

August 21, 2017

The Honorable Seema Verma
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: CY 2018 Updates to the Quality Payment Program (CMS-5522-P)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the 2018 Quality Payment Program (QPP) proposed rule. The AMA supports many of CMS' proposals and appreciates that the agency is working to create a new program that reduces burden while promoting innovative approaches to improving quality. In particular, we appreciate that CMS listened to the recommendations of physicians and other stakeholders and is proposing another transition year for the Merit-Based Incentive Payment System (MIPS). CMS was also responsive to our concerns with the need for greater assistance to small and rural practices as well as several improvements to Advanced Alternative Payment Models (APMs).

We recognize that beginning a new payment program requires a significant learning curve and that experience from these early years will help guide changes in the future program. Accordingly, we are committed to working with CMS to provide feedback on the QPP and highlight ways to improve successful participation. With respect to the 2018 program year, while we believe CMS has included many improvements, we continue to urge the agency to seek ways to simplify and further streamline the program.

The following outlines our principal recommendations on the 2018 QPP proposed rule:

MIPS:

- The AMA supports the expansion of the low-volume threshold, and urges CMS to notify individuals and groups as soon as possible that they qualify for the low-volume threshold exemption.
- The AMA opposes including items or services beyond the physician fee schedule, especially Part B drugs, when determining MIPS eligibility, applying the MIPS payment adjustment, and in cost score calculations.

- The AMA provides a number of recommendations to simplify the overall MIPS scoring methodology, including setting a low performance threshold, maintaining the 70-point additional performance threshold, eliminating bonus points from the calculation of future performance thresholds, maintaining stability in program requirements in future years, and increasing the reliability threshold.
- CMS should continue to seek feedback and analyze data before adopting an approach to measure and score improvement, which may add complexity to the program and, once implemented, may be difficult to change.
- The AMA is supportive of CMS' proposal to allow physicians to select a facility-based measurement option; however, CMS should reduce the thirty percent floor in the quality category for physicians electing to use facility-based measurement to better align program requirements for both facility and non-facility physicians.
- The AMA strongly supports the ability for small groups and solo practitioners to form virtual
 groups and believes physicians should have maximum flexibility in the formation of virtual
 groups.
- The AMA strongly supports many of CMS' proposals that will create stability within the quality performance category for physicians, including not increasing the number of quality measures a physician is required to report, setting the data completeness threshold at 50 percent, eliminating cross-cutting measures from many of the specialty measure sets, and keeping the minimum point floor at three points for physicians who report on quality measures that meet the data completeness threshold. There are a number of modifications needed within the quality performance category, however, including the elimination of the outcome/high priority measure requirement, the removal of the requirement to report on all-payer data, the elimination of administrative claims measures, the topped-out measure removal process, and the proposed benchmarking methodology.
- The AMA strongly supports CMS' proposal to maintain the cost category weight at zero for the 2018 performance period. The AMA believes CMS needs additional time to develop, test, and refine new episode-based cost measures prior to including them in the MIPS program in future years.
- The AMA supports CMS' proposal within the Advancing Care Information (ACI) category to extend certified electronic health record technology (CEHRT) flexibility for performance year 2018 and the proposed hardship exemption for small practices. We recommend improvements to the ACI category, including adding flexibility within the base score, reducing information blocking attestation requirements, , and creating a pathway for physicians to achieve ACI credit by using CEHRT to participate in a Qualified Clinical Data Registry (QCDR).
- The AMA supports CMS' proposal to maintain the reporting and performance requirements within the Improvement Activities (IA) category to provide stability within the MIPS program. The AMA urges CMS to continue to avoid adding complexity to the IA category by maintaining reporting through attestation, not removing any IA activities, and not requiring a future minimum

participation threshold. In addition, the AMA encourages CMS to continue to increase opportunities to promote health information technology and increase the participation credit to APM participants within the IA category.

APMs:

- The AMA appreciates the proposals to: extend the eight percent revenue-based nominal amount standard for APMs for an additional two years; allow Other Payer APMs to use the revenue-based standard; and allow the Physician-focused Payment Model Technical Advisory Committee (PTAC) to recommend Medicaid APMs.
- We reiterate our previous recommendation that the revenue-based nominal risk standard not be increased above eight percent in years 2021 and beyond. We also recommend that CMS: phase-in the eight percent standard for Advanced APMs; extend the medical home nominal risk standard to small and rural practices participating in all Advanced APM models, specialty medical homes, Other Payer medical homes, and medical home organizations with 50 or more clinicians; base the revenue standard for nominal risk on the revenues of the individual APM entity participating in the APM that is responsible for repayment of any losses; exclude reimbursement for Part B drug costs from the nominal amount definition; and modify the requirement to base the revenue standard on both Part A and Part B revenues.
- CMS should allow participation in Medicare Advantage APMs to be included under the beneficiary count test for Qualified Participant (QP) status determinations affecting 2019 and 2020 payment adjustments.
- Physicians who begin participating in an Advanced APM should be exempt from MIPS and have access to the five percent bonus payment during the year immediately following their first year of Advanced APM participation.
- The AMA recommends several improvements in the process for assessing physicians' participation in the all-payer combination option.
- The AMA recommends providing technical assistance and data to facilitate development of physician-focused APM proposals, and urges the Secretary to respond to the recommendations of the PTAC within 60 days.

We thank you for the opportunity to provide input on this proposed rule and look forward to continuing to work with CMS to ensure that MIPS and APMs realize their potential to support the ongoing transformation of health care delivery. 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

2 Modean

Attachments

2018 Quality Payment Program Proposed Rule Detailed Comments of the American Medical Association August 21, 2017

A. Overarching Topics

- a. Low-Volume Threshold
- b. Limit MIPS to the Physician Fee Schedule
- c. Reporting Period
- d. Scoring
 - i. Stability in Program Requirements
 - ii. Performance Threshold
 - iii. Additional Performance Threshold
 - iv. Bonus Points
 - v. Reliability Threshold
- e. Category Weights
- f. Measuring Improvement
- g. Facility-Based Measurement
- h. Virtual Groups
- i. Multiple Submission Mechanisms
- j. Small Group Definition
- k. Subgroups in Multispecialty Practices

B. The Merit-Based Incentive Payment System (MIPS)

- a. Quality
 - i. Reporting Requirements
 - ii. Scoring the Quality Performance Category
- b. Cost
 - i. MIPS Measures
 - ii. Scoring the Cost Category
- c. Advancing Care Information (ACI)
- d. Improvement Activities (IAs)

C. Other MIPS Issues

- a. Performance Feedback
- b. Physician Compare
- c. Targeted Review
- d. Program Integrity

D. APM Provisions

- a. MIPS APMs
- b. Advanced APMs
 - i. Revenue-Based Standard for More than Nominal Financial Risk
 - ii. Medical Home Models
 - iii. Count Medicare Advantage APM Participation in Patient Threshold Calculations for OPs
 - iv. Exempt Advanced APM Participants from MIPS After First Year
 - v. Improve All-Payer Combination Option Determinations
 - vi. Physician-Focused Payment Models

MIPS PROVISIONS OF 2018 QPP PROPOSED RULE

Low-Volume Threshold

The AMA supports the expansion of the low-volume threshold to individuals and groups that have Medicare Part B allowed charges less than or equal to \$90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries. As noted in our previous comments, we believe that CMS should consider the impact of MIPS on small and rural practices when determining the low-volume threshold. We therefore applaud CMS for proposing additional relief to many in these practice settings.

We also encourage CMS to notify individuals and groups as soon as possible that they meet the low-volume threshold requirement. **Ideally, this notification should occur before the 2018 performance year.** The delay of low-volume letters for the 2017 program left many confused and potentially unprepared to meet the MIPS requirements. Notification for 2018, if the proposal is finalized, will be even more important since some participants who reported in 2017 may not realize that they now qualify for an exemption. In addition, participants interested in joining virtual groups in 2018 will want to know if they are included in the low-volume threshold before deciding to pursue this option. We therefore urge CMS to issue these notices in a timely manner and explain the potential change in its policy from the 2017 performance year.

While we support the expansion of the low-volume threshold, physicians should be allowed to opt-in to the MIPS program if they wish to participate in future years. This will allow those who are ready to report or wish to gain experience with the program to learn the MIPS requirements and have an opportunity to earn an incentive payment. CMS, however, notes that it is unable to provide this flexibility for the 2018 performance year. We recognize this problem but ask that the agency begin working to find a solution in future program years. CMS should also not limit optional performance to only those who meet or exceed one, but not all, of the low-volume threshold determinations. Rather, CMS should allow all of those in the low-volume threshold the ability to opt-in and participate in MIPS in future years.

We also believe that the proposed rule creates complexity through its inconsistent treatment of the low-volume threshold compared to other excluded categories (i.e., new Medicare enrolled clinicians, Qualifying APM Participants (QPs), and partial QPs). Unlike these other exempt categories, a low-volume eligible clinician who reports through a group will not be excluded but will incur the MIPS payment adjustment. We urge CMS to exempt low-volume participants reporting in groups from the MIPS payment adjustment. Allowing this exemption would also better align group reporting and virtual group reporting. Under virtual group reporting, if a practice elects to participate in a virtual group, and the group includes physicians who fall below the low-volume threshold, those physicians will not be included in the calculation of the groups' composite performance score and will not receive a payment adjustment. Therefore, CMS should adopt this same approach for physicians electing to report as a group, and exempt low-volume participants reporting in groups from the MIPS payment adjustment. If CMS is unable to allow for this exclusion 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).

Finally, CMS solicits comments on whether it should add a threshold for items and services furnished to Part B individuals in determining the low-volume threshold. We believe this is unnecessary and that the current process of looking at the minimum number of individuals treated and allowed charges will generally capture those who should qualify for an exemption. In addition, we think adding a third

criterion will create more complexity for CMS as well as physicians and could further delay notices to those practices who have met the low volume threshold. Instead, we urge CMS to create stability by maintaining the current approach to calculating the low-volume threshold. Also, CMS should not reduce the low-volume threshold; otherwise physicians will face uncertainty about their status and could be unfairly penalized.

Limit MIPS to the Physician Fee Schedule

The AMA continues to oppose including items or services beyond the physician fee schedule, especially Part B drugs, when determining MIPS eligibility and applying the MIPS payment adjustment. We believe that changing this policy would create significant inequities and also potential legal challenges in administering the MIPS program.

Including these additional items and services would be a significant departure from previous policy. Although in the past CMS has counted Part B drugs in the calculation and comparison of physician costs under the Value-Based Modifier (VM), none of the MIPS legacy programs, including Meaningful Use (MU), Physician Quality Reporting System (PQRS) and VM applied related adjustments to reimbursement for the drugs. Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was intended to build-off of these previous programs. Yet, nowhere in the legislative history is there notice or discussion of making a significant change to include additional items and services. We therefore believe Congress intended and CMS should carry over a similar policy under the MIPS program. At a minimum, CMS should seek clarification from Congress before unilaterally making this change that does not appear to be addressed when enacted into law.

In particular, changing this policy would create serious challenges and potentially negative consequences for participants and patients that we believe are not intended by the MACRA statute. In addition to Part B drugs, the proposed policy is expected to affect certain other services such as durable medical equipment that physicians may purchase and then dispense to patients. In all these instances the Medicare payment is merely a pass-through that covers physicians' acquisition costs but the impact of the policy will be particularly acute for Part B drugs due to their high cost and utilization within a few specialties and subspecialties. Consequently, we have repeatedly argued in past comments that CMS should remove Part B drugs from its calculation and comparison of physician costs in MIPS and the predecessor VM program. To now apply the payment adjustment to the physicians' reimbursement for the drug as well as its administration would magnify the problem, penalizing certain specialties and subspecialties and creating a potential windfall for others.

Medicare already makes a negative two percent sequestration adjustment to physician's Part B drug reimbursement, which brings Medicare's drug payment rate of Average Sales Price (ASP) plus 6 down to ASP plus 4.3 percent. Even in the first year of MIPS, a physician subject to MIPS' maximum four percent penalty would barely cover the direct cost of the drug with nothing left over for other associated costs such as storage and compliance with various safety regulations. With a nine percent penalty, payment for the drug would be well below its actual cost to the physician. Many physicians who provide these critically important drugs will have little choice but to refer their patients to hospital outpatient departments where Medicare and its beneficiaries will face higher costs. Some might simply avoid Medicare patients or those with the most advanced diseases. Those in a position to do so could potentially influence gains and losses through their choices of which drugs are purchased by a facility and which by physicians.

CMS itself notes that it cannot administer a policy on the additional Part B items and services in a cohesive manner. The proposed rule recognizes that when a participant is both a supplier and MIPS eligible clinician there are operational issues that could lead to significant differences in the size and application of MIPS payment adjustments depending on where physicians practice and the drug purchasing polices employed there. We understand that there could also be variations across Medicare Administrative Contractors (MACs) that will create inconsistencies. We therefore believe it is inappropriate and arbitrary to apply such a policy.

We also oppose including Part B items to the 2017 performance year given the lack of notice provided to participants. Questions about how Part B drugs would factor into MIPS were brought up during the 2017 comment period; however, CMS answered by stating "we did not address this issue in the proposed rule. We will consider this issue and intend to provide clarification in the future." Given this lack of guidance and the significant impact it would have on participants, we believe it is inappropriate for CMS to apply this change retroactively and without flexibility for participants. Participants for 2017 already evaluated whether it was appropriate for them to participate in the program and likely relied on the fact that these items and services were not applied in previous programs along with the lack of clarity provided in the final rule. Without notice and comment of this change, we do not believe it should be applied to the 2017 performance period.

Finally, for the same reasons noted above, we continue to oppose CMS including Part B drugs in the cost score calculations. Given the life-changing impact of many Part B drugs, items, and other services and the significant adverse consequences that inclusion in MIPS could have for some of Medicare's frailest patients, we urge CMS to limit MIPS applications to the physician fee schedule. At a minimum, CMS should ask Congress to clarify its intent before it proceeds to apply MIPS adjustments more broadly.

Reporting Period

CMS is proposing different reporting periods for the MIPS categories—90days for both the ACI and IA components and a year for quality reporting. As we have noted previously, a full calendar year reporting period can create significant administrative burden while not necessarily improving the validity of the data. We also believe that these different timeframes may create confusion and adds to the complexity of the MIPS program. **To better align the MIPS categories, we urge CMS to allow physicians to choose a shorter reporting period for the quality reporting period.** This would permit reporting on a full calendar year for those physicians who believe it is more appropriate for their practice. A MIPS participant would also have the flexibility to select a 90-day quality period if they preferred to harmonize their MIPS reporting. We believe this flexibility would also resolve problems that may occur if a physician updates or switches their EHR during the performance year.

We understand that CMS' systems and some vendors may have challenges in using a shorter reporting period or multiple reporting periods. We, however, urge the agency to work with physicians to develop options and a specific plan to provide accommodations where possible. For example, CMS could allow physicians to select from one of four reporting periods: 90 days, 180 days, 270 days, or 360 days. This option could alleviate some of technical challenges while still providing flexibility to participants.

¹ 2017 Final Quality Payment Rule 81 Fed. Reg.77,008, 77,340 (June 30, 2017).

Scoring

The AMA continues to believe that the overall scoring methodology for the MIPS program should be simplified. If physicians do not comprehend the scoring, they are likely to view the program as unfair and may be subject to financial penalties solely due to confusion rather than their actual performance. While we understand part of this complexity is due to statutory language and the requirement for a composite score, we believe the following recommendations would improve the proposed scoring structure.

• Create Stability in Program Requirements

A goal that should be set throughout the MIPS program is to create stable requirements that do not change from year to year. This is the easiest way to ensure participants can learn about and prepare for the MIPS requirements. Accordingly, we urge CMS to avoid changes or short-term policies that disrupt understanding of the program. If such changes are necessary, they should generally be made in a fashion that protects participants as opposed to placing more individuals at risk for a financial penalty.

For example, if CMS adopts certain bonus points, these incentives should be maintained over time and not be taken away from one year to the next. Similarly, exemptions should not drastically shift to avoid catching physicians off-guard regarding what is required in the upcoming program year. Throughout the scoring methodology, we encourage CMS to try and keep the program as consistent as possible so that physicians can learn the new requirements and successfully participate.

• Set a Low Performance Threshold

The AMA was extremely supportive of the pick-your-pace approach CMS adopted for the first performance year and the decision to set the performance threshold at three. This provided physicians with an opportunity to learn the MIPS program and adopt practices that will help them to successfully participate in the future. We believe that CMS should maintain its transitional year policies and continue to set the performance threshold at an achievable level for all participants as they gain experience with the MIPS program. We therefore urge CMS to set the performance threshold for the second program year at six points.

Our reasoning for setting the performance threshold at six reflects several considerations. First, we continue to believe that the MIPS program should adopt a "do no harm" mentality, whereby the program seeks to promote participation and allow physicians to learn the requirements before repositioning towards penalties. By setting the threshold at six, CMS is moving the needle of MIPS performance forward without discouraging physicians or creating a bar that is unachievable, especially for small practices and new participants. This benefit is highlighted in the proposed rule, where CMS notes a lower threshold could result in "potentially smaller total amount of negative MIPS payment adjustment." In comparison, the trade-off of a higher threshold would be "potentially higher positive MIPS payment adjustment for those that exceed the performance threshold." We continue to believe that, at this stage of the program, CMS should focus first on protecting the majority of physicians as they transition to this new program before increasing bonus payments to a group of high performers.

Second, setting the performance threshold at six creates stability in the MIPS requirements. MIPS participants are still learning the program and will only have had one year of experience with the different categories, scoring methodology, timelines, and other requirements. Gradually increasing the threshold

for the second performance year ensures that participants can continue to gain familiarity with the program and can work to restructure their practices to prepare for future MIPS reporting.

We acknowledge CMS' concerns that setting a lower performance threshold in year two could lead to a jump in the performance threshold for the 2019 reporting period, when CMS is required to use the mean or median score from a previous MIPS period. However, setting a lower threshold actually mitigates against this problem by focusing achievement at six points, driving most participants towards this lower final score. Conversely, increasing the threshold to 15 points will likely drive up the mean or median performance, resulting in even higher subsequent thresholds.

Setting a lower threshold is especially important since we still do not have data from the first performance year and are unsure how well physicians understand MIPS requirements and whether physicians are ready for a more challenging program. CMS notes in the proposed rule that "[b]y the 2021 MIPS payment year, MIPS eligible clinicians would likely need to submit most of the required information and perform well on measures and activities to receive a positive MIPS payment adjustment." Yet, we believe CMS' current program estimates are overly optimistic and that these numbers are significantly inflated. Discussions with our own members suggest that most physicians are working to gain a basic understanding of the program and will likely seek to meet the 2017 threshold of three points, rather than try for much higher reporting requirements.

CMS could then use the 2017 data to set subsequent MIPS performance thresholds, which could avoid a steep jump for future program years. We, however, urge CMS to share with us additional information and data that it may have to understand how it will establish future performance thresholds and the differences in selecting the mean vs. the median. We continue to believe that our estimates are very different from those in the proposed rule and are concerned that these disparities could drive policy decisions that create significant challenges for physicians.

In addition, we are pursuing a legislative fix that may provide CMS additional flexibility to maintain its transitional year policies and to set the performance threshold at a lower level than the mean or median for three additional years. Therefore, we urge CMS to set the performance threshold for the second year at six points in order to allow the maximum number of physicians to avoid a penalty in 2020.

• Maintain the 70 point Additional Performance Threshold

We agree with CMS' proposal that the additional performance threshold should be maintained at 70 points. This avoids shifting program requirements and rewards those who submit data on multiple MIPS performance categories. Raising the threshold above 70 points would be challenging for participants since it would potentially require a perfect score in the quality performance category as well as additional points in another category or mandate use of an EHR to earn points in the ACI category. Given that we are still in the early stages of the program, we believe that the current threshold is sufficient to drive improvement and reward those with high performance.

Provide Data and Analysis Before Setting Future Performance Thresholds

The proposed rule asks for comments about future performance thresholds, including whether to use the mean or median when setting the 2019 performance threshold and which statutory option to use for calculating the additional performance threshold. As noted in our previous comment letters, we do not

believe that we have sufficient data to determine which alternative is better or how selecting one may affect particular categories of physicians and their patients. Specifically, CMS should run and publish analyses that detail how selecting the mean vs. the median 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 specialties, 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. Yet, CMS also has not released analyses or data on this issue, limiting our ability to provide guidance on this topic. We again ask that, once 2017 data is available, CMS share it with stakeholders and highlight any trends in performance.

Overall, we again urge CMS to focus the program away from penalties when making these decisions. If one alternative would result in more physicians receiving negative payment adjustments, we would generally urge CMS to select the opposite option. At this early stage in the program, we believe it is most appropriate to focus on holding participants harmless before creating larger penalties and incentives.

