

June 27, 2016

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

Re: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM)
Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment
Models; Proposed Rule (CMS-5517-P)

Dear Acting Administrator Slavitt:

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) regarding the notice of proposed rulemaking (NPRM) on the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). When Congress passed the Medicare Access and CHIP Reauthorization Act (MACRA), it created an opportunity to move away from the flawed sustainable growth rate methodology and address problems found in existing physician reporting programs (i.e., Physician Quality Reporting System (PQRS), Meaningful Use (MU), and Value-Based Modifier (VBM)). The law also sought to promote innovation by encouraging new ways of providing care through APMs and physician-focused care models.

While the law made these improvements possible, we recognize that implementing MACRA is a significant undertaking. The intent of MACRA was not to merely move the current incentive programs into MIPS but to improve and simplify these programs into a single more unified approach. This will require numerous changes in the way cost and quality are measured and compared across physician practices, including better risk adjustment, more granular group comparisons, more sophisticated attribution methods, and more timely and actionable feedback to physicians. Similarly, in passing MACRA, Congress clearly intended to create an accelerated pathway for physicians to develop and implement APMs. We strongly urge CMS to vigorously pursue this objective and establish a much more progressive and welcoming environment for the development and implementation of specialty-defined APMs than proposed in the NPRM.

While the proposed rule seeks to address many of these concerns and provides improvements over current law in several areas, we believe that certain provisions require considerable modifications. Our objective is to work collaboratively with CMS to address these issues and resolve them before implementation of the new programs to ensure a successful first year and allow MACRA to fulfill its promise to create a more value-based health care system.

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Areas we want to highlight are: 1) finding ways to make the MIPS program into a single unified approach; 2) creating a pathway from MIPS to APMs; and 3) expanding the APM proposal to recognize and include important models that can improve patient care and health care quality.

To improve upon the current proposal, we urge CMS to adopt the following high-level recommendations:

- Establish a transitional period to allow for sufficient time to prepare physicians to have a successful launch of MACRA.
- Provide more flexibility for solo physicians and small group practices, including raising the low volume threshold.
- Provide physicians with more timely and actionable feedback in a more usable and clear format.
- Align the different components of MIPS so that it operates as a single program rather than four separate parts, such as creating a common definition for small practices.
- Simplify reporting burdens and improve chances of success by creating more opportunities for partial credit and fewer required measures within MIPS.
- Reduce the thresholds for reporting on quality measures.
- Reward reporting of outcome or cross-cutting measures under a bonus point structure rather than a requirement in order to achieve the maximum quality score.
- Improve risk adjustment and attribution methods before moving forward with the resource use category.
- Replace current cost measures that were developed for hospital-level measurement and refine and test new episode measures prior to widespread adoption.
- Permit proposals for more relevant measures, rather than keeping the current MU Stage 3 requirements.
- Remove the pass-fail component of the Advancing Care Information (ACI) score.
- Reduce the number of required Clinical Practice Improvement Activities (CPIAs) and allow more activities to count as "high-weighted."
- Simplify and lower financial risk standards for Advanced APMs.

The attachment to this letter provides additional comments on these recommendations, including the detailed reasoning behind these suggested changes. The AMA worked collaboratively with a number of national specialty and state medical societies to compile these comments. Although each society may have its own unique perspective, our comments generally reflect common ground within organized medicine regarding these issues.

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We are hopeful that a true partnership and continuous dialogue between CMS and the physician community will help guide discussions on this proposed rule. Specifically, we ask that CMS issue an interim final regulation as its next step to allow for continued improvement and refinement of these approaches in the future. By working together and maintaining an open dialogue, we believe we can make changes that allow physicians to achieve better care for their patients while reducing administrative burden and costs on practices. We look forward to working with you on achieving a successful implementation of MACRA. 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

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Attachment

CMS MIPS and APMs Proposed Rule Detailed Comments of the American Medical Association June 27, 2016

A. Overarching Topics

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 - ii. Future Program Years
- b. Impact on Small, Rural, Health Professional Shortage Areas (HPSAs) and Similarly Situated Practices
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B. The Merit-Based Incentive Payment System (MIPS)

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- b. Quality
 - i. Reporting Requirements
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- a. Nominal Risk
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- a. Physician Compare
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Overarching Topics

Performance and Reporting Periods

The proposed rule requires that APM and MIPS performance be measured starting January 1, 2017, with the first MIPS payment adjustments being made in January 2019, and the first incentive payments to Advanced APM participants being made in mid-2019. The proposed start date is inconsistent with the intent of Congress to establish a performance period that is much closer to the payment adjustments and leaves insufficient time for physicians and other stakeholders to prepare for the new programs. The AMA strongly urges CMS to create an initial transitional performance period from July 1, 2017 to December 31, 2017 to ensure the successful and appropriate implementation of the MACRA programs. In future years, for all required reporting requirements, CMS should allow physicians to select periods of less than a full calendar year to provide flexibility.

