF)
	conditions.		
Integrated Behavioral and Mental Health	Depression screening and follow-up plan: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including depression screening and follow-up plan (refer to NQF #0418) for patients with co-occurring conditions of behavioral or mental health conditions.	Medium	Clinical Decision Support (CF)
Integrated Behavioral and Mental Health	Major depressive disorder: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including suicide risk assessment (refer to NQF #0104) for mental health patients with co-occurring conditions of behavioral or mental health conditions.	Medium	Clinical Decision Support (CF)

Improvement Activities

The AMA is supportive of many of CMS' proposals for the IA component of MIPS. Specifically, we appreciate CMS' response to our concerns that the proposed number of required IAs was too high. We believe that the finalized number of required activities is more manageable for physicians and will result in more meaningful practice improvement. We strongly urge CMS to avoid increasing the number of required activities moving forward. The AMA also thanks CMS for increasing the number of highly-weighted activities. We note, however, that there are still only 14 out of more than 90 activities that are weighted as "high," and suggest that CMS seek the advice of specialty and state societies to designate additional IAs as highly-weighted. Finally, the AMA applauds CMS' recognition of the use of health IT to accomplish IAs. As described in our comments on the ACI performance category, we support CMS' efforts to continue this holistic approach and have provided suggestions for additional activities for which physicians should receive bonus ACI points when they use CEHRT. The following provides AMA recommendations for changes in future IA policies from those outlined in the MACRA final rule.

- **Provide additional clarification**

CMS has stated that for 2017 it does not intend to publish any additional guidance on how physicians must perform and report on the listed IAs. While we recognize that this allows flexibility, we are concerned that many participants will have questions about how to ensure they are meeting program requirements especially since several of the listed IAs could include a broad range of activities. For example, we believe the subcategory on population management should include activities related to prediabetes, diabetes, and hypertension, including the Centers for Disease Control and Prevention (CDC) recognized diabetes prevention programs and the AMA-American Heart Association Target Blood Pressure (BP)™ initiative. Other questions may include what is required to complete an IA. For example, we appreciate that the AMA STEPSforward™ program is explicitly included as an IA but would like to provide additional guidance on the relevant modules for the MIPS program.

We are also concerned that CMS has stated that participants must maintain appropriate documentation for future MIPS audits. **If CMS intends to not publish any additional specifications, we urge them to clarify that physicians have the authority to broadly interpret the IAs to best meet their practice and patient needs and that auditors will not review the IA category for the 2017 performance year**.

- **Develop a plan for adding additional IAs**

Physicians remain unsure of the process for adding to the list of IAs. We seek clarification from CMS as to the criteria necessary for including additional activities, as well as information about what entity will make the determination of whether and how the activities are added. Since the MACRA statute requires that stakeholders be consulted to recommend IAs, we again ask that CMS seek the advice of specialty and state societies to determine the best process for adding to the existing list. For example, we continue to urge CMS to include certified and accredited continuing medical education as an IA activity. These activities take up considerable time for physicians but ensure patient care is of the highest quality and reflects the latest medical knowledge and innovations. We therefore believe such activities should be included in the future.

- **Include Appropriate Use Criteria (AUC) in IAs**

The AMA recognizes CMS' incorporation of AUC into certain IAs aimed at non-patient facing participants. We ask that CMS go a step further and include the use of AUC as an IA for ordering physicians. In addition, we oppose CMS' request that physicians already using AUC report an IA other than one related to appropriate use; this approach unfairly penalizes practices who currently utilize AUC and creates a perverse incentive for practices who have not already implemented AUC to refrain from doing so.

- **Avoid complex reporting requirements**

MACRA intended the IA component of MIPS to provide credit for ongoing or already established activities. Physicians should therefore be able to continue to report through attestation and not face time limits on when IAs will count under the MIPS program. CMS should also not add future lengthy documentation or other submission requirements that will increase administrative burden.

- **Provide guidance on EHR implementation specifications**

Physicians and vendors are unsure of how to incorporate IAs into their EHRs. The AMA recommends that CMS issue guidance informing vendors of how to assist practices with ensuring their systems can track and report on IAs.

- **Create stability in program requirements**

The IA component is a new aspect of physician evaluation. As such, the administration should refrain from imposing more stringent requirements on scoring in future years. Similarly, the administration should permit—and even incentivize—physicians to perform the same activity over multiple years to effectuate change over the long-term and provide stability to the program. Physicians should not have to reevaluate and change IAs each time they participate in the MIPS program.