Finally, once CMS establishes an appropriate performance threshold, it should not be increased every year but should remain stable. Constantly escalating the threshold will force physicians to change their reporting plan every year. Instead, the MACRA statute permits CMS to reassess the threshold every three years, creating a sense of consistency for participants. We also note that CMS is not required to change the threshold after three years but can merely reassess to see if the program warrants such a change.

• Seek to Hold More Participants Harmless

The AMA remains concerned with the structure of the MIPS scoring, which creates a single cut-off that divides participants into penalties or incentives. While we understand the MACRA statute requires that the MIPS program be budget neutral and assign values on a "linear sliding scale," CMS should seek to avoid arbitrary cutoffs for participants who are near the performance threshold.

Rather than a structure where everyone is either a "winner or a loser," CMS should adjust payments mainly for those on the high and low-end of MIPS performance. Clinicians at or near the performance threshold should be held harmless. We believe this is a more accurate way to judge physicians and will avoid subjective penalties and incentives for those whose performance is very similar to one another or where scores are based on relatively low numbers of beneficiaries and therefore likely to shift around from year to year.

• Address Concerns Related to Bonus Points

CMS is proposing to include a number of different bonus opportunities, including additional points for small practices and providers who see complex patients. The AMA appreciates CMS' efforts to recognize and reward physicians who face unique challenges in the MIPS program. We therefore support these bonus points and believe they should be finalized in the final rule.

We, however, do not understand the reasoning for the different points being awarded to each bonus category. For example, small practices would earn an additional five bonus points to their final MIPS score. In comparison, those with complex patients would receive between one and three points. These differences are not explained in the final rule and appear to create biases. To simplify MIPS scoring and to avoid arbitrarily awarding points, we recommend that these additional bonus points be equal to one another.

The AMA is also concerned that the bonus points will impact the MIPS scoring methodology, especially if CMS removes or changes the bonuses in future years. In the proposed rule, CMS states that the bonuses are only a "short-term strategy" and may not be provided in future performance periods. Temporary bonus points not only create complexity but will artificially inflate the performance threshold for participants. These participants will then be disadvantaged in future program years when the bonus points are removed or reduced, essentially creating greater hardship for the categories of participants who need the most assistance. Furthermore, depending on how CMS chooses to score improvement (discussed in more detail below), participants could also appear to "not be improving" simply because of changes in CMS' policy related to bonus points. To avoid these problems, we urge CMS to make these bonus points permanent. We also believe that the bonus points should not be factored into setting future performance thresholds. The MACRA statute did not anticipate the addition of bonus points and therefore did not address how such points should be treated when setting MIPS thresholds. Since bonus points artificially raise performance scores, we are concerned that including them in threshold calculations will distort these values and create a more challenging program for all participants. Instead, CMS should simply not include these points when determining the median/mean performance and setting the MIPS threshold in future years.

In addition, we are concerned about the administration of the bonus points. We believe CMS will be responsible for adding the appropriate number of points to a participant's score; however, this will require significant technical resources for the agency. We also have questions about the transparency of awarding these points—physicians should be able to anticipate and confirm the additional points added to their scores and appeal if they believe points were not correctly awarded. We therefore ask the agency to outline how it plans to ensure points are awarded correctly, how and when physicians will be notified that they are qualified for a particular bonus, and what options physicians would have for appealing eligibility for a particular bonus.

Lastly, we believe that participants may become confused about the different types of bonuses—under the proposal there are now bonus points added to your final score as well as accommodations or bonuses within each MIPS categories (e.g., for reporting using 2015 CEHRT, or reporting outcome/high priority quality measures). Again, these different policies create complexity within the MIPS program, and we fear participants may believe that all points are added to their final score. CMS should therefore provide clear guidance outlining the different types of bonuses and how they apply. Another option would be for CMS to work towards creating one bonus structure that avoids the multiple points awarded within the categories and simply adds on a single bonus to the final score. At this time, however, we do not think that the existing bonuses and accommodations in the different MIPS categories should be removed, but urge CMS to consider ways to streamline and coordinate these different point structures in future program years.

In addition to these overarching comments related to the proposed bonuses, the following provides our views on comments raised by CMS in the proposed rule.

• Small practice bonus

The AMA strongly supports the small practice bonus and agrees that this bonus should be available to group practices, virtual groups, and APM entities that consist of 15 or fewer clinicians. We also urge CMS to consider whether the small practice bonus should be extended to certain rural practices, noting that some physicians in these settings face challenges that are similar to those of small practices, especially with respect to adopting health information technology and the other resources required for successful MIPS participation. In addition, CMS should consider whether adding a new participant bonus would help encourage entrance to the program and avoid disadvantaging those who are unfamiliar with the requirements.

• Accounting for social risk factors

The AMA strongly believes that Medicare's current risk adjustment methodologies do not adequately address treatment and outcome differences related to patient characteristics, including complexity of their illness and social-economic factors that are outside the control of physicians. We do not agree that stratification of scores, especially if they are publically reported, is an adequate long-term solution because we do not concur with the underlying assumption that outcome disparities are largely the result of low quality care. Therefore, we strongly encourage CMS to push for rapid identification and incorporation of additional risk factors that influence how patients respond to care. In the meantime, we agree that a complex patient bonus could help ensure that the physicians are not penalized by Medicare if they treat large numbers of high-risk and/or disadvantaged patients.

• Complex patient bonus

As shown in data from the Value Modifier (VM) program, current cost and quality measures tend to unfairly disadvantage physicians who care for complex patients. The VM tried to address the problem by increasing the bonus for practices with the highest proportions of high risk patients but this only helped those who had already succeeded despite the odds and did nothing to improve the odds and prevent penalties for all of the high risk practices. **The complex patient bonus is a distinct improvement in that it would help them on the front end rather than enlarging the reward for those that succeed.** We are also pleased that CMS sees this as a "helpful starting point" rather than a complete solution, and that there is a recognition that the Hierarchical Condition Category (HCC) risk adjuster works better at the level of a large health plan than at the physician level.

Without more information, we cannot tell which of the two options—HCC or dual eligibility—is the best way to determine the bonus. We appreciate CMS' effort to provide specialty specific statistics that provide some indication of how each of the options might play out, though we have some concern that the statistics are based only on practices that successfully reported at least six quality measures since those with larger numbers of high-risk patients may have been unable to successfully report. It would also have been helpful to know how many groups and how many physicians would be eligible for a bonus under each of the two options and how big the overlap between the two would be.

A simpler process might be to provide some set number of bonus points to a set of practices that qualified based on either of the two potential criteria. For example, the bonus could be awarded to the 25 percent of practices that have the highest average HCC scores and to those with the highest percentages of dual eligibles. Or it could be provided to all practices with either above average HCC risk scores or dual

eligible percentages. Furthermore, as described above, we believe that assigning different points for this bonus is overly complex. Rather, CMS should align the bonus points with that awarded for small practices.

• Increase Reliability Threshold

As CMS states in the Physician Compare section of the 2018 QPP proposed rule, "high reliability for a measure suggests comparisons of relative performance across entities, such as [eligible clinicians] ECs or groups, are likely to be stable and consistent, and that the performance of one entity on the quality measure can be confidently distinguished from another." The AMA agrees with this statement, but is extremely concerned with CMS' statement that a reliability standard for public reporting and reliability for scoring need not align. CMS' disregard for high reliability for measuring performance ignores the fact that MIPS is an accountability program and the same data standards should be held for adjusting payment. Without such high standards, CMS runs the risk of inappropriately penalizing physicians and group practices.

As the AMA has repeatedly stated in past comments, it is unclear 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. Similar standards are considered acceptable for administrative claims quality measures, such as the All-Cause Hospital Readmission measure. However, CMS considered measures unreliable for public reporting on Physician Compare in 2016 if the 25th percentile of the reliability score fell below 0.90. While we greatly appreciate CMS' attempt to improve reliability for public reporting, we see no reason why the same level of reliability should not be required across the different measures and for different intended uses (i.e., public reporting and accountability/payment adjustments).

The AMA continues to believe that physician performance on any administrative claim measure (cost or quality) 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. Accordingly, CMS should not rely on measures that have suboptimal reliability scores, recognizing that doing so could lead to incorrectly categorizing and penalizing physicians and be misleading to patients and physicians. Furthermore, we request that CMS be transparent with what it considers acceptable reliability for public reporting and measuring performance so measure stewards can develop and test their measures appropriately.

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. https://web.stanford.edu/dept/SUSE/SEAL/Reports Papers/methods papers/G%20Theory%20Hdbk%20of%20Stat

istics.pdf

³Del, Siegle. Instrument Reliability. Educational Research Basics. University of Connecticut. Accessed 08/14/2017. http://researchbasics.education.uconn.edu/instrument_reliability/

⁴Adams, 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.

Category Weights

• Avoid Imbalances when Reweighting Categories

Participants may have their ACI category score reweighted to zero as a result of a hardship exemption or measure unavailability. The AMA continues to be concerned that CMS' reweighting policy creates an over-emphasis on the quality category. We therefore support CMS' alternative option to more evenly distribute the performance category weights between the quality and IA categories when participants cannot report on ACI. We further urge CMS to consider increasing the amount of weight it would add to the IA category by 20 percent (for a total of 35 percent in IA and 65 percent in quality).

While we understand that the IA category is new, we do not agree with CMS' concerns about moving additional weight into this category. First, concerns about measure maturity may not be applicable given the IA category is intended to reflect and provide credit for existing and ongoing activities. Second, MACRA defines IAs as activities that relevant eligible clinicians and other stakeholders "identify as improving clinical practice or care delivery and...[are] likely to result in improved outcomes." The IA category should not be undervalued simply because it is new; indeed, CMS states in the proposed rule that IAs "have elements of quality and care improvement which are important to emphasize." We therefore urge CMS to increase the amount of weight it would distribute to the IA category. Doing so would avoid creating an undue emphasis on only one category, help to create a more unified program, and would demonstrate the value of the IA category while still prioritizing quality.

• Address Extreme and Uncontrollable Circumstances

The AMA is supportive of CMS' proposal to include an extreme and uncontrollable circumstances policy that acknowledges there are occurrences that can make reporting not feasible for MIPS participants. While the rule highlights natural disasters and other extreme events, we also believe that issues with third party intermediaries, such as EHR vendors and registries, warrant inclusion in this exemption. Like a natural disaster, the failure of these sources is completely outside the control of the participant and can prevent all data submission to CMS. Without such a policy, CMS has had to create hardship exemptions and other accommodations to address these problems in the past, which often require extensive resources to correct the issue, education on how it is being resolved, additional deadlines for participants, and other confusing changes to the program. Instead of dealing with these problems on a case-by-case basis as they arise, we believe CMS should establish a process now to leverage the extreme and uncontrollable circumstances policy to address these issues. This will simplify the program and avoid having to handle these issues in a separate manner.

• Build-in Category Weights

Currently, each of the MIPS categories is scored out of a 100 points and then the points are multiplied by the percentages assigned to each category to determine the composite score. This approach is likely to create confusion as it requires physicians to understand that points awarded in a category are reweighted. For example, because the IA score is weighted at only 15 percent, earning 40 points—full credit—in this

⁵ 2018 Proposed Quality Payment Rule 82 Fed. Reg. 30,010, 30,145 (June 30, 2017).

category is really only worth six points of your final MIPS score (40 X .15). We are worried that physicians will mistakenly believe the category points are their composite scores and inadvertently fail the program.

To avoid this problem, we suggest that, where possible, CMS simply build-in the category weights to the scoring within each MIPS category. The following chart illustrates this change across the different MIPS categories:

Categories	Current points	Built in Category Weights
Quality	100 pts – 60% score	60 pts – 60% score
Cost	0%	0%
Advancing Care Information	100 pts – 25% score	25 pts – 25% score
Improvement Activities	100 pts – 15% score	15 pts – 15% score

To address reweighting, the built-in scores would still need to be adjusted to reflect the different category percentages; however, this would only be required for a subset of MIPS participants, as opposed to everyone in the MIPS program.

Measuring Improvement

The MACRA statute requires that the MIPS program take into account improvement with respect to the quality and cost performance categories "if data sufficient to measure improvement is available." CMS is therefore proposing that it will start measuring improvement in 2018 at the performance level for the quality category and at the measure level for the cost category; although the cost improvement methodology would not impact final MIPS scores if CMS finalizes its proposal to keep this category weight at zero.

The AMA supports several of CMS' proposals with respect to improvement. In particular, we agree that improvement should be counted as bonus points and not used to penalize participants. Physicians should also still be able to receive full credit based on achievement so they are not penalized for their previous high performance. We also appreciate that under the proposed rule, improvement could only increase, not decrease a physician's pay. In a budget neutral system, however, improvement-related bonuses for some physicians will mean smaller bonuses for others.

In addition, we are concerned that trying to establish improvement scoring now will only complicate the MIPS program. In particular, we do not believe that the one year of data on the MIPS program is sufficient to begin measuring improvement, as required by the statute. CMS has not even collected this information yet and seems to be putting the cart before the horse by proposing methodologies for the cost category, which was not scored in 2017, is proposed to remain at zero for 2018, and will be undergoing significant measure modifications over the next few years. The data may also not be representative given the pick-your-pace approach that was adopted for the 2017 performance year. Also, this additional scoring consideration will add complexity to an already complicated program and require physicians to factor in additional considerations when they are just trying to learn the program. For example, some practices may not understand that they must fully participate in the quality category in order to receive an improvement score. Therefore, we do not believe CMS will have sufficient data to analyze and score improvement until physicians have participated in the MIPS program for several years.

In addition, we are concerned with the different improvement approaches proposed for the cost and quality components. Two separate methods will add further complexity to the MIPS program. Until a stable set of cost measures has been developed and in place for several years and until there is more data to base a decision on, we do not think it is possible to judge the impact or appropriateness of either of these two approaches. For example, the improvement scoring appears to assume that the quality measure benchmarks will remain static when, in fact, the deciles will likely shift over time. Consequently, physicians may be improving their performance but this will not be captured in their overall points in the quality category. We recognize this is the trade-off of scoring improvement on a category vs. measure basis, but without more experience with the MIPS program, we are unclear how often this will happen and if it warrants a different approach.

We also believe that CMS should consider other ways to score improvement. For example, improvement points could be awarded when physicians report on a new quality measure or when a participant agrees to test and provide feedback on new cost measures and/or patient relationship codes. Improvement points could also be awarded for overall improvement of a participant's composite score, rather than just focusing on individual categories. CMS could also define improvement more broadly to encourage participants to report new aspects of the MIPS program, participate in pilots, use registries, or other tools that CMS seeks to promote. Yet, we believe there has not been sufficient discussion with stakeholders to understand how they view improvement or the challenges that may impact certain specialties, sites of services, and other participants.

In sum, we believe that adding improvement scoring at this time is premature. We recommend that CMS continue to seek feedback and experience regarding improvement methodologies at least through the MIPS transitional period before adopting an approach which, once put into motion, may be difficult to change.

Facility-Based Measurement

The AMA supports CMS' proposal to adopt a new scoring option for the quality and cost performance categories that allows facility-based MIPS eligible clinicians to be scored based on their facility's performance.

• Adopt a Facility-Based Measurement Option

The AMA believes allowing physicians to select a facility-based measurement option can reduce duplication and reporting burden by using quality and cost data that is already reported at the facility level to determine a physician's quality and cost score. CMS notes that it plans to implement this program in a narrow fashion in the first year by limiting the facility-based measurement option to inpatient hospitals.

The AMA urges CMS to also design facility-based measurement options for physicians that practice in facilities such as skilled nursing facilities, ambulatory surgical centers, and inpatient rehabilitation facilities.

The AMA also strongly supports CMS' proposal to allow physicians to voluntarily elect to have their quality and cost performance category scores determined based on a facility's performance.

• Reduce the Facility-Based Measurement Point Floor

CMS proposes to adopt a floor of 30 percent for any physician who chooses the facility-based measurement option for quality reporting purposes. A score of 30 percent in the quality category is equal to 18 points, which is higher than the 15 point performance threshold that CMS has proposed. Therefore, any physician that selects the facility-based measurement option would automatically score above the performance threshold regardless of the performance of his or her facility. **The AMA believes this high point floor is unfair to non-facility based clinicians and urges CMS to reduce the point floor for physicians opting into facility-based measurement.** Physicians opting into facility-based measurement already have some advantages in the quality category, such as the requirement that if a physician elects facility-based measurement, but also submits quality data through another submission mechanism, CMS will use the higher of the two scores for the quality category. Furthermore, non-facility based MIPS eligible clinicians are already at a disadvantage since they will not have their MIPS scores in advance of their data submission, whereas facility-based physicians will be able to ascertain their facility-based measurement scores prior to the deadline to submit MIPS data.

We are also concerned that if the point floor is maintained, facilities may not be incentivized to invest additional resources into physician-level quality reporting tools, which would create problems for physicians that choose to report separately from the facility. Specifically, there would be no incentive for the facility to coordinate with individual physicians or specialties on meaningful quality measures when the physician can achieve a score higher than the performance threshold regardless of their performance in the Value Based Purchasing (VBP) program. Therefore, CMS should reduce the 30 percent floor in the quality performance category for physicians electing to use facility-based measurement to ensure the program is equitable for both facility and non-facility based physicians.

We also encourage CMS to monitor this option to see if it leads to further consolidation of physician practices or other patterns in the healthcare marketplace.

• Expand the Facility-Based Definition

The AMA is somewhat concerned that the requirement that physicians treat 75 percent or more of their patients in an inpatient setting in order to qualify for the facility-based measurement option is too high. This threshold may exclude many physicians who provide the majority of their services in an inpatient setting but do not reach the 75 percent threshold. We urge CMS to provide a sensitivity analysis illustrating how many additional physicians would be able to opt-in to facility-based reporting if CMS lowered the threshold to 50 or 65 percent. CMS should also ensure the hospital-based physician threshold in the ACI category continues to align with the facility-based requirement. The AMA also urges CMS to consider expanding the facility-based measurement option to settings other than inpatient hospitals in future years such as post-acute and long-term care facilities.

Virtual Groups

The AMA strongly supports the ability for small groups and solo practitioners to form virtual groups and have their performance assessed at an aggregate level. As we have stated in our previous letters to CMS, there should be maximum flexibility for physicians, small practices and other eligible professionals to form virtual groups.

• Ensure Flexibility for Physicians to Form Virtual Groups

The AMA appreciates CMS' acknowledgement that virtual groups must have the flexibility to determine their own composition, and supports CMS' decision not to limit virtual groups by geographic area or specialty. Similarly, CMS should not establish a limit on the number of Tax Identification Numbers (TINS) that may form a virtual group. CMS notes concerns that virtual groups may become so large that it makes comparison of performance between clinicians difficult; however, it is unlikely this will occur given the significant administrative and contractual requirements to become a virtual group. Allowing physicians to form virtual groups without restriction simplifies an already complicated program.

CMS should also not limit the number of virtual groups that can be approved each year. As CMS notes in the proposed rule, there is unlikely to be a flood of virtual groups in 2018 given the short time between the release of the rule and the start of the performance year.

Setting limits on the establishment of virtual groups, including the maximum number of groups, size of groups, geographic proximity, or specialty, would have a chilling effect on the formation of virtual groups. Such limitations could harm practices with limited resources and administrative support, which may benefit most from being in a virtual group.

• Assist in the Election Process

The AMA supports CMS' proposal to provide technical assistance to physicians who come together as a virtual group. Given the complexity of the QPP program, it would be extremely beneficial for physicians to be able to contact a designated technical assistance representative to determine whether they are eligible for a virtual group. In addition, the AMA supports allowing physicians to confirm whether or not they are eligible to form a virtual group prior to executing formal written agreements or allocating resources for virtual group implementation. We encourage CMS to extend this technical assistance to help small practices forming virtual groups with issues such as preparing health IT systems, drafting contract agreements, or training staff. We also encourage CMS to leverage CMS technical assistance small practice contractors to assist with virtual group eligibility and requirements since many of these contractors have existing relationships with small practices.

The AMA supports CMS' plans to provide an electronic election process for QPP year three if possible. We also support the opportunity for virtual groups to make an election prior to the publication of the final rule in order to allow sufficient time for virtual group formation.

• Harmonize Virtual Group Determinations

If a practice elects to participate in a virtual group, and the group includes physicians who fall below the low-volume threshold, those physicians will not be included in the calculation of the groups' composite performance score and will not receive a payment adjustment. The AMA supports this approach, which is prescribed for virtual groups in the MACRA statute.

Conversely, group practices that choose to report through the group practice reporting option will include physicians who fall below the low-volume threshold in the calculation of the groups' composite performance score and those physicians will receive a payment adjustment. The variance in calculation of individual physicians who fall below the low-volume threshold in virtual groups versus the group practice reporting option adds unnecessary complexity to the MIPS program. **Therefore, CMS should**

apply the same methodology used for virtual groups to practices electing to participate in group reporting. This would allow any physician who met the low-volume threshold, regardless of whether they were part of a TIN that elects to report as a group, to be excluded from MIPS reporting and avoid a payment adjustment. This approach would eliminate the inconsistency between virtual group reporting and the group practice reporting option, and reduce program complexity.