In addition, the AMA supports CMS' efforts to reduce the reporting burden for eligible clinicians in MIPS APMs. In order to further reduce this burden, we urge CMS to grandfather the MIPS APMs receiving full IA credit in 2017 so that they do not need their IA credit to be re-approved each year. Each

of these MIPS APMs has already entered into an agreement with CMS that requires certain activities to be performed. Since CMS has already determined that those activities are sufficient for full IA credit, it should not put MIPS APM participants in the uncertain position of having to determine each year whether they will need to undertake additional activities to fulfill their IA quota.

Advanced Alternative Payment Models

The AMA is grateful for and strongly supports the significant changes that were made in the final rule to improve the financial risk standards for Advanced APMs. These include allowing APM entities to base risk on eight percent of their Medicare Parts A and B revenues instead of four percent of the total cost of care. As described in detail in AMA comments on the proposed rule, this change is crucial because physician spending is generally such a small proportion of total Medicare spending. We greatly appreciate CMS' recognition of and responsiveness to this concern. AMA comments also stated concern about the overly complicated and confusing definition of risk, and we are pleased that the final regulations focus only on the maximum financial risk to which an APM Entity must be exposed, instead of mandating specific marginal risk and minimum loss rates. We also support the reduction in Advanced APMs' minimum risk from four percent to three percent of spending if APM benchmark spending is used instead of revenues.

We are also pleased that CMS plans to propose a Track 1+ for accountable care organizations (ACOs) that will be able to qualify as an Advanced APM without the steep financial risk requirements for the current two-sided ACO models.

We urge the agency to give serious consideration to a separate, joint comment letter from the AMA and other organizations providing recommendations for how the new ACO track should be designed.

The balance of this section provides AMA recommendations for changes in future Advanced APM policies from those outlined in the MACRA final rule.

- **Do not increase the nominal risk revenue threshold**

As noted above, under the final rule, Advanced APMs can meet the MACRA standard for "more than nominal financial risk" if they risk losing eight percent or more of total Parts A and B revenues, instead of tying risk of losses to a percentage of total spending. The regulations, however, state that eight percent is only the standard for performance periods 2017 and 2018. In the preamble, CMS states its intention to increase the revenue-based nominal amount standard for the third and subsequent performance periods, and seeks comment on: (1) setting the revenue-based standard for 2019 and later at up to 15 percent of revenue; or (2) setting the revenue-based standard at 10 percent so long as risk is at least equal to 1.5 percent of expected expenditures for which an APM entity is responsible under an APM.

The AMA strongly urges CMS to preserve stability and predictability for APMs by maintaining a revenue-based standard of eight percent for the 2019 performance period and at least three additional years. In the MACRA statute, Congress has already provided for steep increases in financial risk requirements for Advanced APMs. Specifically, the statute increases the percentage of participants' revenues that must come through the APM in order for participants to attain Qualified APM Participant (QP) status. An APM entity that is accountable for losses of up to eight percent of 50 percent of its total Parts A and B revenues in the 2019 performance period and eight percent of 75 percent of its revenue in the 2021 performance period will clearly be at much higher financial risk than in the 2017 and 2018 performance periods, when a minimum of eight percent of 25 percent of its revenues would be at stake. Congress clearly intended for a six-year period of stability for physicians, and it provided time-limited

APM incentive payments to help offset practice transformation costs that physician practices will incur as they transition to APMs. We are very concerned that if CMS requires rapid increases in requirements for financial risk, it will discourage physicians from working to design and participate in Advanced APMs or place them in financial jeopardy after an initial period of success in an APM.

Any future changes in the amount of required financial risks should only be made after careful consideration of the experience and evidence that will be gleaned about physician participation in Advanced APMs during this six-year period. Experience to date with the Medicare Shared Savings Program, for example, indicates that the imposition of steep downside risk requirements causes financial problems for small organizations and discourages participation in the ACO program. With initial APM agreement periods being from three to five years, and fewer than 10 percent of eligible clinicians projected to be QPs in 2017, if CMS increases the risk standards in 2019, then many physicians who initially participate in APMs in 2018 will only have the more feasible eight percent of revenue risk standard available for a fraction of the APM's initial agreement period.

This problem is compounded by the agency's refusal to recognize the start-up and ongoing costs that APM participants incur as part of their financial risk. As noted in our comments on the proposed rule, these costs include: hiring care coordinators and patient and family educators whose services cannot be billed under the Medicare Fee Schedule; training existing staff in the new way of delivering care; ongoing data analysis to determine which patients need to be proactively scheduled for visits or tests; communicating with patients electronically or by phone about self-management to control symptoms and properly take medications; reengineering scheduling systems, leaving appointment slots open, and providing evening and weekend hours in order to provide rapid access for high risk patients; developing treatment plans; participating in clinical data registries; supervising care managers; and organizing multidisciplinary teams to improve care coordination and quality.

The best way to stimulate more rapid movement towards APMs is to provide more choices and flexibility for physicians and to design models based on the current capabilities of practices. Successful private sector models have taken this approach, often requiring no downside risk because it is a barrier to physician participation. While a downside risk of 15 percent might be acceptable in a large health care system with good access to capital, imposing that level of risk on all physician practices, particularly small practices, would significantly reduce physician movement into APMs and prevent MACRA from fulfilling its potential. The rule's regulatory impact analysis notes that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based on Small Business Administration standards. In addition, losses in excess of three percent of revenues remain the Department of Health and Human Services' standard for determining whether an economic effect is "significant." A new report from the U.S. Government Accountability Office, mandated by MACRA, "Medicare Value-Based Payment Models: Participation Challenges and Available Assistance for Small and Rural Practices," confirms that resource constraints make participation in APMs challenging for small and rural practices. In particular, the report notes that small and rural practices face significant challenges securing technology, including interoperable EHRs, to implement models and often struggle with the amount of time it takes to recoup the investments made to participate in an APM. It would be unfortunate if Congress's goal of encouraging physician creativity in the design of better payment and delivery systems falls victim to excessive requirements for risk.

In addition, in order to ensure there is no confusion about the definition of maximum financial risk, we recommend that the regulations be modified to clearly state that the nominal amount standard is either eight percent of Medicare Parts A and B revenues or three percent of expected expenditures, "whichever is less."

- **Align Medicare and Other Payer APM financial risk standards**

As noted above, the AMA commends CMS for changing the final rule to allow Medicare Advanced APMs to meet the nominal financial risk requirement based on eight percent of the APM entity's Medicare revenues and to reduce from four percent to three percent the required amount of expected expenditures to be at risk. Unfortunately, CMS did not make similar changes in the financial risk standards for Other Payer APMs.

Research on physician participation in new payment models has found that the need to manage multiple and conflicting requirements from different payers is a strong disincentive to broader participation in these models and can also reduce the ability of physicians to improve quality and reduce spending. Different goals, quality metrics, performance feedback reports, payment models, benchmarks, and attribution and risk adjustment methods increase the time and costs that practices must spend on administrative activities rather than in patient care. CMS itself has urged alignment of payment structures in the multi-payer models that it has created.

Consequently, the AMA recommends that CMS establish the same financial risk requirements for Other Payer Advanced APMs that it has set for Medicare Advanced APMs in order to facilitate the development of multi-payer models. In particular, Other Payer APMs should qualify if they limit financial risk to eight percent of the APM entity's revenues from that payer. The final rule already requires "the amount of revenues for services furnished through the arrangement" and "the total revenues from the payer" to be provided to CMS for each other payment arrangement, as well as an "attestation from the payer that the submitted information is accurate," so it will be a simple matter for CMS to verify whether an Other Payer APM meets a standard based on a percentage of practice revenue.

- **Require the same financial risk standards for medical homes regardless of the number of clinicians**

The AMA continues to strongly oppose requiring medical homes with more than 50 clinicians to meet a different set of financial risk requirements beginning in 2018. No evidence has been provided by CMS to demonstrate that there is a meaningful difference in the amount of financial risk that primary care practices with more than 50 clinicians can absorb compared to those with 50 or fewer clinicians. Instead, this policy appears to be based solely on CMS' "belief that organization size is a meaningful proxy for potential risk-bearing capacity." We disagree and urge that CMS not increase the financial risk standards for larger entities.

- **Allow specialty medical homes to use the primary care medical home financial risk standards**

The final rule allows physician practices in medical home payment models to meet the more than nominal risk standard with a lower percentage of physician practice revenues than in other Advanced APMs and with "loss of an otherwise guaranteed payment." However, the rule limits medical home models to participants that "primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services." There are a growing number of specialist physician practices and commercial payers that have established medical home models for patients with serious medical conditions and chronic diseases, and most of these models meet the other requirements for medical home models in the regulations, such as coordination of care and risk-stratified care management. AMA comments on the proposed rule provided examples of ongoing work by numerous national specialty societies to develop or expand opportunities for payment and delivery reforms in specialty care for serious medical conditions affecting patients with Medicare. CMS policies

and rules should provide a welcoming environment for the development of these models. One of most frequent criticisms of the models that have so far been made available by the Center for Medicare and Medicaid Innovation (CMMI) is the dearth of opportunities for specialists to participate. Moreover, in MACRA, Congress specifically called for development of models for specialist physicians. Allowing specialty medical home models to use the same financial risk standards as primary care medical home models would be a key step in this direction.