• Address Program Integrity Concerns

Many solo practitioners and groups of 10 or fewer MIPS eligible clinicians have limited resources and technical capabilities. Virtual groups will involve preparation of health IT systems and training staff to be ready for implementation, sharing and aggregating data, and coordinating workflows. While these are necessary steps to ensure the success of virtual groups, these steps could raise concerns involving fraud and abuse. Therefore, AMA requests that the Secretary exercise prosecutorial discretion by not enforcing the requirements under the Anti-Kickback Statute (section 1128B(b)) and the physician self-referral law (section 1877) for activities involving the development and operation of a virtual practice group.

Multiple Submission Mechanisms

CMS proposes to score measures submitted across multiple submission mechanisms within the quality performance category. The AMA supports CMS' efforts to provide physicians additional flexibility in MIPS reporting. However, as proposed, scoring measures across multiple submission mechanisms may make reporting quality measures more complex, costly, and burdensome for physicians.

Under this proposal, physicians who have fewer than six measures available under one submission mechanism may be required to use a second submission mechanism in order to receive a maximum quality score. For example, if a physician only had four applicable quality measures available to report through their registry, that physician would be required to search all measures available via other submission mechanisms such as claims and other registries to determine if there are additional measures they should report. Physicians may be required to review hundreds of measures and tools to determine if there are additional applicable measures. In addition, this could substantially increase costs for physicians, as it may require a physician or group practice to purchase an additional data submission mechanism in order to report six measures.

Therefore, the AMA urges CMS not to adopt this new scoring methodology as proposed because it will greatly increase the complexity and cost of reporting quality measures for some physicians. If CMS decides to move forward with allowing physicians to report under multiple submission mechanisms, it should not require physicians to explore alternative submission mechanisms to determine if there are applicable measures available. Instead, CMS should only review the measures available to a physician given their chosen submission mechanism—claims, registry, EHR or QCDR—to determine if a physician could have reported on additional measures.

Small Group Definition

CMS determines a small group size by the number of National Provider Identifiers (NPIs) associated with a TIN, which includes clinicians who may be excluded from MIPS participation and do not meet the definition of a MIPS eligible professional. For example, a small group would include clinicians who had

been excluded from MIPS participation such clinicians newly enrolled in Medicare, qualifying participants in APMs, partially qualifying participants in APMs and clinicians who fall below the low volume threshold.

In addition, small groups would include other eligible professionals defined by 1848(k)(3)(B) of the Social Security Act that may not be counted as MIPS eligible professionals in performance year 2018 including:

- A certified nurse-midwife;
- A clinical social worker;
- A physician or occupational therapist or qualified speech-language pathologist;
- A qualified audiologist;
- A clinical psychologist; and
- A registered dietitian or nutrition professional.

MIPS eligible professionals are more narrowly defined as follows:

- "(I) for the first and second years for which the MIPS applies to payments (and for the performance period for such first and second year), a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5)), a certified registered nurse anesthetist (as defined in section 1861(bb)(2)), and a group that includes such professionals;"
- (II) for the third year for which the MIPS applies to payments (and for the performance period for such third year) and for each succeeding year (and for the performance period for each such year), the professionals described in subclause (I), such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary, and a group that includes such professionals."

The AMA urges CMS to only include MIPS eligible professionals in determining whether a practice qualifies as a small practice with 15 or fewer eligible professionals. While the AMA understands that CMS may be constrained by statutory definitions, we are also concerned that the definition of a small practice could cause confusion and be misinterpreted by physician practices. Specifically, we have concerns that a practice may assume it is small if it has fewer than 16 MIPS eligible professionals, when in fact it may have more than 15 NPIs within its TIN. Practices may incorrectly rely on beneficial scoring for small practices or on the overall small practice bonus, when calculating the data they need to report. It is likely that these practices may inadvertently receive a penalty for not reporting enough information because they misunderstood the definition of a small practice. Therefore, the AMA urges CMS to define small practices as those practices with 15 or fewer MIPS eligible professionals.

Alternatively, if CMS is not able to define small practices as only including MIPS eligible professionals, the agency should provide significant education to physicians regarding who will be included in the definition of small practices. CMS should also display this information prominently on the QPP website. Currently, the QPP website participation look-up tool only lists the types of clinicians that are MIPS eligible professionals, but does not include an explanation of eligible professionals that count toward the definition of a small practice. This information should be included on the QPP website and in educational materials CMS distributes to physicians.

Given the significant confusion around the definition of small practices, the AMA also believes that CMS should continue to make the small practice eligibility determination using claims data. While an

attestation option may be easier for physicians, we are concerned that physicians may incorrectly attest that they are a small practice and find out later that they received a penalty based on an incorrect assumption that their practice was small.

Subgroups in Multispecialty Practices

CMS asked for feedback on whether physicians should be able to form subgroups for MIPS reporting within multispecialty practices. Currently, a physician must choose to report MIPS data individually or through a group reporting option which includes all MIPS eligible clinicians within a TIN. **The AMA** has heard from physicians that are part of a group practice that would like to report separately from the larger group, and supports allowing an option for a portion of a group to report as a separate subgroup. This would allow a specialty in a multispecialty group to form a subgroup in order to report on measures and activities that are more relevant to that particular specialty. In order to identify subgroups, CMS could create unique subgroup identifiers, similar to the virtual group identifiers they are proposing to create for virtual groups in 2018. The AMA would appreciate the opportunity to work with CMS to ensure that this option would not add complexity to the MIPS program and would offer a more meaningful reporting option to specialists that are part of multispecialty groups.

Quality

The AMA strongly supports many of CMS' proposals that will create stability within the quality performance category for physicians. First, we support CMS' proposal not to increase the number of quality measures a physician is required to report in 2018. The AMA also strongly supports CMS' proposal to maintain the data completeness threshold at 50 percent in 2018, which will reduce physicians' reporting burden and ensure more physicians will be successful in MIPS. In addition, we support CMS' continued elimination of the requirement that physicians report on cross-cutting quality measures or quality measures within specific domains. The AMA also supports the removal of cross-cutting measures from specialty measure sets, which will allow physicians to report on the quality measures that are most relevant to their specialty.

The AMA also appreciates CMS' proposal to maintain a minimum point floor for physicians reporting on a quality measure that meets the data completeness threshold, regardless of performance on the measure or the measure type. This rewards participation in the MIPS program and encourages physicians to continue to participate in MIPS in future years. Finally, the AMA supports maintaining reporting on Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS as a voluntary measure. While patient experience data collected in the CAHPS survey is important, it does not always correlate with better outcomes. Allowing CAHPS for MIPS to be voluntary acknowledges the diversity of practices participating in the MIPS program, as CAHPS for MIPS may only be applicable to internal medicine practiced in a traditional office setting.

There are also a number of modifications needed within the quality performance category. These changes include the elimination of the outcome/high priority measure requirement, the removal of the requirement to report on all-payer data, and the elimination of the current and future global and population health and administrative claims measures. The suggested changes AMA provides below will simplify the program and reduce administrative burden for physicians. Currently, physicians are spending too much time away from patients meeting various quality reporting requirements. According to a 2016 Health Affairs article, practices spend about 15.1 hours per week dealing with external quality measures and in total U.S.

practices are spending \$15.4 billion annually to report quality measures.⁶ We urge CMS to consider our modifications as a way to help reduce administrative burden for physicians.

Quality Reporting Requirements

• Maintain the Data Completeness Threshold at 50 Percent

CMS proposes to increase the threshold for successfully reporting on a measure from 50 percent to 60 percent in 2019 and beyond. If a physician fails to meet the data completeness threshold they only receive one point (three for small practices) for reporting on the measure. We recognize that increasing the data completeness threshold may increase the sample size of data; however, maintaining the threshold at a minimum of 50 percent does not prohibit physicians or practices from submitting more data. Changing the threshold level while physicians are still learning the complex requirements for successful MIPS participation is premature and ignores the burden associated with increased reporting thresholds.

Increasing the threshold will also discourage physicians from reporting on certain high priority measures due to the large administrative burden and cost associated with collecting information and reporting on all-payer data using a QCDR, registry, EHR or web-interface reporting mechanism. Increasing the threshold, coupled with the requirement of reporting on all-payer data, is especially burdensome for small practices that do not have the resources to hire an employee to collect and document such information. Even if the practice has an EHR, much of the information that supports the high priority measure is not captured within the EHR system but is collected through surveys and manual key entry.

The AMA strongly disagrees with the notion that a 50 percent threshold could lead to possible gaming. In addition, a 50 percent threshold still requires reporting on a majority of patients, which prevents cherry picking. A 50 percent threshold is simply a more realistic reporting level that acknowledges potential problems that may arise prior to or during the reporting period, such as the following:

- A vendor that fails to update measure specifications at the start of the reporting period.
- A delay in publication of CMS' approved qualified registries or QCDR list. Historically, CMS has not finalized the approved list until late spring or early summer of the reporting period.
- A delay in a practice determining their reporting status (low-volume threshold, non-patient facing, or facility-based).
- A practice switching EHR vendors.
- Power outages, inaccurate coding, or natural disaster.

Therefore, we urge CMS to maintain the quality reporting threshold at 50 percent.

• Eliminate the Requirement to Report on All-Payer Data

As part of MIPS reporting, physicians are required to report on all-payer data (except if reporting through claims) to satisfy reporting on 50 percent of applicable patients. While we recognize CMS' intent is to increase the sample size of eligible patients a physician has to report on a measure, this requirement is

⁶ Casalino, Lawrence P., Gans, David, et. Al. US Physician Practices Spend More Than \$15.4 Billion Annually To Report Quality Measures. *Health Affairs*. 35, no. 3 (2016): 401-406.

extremely burdensome and outweighs the potential perceived benefits by CMS. We urge CMS to eliminate the all-payer data requirement and make it optional.

We frequently hear from physicians that the all-payer data requirement is extremely time-consuming due to the amount of data entry required. It also takes away time from patient care and ignores the fact that physicians are still contractually obligated to meet various other private payer quality initiatives using different data. If their MIPS quality data could potentially be used to satisfy their private payer pay-for-reporting requirements and obligations, then physicians might see the value in reporting on all-patients, regardless of payer.

We also note that CMS states that it wants to incentivize electronic reporting; however, the requirement to report all-payer data does the opposite. If you report measures through the claims option it is only based on Medicare Part B patients. CMS is placing the highest burden on physicians who choose to report via methods it should be incentivizing—EHR, qualified registry, or QCDR. Therefore, physicians may be deterred from adopting electronic reporting mechanisms.

In addition, the all-payer data requirement is especially burdensome for small practices that do not have the resources to hire a full-time or part-time employee to collect and document quality information, especially when reporting measures that require capturing patient information through surveys. Even if a practice has an EHR, much of the information that supports outcome and high priority measures is not captured within the EHR system, but instead is collected through manual key entry.

Therefore, we urge CMS to eliminate the all-payer data requirement and make it optional. Alternatively, we encourage CMS to re-instate the PQRS requirement that physicians reported on a majority of Medicare Part B patients and submitted other payer data as the practice or reporting entity felt was appropriate.

• Ensure Valuable Process Measures are Maintained

Process measures continue to serve a purpose, especially when coupled with cost, because it is often the breakdown in a process that contributes to poor outcomes and increased resource use. Under the current MIPS structure, it may appear that quality process measures do not hold much value because the quality category forces physicians to pick random measures that may or may not align with a clinical end goal. However, if the MIPS program was structured to allow physicians to focus on a targeted clinical or disease area, such as preventing diabetes and the measures correlated with the clinical episode, process measures would be seen as more valuable. We refer CMS to the Quality section, Instituting Clinical Continuums of Care, for more details on creating a unified MIPS program.

• Make Outcome/High Priority Measures Optional

Mandating that physicians report on an outcome measure, or high priority measure if an outcome measure is not available, may disadvantage certain specialties as well as rural practices and practices that treat high risk patients. As the AMA highlighted in previous comment letters, there are a number of methodological issues that must be addressed before requiring reporting on outcome measures, such as the development of better risk-adjustment models at the measure level (not just the program level as proposed) and stratification by specialty.

In addition, infrastructure challenges may prevent physicians from having the ability to report on outcome measures, such as not having appropriate data elements in the EHR. Practices may also experience interoperability issues that may interfere with the exchange of information needed to report outcome measures, or may be unable to do longitudinal tracking due to the lack of uniform patient identifiers and patient attrition when tracking outcomes.

We also remind CMS that under the current scoring rules practices that report through the web-interface, which are primarily large practices, automatically satisfy the full reporting requirements and automatically receive extra points for reporting on numerous outcome and high priority measures. Essentially, CMS has developed a program in which web-interface participants will most likely perform better than non-web interface participants. Unfortunately, the web-interface reporting method is not applicable to all practices because the measures are primary care/internal medicine focused and practices must have a sufficient sample of patients to be eligible to report through web-interface. CMS has also maintained more consistency and stability with the web-interface measures than with measures available through other reporting methods, which further increase a practice's chance of scoring well when reporting through the web-interface. Therefore, to make the program more equitable regardless of practice size or specialty, we strongly encourage CMS to make quality reporting more flexible by not requiring the use of any specific type of measure. Instead, CMS should recognize the importance of these measures through bonus points rather than a mandate. 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.

• Eliminate the All-Cause Hospital Readmissions (ACR) Measure

MACRA allows for the refinement of existing measures and program adjustments to avoid using inaccurate ways of assessing physician performance. We, therefore, have serious objections to CMS continuing to use a problematic VM measure, the ACR measure, in the MIPS quality category. Reclassifying the measure as a "population health measure" under the quality category does not fix any of the inherent problems with the measure and limits CMS' ability to create an improved, equitable MIPS program. Specifically, MACRA section 1848(q)(2)(C)(iii) does not require CMS to use global and population based measures but states that CMS "may use" such measures. Given this flexibility and due to the concerns we outline below, we urge CMS not to include the ACR measure in MIPS.

The ACR measure lacks transparent evaluation on whether it is appropriate to use at the physician-level. The AMA is extremely concerned with potential unintended consequences related to the use of the measure at the group practice level (16 or more eligible clinicians) without the proper vetting of the measure's reliability and validity. It remains unclear how CMS determined the reliability of the readmission measure at the physician level and there is not enough information in the 2017 or 2018 QPP rules or the VM quality and resource use reports (QRURs) to ensure that physician performance is accurately represented, even when applied only to practices of 16 or more eligible clinicians.

Furthermore, the continued lack of sociodemographic factors in the risk adjustment model is concerning and could lead to potential negative consequences. When the measure was used in the VM, practices that served a higher number of patients with social risk-factors were more likely than other practices to have

received a negative adjustment.^{7,8} If the ACR measure remains in the MIPS program, the measure may create inequities rather than enhancing quality of care. The Institute of Medicine (IOM) Committee on Accounting for Social Economic Status (SES) in Medicare Payment Programs has recently outlined concerns that decreased payments, particularly for those physicians caring for patients who are socially at-risk, could lead to underinvestment in the quality of care and that maintaining the status quo will introduce new ills into the healthcare system, as opposed to improving care.⁹

If CMS retains the measure, we urge CMS to perform additional analysis that demonstrate the following:

- Assurance that there are demonstrated structures and processes that physicians can complete in order to improve patient outcomes.
- Identification of possible attribution models, and testing of each, to determine the impact on performance scores and how each model affects reliability and validity of the measure. To date, CMS has not been transparent regarding how it selected current attribution models.
- Exploration of how sample size/minimum number of cases (along with the attribution model) impact the reliability and validity of the measure and provide this information for more than one case size. For instance, publicly stating that a measure met 0.4 reliability using 25 cases is not sufficient.
- Determination of the usefulness and usability of the measure for improvement purposes, particularly if claims are used. The National Quality Forum (NQF) under-emphasizes this important point during its reviews, but it is a critical question that should be answered before this measure or any administrative claims measure is implemented in MIPS or other federal programs.

The recommendations for improvements are also applicable to other administrative quality measures, such as the repurposed Inpatient and Outpatient quality measures CMS is developing under contract.

If CMS continues the use of the ACR measure, at a minimum physician or group performance should not affect payment or be publicly reported unless a reliability of 0.80 can be demonstrated and the risk adjustment model is developed, tested, and released for comment prior to implementation.

• Expansion of Administrative Claims Quality Measures

CMS has been working with numerous contractors to develop and expand the suite of administrative claims quality measures to incorporate into MIPS. However, we remain extremely concerned because there does not appear to be a clear strategy or direction of how the measures would fit into the quality category and the overall MIPS program. It appears CMS is trying to take a one-size fits all approach with the development of these measures as opposed to continuing on a path that is more tailored to individual

⁷ 2015 Value Based Payment Modifier Program Experience Report. Center for Medicare and Medicare Services. June 16, 2015. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2015-VM-Program-Experience-Rpt.pdf

⁸ 2016 Value Modifier Overview Memorandum. Center for Medicare and Medicaid Services. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2016-VM-Overview-PDF-Memo.pdf

Ommittee on Accounting for Socioeconomic Status in Medicare Payment Programs. Accounting for Social Risk Factors in Medicare Payment- Report IN BRIEF. Institute of Medicine. July 2016. http://nationalacademies.org/hmd/~/media/Files/Report% 20Files/2016/Medicare-SES-3-RIB.pdf

physician specialties and practice sizes. These measures may also increase the complexity and administrative burden placed on physicians.

While the AMA understands CMS' desire to measure and track quality and costs associated with the health of a population, we do not believe creating a suite of administrative claims quality measures is the answer. The MIPS program, with its various reporting requirements, already measures the health of a defined population for whom a physician or practice provides continuous care. We expect and anticipate that a more holistic view of population health will become more evident as the number of specialty specific measures, especially those captured through QCDRs, grows. These measures are implemented to measure the performance of a specific clinical condition, often within 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 CMS sees the need to modify existing population health, inpatient, or outpatient measures.

In addition, just because a measure is calculated through claims does not mean there is no administrative burden on physicians. Physicians must still track the information and implement many necessary changes based on the measures. Adding to this complexity CMS' data feeds are insufficient. It is not until six months after the close of the reporting period that a physician may learn how they performed on an administrative claims measure.

It is also our expectation that any administrative claim quality measure developed today and used in the future will have to be re-specified to accommodate the new patient relationship categories and codes to account for clinical and social risk factors. Based on our interactions with CMS' contractors working on the new administrative claims measures, it does not appear this work is being addressed.

We are also concerned with what may be considered a minimum patient sample and threshold for reliability. If CMS moves forward with additional administrative claims measures, the **measures**, **including global and population health measures, must meet a reliability threshold of 0.8 at the individual physician and group level before a physician or group is held accountable for the measure.** When applied at the group level, CMS must also test whether the specific size of the group meets the 0.8 reliability threshold. A lack of reliability in the data and minimal variations in care can lead to incorrectly categorizing and penalizing physician performance.

• Delay "Topped Out" Measure Removal Process and Remove Point Cap

The AMA supports CMS' phased-in approach for removing topped out measures from MIPS, however, we do not support CMS' proposed timeline for classifying measures as "topped out" or its proposal to cap achievement points for such measures at six points. CMS' current strategy bases performance scores and benchmarks on data that may or may not have sufficient sample sizes and utilizes PQRS reporting rates as a starting point. PQRS had low participation rates, and it is questionable whether the numbers represent a true indication of quality. MIPS should be based-off of MIPS reporting, not a program that sunset in 2016. Beginning the phased-in removal of "topped out" measures with only one year of MIPS data is also problematic due to the 2017 transition year. Because of the pick-your-pace approach used in 2017, year one data may not be representative sample of how physicians are actually performing on quality measures. CMS has already removed a significant number of measures under MIPS, particularly measures available under the claims and EHR reporting methods, and we continue to

remain concerned that removing and capping measures too soon may lead to a gap within the measure portfolio.

The AMA does support the removal of measures when clinical evidence has changed, but we are concerned with the potential future gap that will be created by solely relying on benchmark data, without consideration of clinical factors, scientific evidence, and the importance of a measure. More research also needs to be done to determine the appropriate sample size for each quality measure before a quality measure can be determined to be "topped out." The following are two examples of measures that are listed as "topped out" and subject to special scoring rules starting with the 2019 performance period based on an extremely limited sample of 2015 PQRS participants:

- Measure 71: Breast Cancer: Hormonal Therapy for Stage IC—IIIC Estrogen
 Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer—105,690 EPs were eligible to
 report on the measure in 2015. However, only 839 EPs satisfactorily reported on the measure
 (less than 1 percent).
- Measure 109: Osteoarthritis (OA): Function and Pain Assessment—207,389 EPs were eligible to report on the measure in 2015. However, only 1,723 EPs satisfactorily reported on the measure (less than 1 percent).¹⁰

We are concerned with CMS' blunt approach to removing "topped out" measures, and offer the following recommendations to improve this process:

- Prior to removing any "topped out" measures, CMS should review measures to determine if they are tied to our nation's most important "Vital Signs" as described by the National Academy of Medicine in its report with the same name. This will ensure that key measures that help improve health and monitor the health of the nation will not be removed.
- Process measures that are proximal to an outcome and for which there is strong evidence that fulfillment of the measure intent, such as providing or not providing a specific treatment, will improve patient outcomes should be retained. The unintended consequences of removing key "topped out" measures are unknown. If a "topped out" measure directly impacts outcomes and is no longer reported, could its removal cause negative effects on patient care? CMS should exercise caution in measure removal until possible unintended consequences of removing each measures have been explored.
- Analysis: Physician performance can vary by practice setting, patient population, geography, years in practice, volume of cases of a particular condition, or how long the physician has been reporting. CMS must examine the breadth and depth of reporting based on the number of physicians who successfully report on a measure. CMS must examine the breadth and depth of reporting based on the number of physicians who successfully report on a measure and the length of time a measure is reported on within a given performance year.
- *Performance Results:* Performance results of a measure that is being considered for removal should be examined for any evidence of variation among subgroups defined by the above factors and other nonclinical factors.
- Reporting Options: Do not remove or classify a measure as "topped out" until it is "topped out" across all reporting options.

¹⁰ 2015 Reporting Experience, Including Trends (2007-2016), Physician Quality Reporting System. 2015 Appendix. Center for Medicare and Medicaid Services. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html. Accessed Aug. 01, 2017.

- Data Sources: One potential way to see if the numbers are reflecting true performance is to compare it to other current data. For example, if a study or clinical registry shows that there is still a gap in care, then the performance scores in MIPS may not reflect performance across all physicians. The results of these subgroup analyses should also be shared with the relevant stakeholders.
- Small Sample Size: CMS has a history of removing measures that have low reporting rates without necessarily considering the specialties that might use them. For example, some measures may only be reported by a small number of clinicians, such as pediatric specialists, and yet that small number represents a significant percentage of those caring for the patients to which the measure applies.
- *Public Health:* We recommend keeping measures that track performance on major public health issues such as tobacco use and counseling, screening for alcohol use, prediabetes, hypertension, opioid use, immunizations, and hepatitis C.
- Measures Used in Other Programs: There are many health plan-level measures that are part of
 the Medicare Advantage Star Ratings system that are reliant on clinical action. To ensure
 compliance, the private plans incorporate them into physician contracts. For purposes of
 alignment, CMS should evaluate how physician measures may relate to other quality programs.
 Therefore, CMS should consider alignment across other program when deciding whether to
 remove or retain certain measures.

Furthermore, CMS should not penalize physicians for reporting on "topped out" measures by capping the number of achievement points at six. Physicians should be eligible to earn maximum achievement points for reporting such measures until a measure is removed. As stated in our section on Physician Compare and Quality Scoring Benchmarks, CMS should explore using the ABC methodology to evaluate measures that may not have much variation in performance. Capping achievement points adds to the complexity of scoring and ignores that there are multiple factors that go into the decisions physicians make for reporting on specific measures. It also ignores that CMS is making classifications on measures based on extremely faulty data with low reporting rates.

• Delay Removal of Measures

CMS specifically seeks comment on the best timeline for removing non-outcome and outcome measures that do not have adequate reporting (either by physician or cases). The AMA believes that the MIPS program is too new to know what measures will be the most relevant to individual physicians and groups. CMS should not consider removing measures with inadequate reporting until after physicians have a few years of experience with the program. At a minimum, a measure should be in the program for three years before it is proposed for removal, but not until the program is more mature.

• Provide Further Analysis on Benefits of Expanding Patient Experience Data Available for CAHPS for MIPS Survey Measure

Based on CMS user testing with patients and caregivers for the Physician Compare Web site, CMS found that users regularly ask CMS for more information from patients similar to themselves, such as patient narratives. Therefore, CMS is seeking comment on the expansion and feasibility of the survey to include patient narratives. Generally, it appears that collecting open-ended questions may provide valuable feedback to physicians for quality improvement purposes, but we believe it is premature to move to publicly posting patient narratives in-conjunction with CAHPS for MIPS survey data. The Agency for

Healthcare Research and Quality (AHRQ), the entity responsible for administering CAHPS, has just started the initial work to determine the feasibility of data collection and the numbers of those surveyed remains small. To date, AHRQ has only tested the open ended questions or patient narratives using an existing Internet Panel and tested in Massachusetts and California. A subgroup (332 members) of the Internet Panel completed the narratives, but the entire Internet Panel consists of more than 60,000 households considered representative of the U.S. population in demographics and health status. Of those surveyed, 80 percent of the surveys were completed online with the remainder completed by phone. Based on the pilot, AHRQ determined the following:

- Commentary that was more positive was associated with higher scores on the doctor communication composite, access composite, care coordination composite, global ratings of the provider and a greater willingness to recommend the provider.
- Race/ethnicity, gender and education background were not associated with the overall variance of
 patient narratives; older patients and those with better self-rated health were more positive in their
 narratives.

The pilot, particularly in Massachusetts, identified the following challenges. 12

- The need to collect this information electronically, which requires a process to store and maintain up-to-date email addresses while also protecting patient information.
- A systematic process to analyze the narrative feedback is required.
- How to report this information to providers in a user-friendly way.
- The need to determine how to integrate this information into quality improvement efforts effectively.

Due to the identified challenges, additional research is needed to explain the reasons for variations among patients, especially more complex and sick patients. The analysis performed was also on an extremely small sample, so it is premature to make a generalizable statement and for CMS to move to implement the patient narratives in a national program. It also remains unclear how the data will be used because posted protocol on the CAHPS database on AHRQ's website states that AHRQ has no plans at this time to accept submissions on patient narratives, nor is there an explanation offered by CMS or AHRQ on how narratives will be assessed/scored and by whom. We suspect collecting this additional information will be costly, creating an added expense practices will have to consider if they would like to continue to report the CAHPS for MIPS measure. Therefore, it is too early to support the expansion of the CAHPS for MIPS measure without more testing and explicit information on how the information will be used and the purpose of collecting and publicly posting the information.

• Remove Limitations on QCDRs

Since the passage of MACRA, CMS has routinely stated that it wants to encourage reporting through QCDRs given their potential for advancing quality care. Specialties are currently spending millions of

¹¹ Grob R., Schlesinger M., et al., Breaking Narrative Ground: Innovative Methods for Rigorously Eliciting and Assessing Patient Narratives. *Health Serv Res.* 2016;51:1475-6773.

¹² Introducing a Protocol To Obtain Patient Comments Using the CAHPS Clinician & Group Survey (Webcast). Agency for Healthcare Research and Quality. Jan. 26, 2017. https://www.ahrq.gov/cahps/news-and-events/events/webinar-012617.html. Accessed Aug. 10, 2017.

dollars to further develop QCDRs to allow physicians to receive more timely and relevant feedback and benchmark information. In addition, QCDRs enable physicians to report on quality measures that are robust, outcome oriented, and more applicable to a physician's patient population compared to traditional MIPS measures. We are therefore concerned with CMS' recent direction related to the approval of QCDR measures since it severely limits their flexibility. The following are complaints the AMA has heard from specialty societies on this issue:

- Inconsistent Feedback and Decisions: Specialties have received conflicting responses and decisions from QPP contractors and staff during the QCDR review process in regards to their measures.
- Impractical Timelines: CMS has frequently set unreasonable deadlines for specialty QCDRs to make changes to measures or replace certain measures. For example, CMS asked one specialty QCDR to combine two measures within a single day. CMS asked another specialty QCDR for additional information on five measures with a one-day deadline even though the QCDR steward already asked CMS for feedback on these measures in the months prior.
- Lack of Rationale for Rejected Measures: CMS has repeatedly rejected measures without providing sufficient rationale. It appears CMS reviewers did not understand the clinical rationale behind some of the measures, but never asked for clarification. For example, one of the rejected measures involved peripherally inserted central catheter (PICC) placement in patients with Stage IV or V renal disease. CMS did not give a reason for rejecting this measure, and it is unclear why the measure would be rejected since it important for an interventional radiologist that placement of such catheters into peripheral veins should be avoided in patients who require a fistula or graft for optimizing safety. Another specialty reported that three approved measures were missing from the public posting for the QCDR. Upon inquiring about the status of the measures, CMS said they were either rejected or still under review. Shortly afterwards, CMS told the QCDR that the measures were denied for being "low bar" without any additional details or warning.
- Inappropriate Measure Consolidation: CMS has rejected, opposed, or required consolidation of measures that appear too similar to existing MIPS measures. However, frequently when measures have similar description, they are actually quite different based on the nature of the condition and/or area of the body affected. In addition, harmonizing QCDR measures does not ensure accurate benchmarking. In theory, harmonizing measures for use in the public domain facilitates cross-cutting comparisons. However, harmonizing quality measures across registries alone does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation, including the lack of standardized data definitions, standardized risk-adjustment/data analytics, inconsistency of data ascertainment methods and lack of common normalization methods. For more details, please see our quality benchmark section under Quality Scoring.
- Lack of Responsiveness/Communication: One specialty QCDR reported that it gave CMS edits to
 the final QCDR posting to ensure correct measures were listed. When the postings were
 published, the member noticed that CMS ignored several of the corrections made to the posting.
 Specialty QCDRs also report receiving contradictory emails about whether CMS approved or
 denied measures.
- Other QCDR Approval Issues: Specialty QCDRs also expressed concern during the 2017 QCDR measure review process on the effect of "topped out" measures, inappropriate measure consolidations, approval time for new MIPS measures, provisional measure approval, and limitations due to the 30 non-MIPS measures cap.

We offer the following suggestions to improve the process:

- Assign a single point of contact to each QCDR to reduce communication breakdowns and conflicting messaging.
- Set up a review process where CMS and its contractor consult with appropriate physician experts and QCDR stewards to ensure sufficient clinical expert review and reduce confusion around the importance and relevancy of a measure. One entity suited to do this is the National Quality Registry Network® (NQRN) through the Physician Consortium for Performance Improvement (PCPI®), of which the majority of specialty society QCDR stewards are members. Importantly, PCPI® membership, and participation in NQRN®, is open to a broad range of healthcare industry stakeholders who would contribute their diverse and well-informed perspectives to the QCDR review process. The NQRN® is a network of individuals affiliated with PCPI® member organizations that are operating, planning, or otherwise interested in registries; using information from registries to improve patient outcomes; and providing technology and infrastructure e.g., registry platforms, data standards. The PCPI ®QCDR committee is another forum for addressing common issues.
- Set up a system to properly record and track ownership rights, including making ownership information CMS collects available to QCDRs to better facilitate sharing of QCDR measures between QCDR stewards.
- Provide clarification from CMS regarding what form of proof must be submitted to show permission to use another QCDR's measure.
- QCDR self-nomination application and materials should be updated to outline all of the information needed to determine QCDR status to avoid delays and misunderstandings.
- Increase the length of the QCDR approval from one to two years for QCDRs in good standing. Even with the proposed simplified self-nomination process, it is still administratively burdensome to report changes to CMS on an annual basis.
- If a measure is provisionally approved and CMS must receive data, allow for the QCDR to collect such data for at least one full year. Therefore, measures provisionally approved for the 2017 performance period would be submitted with the 2019 self-nomination application.
- The 30-non MIPS measure cap can restrict the ability of QCDRs to report on meaningful subspecialty focused measures. This is particularly limiting for subspecialties that share a QCDR, as each subspecialty is effectively limited to 15 non-MIPs measures instead of 30. CMS should increase the measure cap to 30 non-MIPS measure per subspecialty for all QCDRs.

We urge CMS to work with the specialty society QCDR stewards to further improve the process and ensure a viable and private sector run innovative reporting option. If changes are not made many specialty QCDRs have stated that they may not continue to seek QCDR status because of the escalating administrative burden required to participate on a long-term basis. QCDRs are successful in improving quality because physicians recognize that QCDR measures are meaningful to the profession and improve patient care, even though participation may cost in the hundreds to thousands of dollars.

Remove Testing Data Requirements for Measures Under Consideration and QCDR Submission

The AMA is concerned with recent changes to CMS' policy on testing data related to the 2017 Annual Call for Measures. We have heard from stakeholders that CMS implemented a policy change to require testing data at the time a measure is submitted. Stakeholders have reported that CMS did not provide

advance warning of this policy change, and measure developers only discovered the new requirement after their measures were rejected by CMS. As part of measure rejection notice, CMS referred stewards to an obscure web link that is not easily searchable on the CMS website, not listed on CMS' JIRA website, and not included as part of the quality measure submission notice. Historically, CMS encouraged developers to submit their measures without testing data due to the time between when a developer must propose a measure for use in a CMS quality program, and the time the measure is finalized for use in rulemaking. For example, if a developer proposed a measure during the 2017 Annual Call for Measures, it would not be proposed for use until the 2019 QPP. Therefore, the requirement to include testing data is a departure from previous policy and is creating confusion among measure stewards.

The AMA recognizes the value in testing data; however changes with the measure submission process must be clearly articulated and released with adequate notice. Measure testing is resource intensive, time consuming and costly. Therefore, CMS must be transparent regarding what is required in measure testing and whether a whether a minimum standard for reliability and validity must be met.

• Institute Clinical Continuums of Care as a Reporting Option

To move to a more unified MIPS program, we recommend and propose that an option for quality reporting is measurement through clinical continuums of care that tracks an episode. This allows for shaping measurement around improving or managing a disease or condition—similar to the concept of measure groups that CMS eliminated in 2017. For example, there were measure groups that revolved around cataract or colonoscopy procedures. Under the measure group option, the groups became problematic once CMS started incorporating unrelated measures into the individual measure groups outside of the original developer construction.

Under the current MIPS quality structure, CMS utilizes specialty measure sets, which still forces physicians to pick random individual measures and lumps a specialty together, regardless of subspecialization. When you tie this to cost/an episode it does not ensure that the specialty set matches up with the episode and can appropriately evaluate potential for stinting on care to appear low cost. Many QCDRs also operate through clinical continuums of care and, with the right signal, specialty QCDRs could further move in this direction. Our proposal also makes the transition to APMs easier since many of the APM proposals are focused on episodes. It also assists with re-designing ACI because continuums of care can be used as use cases. Even with this more comprehensive approach, initial coordinated measure sets will not be relevant for every physician, but at least it will move MIPS in a direction that is more thoughtful and patient centered. A patient can more easily use the continuum of care to evaluate a physician in relation to how well they treat a particular disease or condition. The AMA welcomes the opportunity to discuss this proposal in more detail.

Scoring the Quality Performance Category

• Expand Protections for Reporting on New Measures

To encourage reporting on new measures, CMS should institute protections to ensure that physicians are not penalized for reporting on new measures. Under the current scoring criteria, CMS does not create a benchmark or provide associated achievement points on a measure until after receiving first year data. If CMS cannot create a benchmark because less than 20 physicians report on the measure the maximum

amount of points a physician can earn for reporting on the measure is three achievement points. The AMA has heard from physicians that they are discouraged from reporting on new measures because of the scoring rules. CMS is also contradictory in its statements because, on the one hand it caps achievement points on "topped out" measures at six points to encourage reporting on new measures; however, a physician may potentially only earn a maximum of three points for reporting on a new measure. To encourage reporting on new measures, we recommend that CMS automatically award maximum achievement points for reporting on new measures as long as the physician meets CMS' data integrity requirements.

Score Outcome Measures and High Priority Measures Equally

Under the current scoring rules if a physician reports on additional outcome measures they receive two achievement points, but if a physician reports on additional high-priority measures they only earn one achievement point. The inconsistency between the scoring rules is confusing, and CMS does not clearly distinguish the difference on the QPP website. Outcome and high priority measures are classified in the same category on the QPP website, and both are designated as high priority measures. In addition, to fully satisfy the quality requirements, a physician must report on an outcome measure. If they do not believe there is an applicable outcome measure for their practice, and they pick a high priority measure as an alternative, they are penalized in their scoring. To simplify the rules, CMS should make outcome measures and high priority measures optional and award bonus points to encourage and recognize the additional work that goes into reporting these measures. Regardless of whether CMS maintains the outcome measure requirement, outcome measures and high priority measures should be scored the same. Physicians should receive two achievement points whether they report on an outcome or high priority measure.

• Remove Point Limits on "Topped Out" Measures

As we stated earlier in our comments, we are concerned with CMS' scoring rules for measures it considers "topped out." CMS is essentially punishing high achievers by limiting the maximum number of points a physician can receive by reporting on a "topped out" measure. CMS' own analysis highlights that over half of the quality measures currently proposed for the MIPS program is considered "topped out," raising the concern that most physicians will be unable to achieve the highest scores possible in the Quality component of MIPS. This is especially problematic given the significant weight placed on the quality performance category. CMS also assumes that, when a measure is reported in the 95 percent range, that it no longer encourages quality improvement. The AMA is concerned that CMS is overly scrutinizing physicians and arbitrarily assigning a poor quality designation when a difference between physicians' quality data may be less than one percent. We urge CMS to remove the six point cap on achievement points for reporting on "topped out" measures.

• Improve Quality Benchmarks

The AMA is extremely concerned with the lack of transparency in the methodology used for creating each quality measure benchmark. It appears benchmarks for 2017 MIPS were created using data from a small number of physicians and it is not clear whether the scores truly reflect performance. The benchmarks were also developed based on 2015 PQRS reporting data and if CMS follows the same timeline, 2018 MIPS benchmarks will be based off of 2016 PQRS reporting data. Increasing the low volume threshold, which the AMA strongly supports, could also have an impact on MIPS benchmarks

because a greater number of physicians would be exempt from MIPS, but might be included in the benchmarks developed using previous PQRS data. For example, as communicated to us by the American College of Gastroenterology (ACG) and American Society for Gastrointestinal Endoscopy (ASGE), the decile breakdowns for the adenoma detection rate (ADR) measure #343 are inconsistent with current evidence. The recommended performance targets for identification of one or more adenomas is 25 percent (men and women combined age > 50 years undergoing screening colonoscopy). The recommended performance targets for ADR were increased after observations suggested that raising the ADR target above 20 percent for a male/female population might have benefit, but evidence that increasing the target results in either improved cancer prevention or increased detection of advanced lesions has been lacking. The tables below show the CMS-derived 2017 Quality Measure Benchmarks for the ADR measure #343 and the ADR measure reported to (GI Quality Improvement Consortium) (GIQuIC) American College of Gastroenterology-American Society for Gastrointestinal Endoscopy-Qualified Clinical Data Registry(ACG-ASGE QCDR). The decile ranges for the GIQuIC measure is what ACG-ASGE expects, which raises additional concern with the validity of the decile ranges for measures #343.

Screening Colonoscopy, Adenoma Detection Rate (#343)

Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 10
29.63 - 38.09						>= 80.33

Adenoma Detection Rate (GIQuIC 1)

Decile 3	Decile 4	Decile 5	Decile 6		Decile 8	Decile 9	Decile 10
	32.19 - 35.75	35.76 - 38.80		41.93 - 45.74		49.30 - 54.69	>= 54.70

In an effort to help CMS achieve its goal of better measure harmonization, the ADR measure in GIQuIC will be recognized as measure #343 for the 2017 MIPS performance year. In light of this new harmonization change and because of the significant discrepancy in the decile ranges for measures #343 and GIQuIC, physicians reporting measure #343 through GIQuIC will be disadvantaged when data from GIQuIC participants are combined with clinicians who are reporting measure #343 through another registry or QCDR.

The American College of Surgeons (ACS) has also noted benchmark and scoring discrepancy. When they harmonized the surgical site infection (SSI) National Surgical Quality Improvement Program (NSQIP) measure with the CDC National Healthcare Safety Network (NHSN) SSI measure results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry participants. Through further study, ACS found that this discrepancy was not because NSQIP participants had poorer surgical outcomes, but due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP. ACS also found that standardized risk-adjustment methodologies are critical when comparing clinical outcomes across different registries/cohorts. For example, in the ACS

Surgeon Specific Registry, unadjusted SSI PQRS measure rates were compared to the risk-adjusted SSI PQRS rates and ACS found that approximately 50 percent of cases were misclassified when risk-adjustment was not performed. To improve the benchmarks CMS should continue to stratify benchmarks by reporting mechanism but further delineate benchmarks by the registry and QCDR mechanism. Further stratifying registry and QCDR data will improve the validity of the benchmarks. We also urge CMS to consult with specialty societies and measure stewards when developing quality measure benchmarks to ensure the measure's clinical recommendation statement in relation to that measure's decile ranges are appropriate.

The following are additional issues that could lead to unreliable benchmarks that CMS should consider:

- It is unknown how many physicians attempted reporting on a measure but had their data removed due to lack of data completeness (physician reported less than 20 patients) or zero percent performance.
- The number of physicians whose data is included in the benchmarks for each reporting method. If the "n" on some of the benchmarks is only 20 physicians while others are 1,000 it will most likely impact the reliability of scores, especially if CMS moves to measure improvement.
- It is unclear how valid the performance scores are within each of the benchmarks. For example, are some of the lower rates for the EHR reporting option due to the poor data quality and not due to actual performance by physicians?