- **Do not limit the medical home nominal amount standard for Other Payer APMs to Medicaid models**

Many primary care physician practices are participating in medical home programs with private health plans. Indeed, the Comprehensive Primary Care Initiative and the new Comprehensive Primary Care+ model require participation of private plans in addition to Medicare. The current final regulations for APMs, however, would apply a higher financial risk standard to the payments medical homes receive for their privately-insured patients than for their Medicare and Medicaid patients. As discussed above, this is inconsistent with the goal of aligning the requirements of payment models across all payers and should be modified.

- **Exclude Part B drug costs from physician practice revenues used to calculate maximum risk under Advanced APMs**

In general, the AMA supports defining financial risk for an APM Entity as a percentage of its total Part A and B revenues. However, it is inappropriate to include Part B drug revenues as part of this calculation. Medicare policy on drug payments effectively treats about 96 percent of payments for Part B drugs administered in a physician practice (after applying the sequester) as pass-through payments to cover the practice's costs of acquiring the drugs. For some physician practices, such as oncology and rheumatology, the revenues and costs for these drugs are many times higher than the revenues used to pay for physicians' professional services, so placing the practice at risk for eight percent of its total Part A and B revenues would mean that they could be at risk for losing most or all of their revenues for professional services.

Practices should also be exempt from financial risk penalties for increases in actual expenditures beyond expected expenditures that are due to increases in the prices of drugs. Neither CMS nor physicians can control the prices paid for Part B drugs. The regulations should be modified to require that calculations of whether actual expenditures in an APM exceed expected expenditures should exclude any portion of an increase in expenditures that is due to increases in drug prices.

- **Define physician-focused payment models as APMs in which either Medicaid or Medicare is a payer**

The final rule limits the definition of physician-focused payment models that the Physician-focused Technical Advisory Committee (PTAC) can review and recommend to APMs in which Medicare is a payer. Although, in general, this restriction is appropriate, it prevents the PTAC from reviewing and recommending APMs focused on maternity care, pediatric care, and other models with potential to improve the delivery of care for patient populations that are far more likely to be insured by Medicaid than Medicare. Maternity care is one of the largest areas of Medicaid spending, for example, but Medicare is unlikely to be a payer. In MACRA, Congress specifically amended the list of payment models in Section 1115A(b)(2) of the Social Security Act to include payment models "focusing primarily on title XIX," so the PTAC should have the ability to review these types of payment models.

Surveillance and Data Blocking Attestations

In October 2016, the Office of the National Coordinator for Health Information Technology (ONC) released its Enhanced Oversight and Accountability final rule. The AMA welcomed ONC's response to our concerns regarding certification and data blocking and appreciates the agency's approach to in-the-field surveillance and direct review of CEHRT. We believe this response, along with CMS' decision to limit physician surveillance attestation to an acknowledgement of the ONC direct review requirement, will continue to promote vendor transparency and enhance physicians' consumer power.

- **CMS should, however, reevaluate its misplaced attestation requirements for data blocking**

In the AMA's proposed MACRA rule comments we highlighted our concerns with holding physicians accountable for the performance of EHR technology and questioned why a multi-step attestation process was appropriate. We also noted that the detail CMS required in the attestation went well beyond statutory intent and imposed new obligations on physicians. While CMS noted in their final rule that a majority of commenters stressed physicians have no control over most factors that limit the exchange and use of electronic health information, CMS still finalized its proposed multi-step physician attestation. This misguided effort holds physicians responsible for what is widely considered the failure of technology and EHR interoperability.

Physicians should not be required to attest to the EHR vendor's ability. Many in the health IT industry, including ONC, have identified the complexity of structuring medical data, transmitting it, and then incorporating it back into EHRs, which is well beyond the scope and knowledge of most practicing physicians. Yet, CMS continues to hold physicians responsible for verifying that their EHRs are "connected in accordance with applicable standards." This statement is contradictory, goes beyond the statutory language, and will only serve to obfuscate compliance. **We question how this attestation can appropriately apply to physicians and how the agency will handle the purely technical interoperability questions that will inevitably arise. We are also concerned that many of these questions will fall into a grey area—adding to the lack of clarity physicians encounter with health IT policy.**

In addition, the AMA questions how CMS will manage the data blocking audit process. CMS states they will provide guidance; however, from our experience with the Meaningful Use (MU) program, there is wide variability on how this process has been performed. The AMA has engaged in many discussions with physicians who have encountered MU audits, and it is clear there is a lack of audit controls. **We therefore request that CMS directly engage with the medical community to collaboratively develop data blocking guidance so that it is clear, consistent, and appropriate for physicians and not audit physicians until such consensus is reached.**