It is worth noting that EHRs do not uniformly calculate electronic Clinical Quality Measures (eCQMs) measures across vendors and practices due to the lack of specificity within CMS' Implementation Guides. Incorporation of data requires the development, maintenance, and refinement of administrative codes such as the International Classification of Diseases (ICD), Current Procedural Technology (CPT®) and clinical vocabulary standards such as SNOMED Clinical Terms® (SNOMED CT®), Logical Observation Names and Codes® (LOINC) and RxNorm. Creating standards and mapping tools will facilitate working across these different codes and ensure consistency when data is exchanged. The AMA, through CPT®, is participating in activities to support ontological structures that will provide pathways for better data collection and analytics. We encourage CMS to incorporate this work into its implementation guides to ensure eCQM calculations and benchmarks are accurate and that EHRs are accurately capturing eCQMs.

• Benchmark Stratification by Practice Size, Specialty, or Site of Service

CMS is also interested in whether benchmarks should be further stratified by practice size, practice mix, or site of service. The AMA does not believe stratifying by practice size, practice mix or site of service is necessary for process measures. For outcome and intermediate outcome measures there may be value in some form of stratification. As data improves, CMS may want to consider stratifying benchmarks based on social risk factors within a community. Resources that are available within a given community may impact patient compliance and outcomes.

Consider Alternatives to Benchmark Methodology

As noted in the Physician Compare section of this comment letter, CMS' methodology for creating the MIPS benchmarks and calculating achievement points might conflict with the ABC methodology used to determine Physician Compare star ratings. Differences in the methodologies include how the top decile

or benchmark is determined and how performance is distributed across the deciles. In addition, the MIPS benchmark methodology uses a ten point achievement scale versus the star ratings methodology which uses five stars.

It is difficult to analyze how these two methodologies would affect physician scores due to the lack of access to data. It is unclear whether any change to the quality measure benchmark methodology would significantly affect physicians' scores, but we urge CMS to further explore this issue. For some measures, it may not make a difference, while for others it could potentially have a large impact on how many points a physician or practice could achieve. **To illustrate our concerns please see Appendix A**.

• Make Incentives to use CEHRT More Flexible

To encourage the use of CEHRT for quality improvement, CMS provides bonus points if a physician meets CMS' "end-to-end electronic reporting" standard when reporting on an individual measure. The bonus is available to all submission mechanisms except claims. However, to achieve the bonus points on an individual measure, a physician must have the ability to: 1) record a measure's demographic and clinical data elements in CEHRT; 2) electronically export data to a third party or transmit data electronically directly to CMS; and 3) the third party can perform operations (e.g., aggregate, calculate, filtering) and submit data electronically to CMS. Essentially, for a physician to meet the bonus point requirements, data must always be managed electronically. Hand keying data into a registry's web portal would not count.

We support awarding a bonus point to encourage electronic reporting; however, given the high costs and limitations of today's EHRs, we are highly concerned that this incentive undervalues the usefulness of registries. Many registries still rely on both automated and manual data entry. A large percentage of 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. While end-to-end electronic reporting is a goal for many registries, it is essential that CMS does not place too much value on purely end-to-end reporting. Rather, CMS should reward physicians for utilizing registries, leveraging electronic capture, reporting meaningful data, and using alternative methods to report data when they are more efficient. We caution CMS from incentivizing end-to-end reporting simply because it bypasses a manual data entry step.

In the spirit of incentivizing the reporting through electronic sources and following the intent of the law, a physician should have the ability to report a mixture of eCQMs and chart abstraction, and such actions should be rewarded regardless of whether they are considered to be completely "electronic" from end-to-end.

For comments on measuring improvement in the Quality Performance Category, please refer to the scoring section.

Cost

Over the past year, CMS has taken a number of important steps to improve its ability to fairly and accurately measure and compare physician resource use. The AMA greatly appreciates the agency's efforts to increase clinical input into the development of new measurement tools such as patient relationship categories and episode-based measures. **Recognizing that more time is needed to complete**

this very important work, we also strongly support the proposal to keep the weight of the cost category at zero and believe that the weight of this category should remain at very low levels for at least three more years.

• Weighting the Final Score

In proposing to reduce the cost category weight for the 2018 performance/2020 payment year to zero rather than previously finalized 10 percent, CMS says it is acting out of continuing "concerns about the level of familiarity and understanding of cost measures among clinicians." The agency further notes that taking an extra year to prepare for implementation of the cost category will give it time to educate physicians about cost measurement and to develop new measures that are based on episodes of care and have involved significant input from physicians and other clinicians. CMS, however, worries that this will create a "sharp increase" to the MACRA-required weight of 30 percent in 2021 and is therefore seeking comments on the relative merits of a zero versus a 10 percent cost category weight.

The AMA strongly urges CMS to finalize a zero weight for this category for a second year and concurs that more time is needed to educate physicians about the measures. However, the most important reason for delaying full implementation of the cost category is the current lack of any reliable and valid cost measures. It will take longer than a year to produce, test and refine enough appropriate cost measures to cover large percentages of physicians and then educate physicians about them. Also, although CMS says the clinicians it spoke to agreed that they could be ready for a 30 percent cost category by the third year of MIPS, we wish to emphasize that the AMA does not believe, and has never said, that.

• MIPS Measures

For the second MIPS year, CMS proposes to continue using the two cost measures (Total Cost of Care and Medicare Spending Per Beneficiary) carried over from the value-based modifier. In the meantime, a CMS contractor (Acumen LLC) is working on improvements to the two VBM measures and is also overseeing the development of new episode cost measures being constructed with the input of expert clinical panels. An initial wave of five to ten episodes will be tested using Medicare claims data to calculate costs per episode for individual physicians who will then be shown their results and asked for feedback on the episodes. Additional panels and waves of episodes would then follow. Despite a diligent effort by Acumen and the clinical teams, however, it seems highly unlikely that a large number of episodes will be completed and thoroughly tested even by the end of 2019. In fact, the rule specifically observes that although CMS "will endeavor to have as many episode-based measures available as possible for the proposed 2019 MIPS performance period," staff is "unable to provide a list" of measures that might be included.

AMA has repeatedly urged CMS to retire the Total Cost of Care (TCC) and Medicare Spending Per Beneficiary (MSPB) measures from use in physician cost measurement. Both measures hold clinicians responsible for total Part A and B expenditures, including costs that the physician had no control over and that may even have occurred before the physician ever saw the patient. As a result, the measures are largely irrelevant to many physicians and inapplicable to others. The MSPB measure fails to adjust for physician specialty or type of service despite the fact that CMS previously determined that specialty adjustment is an important factor in evaluating cost. The TCC was never endorsed by the National Quality Forum which questioned the measure's validity and its method of attributing costs.

We are pleased that CMS is pursuing improvements in the TCC and MSPB measures but until that work has been completed, tested and validated, neither should be used in any way that would affect physicians' Medicare payment rates. We also continue to believe that appropriately-designed episode cost measures have the potential to measure costs more accurately and agree with CMS that the eight episodes finalized for use in the 2018 performance year should be replaced with episodes that have had more clinical input. None of these improvements could be implemented before 2019 at the earliest, however, and at least in the case of the new episode-based measures, we believe it will take several years to develop a set of measures that would cover a large percentage of physicians.

Under either a zero or a 10 percent cost category weight, feedback based on the current version of the measures will be of little to no value to most physicians and could even send the wrong signals to some. To base 10 percent of physicians composite MIPS score on these faulty measures would be completely unacceptable. A zero weight in 2018/2020 would protect physicians for one year but do virtually nothing to educate them about their true performance or to ensure their success the following year when CMS says costs must jump to 30 percent of the composite score.

• Scoring the Cost Category

CMS also proposes to calculate both an achievement and an improvement score for the cost category. Achievement would be based on the equally weighted average of any applicable cost measures. Performance benchmarks would not be known in advance of the performance period. No cost scores would be calculated for clinicians or groups that did not meet case minimum requirements or did not have any measures where CMS had enough cases to construct a benchmark. Improvement would be based on a comparison of scores on the TCC and MSPB measures for a given performance year and the immediately preceding performance year, in this case 2018 and 2017. A complicated process that would make comparisons at the measure level and then look at the sum of positive and negative annual changes is proposed for determining improvement. Only positive scores would be recognized and the contribution of improvement to the total cost score initially would be quite limited.

As noted earlier, it is impossible to evaluate this proposal without more information and data regarding the potential number of practices that would receive scores, how different types of specialties and practices are affected, and how changes in the measures from year to year would affect improvement scores. What we do know is that the current measures are flawed so that as has happened with the VM, some physicians may be unduly punished while others are inappropriately rewarded. In addition, low minimum case thresholds and very modest measure reliability means that success or failure may bounce around from year to year.

Also, at a time when cost measurement is still an immature science, changes in the measures and accompanying methodologies such as attribution and case minimums are still occurring on an almost annual basis. While CMS notes that there were no changes in how they calculated MSPB and TCC between 2017and 2018, there were significant changes between 2016 and 2017 when changes were made in the TCC attribution method and the MSPB minimum case threshold. Also, as discussed earlier, CMS is contemplating changes in both of those measures as well as complete replacement of the cost episodes between 2018 and 2019. Continual updates of "specifications, risk adjustment and attribution" are expected too. We do not see how it will be possible to compare apples to apples and identify improved performance so long as such changes, which in many cases are helpful, are occurring.

• Future Cost Category Policies

The above discussion is why the AMA and other physician organizations are pursuing legislation that would extend MACRA's two-year cost transition period to five years. It is our hope that CMS will support and Congress will adopt this change. As a precautionary step we believe CMS should also consider alternative approaches that, while not ideal, could serve to mitigate some, but not all, of the negative consequences of moving forward with full implementation of the cost category before the necessary measures are tested an in place. As laid out in past comments, we believe policies which should be considered include assigning an average score to all physicians and then awarding bonuses to those who agreed to pilot test new tools—such as episode groups or patient relationship categories—that are being developed to improve cost measurement.

Advancing Care Information

• Finalize Certified Electronic Health Record Technology (CEHRT) flexibility

CMS is proposing to extend flexibility in the use of EHRs by allowing physicians to use CEHRT certified to either the 2014 or 2015 Edition, or a combination of the two, in the 2018 performance year. **The AMA strongly supports this proposal and appreciates CMS' recognition that flexibility is especially necessary to support small practices and solo practitioners.** We also note that this flexibility will provide more time to health IT vendors, particularly lending smaller developers additional time for upgrade development, testing, and certification. These developers often cater to the specific needs of medical specialties, and, without this increased timeline, specialists would encounter a limited number of products available on the market—forcing them to switch vendors and utilize systems that are not suitable for their specialty or patient population.

• Adopt the 2015 CEHRT Bonus

The AMA supports CMS' proposal to offer a bonus for the use of 2015 Edition EHRs. The adoption and implementation of a new EHR, or the upgrade from one edition to another, requires considerable resources and time. This bonus will help recognize physicians' investment in health IT and encourage moving to more advanced technology.

• Finalize a 90-day ACI Reporting Period in Perpetuity

CMS is proposing to maintain a 90-day reporting period for the 2018 and 2019 performance years. This is an appropriate approach—adding flexibility while still providing a "snapshot" of a physician's use of CEHRT. Since the 2014 reporting period, the Meaningful Use (MU) program has operated on a 90-day reporting period, rather than a full calendar year, to accommodate issues with the program. In particular, this shorter reporting period permitted necessary technology updates, system downtime, accommodations to improve usability, and facilitated physicians' transition to new measures and objectives. As we have discussed in past comment letters, reporting the MU/ACI measures for an entire year would hinder efforts to test new technology or ensure the security of health IT.

Accordingly, we recommend that CMS maintain the 90-day reporting period for the ACI category in perpetuity. Our members have expressed a desire for both simplicity and stability in the QPP. We also want to encourage physicians to focus on the use of their health IT tools rather than solely reporting

on measures. A shorter reporting period enables physicians to adopt innovative uses of technology and permits flexibility to test new health IT solutions.

• Add Flexibility to the Base Score

The ACI scoring system, which creates performance and base scores, remains extremely complex and creates significant barriers to achieving CMS' goal of a simplified holistic program. Physicians continue to express concern with the ACI category's pass-fail approach in the base score. Maintaining this rigid structure will increase the risk that physicians will fail the entire ACI component of MIPS. We again reiterate that CMS use the flexibility offered in the MACRA statute and allow for partial credit in the base score.

We do, however, agree that the base score represents the foundation of the ACI category, requiring physicians to initially attest to a measure. This approach reflects CMS' goal of incentivizing physicians to use health IT in a meaningful way, while protecting physicians from unnecessary penalties. To first ensure that MIPS eligible clinicians are focused 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. We do not support a greater base score weight if CMS maintains the pass-fail scoring approach.

• Further Align MIPS Categories

For the 2018 performance year, we urge CMS to consider the challenges facing physicians who are reporting on new measures for the first time. Physicians who adopt 2015 Edition EHRs will encounter measures that require the use of new EHR functionality. While we expect that over time capabilities such as application programing interfaces (API) and patient-facing apps will bolster patient-centered care, the initial use of these functions will be foreign to both patients and physicians and will lead to low uptake—negatively affecting a physician's overall score. CMS should utilize the approach to new quality measures by creating a floor or "hold harmless" provision for new ACI measure performance. This approach will help streamline MIPS categories and will encourage physicians to explore potential in their new EHRs while reducing the risk of penalties.

Achieving CMS' goal to promote the use of health IT to improve patient care will, however, require a reevaluation of the ACI measures themselves. CMS has initiated this by aligning ACI bonuses with the use of CEHRT to accomplish IAs. This approach helps physicians earn credit for the use of health IT—not simply for measurement's sake—but as part of an activity that improves clinical outcomes and patient care. We strongly urge CMS to continue this innovative approach and to extend alignment between ACI, IA, and the quality component of MIPS. For example, physicians who participate in IAs that incorporate aspects of quality improvement, such as participating in a QCDR, and use CEHRT, could be rewarded credit in their quality score. This is the next logical progression in creating a more unified MIPS program.

• Expand the Utility of ACI Measures

To continue down CMS' trajectory of improving the ACI program, CMS should broaden the ACI measures to promote health IT innovation and improve outcomes. Focusing on existing ACI objectives, as opposed to the current prescriptive measure approach, will promote the meaningful use of EHRs rather

than narrowly defining how technology must be used. For example, CMS could create a measure called, "Co-manage care with patient," in which the physician could utilize the view, download, transmit; secure messaging; and/or patient-generated health data (PGHD) functionalities in any combination. This less prescriptive method extends the use of EHRs to real-world patient and physician needs rather than solely for the purpose of measuring, tracking, and reporting.

In addition, given that technology continues to evolve, ACI measures are likely to become quickly outdated or fail to include more innovative uses. Creating broader categories of ACI measures allows patients and physicians to test new uses of technology. These "proving ground" measures should utilize not only CEHRT but health IT that "builds on" CEHRT—a concept taken directly from one of CMS' priorities for new ACI measures. For example, CMS could create a measure called, "Chronic disease management enabled by digital medicine." This measure would allow a physician to use not only emerging CEHRT functionalities, like APIs and PGHD, but could also promote the use of digital health tools, such as remote patient monitoring services. While broadening ACI measures may not be practical prior to the 2019 performance year, adopting our flexibility and alignment suggestions mentioned above would establish a stable glide path towards value-based care models and better position physicians to succeed across the QPP.

• Maximize Support for Small Practices

CMS is proposing a significant hardship for the ACI category for physicians in small practices and would reweight the performance category to zero percent of the MIPS final score. The AMA is very supportive of CMS' proposal to make accommodations for small practices. We agree that there are a number of administrative and financial barriers that small practices would be required to negotiate in order to be successful in the ACI category. We appreciate CMS' sensitivity to this concern and believe this exception will protect many physicians from significant hardship and penalties.

It is important to note that some rural practices often experience many of the same barriers as small practices. These include unique dynamics and challenges such as fiscal limitations and workforce shortages. The effects of these challenges are magnified since rural physicians serve as critical access points for care and often provide a safety net for vulnerable populations. CMS includes both small and rural practices in many of their accommodations proposed to reduce burden, including the low-volume threshold and IA flexibility. However, CMS has neglected to include rural practices in its ACI hardship proposal. We view this as an oversight and strongly urge CMS to include physicians that practice in rural areas as eligible to receive a hardship exception for the ACI category.

However, CMS' proposal that exception applications demonstrate "overwhelming barriers" is counter to CMS' stated goals of minimizing participation burden, fairness, and transparency. We recognize the need for a minimum level of documentation; however, CMS already acknowledges a myriad of issues small and rural practices face when adopting and using EHRs and the potential challenges with ACI requirements. Furthermore, CMS states that it "has taken efforts to review existing policies to identify how to move the program forward in the least burdensome manner possible." Conditioning an exception for small and rural practices with the burden of demonstrating "overwhelming barriers" further complicates the OPP's structure, adds confusion, and does not align with CMS' stated

 $^{^{\}rm 13}$ 2018 QPP Proposed Rule at 30,011.

goals. We recommend that CMS refrain from any application requirement that is not clear, concise, or that detracts from program goals.

We also recommend that CMS consider methods to evenly and fairly distribute the reweighted ACI performance category across the other MIPS components. If CMS' goal is to support small and rural practices and enable them to be successful in the QPP, we caution against forcing physicians to base their success in the program in, essentially, one category. In the spirit of fairness and maximizing a physician's opportunity for MIPS success, we recommend reweighting the ACI component more evenly across both the quality and IA components. As highlighted earlier in these comments, a more balanced reweighting scheme would be based on 65 percent quality and 35 percent IA. We believe this structure still accomplishes CMS' goals of prioritizing quality participation while balancing the flexibility offered with achieving improvement activities.

• Ensure Protections for All Modified EHR Certification Statuses

CMS is proposing to provide an exception for physicians who use CEHRT that becomes decertified under ONC's Health IT Certification Program. CMS' proposal would require a physician to submit an application for an exception and would reweight the ACI performance category to zero. This proposal extends current guidance on decertified CEHRT (as discussed in CMS' FAQ12657), to include ONC's Enhanced Oversight and Accountability (EOA) final rule. The AMA supports CMS' proposal to provide physicians with this exception. We, however, urge CMS to use at least a two-year exemption period and allow physicians to seek additional time if necessary before once again being subject to reporting requirements. In line with our reweighting suggestion above, we similarly suggest that CMS consider a more balanced MIPS score by spreading the ACI performance category across both quality and IA.

In addition, ONC has new authority under the EOA to not only terminate, but also to suspend certification of CEHRT.¹⁵ Suspending certification results only when ONC identifies that certified health IT poses a "potential risk to public health or safety" and notes that those situations "would require immediate action." While certification suspension is under a narrower scope of review than certification termination, issues that warrant a suspension may have major repercussions on physicians' use of CEHRT, and more importantly, on patient care. For instance, ONC may suspend certification if it believes health IT contributes to a patient's health information being unsecured and unprotected, increase in medical errors, or decrease in the detection, prevention, and management of chronic diseases.

While ONC states suspended health IT could still be identified as CEHRT for HHS program purposes (e.g., ACI participation and MU), ONC's suspension rubric clearly outlines the potential risks of using suspended EHRs. Physicians should not be required to use suspended health IT to participate in any federal reporting programs, including the ACI category. The AMA therefore strongly urges CMS to extend their ACI exclusion proposal to cover where certification has been suspended and to provide physicians the same hardship protections proposed for decertified CEHRT.

• Reduce Information Blocking Attestation Requirements

¹⁴ See CMS FAQ available at https://questions.cms.gov/faq.php?id=5005&faqId=12657

¹⁵ See EOA available at https://www.gpo.gov/fdsys/pkg/FR-2016-10-19/pdf/2016-24908.pdf

The 2017 QPP final rule created an information blocking attestation requirement for physicians participating in the ACI category. We agree that information blocking is a major impediment to interoperability and actions should be implemented to limit this behavior. However, as we have stated in previous comments to CMS, data blocking overwhelmingly occurs outside the control of physicians. We recognize that MACRA directs the Secretary to implement a process for physicians to demonstrate that they are not knowingly or willingly blocking information. However, we reiterate that CMS' choice to prescribe a multipart attestation process is overly burdensome and unnecessary—a clearer and more simplified approach should be utilized.

Physicians participating in ACI during the 2017 performance year will be required to attest that they have not blocked information. We have repeatedly sought guidance on this process, especially with respect to a physician's obligation to communicate policy requirements and to obtain adequate assurances from health IT developers. Feedback from our members has highlighted an overall confusion regarding what specifically is required, including what would constitute the proper documentation of the process. We are concerned that without this needed guidance from CMS, physicians may attest to actions their EHR vendors may or may not be performing. Consequently, physicians would be at risk of failing an ACI audit—creating familiar scenarios where physicians' success in an EHR reporting program is tied to the actions of someone other than the physician. Given CMS' lack of guidance to this point, and the constrained timeline left for the 2017 reporting year, we urge CMS to create a broad exception for all physicians participating in the ACI program related to the information blocking attestation. We furthermore request that CMS reevaluate its information blocking priorities given the lack of coordination to date in implementing this policy.

• Finalize the Proposed Definition of "Timely"

For ACI measures that stipulate electronic access to patient information, CMS is proposing to define "timely" as within four business days of the information being available to the physician. The AMA supports this definition and appreciates CMS' proposal to better align ACI measure requirements with those under the EHR Incentive Program. Furthermore, the proposed definition supports physician workflows where patient information may become available to the physician prior to a weekend or holiday. This proposal would allow the necessary time for a physician to review and ensure accurate information is made available to patients.

• Include Exclusions for Electronic Prescribing and Information Exchange

CMS is proposing to add exclusions to the measures associated with the Health Information Exchange and Electronic Prescribing objectives. We echo CMS' concern that, absent these exclusions, some physicians may be unfairly penalized for not meeting ACI base score requirements. We support CMS' proposal to reinstate the low information exchange and electronic prescribing thresholds (i.e., fewer than 100 referrals or transitions of care and fewer than 100 prescriptions) from the EHR Incentive Program into the ACI category. We further support CMS' proposal to allow physicians to select "yes" to the exclusion and submit a null value for the measure in the base score.

• Public Health and Clinical Data Registry Reporting

CMS is proposing to allow physicians who are in active engagement with a specialized registry to be counted for purposes of reporting the Public Health Registry Reporting Measure or the Clinical Data

Registry Reporting Measure. CMS seeks to continue encouraging physicians to engage in public health and clinical data registry reporting. The AMA appreciates CMS' intent to encourage registry reporting and supports CMS' efforts to add flexibility in meeting ACI registry measures. However, we have identified an issue that, if modified, could further CMS' goals of encouraging registry reporting while also reducing burden.

CMS proposes to require physicians to demonstrate active engagement as described under active engagement option 3: production in the 2015 EHR Incentive Programs final rule; meaning that the physician has already completed testing and validation of the electronic submission and is electronically submitting production data to the public health agency or clinical data registry. Proposing to require a production level of registry exchange based solely on the *electronic* exchange ignores the realities of registry reporting. We also note that CMS has leveraged "end-to-end" electronic registry reporting as a prerequisite for bonuses. As we have highlighted in previous comments, registries can play an important role in quality improvement but also can require a granularity of patient data that is not easily captured in the EHR. Many registries (e.g. The Society of Thoracic Surgeons National Database) utilize chart abstraction as a primary method for capturing information. Physicians participating in these registries contribute heavily to national efforts in quality improvement, patient safety, and clinical research and should still be rewarded even if patient information is manually entered. We therefore recommend removing the term "electronically" from the proposed requirement. We again emphasize that CMS should refrain from incentivizing based on a single process. Rather, we urge CMS to accommodate optimal data extraction methods—already identified and used by professionals in the registry space—as a method to encourage registry participation.

 Establish a Pathway for Physicians to Achieve ACI Credit by Using CEHRT to Participate in a QCDR

We urge CMS to establish an alternative pathway to fulfilling the ACI category by recognizing physicians who use CEHRT to participate in a QCDR. QCDRs advance improvements in quality and patient outcomes by providing real-time, actionable feedback to participating physicians related to their performance on key quality metrics. Participation in a clinician-led QCDR enables physicians to monitor patient interactions, track interventions, identify and address gaps in quality of care, and measure quality outcomes. In addition, QCDRs allow physicians to manage patient populations, benchmark their practice's performance and identify strengths and weaknesses, and enhance quality and practice efficiency. Conversely, compliance with current ACI requirements imposes significant burden on physician practices, and there is limited evidence demonstrating that the ACI requirements have a positive impact on the quality of care and patient outcomes. Furthermore, not all ACI measures are relevant to all physicians and patients.

We believe the requirements of the MU statute are met when physicians adopt these important tools. The statute requires the electronic exchange of health information to improve the quality of health care, electronic prescribing (e-prescribing), and reporting on quality measures. Because certification requires that an EHR include an e-prescription functionality, and QCDRs report on quality and require the exchange of information, all three MU requirements can be achieved by using CEHRT to participate in a QCDR. If necessary, the Secretary could use his authority under HITECH to create a new e-prescribing exclusion for participants using a QCDR, or he could simply determine that the appropriate use of e-prescribing amounts to a participant attesting through a QCDR to e-prescribing for at least one patient. Therefore, CMS should further recognize the value that clinician-led QCDRs bring to healthcare

and encourage their use by recognizing physicians utilizing CEHRT to participate in a QCDR as satisfactorily achieving full credit for ACI.

Improvement Activities

The AMA is supportive of many of CMS' proposals for the IA component of MIPS. Specifically, we agree with CMS' proposals to maintain reporting and performance requirements, which will lend much-needed stability to the program. Similarly, we welcome CMS' continuation of a 90-day reporting period for IA. The AMA also thanks CMS for its inclusion of new and amended IAs, a number of which were proposed by the AMA. We continue to applaud CMS' efforts to recognize the use of health IT to accomplish IAs and have included additional suggestions for ways that physicians can demonstrate their use of health IT in non-prescriptive ways. The following provides AMA recommendations for changes in future IA policies from those outlined in the proposed rule.

Maintain Reporting through Attestation and Do Not Evaluate Success Based on Improvement

CMS is soliciting comment on how to measure improvement in this category and that it is specifically seeking to avoid increasing burden on participants. However, MACRA intended the IA component of MIPS to provide credit for ongoing or already established activities and the statute does not require the IA category to measure improvement. Accordingly, CMS should refrain from imposing improvement criteria or lengthy documentation requirements that will increase administrative burden. CMS will be able to tell whether clinicians are performing more or fewer IAs from year to year based on the clinician's score in the performance category and, if desired, CMS can create specific validation criteria to demonstrate appropriate fulfillment of an IA.

• Do not Remove Activities from the IA Inventory

CMS is requesting comment to inform future proposals to remove activities from the IA library. We believe removing activities is contrary to the intent of the IA category and strongly urge CMS to refrain from establishing such a process. CMS' primary goal in the IA category should be to support the performance of any IA that improves patient care. Yet, a policy that removes activities from the IA inventory would stymie this goal, suggesting that practices should only implement temporary rather than long-term changes. In fact, removing activities could harm practices and patients, particularly those in small and rural practices, which often have limited financial and personnel resources. Furthermore, many practices have made financial investments to perform a particular IA (for example, paying to connect an EHR to a QCDR). CMS' removal of activities could jeopardize the practice's return on that investment while requiring new program costs. We therefore believe CMS should not proceed with a proposal to remove activities from the IA inventory.

• Increase Opportunities to Promote Health IT

As mentioned above, the AMA fully supports CMS' efforts to promote health IT throughout the MIPS program. We urge CMS to expand this recognition beyond the bonus points that a clinician can receive in ACI for using CEHRT to accomplish IAs. Namely, CMS should add IAs that give credit to physicians who use health IT—both certified and non-certified—to enhance patient safety, beneficiary engagement, and security of health information.

For example, given increases in cyber threats, CMS should reward clinicians who are proactive in ensuring the safety of their electronic patient information, including recognizing actions that HIPAA may not address. The AMA submitted several IA proposals intended to increase patient safety, enhance privacy and security of patient records, and provide education to patients around the use of health IT during CMS' 2017 call for measures:

- Compile and provide a list of patient-facing apps to consumers: Eligible clinicians discuss availability and usage of patient-facing apps with their EHR vendor.
- *Initiate implementation of a cybersecurity framework*: Adopt a cybersecurity framework and identify an implementation process. Examples of a cybersecurity framework are the HITRUST framework and the NIST framework. This IA should be weighted as high due to the considerable amount of work involved with implementing the framework.
- Collaborate on improved health IT solutions in healthcare: Ensure patient-centered health IT through physician engagement with IT developers and organizations. Examples include participation in a physician innovation network, participation in a technology incubator, and providing written feedback to their health IT vendor.
- Take steps to increase patient matching rates: Implement programs or procedures to improve the accuracy of demographic collection. These could include: implement cross-organizational patient matching rules; adopt a framework for methodical improvement; and/or a maturity model serving as a roadmap for future growth and improvement.
- Provide patient education on accessing health information securely: Provide education to consumers about privacy and security considerations when electronically accessing health data. Examples include written materials and face-to-face information sharing.
- Complete one or more SAFER Guide: Eligible clinicians use one or more SAFER Guides to identify recommended practices to optimize the safety and safe use of EHRs.

Adding these types of non-prescriptive activities to the IA inventory—and threading them into existing IA subcategories—would provide clinicians an opportunity to demonstrate their use of health IT in ways that improve their practices and assist their patients.

Furthermore, we note that the existing IA subcategories are based on desired outcomes (e.g., beneficiary engagement, achieving health equity). If CMS creates a new health IT subcategory, it may suggest that the use of technology is more important than the outcome the technology facilitates. Accordingly, rather than creating a new health IT subcategory, we suggest that CMS focus on integrating activities that utilize health IT into existing subcategories to demonstrate its prioritization of outcomes over means. This way CMS can avoid prescribing specific types of technology or limiting innovation. We believe this approach would also support future program policies aimed at increasing alignment of the ACI, IA, and quality components of MIPS.

• Increase the Credit for Participation in an APM

Section 1848(q)(5)(C)(ii) of MACRA requires that APM participation earns **a minimum** of one-half of the highest potential score for the IA performance category (emphasis added). Accordingly, the statute provides CMS with the authority to grant those participating in APMs anywhere from half to full credit for the IA category. **In light of the extensive resources required for APMs to be categorized as**

Advanced APMs and the limited number of MIPS APMs, we reiterate our previous request that CMS provide full IA credit to APMs. We believe APM participants are already fulfilling the IA category requirements and should not be required to report twice. Decrease Reporting Burden for Participants in Center for Medicare & Medicaid Innovation (CMMI) Models

In addition to the minimum credit provided to APMs under the MACRA statute, participants in CMMI models, such as the Million Hearts Cardiovascular Risk Reduction Model Campaign, will receive additional IA credit in 2017, as will participants in the Transforming Clinical Practice Initiative (TCPI).¹⁶

We recommend that, just as CMS will use its list of participants to automatically award credit for participation in an APM, CMS should automatically award IA credit for these CMMI participants. This would reduce the participant's reporting burden without drastically increasing CMS' workload since CMS will already be reviewing its CMMI model participation lists to provide credit to APMs.

• Decrease Performance Thresholds for Glycemic Screening and Referring Services Activities

The AMA thanks CMS for recognizing the importance of and proposing two new IAs related to diabetes prevention: glycemic screening and referring services. However, based on past CMS threshold proposals, a review of relevant medical literature, and interviews with clinicians involved with diabetes prevention programs (DPPs)¹⁷, we urge CMS to adjust the proposed thresholds for these IAs.

The proposed "Glycemic Screening Services" IA would require clinicians to implement systematic approaches for screening at least 75 percent of medical records for abnormal blood glucose levels. Because this activity is new—it is not an existing quality measure with which clinicians are familiar—we suggest that CMS lower the threshold for glycemic screening services to 60 percent in the first year. This is the threshold that CMS proposed for similar IAs in the 2017 program year (for example, "Participation in symptomatic anticoagulation program", IA_PM_1, and "Consultation of the Prescription Drug Monitoring Program", IA_PSPA_6), and we believe this would be a more appropriate threshold for the first year that clinicians perform this activity.

The proposed "Glycemic Referring Services" IA also includes a 75 percent threshold. This threshold is significantly higher than the current referral rates reported in medical literature; many studies and conversations with DPP providers relay that DPP referral rates are in the single digits. One reason for this is that DPP providers are often community based organizations. Many healthcare providers do not have existing infrastructure to send referrals to these community based organizations, so this infrastructure must be established before referrals can be made. Furthermore, there are a number of reasons why patients who are identified as having prediabetes are not referred to DPPs, particularly within the Medicare population DPPs require physical activity that Medicare patients can not engage in or patients may be in an end-of-life stage or suffering from dementia. In short, even when Medicare patients are screened and identified as pre-diabetic, referral rates can remain low due to confounding factors. Lastly,

Given this credit, we recognize and agree with CMS' proposal and rationale for removing "Participation in CMMI models such as the Million Hearts Campaign (Activity ID IA_PM_8) from the IA inventory, as well as for decreasing the weight of "Participation in the CMS Transforming Clinical Practice Initiative" (Activity ID IA_CC_4) from high to medium.

¹⁷ References on file with the AMA.

even if a healthcare provider was able to achieve a high referral rate, at this time many regions lack an adequate supply of DPPs to handle such a referral load, so many of those referrals would not result in an enrollment in a DPP. Accordingly, we strongly urge CMS to modify this activity to attestation that the clinician has instituted a systematic referral process for the 2018 program year, without an attached threshold. Subsequently, we suggest that CMS establish a 10 percent threshold with incremental increases over time. This would allow the demand for DPP classes prompted by provider referrals to more closely match the supply of DPP classes available. If CMS chooses to keep the 75 percent threshold in place, we ask that CMS weight the activity as "high" in recognition of the substantial time, effort, and challenge of meeting such a high standard.

• Maintain the ACI Bonus for Dissemination of Self-Management Materials

CMS is proposing to change the eligibility status for an ACI bonus from "Yes" to "No" in the "Improved Practices that Disseminate Appropriate Self-Management Materials" (IA_BE_21) IA. The AMA disagrees with this proposal and notes that such self-management materials may be provided through the patient-specific education function of CEHRT.

Include Accredited and Certified Continuing Medical Education (CME) as an IA

We thank CMS for including accredited performance improvement CME programs that address performance or quality improvement as an IA ("Completion of an Accredited Safety or Quality Improvement Program"). However, we continue to encourage CMS to include both accredited and certified CME programs to the IA inventory and ask CMS to revise this IA to include certified CME. Numerous CME programs are available to physicians of all specialties. These programs 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.

• Expand the Scope of Opioid-Related IAs

Drug overdose deaths involving opioids have been escalating rapidly in the United States, with more than half a million people dying from an overdose during 2000-2015 and an average 91 people dying from opioid, including heroin, overdoses every day. Despite this, CMS' only newly proposed IA is "CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain." The AMA submitted an IA proposal during the 2017 call for measures suggesting that CMS add activities to reduce opioid overdose deaths. In this proposal, we provided examples of prescribing naloxone to prevent overdose deaths and becoming certified to provide medication-assisted therapy (MAT) with buprenorphine, in addition to education to achieve competence in safe opioid prescribing.

The effectiveness of long-term treatment with MAT in allowing patients with opioid use disorder to lead satisfying, productive lives means that many of these deaths could be prevented if more patients received evidence-based therapy. An estimated 2.5 million people need treatment for opioid use disorder, but fewer than 38,000 physicians have met the federal requirements to prescribe office-based buprenorphine to their patients. A recent report from the Rural Health Research Center found that nearly 1,200 rural counties (60 percent) had no waivered physicians in 2016. In addition, it is estimated that about 40 percent of those who take the required training never write any prescriptions for buprenorphine. While we appreciate CMS' recognition of the need for education around prescribing opioids, CMS should

go further and provide credit to physicians who become certified to provide MAT with buprenorphine, as well as to physicians who prescribe naloxone to prevent overdose deaths.

We further recommend that certified and accredited CME courses in safe prescribing and/or pain management count for this IA. Limiting this IA to education on only the CDC guidelines is an implicit endorsement of a one-size-fits-all approach that is not appropriate. Physicians need different types of education related to opioids and pain depending on their practice; not all physicians need to learn about prescribing for chronic pain patients. For example, it might be better for an obstetrician-gynecologist to take a course in pain management for pregnant women with substance use disorders than to learn about the CDC guidelines for chronic pain, and it might be more beneficial for a surgeon to take a course in managing post-operative pain instead of chronic pain.

• Do Not Require a Minimum Participation Threshold

CMS is requesting comment on whether it should establish a minimum threshold (for example, 50 percent) of the clinicians (NPIs) that must complete an IA in order for the entire group (TIN) to receive credit in the IA category in future years. **The AMA disagrees with this proposed change, especially during the early program years.** Creating a separate threshold at this time will add to complexity of the program, which we believe CMS should avoid. Furthermore, the 50 percent threshold would be a significant change and would create complexity for groups who would need to evaluate members of their TIN to determine which IAs would be appropriate to meet the 50 percent threshold. This adds to administrative burden and may deter reporting on certain IAs.

• Provide Additional Clarification on the STEPSForward TM IA

We have reviewed the Data Validation Criteria for IAs that CMS released in April 2017, but questions remain about what is required to complete certain IAs. For example, we recognize that the validation criterion for the AMA STEPSforwardTM program is a certificate of completion, and urge CMS to clarify that physicians may complete any relevant module to receive credit in the IA category.

Other MIPS Issues

Performance Feedback

The AMA has repeatedly highlighted problems with the lack of timely feedback to physicians and called for improved performance reports that provide more understandable information. Given the complexity of calculating MIPS scores, it is imperative that physicians be provided timely feedback in order to give them a reasonable opportunity for successful participation in the program and so that they have actionable information to help them improve their practices. The AMA urges CMS to develop systems and technologies to provide physicians with real-time feedback on their performance throughout the performance year. Receiving timely feedback also becomes more important as CMS moves toward measuring improvement and reporting data publicly on Physician Compare.

• Annual Performance Feedback Reports

Under MACRA, CMS is required to provide MIPS eligible clinicians with timely feedback on their performance under the quality and cost categories beginning July 1, 2017. In this rule, CMS proposes beginning July 1, 2018, to provide performance feedback to physicians on the 2017 performance period

for the quality and cost categories, and if feasible for the IA and ACI categories. The AMA is disappointed that CMS does not propose to provide complete MIPS data to physicians until mid-2018. Physicians need all of their 2017 performance feedback prior to July 1, 2018 in order to make necessary adjustments to ensure success in the MIPS program in future years. It would be most beneficial for physicians to receive performance feedback during a performance period so they can make any necessary adjustments. **Therefore, we urge CMS to release mid-year individualized performance reports to physicians beginning with the 2018 performance period.** In addition, the AMA notes that while general Experience Reports, which CMS has used in prior reporting programs, are helpful to illustrate trends in the MIPS program, they cannot supplant individualized feedback reports to physicians that provide feedback on all of the specific MIPS measures reported by an individual physician. MIPS utilizes different scoring and benchmarking methodologies so relying on data from legacy programs is inadequate.

As technology is constantly changing, it is critical that CMS take an ongoing approach to improving the way performance information is disseminated to physicians and practices. As we have commented previously, physicians should be able to choose to receive more current information, such as MACRA's recommendation that the data be available on a quarterly basis.

CMS notes it will continue to leverage third party intermediaries as a mechanism to provide physicians with performance feedback. While we support CMS' intent, the information provided by QCDRs is only relevant to quality and limited to a single source—physician participants within a single QCDR. Therefore, we encourage CMS to move towards a more iterative process where physicians and vendors submit data more routinely to CMS. This will allow CMS to produce more frequent feedback information in terms of how a physician is performing throughout MIPS and how a physician compares to all MIPS participants.

• Performance Feedback Template

The AMA supports CMS's proposal to work with the stakeholder community in a transparent manner to develop the performance feedback template. As the AMA has noted in previous comments, we believe CMS should aim to display feedback and performance measurement information in graphic form wherever possible. In addition, the reports should include high-level overall performance information and drill down tables with individual patient information. It should also be possible for individual physicians within a group practice to access their own reports directly rather than through a group. The AMA has worked with CMS in the past to seek input from state and specialty medical societies on the Quality and Resource Use Reports and would be willing to work with CMS to disseminate draft MIPS report templates to medical state and specialty societies for review and feedback once they have been developed. CMS should create an ongoing dialogue with the AMA and other stakeholder groups regarding the most meaningful format for sharing actionable performance feedback with physicians.

Physician Compare

The AMA supports public reporting of physician data when it is valid, reliable, and meaningful to both consumers and physicians. Recognizing the MACRA statute requires increased public reporting on the Physician Compare website, we want to continue to work with CMS to ensure information is accurate, not misleading, and presented in a format consumers can understand and use appropriately.

• Achievable Benchmark of Care (ABC)

CMS proposes to use the ABC methodology to calculate benchmarks for MIPS quality data that will be published on the Physician Compare website. The AMA has previously expressed our concerns to CMS that the development of the ABC methodology has not allowed for adequate time or provided sufficient detail for stakeholders to provide useful feedback. For example, CMS hosted a call in April asking for stakeholder feedback on two possible applications of the ABC methodology on quality measures—the equal range and cluster methods. However, CMS only allowed 10 days for stakeholders to provide informal feedback, and failed to provide adequate detail on the differences between the two methods. In this proposed rule, CMS provides a single example of how the ABC methodology would be applied in the MIPS program and refers readers to the 2017 QPP rule; however, the 2017 rule provides minimal information on this methodology. Furthermore, CMS notes that it determined the use of a beta binomial model adjustment is the most appropriate way to account for low denominators under the ABC methodology, but fails to provide any information on how the beta binomial model will be applied.

Based on the limited information CMS has provided, one concern is that CMS is mixing various reporting mechanisms when developing the benchmarks for Physician Compare, which CMS does not do when setting MIPS benchmarks. The AMA urges CMS to create separate benchmarks for each reporting method instead of aggregating data from all reporting mechanisms. Furthermore, under MIPS, CMS will calculate a physicians' quality score based on a physician's most successful reporting mechanism. Conversely, under Physician Compare, CMS publicly reports a physician's quality data from all submission mechanisms. We urge CMS to maintain consistency, ensure that it is comparing like data, and accurately represent performance.

CMS also states that it will use the ABC methodology to systematically assign one to five stars to each physician under the Physician Compare five-star rating program. CMS states that the details of how the benchmark will be specifically used to determine the five-star categories for all applicable measures is being determined in close collaboration with stakeholders and measure experts. CMS also states that they plan to publicly report the five-star rating on Physician Compare in late 2017. **The AMA is very concerned that physicians may be rated in 2017 under a new program using a new methodology that has not yet been publicly shared with stakeholders.**

Before offering any further recommendations the AMA requests the following information from CMS:

- Additional information on how physicians would score under the equal range or cluster methods, and how these methodologies would be used to assign stars to physicians under the Physician Compare star rating program.
- Additional data on the equal range and cluster methods that incorporates the finalized socioeconomic and demographic factors risk adjustment methodology. Under Hospital Compare, socio-economic and demographic factors have had a big impact on publicly reported data.

Upon release of more specific information and data, CMS must allow sufficient time for stakeholders to comment on the ABC benchmarking methodology and the five-star rating program, specifically how it intersects with the MIPS scoring rules. Based on preliminary analysis, the AMA believes the ABC methodology could be a better approach than using deciles for setting MIPS quality

benchmarks. This methodology may also provide more accurate data on "topped out" measures. Under the MIPS methodology, CMS uses deciles; however, the deciles may yield lower ratings and numbers than the five-start method due to the decile cap on "topped out" measures. The AMA urges CMS to provide further information on this methodology and analysis on whether this methodology should be used to calculate MIPS benchmarks as well as in the Physician Compare five star rating program.

In addition, CMS must provide adequate time for the agency to make any necessary changes based on stakeholder feedback prior to adopting a new rating program. Therefore, we urge CMS not to implement a Physician Compare five-star rating program until there is sufficient time to develop and test an effective methodology. The AMA would appreciate the opportunity to work with CMS to further develop these methodologies.

• Increase Public Reporting Gradually

We encourage CMS to include new data on Physician Compare gradually. The AMA is concerned with CMS' ability to move forward with posting additional information, such as Cost and Improvement Activities given the issues that have occurred previously with the accuracy of published data. MIPS is a new program that includes new measures, data sets and reporting categories. We believe there is still significant testing and evaluation of MIPS performance data that must be completed. In addition, there are still problems with the comparison of practices that report the same measures through different reporting methods. The AMA also continues to have concerns regarding risk-adjustment and lack of timely feedback CMS is able to provide to physicians. Given these limitations, we believe CMS should increase data publicly reported on the Physician Compare website gradually.

• Expand the Preview Period

The AMA has repeatedly urged CMS to extend the preview period from 30-days to 90-days, in order for physicians to review and ensure the accuracy of their information. It currently takes practices several weeks or months to request, obtain, and review information such as a QRUR report. To expect physicians to access, review, and contest their Physician Compare data in 30-days ignores the demands of patient care and competing priorities physicians face on a daily basis. **The AMA urges CMS to extend the preview period to at least 90-days to allow physicians reasonable time to review and correct their data**. In addition, data under appeal should not be publically reported. As AMA has stated in previous comment letters, if at any time a physician files an appeal and flags information as problematic, CMS should postpone posting the information until all issues are resolved.

• Allow Physicians Three Years to Report on Measures Prior to Public Reporting

CMS has previously finalized that they will not report first year measures that have been in use for less than one year. The AMA urges CMS to expand this exclusion to measures that have been in use for less than three years. Including measures after one year of reporting does not allow CMS to adequately evaluate meaningful trends over time or provide physicians with an adequate period to fix data collection issues. Allowing physicians three years to report on measures prior to posting measure data on Physician Compare will improve the chances that only robust and meaningful data is included on the website.

Targeted 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. In the 2017 Quality Payment Program final rule, 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 (VM) 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. 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.

Moreover, CMS should not limit the request for a targeted review to within 60 days after the close of the data submission period. Most physicians will not know if they should request a review of the MIPS adjustment factor until they receive information from CMS about whether they have earned a MIPS incentive or penalty. Physicians will then need to assess what may have impacted their performance, which will take significant time especially in the beginning of a new program. We recommend that CMS allow at least 90 days for targeted review after a physician is notified of their performance in MIPS.

Program Integrity

• Ten-Year Record Retention Requirements

The AMA is adamantly opposed to the ten-year record retention requirements established by 42 C.F.R. §§ 414.1390(d) and 414.1460(e). First, the ten-year period is overly burdensome for eligible clinicians. Administrative burden has increased physician dissatisfaction and is a leading cause of physician burnout. Maintaining and retrieving information for a ten-year period is costly and time-consuming. Books and records would have to be kept much longer than is currently required. This would affect information systems, create additional and competing demands from CMS for investments in information technology, and take valuable staff away from their work of caring for patients and improving the safety and quality of care they provide. Eligible clinicians should have certainty after a reasonable period that they can close their books and not have ongoing liability associated with an overpayment. AMA believes the ten-year window is excessive and will have the opposite effect on these clinicians.

Second, it is not appropriate to use the outer limit of the False Claims Act as the time period. The False Claims Act relates to instances where a party meets the intent requirements of the Act, meaning that an individual knowingly filed a false claim. To apply that same standard to all APM determinations, QP determinations, APM incentive payments, and all MIPS eligible clinicians' submitted data, and require that physicians retain ten years of records is inappropriate and unreasonable. In addition, the regulation

already adds an additional six years for any cases of fraud or similar fault. Moreover, six years is the more commonly used statute of limitations in the False Claims Act and the ten-year period only applies in the rare case where facts material to the right of action were not previously known by the government. Thus, the ten-year period is broader than, and not parallel to, that of the False Claims Act.

Third, the ten-year period for eligible clinicians is inconsistent with existing record retention requirements including the requirements for non-QPP Part B payments. CMS should consider a three or six-year record retention period to avoid regulations that are inconsistent or incompatible with its other regulations. The existing Medicare requirements already set forth an appropriate framework for auditing and handling errors in eligibility determinations and inaccurate payment, and we encourage CMS to work within the current regulations and policies.

AMA proposes that the proper record retention requirements for these eligibility determinations and incentive payments be three years, which would be consistent with the Medicare Recovery Audit Contractor (RAC) program. CMS and medical societies have spent substantial resources over a number of years to educate physicians about RAC audits and the three year time frame. To finalize a different, substantially longer look back period would confound those efforts, cause confusion, and prove unduly burdensome for physicians. Three years provides both providers and RACs with administrative finality and will encourage providers to continue to maintain and operate robust internal audit procedures. We would also stress that a three-year period would in no way preclude an administrative or judicial recovery of overpayments reaching beyond three years where there is evidence of fraud or similar fault.

Alternatively, CMS could also choose a six-year record retention period. A six-year record retention period would be more consistent with existing requirements including the statute of limitations under the False Claims Act and Civil Monetary Penalty authorities. HIPAA also requires a covered entity, such as a physician billing Medicare, to retain required documentation for six years. Moreover, in 2016, CMS proposed a ten-year time period for the recovery of overpayments. However, CMS concluded that a six-year time period was the most appropriate because it addressed many of the concerns about burden and costs to providers.

Regardless of whether CMS chooses a three- or six-year period, the ten-year period creates two different record retention timeframes within Medicare Part B. Non-QPP clinicians would be subject to the already existing record retention requirements, while APM and MIPS eligible clinicians would be subject to a ten-year period. **CMS provides no justification as to why APM and MIPS eligible clinicians need to be treated differently and have additional administrative burden than their non-QPP counterparts.** CMS, in designing its regulations, must consider incentives for innovation, consistency, predictability, costs of compliance to the eligible clinicians, and flexibility. A ten-year record retention requirement for the QPP—which aims to improve outcomes and lower overall costs—accomplishes none of these goals. Thus, AMA strongly believes that all Medicare Part B providers be subject to the same, existing record retention requirements.

• Violation of Any Law or Regulation

The AMA seeks clarification from CMS regarding the rescinding of a QP determination for a violation of "any Federal, State, or tribal statute or regulation" in proposed 414.1460(b)(3). AMA is concerned that this provision is too broad and could be interpreted to include a violation of a law or regulation that has no impact on a QP determination or the provision of health care items and services. This concern is heightened because no judicial or administrative review is available for a QP determination. Thus, an eligible clinician could be determined ineligible as a QP for irrelevant reasons with no recourse to appeal.

AMA suggests that CMS adds clarifying language to limit the violation of any law or regulation that is relevant to the provision of health care items or services. For example, the regulation could state "any relevant Federal, State, or tribal statute or regulation.

APM PROVISIONS OF 2018 QPP PROPOSED RULE

MIPS APMs

The AMA appreciates CMS' proposal to score "Other MIPS APMs" (that is, MIPS APMs that are not required to report through the CMS Web Interface) on quality. This proposal helps to remedy the scoring structure applied to Other MIPS APMs in the 2017 performance year in which ACI was weighted at 75 percent, while IA was weighted at only 25 percent. As stated throughout these comments, we continue to encourage CMS to distribute weight among the categories in a manner that reflects CMS' intent to create a holistic program. In addition, the AMA supports the following proposals:

• Extend the Fourth Snapshot Date to all APMs

The AMA supports CMS' decision to create a fourth snapshot date for "full TIN" MIPS APM participants to identify additional MIPS APM clinicians. We disagree with CMS, however, that the creation of a fourth snapshot date for all MIPS APM participants would essentially encourage gaming by clinicians "briefly" joining a MIPS APM "principally in order to benefit from the APM scoring standard." The current snapshots for APMs are each three months apart and CMS has established that these 90-day windows are sufficient to capture participation in MIPS APMs throughout the year—a 90-day window at the end of the year should also be sufficient. It discounts and unfairly disadvantages physicians who participate in MIPS APMs in the final quarter of the year, including those who relocate in a different region of the country or for any other of the innumerable reasons an individual may seek new employment. Particularly given CMS' desire to move towards value-based care, the agency should seek to capture and reward clinicians who take steps in that direction.

Further, only a limited number of Advanced APMs currently exist. CMS should create policies that incentivize physicians to join Advanced APMs at any point in the year—not just the first three quarters. The current snapshot dates result in requiring some physicians who participate in an Advanced APM to miss an entire annual APM performance period before they are eligible to receive a bonus payment, even though they contribute to the APM's revenue in that performance year. As such, CMS should finalize its proposal to establish a fourth snapshot date for full TIN MIPS APMs, and should extend the fourth snapshot date to all APMs, including Other MIPS APMs and Advanced APMs.

¹⁸ 2018 QPP Proposed Rule at 30081.

• Adjust the Redistribution of Performance Category Weights when Measures for One Category are Unavailable

In the event that an Other MIPS APM does not have sufficient measures available to score in a particular category, CMS is proposing to reweight the remaining performance categories. Other MIPS APMs lacking quality measures would have their category weights shifted to 75 percent in ACI and 25 percent in IA. If ACI measures are unavailable, the percentages would shift to 80 percent quality and 20 percent IA. Both of these proposals create too much of an emphasis on a single category (either quality or ACI) and limit the ability for an entity to average performance across the different MIPS components. **Rather than finalizing its proposed reweighting amounts, CMS should distribute the weights more evenly between the two remaining categories in both situations.** For example, 65 percent quality and 35 percent IA in the event that there are no ACI measures, or 50 percent ACI and 50 percent IA if there are no quality measures. We note that an even split between ACI and IA aligns with CMS' reweighting proposal for general MIPS scoring in the absence of quality measures. Alternatively, CMS could allow Other MIPS APMs lacking measures in a particular category to be scored as average.

• Reduce Number of Required Quality Measures a MIPS APM Must Report

CMS is proposing to adopt quality measures for use under the APM scoring standard and begin collecting MIPS APM quality measure performance data to generate a MIPS quality performance category score for MIPS APMs. The AMA is supportive of this policy, but believes that **MIPS APMs should only have to report six quality measures**, just as clinicians under general MIPS scoring only need to report six quality measures.

• Keep MIPS APMs and General MIPS Participants benchmarks separate

The AMA does not support the proposal to blend results for quality measures reported by APM participants with results from non-APM participants because it will skew the benchmarks. We urge MS to calculate separate quality measure benchmarks for MIPS APMs and MIPS participants. Because APMs have more financial support for preventive strategies, for example, we would not expect non-APM participants to score as well as APM participants on some measures. MIPS participants may be at a disadvantage if compared to MIPS APMS, especially in areas where quality measures may overlap. For additional details, please refer to the Quality Performance Category Section of this comment letter.

Advanced APMS

Revenue-based Standard for More than Nominal Financial Risk

CMS has defined three different standards for more than nominal financial risk:

- 1. Eight percent of APM entities' Part A and B revenues;
- 2. Three percent of expected expenditures for which an APM entity is responsible under the APM; and
- 3. Five percent of APM entities' Part A and B revenues for medical home models.

Current regulations provide that the second and third standards will apply to years 2021 and beyond, but the first standard will only apply to 2017 and 2018. The previous final rule sought comments on alternative revenue standards for future years, including an increase to 15 percent. The AMA greatly appreciates that CMS is not proposing an increase in 2019, but is concerned that the proposed regulations would only extend the first standard to 2019 and 2020. Since the proposed rule states that "8 percent... represents a reasonable standard to determine what constitutes a more than nominal amount of financial risk," there is no good reason why the other two standards should apply in 2021 and beyond but not the first. This creates significant and unnecessary uncertainty for APM entities and physicians.

As we noted previously, MACRA already provides for steep increases in financial risk requirements for Advanced APMs over time by increasing the percentage of participants' revenues that must come through the APM in order for participants to attain QP status. APM entities that are accountable for repaying losses under models that involve 75 percent of their 2021 revenues will be at higher financial risk than in the years when the QP thresholds are set at 25 and 50 percent of revenues coming through the APM. We remain concerned that if CMS does not provide long-term stability in the financial risk standard, it may discourage physicians from working to design and participate in Advanced APMs or place them in financial jeopardy after an initial period of success.

• Phasing In the Revenue-based Standard

CMS seeks comment on whether the agency should consider a lower or higher revenue-based nominal amount standard for the 2019 and 2020 Medicare QP performance periods, and on the amount and structure of the revenue-based nominal amount standard for Medicare QP performance periods 2021 and later. As noted above, the AMA recommends that the eight percent standard not be increased for the foreseeable future. CMS should also consider phasing in the eight percent standard in the same manner as it is phasing in the five percent nominal risk requirement for medical homes. The decision by Congress in the MACRA statute to increase the APM participation threshold from 25 percent in the first two performance periods up to 75 percent in the fourth performance period and thereafter indicates that Congress intends for physicians' exposure to APM-related financial risk to be phased in over time. The AMA recommends that the revenue-based nominal risk amount be reduced to four percent for 2018, be increased to six percent in 2019 and 2020, and be set at 8 percent in 2021 and subsequent years.

• Lowering Nominal Risk Amounts for Small and Rural Practices

The proposed rule also seeks comment on whether CMS should consider a different, potentially lower, revenue-based nominal amount standard for small practices and those in rural areas that are not participating in a medical home model. The AMA urges CMS to set the revenue-based nominal amount standard for small and rural practices participating in APMs at either the same or a lower amount as medical home models. Any requirement to repay a portion of financial losses under an APM will be more problematic for small and rural practices than for larger practices and those in urban areas. Rural communities generally have lower average incomes and higher unemployment, which leads to a greater percentage of uninsured and Medicaid patients. Specialists are more likely to locate in urban areas, so it is more difficult for rural physicians to refer complex patients to specialist practices. Longer travel times can lead to lower utilization per patient and difficulty keeping appointments, which may lower margins, make it difficult to cover fixed practice costs, and make it more difficult for patients to be adherent to treatment plans, thus affecting performance on quality and cost metrics. Barriers for small practices to participate in Advanced APMs are well known, with serious concerns in recent years about regulatory

burdens and physician burnout. Recent <u>research</u> on characteristics of practices participating in accountable care organizations (ACOs) has found, for example, that "74 percent of practices with 100 or more physicians are currently participating versus much lower percentages for smaller practices."

Consequently, lower risk standards should be established for both small and rural practices. CMS expresses concern in the proposed rule that a lower standard could reduce "the likelihood that potential Advanced APMs will ultimately result in reductions in the growth of Medicare expenditures." Experience to date with Medicare ACOs has shown, however, that smaller, physician-led ACOs are more likely to meet spending targets than are larger ACO entities. In addition, the goal of APMs is not just to reduce the growth of Medicare expenditures but to improve the quality of care for Medicare patients, and patients living in rural areas deserve better care every bit as much as those living in urban areas.

In the proposed rule, CMS states that a lower standard should not apply to small or rural practices in a medical home model because the regulations already establish a lower standard for practices with fewer than 50 clinicians. Yet in the proposed rule CMS also states its belief that the "meaning of the word 'nominal' depends on the situation in which it is applied." Requiring a physician practice with fewer than 10 physicians in a sparsely-populated rural area to repay five percent of its revenue to Medicare will likely be a much bigger deterrent to APM participation than for an urban practice with 40 physicians, so lower risk standards are appropriate for smaller practices participating in medical home models as well.

• Revenue Calculations Should Be Made Separately for Each APM Entity

Under §414.1415(c)(3) of the current regulations, an APM entity can meet the "generally applicable nominal risk standard" if the total amount the APM entity potentially owes CMS or foregoes under an APM is at least equal to "8 percent of the estimated average total Medicare Parts A and B revenues of participating APM Entities." Most people believed that this meant that an individual APM entity's losses could be limited to eight percent of that individual entity's revenues.

In the proposed rule, however, CMS indicates that it interprets this language to mean that it will calculate the average Medicare revenues of all of the APM entities that are participating in the APM, and the APM will be determined to meet this standard as long as the amount an individual APM entity potentially owes CMS is less than eight percent of this overall average amount. This is problematic for two reasons:

• The risk for a small physician practice to participate in the APM could be much higher than 8 percent if there is also participation by large APM entities for which the APM represents a smaller portion of revenues. For example, assume that a small, single-specialty physician practice with \$500,000 in total Medicare revenue participates in an APM that will represent \$300,000 of its revenue and will involve \$2.5 million in total Medicare spending for the APM patients, and that a large multi-specialty practice that has \$50,000,000 in total revenue participates in the APM, with the APM representing \$15,000,000 of its revenue and \$130 million in total Medicare spending. If the APM requires repayments to Medicare of up to three percent of Medicare spending, that would only represent an average of 7.9 percent of the revenues of the two entities (3 percent x \$132,500,000/\$50,500,000 = 7.9 percent). Both entities would be responsible for repayment of the 7.9 percent overage. Because the overage represents 15 percent of the small practice's revenue (3 percent x \$2,500,000/\$500,000 = 15 percent) and only 7.8 percent of the large practice's revenue (3 percent x \$130,000,000/\$50,000,000 = 7.8 percent), it puts the small practice at a significant disadvantage. That would not be the case if the calculation

was made at the individual APM entity level in which the eight percent cap would protect that smaller practice from having to pay back 15 percent of its revenue.

• It would be impossible for anyone to know whether an APM met the risk standard or what the risk to any individual entity would be until after the end of each year, when all of the participating entities and their revenues were known.

To address this problem, the regulation should be modified to indicate that an APM meets the nominal risk standard if it caps repayments to Medicare by each APM entity at 8 percent of that individual entity's total revenues.

• Risk-based Revenue Calculations Should Be Limited to Those Responsible for Loss Repayments

In the proposed rule, CMS states that it intends to clarify that the 8 percent standard applies to the estimated total Medicare Part A and B revenue of "providers and suppliers at risk for each APM entity." However, the proposed revision to §414.1415(c)(3)(i)(A) reads "8 percent of the average estimated total Medicare Parts A and B revenue of all providers in that own the participating APM Entity or are otherwise responsible for all or part of any repayments the APM Entity must make to CMS," which is much more ambiguous than what the preamble states. This could be interpreted as meaning the revenues of a hospital would be included if the hospital provided services to patients managed by an APM entity, even if the hospital was not sharing in the risk of the APM.

• Calculation of Part B Revenue at Risk Should Exclude Part B Drug Costs

Medicare payments for drugs under Part B are almost entirely a pass-through from Medicare to a drug wholesaler, not compensation to the physician practice for its services. For some physician practices, such as oncology and rheumatology, the revenues for these drugs are many times higher than the revenues used to pay for the physicians' professional services, and the practice's spending on the drugs is many times higher than the practice's other expenses. This means that placing such a practice at risk for eight percent of its total Part A and B revenues could place it at risk for losing most or all of the revenues it receives to pay for its professional services to patients. That could bankrupt the physician practice and/or reduce access to care for Medicare patients.

Modify the Requirement to Count Part A Revenue toward the Revenue-based Risk Standard

Some APM participating organizations have expressed concern that, by basing the revenue standard for nominal risk on both Parts A and B revenue, CMS is disadvantaging any physician-based organization that includes a hospital in the entity. Physician-only entities by and large are paid only Part B, while any entity including a hospital will trigger the inclusion of Part A revenues, which could dramatically increase required financial risk amounts, even though most of the hospital's revenues may be for services unrelated to the APM. As a foundational goal of delivery system reform is to bring providers together to jointly take accountability for quality and costs, this policy could move instead toward fragmentation and discourage collaboration between hospitals, physician groups and post-acute care providers.

CMS states in the previous final rule, "...our intention in setting a revenue-based nominal amount standard is to tailor the level of risk an APM Entity must bear relative to the resources available to it." However, as a percentage rather than an absolute dollar amount, larger organizations will inherently be expected to carry a higher dollar risk than smaller organizations. It is not necessary to also add to the services on which the threshold is based. By including revenue from all Part A services, the decision to include a hospital in an APM Entity will be driven by decisions about the financial risk of participation rather than whether more coordinated care can be delivered.

Medical Home Models

• Medical Home Models Should Not Exclude Specialty Practices

The provisions in the regulations that require Medicare medical home models and Medicaid medical home models to use primary care physicians and deliver primary care services are unnecessarily and inappropriately restrictive. A growing number of specialty physician practices are providing services to patients with serious chronic diseases that have four or more of the elements listed in characteristic (3) of the definitions in §414.1305. Specialty practices are appropriately able to be recognized as medical homes for the IA component of MIPS, but specialty practices are not currently eligible for the same risk standard as primary care medical homes within the APM pathway under the QPP.

Contrary to what is stated in the proposed rule, there is no provision in MACRA enabling unique treatment of medical home models that have not been expanded under Section 1115A(c), nor does MACRA indicate that only primary care medical home models expanded under Section 1115A(c) would automatically qualify as an Advanced APM. The proposed rule states that the rationale for treating medical home models differently is that they "tend to be smaller in size and have lower Medicare revenues relative to total Medicare spending than other APM Entities, which affects their ability to bear substantial risk, especially in relation to total cost of care." However, just like primary care practices, many specialty physician practices primarily deliver evaluation and management services to their patients, and they receive the same payment amounts for those services that primary care practices receive, so the rationale for separate treatment applies equally to these specialty practices.

• CMS Should Recognize Other Payer Medical Home Models

There is no logical reason for CMS to give a practice favorable treatment for delivering care under a medical home model to Medicare and/or Medicaid patients but not to other patient populations. In fact, private health plans are supporting medical home models of care with more physician practices and in more parts of the country than CMS is. The CMS medical home model that is recognized as an Advanced APM, CPC+, is a multipayer model. Physicians participating in Other Payer medical homes should have access to the same standard for more than nominal financial risk as Medicare medical homes.

Medical Home Risk Standard Should Not Be Restricted to Organizations with Fewer than 50 Clinicians

The fact that a primary care practice has 50 physicians does not mean that it has the ability to manage four times the financial risk that a practice with 49 physicians does, yet that is what the proposed regulations would require. In 2018, a medical home model operated by an entity with fewer than 50 clinicians would

need to be at risk for two percent of total Part A and B revenues, whereas an entity with 50 clinicians would have to be at risk for eight percent of total revenues.

This regulation appears to be driven by a CMS assumption that it is preferable for larger practices to participate in ACOs instead of medical home models. As CMS did not expand the only ACO model that was certified by the Medicare Actuary to qualify for expansion, the Pioneer ACO model, it is not clear to us what the basis is for this CMS assumption. Except for 42 Track 2 and 3 ACOs, all of the APMs that count toward QP status are models that are still being tested, so it is premature for CMS to make policy decisions based on assumptions about which of these models is better for Medicare than others.

Count Medicare Advantage APM Participation in Patient Threshold Calculations for QPs

The proposed rule notes that CMS has received feedback in support of creating a way for those participating in Advanced APMs that include Medicare Advantage (MA) to receive credit for that participation in QP determinations under the Medicare Option, and seeks comment on such opportunities. The AMA recommends that CMS allow participation in MA APMs to be included under the patient count test for QP status determinations affecting 2019 and 2020 payment adjustments. Section 1833(z)(2)(D) of the Social Security Act provides the necessary flexibility to support this policy:

The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1848(q)(1)(C)(iii) by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate.

This section does not include any language that requires CMS to consider only Medicare fee-for-service (FFS) patients but instead refers in general terms to "counts of patients." This is an important distinction and gives the agency the latitude to interpret this provision to include MA enrollees in the patient count methodology beginning in payment year 2019, "as the Secretary determines appropriate." CMS has already used this flexibility to set the patient count thresholds lower than the revenue test for QP status. To avoid unintended consequences, the AMA recommends a two-step process. For those clinicians who have MA contracts but do not yet have Advanced APM structures within those contracts, simply adding MA beneficiary counts would dilute the denominator with no commensurate addition to the numerator. Instead, we suggest that CMS first test clinicians' satisfaction of the Medicare FFS revenue and patient thresholds, and then only proceed to test Medicare FFS and MA together for a second stage patient count test if the APM participant does not reach the threshold using Medicare FFS alone.

Exempt Advanced APM Participants from MIPS after First Year

The regulations require that QP determinations will be made based on a clinician's participation in APMs two years prior to the payment year. This is an unnecessarily long lag time and an inappropriately restrictive approach. For example, assume there are no APMs in which a physician can participate in 2018, but the physician participates in one or more APMs in 2019 at the required threshold amount. Under the regulations, this physician would receive a 2020 payment adjustment based on 2018 MIPS measures even if she is an APM participant as of January 2019, because 2020 QP status would be determined based on 2018 instead of 2019. MACRA states that QP determinations are to be made based

on "the most recent period for which data are available." Since CMS is proposing to make QP determinations based on fewer than 12 months of data, it is quite feasible to use data from the immediately prior year and still make a determination on QP status prior to the beginning of the payment year as well as during the prior year. The determination made two years prior (e.g., 2018) would alert the physician that they would need to report MIPS measures in the following year (2019) if they do not participate in an APM the following year (2019), but if they do participate in an APM the following year (2019), a revised determination would be made in that year (2019) so that the physician's payment adjustments in the next year (2020) would be based on the APM, not on MIPS.

There is also no reason that CMS cannot estimate the amount of the five percent payment based on claims data during the same year in which the QP status determination is made. If needed, CMS can use its waiver authority under section 1115A to reduce the lag time between the performance period and the payment adjustment for APM participants.

Improve All-Payer Combination Option Determinations

• Other Payer Advanced APM Determinations Should Remain in Effect

CMS proposes that its determinations as to whether payment models implemented by other payers meet the requirements for Other Payer Advanced APMs would only be in effect for one year at a time. This creates unnecessary uncertainty for physicians and unnecessary administrative burden on CMS. CMS should automatically renew its determination of an Other Payer Advanced APM as long as either the payer or the physician attest that the key characteristics of the APM that were used to make the initial determination remain in place.

All Payers Should Be Able to Request Other Payer Advanced APM Determinations in 2018

CMS proposes to delay until 2019 determinations of Other Payer Advanced APMs for payers other than Medicaid, CMS multi-payer models, and MA plans. This unfairly penalizes physicians who have many patients insured by other types of payers and who have successfully negotiated APM contracts with those other payers. CMS should be equally able to make a factual determination as to whether an APM meets the requirements for an Advanced APM regardless of the payer type.

• Payers Should Have More Than 10 Days to Respond to CMS Information Requests

CMS is proposing that if a payer has requested an Other Payer Advanced APM determination and the agency determines that additional information is needed, the payer would have only 10 business days to respond, otherwise no determination would be made on the request. This is an unreasonably and unnecessarily strict requirement that could jeopardize the ability of physicians participating in multi-payer APMs to meet the QP thresholds. As long as the payer can respond with the necessary information in sufficient time for CMS to make a determination consistent with other program timeframes, the payer should be given the time it needs to respond. CMS should also establish a reasonable timeframe for submitting requests for information to payers (e.g., 30 days after receiving a payer's submission) so that delays in sending those requests do not make it impractical for payers to respond.

• QP Status Under All-Payer Combination and Medicare Options Should Use the Same Procedures

CMS has proposed that if a physician's QP status is being determined based on the "Medicare Option," the threshold score will be calculated collectively for all of the physicians in the APM entity, but if QP status is being determined based on the "All-Payer Combination Option," the threshold score will be calculated for each physician individually. The rationale given for this policy is a belief that "in many instances ... the eligible clinicians in the APM Entity group ... would likely have little, if any, common group-level participation in Other Payer Advanced APMs."

The AMA disagrees. If it makes sense to determine the threshold score at the APM entity level for the Medicare Option then it is problematic not to do so if the APM entity is participating in Other Payer Advanced APMs. APM participation decisions are likely to be made at the practice level, not the individual physician level, regardless of the payer. Making determinations at the individual level could force physicians to try and selectively see patients of the Other Payers under an APM rather than Medicare patients in order to increase their individual Threshold Score.

In Example 1 below (based on a modified version of Table 55 from the proposed rule), Clinician A would fail to meet the All-Payer threshold score calculated at the individual level, even though the APM Entity as a whole would meet the 50 percent threshold. Consequently, as shown in Example 2, Clinician B might decide to shift attention away from Medicare APM patients to Other Payer APM patients in order to increase their All-Payer threshold score.

EXAMPLE 1

	Medicare Advanced APM Payments	Medicare Total Payments	Medicare Threshold Score	Other Payer Advanced APM Payments	Other Payer Total Payments	All-Payer Threshold Score
C1: • • •	ΦΩΩ	\$200	450/	A = = 0	Φ1 1 7 O	400/
Clinician A	\$90	\$200	45%	\$570	\$1,150	49%
Clinician A Clinician B	\$90 \$200	\$200	45% 25%	\$570	\$1,150 \$500	52%

EXAMPLE 2

	Medicare Advanced APM Payments	Medicare Total Payments	Medicare Threshold Score	Other Payer Advanced APM Payments	Other Payer Total Payments	All-Payer Threshold Score
Clinician A	\$50	\$200	25%	\$625	\$1,150	50%
Clinician B	\$200	\$800	25%	\$500	\$500	52%
APM Entity	\$250	\$1,000	25%	\$1,125	\$1,700	51%

The most appropriate approach would be to determine whether the same APM entity and essentially the same physician members are participating in the Other Payer Advanced APM, and then make the threshold score calculations accordingly. This approach could be done under §414.1440(b) and §414.1440(d)(3) of the current regulations, and there is no reason to change it.

• Other Payer Documentation Requirements for the Use of Certified Electronic Health Record Technology (CEHRT)

CMS is proposing to use information and documentation provided by physicians to validate that other payer arrangements (i.e., Other Payer Advanced APMs) require at least 50 percent of participating physicians use CEHRT. The AMA appreciates CMS' flexibility in this proposal; however, we are concerned that other payer contracts may not explicitly cite CEHRT or may refer to EHRs by another name, preventing physicians from receiving credit. For instance, some contracts may only use the term "EHR," and not specifically reference certification, while other contracts may use the term "EMR," which is often used interchangeably with "EHR." While we recognize the need for Other Payer Advanced APMs to conform to requirements, we also believe CMS should recognize that contract language is typically outside of the control of physicians.

A 2015 National Electronic Health Records Survey (NEHRS) found that 86.9 percent of office-based physicians were using an EHR or EMR system, with 77.9 percent using CEHRT. Accordingly, the majority of physicians using EHRs are using certified EHRs, and we believe that in 2017 this ratio is even higher. In line with CMS' stated goal of reducing regulatory burden and promoting APM participation, we recommend: 1) that CMS accommodate more flexible contract terminology used to describe EHRs; and 2) if CMS seeks alternative information on the use of CEHRT, CMS should accept EHR vendor's Certified Health IT Product List's (CHPL) identification number in lieu of other payer contract language.

Physician-Focused Payment Models

• Allow Consideration of APM Proposals for Which Medicaid is a Payer

In comments on the previous final rule, the AMA urged that the PTAC be able to review and recommend APMs for which Medicaid is a payer even if Medicare is not. The AMA appreciates and supports the current proposal to allow the PTAC to act on these models, which will allow consideration of proposals 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.

• Provide Data and Technical Assistance to Proposal Developers

The AMA has previously urged CMS to make claims and other data available to groups that are developing an APM proposal or testing an APM. Multiple APM developers stated at recent PTAC meetings that they have been unable to obtain the data needed to sufficiently analyze or refine their proposed models. It is unrealistic to expect those developing APMs to acquire Medicare data from a source other than CMS. The AMA strongly urges CMS to work with APM developers to provide relevant data in an easily interpretable format. The AMA also notes that in the PTAC's Report to the Secretary on the Project Sonar proposal, PTAC stated:

¹⁹ NCHS, National Electronic Health Records Survey. 2015.https://www.cdc.gov/nchs/data/ahcd/nehrs/2015_nehrs_web_table.pdf

"PTAC also believes that some concerns could likely be resolved through technical assistance. Because PTAC has been advised that it may not provide technical assistance, the Committee is hopeful that the Secretary would consider options for providing technical assistance to this and other submitters."

The AMA agrees with the PTAC that many physician-focused APM proposals could be improved through technical assistance, and has recommended that the PTAC expand the possible recommendations to the Secretary for each APM proposal by inclusion of a recommendation for technical assistance. This additional category would allow the PTAC to recommend technical assistance be provided for models that have significant potential but need additional development in some areas.

The AMA recommends that the PTAC offer technical assistance to promising APMs in a similar manner to the issuance of the CMS State Innovation Awards. Specifically, upon a recommendation for technical assistance from the PTAC, the APM developer would receive a planning award that could be used to modify the APM based on the PTAC's recommendations for improvement. The APM developer would have the flexibility to use the technical assistance resources in the most beneficial manner to improve the APM's design.

• Respond to PTAC Recommendations in a Timely Manner

The AMA was very pleased that the PTAC was able to endorse two of the initial three proposals it received and recommend them to the Secretary for testing. More than two months have passed since the PTAC provided its reports on these recommendations without any response from CMS or the Secretary. As we have done previously, the AMA again urges the agency to establish a process for responding to the recommendations from the committee so that action can be taken on these proposals in a timely manner. We recommend that the response be provided within 60 days of the PTAC report's submission.

APPENDIX A

Analysis of current MIPS benchmarking and ABC methodology used for Physician Compare star ratings:

Current QPP benchmark approach

Characteristics:

- Separate benchmarks for each reporting option (i.e., EHR, QCDR/registries, claims, CMS web interface, administrative claim measures and CAHPs for MIPS) are created for each measure.
- All reporters (individuals and groups regardless of specialty or practice size) in that reporting option are combined into one benchmark.
- There must be at least 20 reporters that meet the following criteria:
 - Meet or exceeds the minimum case volume (has enough data to be reliably measured)
 - Meets or exceeds data completeness criteria
 - Has performance greater than 0%.
- Benchmarks are determined based on the range or variation of performance scores.
- Performance is not distributed evenly across the available deciles. Rather, it is distributed based on the "curve" of true performance. As a result, as higher numbers of those reporting achieve high rates of performance, there will be less distribution of scores across the deciles with some deciles even remaining null. Examples explaining how this distribution works across deciles are below.

Example 1

For measures with performance scores that are somewhat uniformly spread from 0.0% to 100%, scores are distributed across most if not all of the deciles. Top performers would be at or near Decile 9 or 10.

Моодина	Deciles							
Measure	3	4	5	6	7	8	9	10
113: Colorectal Cancer	29.50-	42.37-	53.85-	64.41-	75.41-	84.68-	93.14-	100.0
Screening	42.36	53.84	64.40	75.40	84.67	93.13	99.99	100.0

Example 2

For measures that are "topped out," the majority of scores are at or above 95%. As a result, there is little variation across those who reported and scores cannot be distributed across most or all of the deciles.

Measure	Deciles	Deciles						
Measure	3	4	5	6	7	8	9	10
71: Breast Cancer: Hormonal Therapy for Stage IC - IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	80.49- 90-78	90.79- 96.48	96.49 - 98.07	98.08- 99.99				100.0

Example 3

For measures that appear to have a somewhat even distribution between the top and bottom performers, it is possible for higher performance rates to appear in lower deciles. This occurs when there are some reporters with low performance rates but the majority of reporters have higher rates.

Measure	Deciles							
Measure	3	4	5	6	7	8	9	10
134: Preventive Care and			62.00					
Screening: Screening for	11.54-	30.68-	62.09	94.04-	99.46-			100.0
Clinical Depression and	30.67	62.08	94.03	99.45	99.99			100.0
Follow-Up Plan			94.03					

ABC with Benchmarks Only

Characteristics:

- Uses true performance rates (unadjusted)
- Benchmark is determined using the top-ranked eligible professionals (EPs) whose denominator represents at least 10% of the overall number of patients on which the measure was reported

Assumptions made:

- CMS will continue the policy of only including samples of 20 patients or more
- Stars are received in each 20% increments with the benchmark reported beside individual results

Eligible	Denominator	Performance Score	Benchmark	Star Assigned
Professional				
Physician A	10	N/A	76%	N/A
Physician B	30	27%	76%	**
Physician C	50	50%	76%	***
Physician C	150	93%	76%	****
Physician D	200	76%	76%	***

If the stars are provided in increments based on the benchmark for that measure (indicating that five stars are those EPs who achieved the benchmark or higher), ratings would appear as follows:

Eligible	Denominator	Performance Score	Benchmark	Star Assigned
Professional				
Physician A	10	N/A	76%	N/A
Physician B	30	27%	76%	**
Physician C	50	50%	76%	***
Physician D	150	93%	76%	****
Physician E	200	76%	76%	****

Replacing the current benchmarking methodology with the ABC methodology

The current benchmarking methodology could be replaced with the ABC methodology. Generally, the approach is the same with the same requirements for a minimum number of reporters and data completeness but there are two key differences:

- The upper benchmark is set based on top-ranked eligible professionals (EPs) whose denominator represents at least 10% of the overall number of patients on which the measure was reported and
- Performance scores are distributed evenly across the deciles rather than based on the "curve" of performance.

Below are three scenarios using measures with an available benchmark in the 2017 MIPS program. Each includes the current benchmark and a revised benchmark using the ABC methodology. We could not determine the top performers using the 10% of the denominator approach, the benchmark for the ABC method used the % in Decile 10 as a proxy. The degree to which these benchmarks would change using real performance data is unknown. One alternative that CMS could explore but is not outlined here would be to set the top decile based on the ABC methodology and still distribute performance based on the curve rather than even distribution across deciles.

Scenario 1

Measure: 113: Colorectal Cancer Screening (Claims)

Benchmark: 100%

Measure	Deciles							
Wieasure	3	4	5	6	7	8	9	10
G (P 1 1	29.50-	42.37-	53.85-	64.41-	75.41-	84.68-	93.14-	100.0
Current Benchmark	42.36	53.84	64.40	75.40	84.67	93.13	99.99	100.0
ADC models of	29.50-	40.00-	50.00-	60.00-	70.00-	80.00-	90.00-	100.0
ABC method	39.99	49.99	59.99	69.99	79.99	89.99	99.99	100.0

Scenario 2

Measure: 71: Breast Cancer: Hormonal Therapy for Stage IC - IIIC Estrogen Receptor/Progesterone

Receptor (ER/PR) Positive Breast Cancer (Registry/QCDR)

Benchmark: 100%

Maggira	Deciles							
Measure	3	4	5	6	7	8	9	10
Current Benchmark	80.49- 90-78	90.79- 96.48	96.49 - 98.07	98.08- 99.99				100.0
ABC method	80.49- 82.99	83.00- 85.99	86.00 - 88.99	89.00- 91.99	92.00- 94.99	95.00- 97.99	98.00- 99.99	100.0

Scenario 3

Measure 128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-up Plan (EHR)

Benchmark: 68.19%.

	Deciles	Deciles						
	3	4	5	6	7	8	9	10
G . B . 1	28.73-	31.81-	34.46-	37.24-	40.20-	43.65-	48.76-	>=
Current Benchmark	31.80	34.45	37.23	40.19	43.64	48.75	68.18	68.19
ADC	28.73-	34.37-	40.00-	45.63-	51.26-	56.89-	62.52-	>=
ABC method	34.36	39.99	45.62	51.25	56.88	62.51	68.18	68.19