Recommended Modifications:

Transitional Period

• Establish an initial transitional period from July 1, 2017 – December 31, 2017

After careful review, the AMA and many other physician organizations believe that the proposed start date is too early and will create significant problems for the launch of the MACRA programs. We believe it is necessary for CMS to recognize the fundamental changes enacted as part of MACRA and treat the first year as a transitional period that allows physicians to move away from the existing Medicare reporting requirements, learn about MIPS and APMs, and implement workflow and system changes to become successful MACRA participants. We, therefore, believe that CMS should offer an alternative first MACRA performance period that begins July 1, 2017.

CMS has noted that it chose the proposed January 1, 2017 start date based on previous experiences with quality programs and that there are significant trade-offs in selecting a later date, including the calculation of outcome and claim-based measures, the feasibility of using different reporting mechanisms, meeting statutory deadlines, postponing changes to the ACI category, and the capability of CMS' own internal processes. CMS could offset potential concerns by allowing physicians to select a shorter six month reporting period or use the full calendar year (with an optional look-back to January 1 in 2017) if they believe it is more appropriate for their practice. We believe that the benefits of creating an initial transition period vastly outweigh starting all the programs on January 1, 2017 for a number of reasons.

As a practical matter, starting the program on July 1, 2017 rather than January 1, 2017 provides additional time between the issuance of the MACRA final rule and the start of the performance period. Physicians need to be educated about the new requirements and change their practices to accommodate the MIPS and APM programs. CMS, however, is unlikely to publish the final rule before the fall of this year, leaving participants with only a few months before the proposed start date. Without adequate notice of final program requirements, a final list of qualified APMs, specified program thresholds, and other details, CMS is setting up the program for potential failure.

The AMA is also concerned by statements made by CMS that physicians do not have to begin reporting at the start of the performance period, indicating that physicians will actually have more time to collect data, change workflows, and implement required MIPS and APM changes. This, however, is completely misleading given that many of the quality measures require actions to be taken at the point of care and cannot be completed at a later date. CMS should realize that in

reality physicians need to prepare and be ready several months *before* the performance date in order to successfully participate, and that these statements simply create more confusion.

Setting the performance year too soon will also compromise the ability for vendors, registries, Electronic Health Records (EHRs), and others to update their systems to meet program requirements. The MIPS program asks that these entities incorporate a significant number of new measures, including an entirely new category of CPIAs. We have serious concerns that there will be inadequate time to not only include new measures but also to test and ensure the data submitted is accurate and reliable. The timeframe proposed simply does not allow for these entities to validate new data entry and testing tools, which can also worsen usability and add to the existing problems with this technology. Furthermore, EHRs are expected to undergo a significant overhaul of their systems to comply with the 2015 certification requirements. To date, however, there are few 2015 certified products available and most believe that physicians will not have this updated technology by January 2017, requiring physicians to use alternatives to meet the ACI requirements and limiting those in APMs from utilizing the benefits of the new technology. If the technology is not ready by January 1, 2017, we do not see it as a benefit to physicians to try and start the new ACI requirements at an earlier time.

Similarly, we are concerned that an early start date will limit the number of available APMs for physicians. A July 1, 2017 start date provides time to modify existing CMS APMs so that they can qualify as MIPS or Advanced APMs. In addition, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) is still in the process of developing a review framework and has not had sufficient time to review or recommend new models. Implementing a July 1, 2017 start date provides more time for the PTAC to begin its work identifying physician-focused payment models.

Finally, a later start date would provide CMS with more time to address several issues that were absent from the proposed rule, including the development of virtual groups, improved risk-adjustment and attribution methods, further refinement of episode-based resource measures and measurement tools and enhanced data feedback to participants. Statements in the proposed rule indicate that CMS did not have sufficient time, was waiting upon report findings, or needed to upgrade its systems before it could fully implement these changes that were required as part of the MACRA statute. If this is the case, we believe CMS should take such time and provide a later start date. To be clear, we are not asking that CMS continue the existing program (PQRS, MU, and VBM) in 2017; the current programs should still end, which avoids having CMS and physicians try to report and calculate performance twice for 2017.

Our analysis of the MACRA statute supports our view that the first performance period should occur later than January 1, 2017. The law states that the performance period shall begin and end prior to the beginning of such year and *be as close as possible to such year* (emphasis added). In drafting MACRA, Congress sought to address CMS' practice of setting a two-year look-back period for Medicare quality programs. The decision to include the "as close as possible" language was intended to urge CMS to select a performance period that closed this two-year gap. CMS, however, has failed to even address or identify ways to implement the "as close as possible" statutory requirement.

MACRA also requires CMS to give "timely (such as quarterly)" feedback to physicians. Yet, by selecting January 1, 2017 as the first performance period, physicians will have not received their first feedback reports, which MACRA requires, by July 1, 2017. This leaves physicians without the information they need to successfully start the MIPS program, keeping them in the dark for over half of the first performance period. Likewise, MACRA requires a quality development plan with annual progress reports, and requires the first progress report to be issued by May 1, 2017. Again, by starting the

¹ Medicare Access and CHIP Reauthorization Act (MACRA). Pub. L. No. 114-10 § 1848(q)(4) (emphasis added).

program on January 1, before the quality progress reports are finalized, CMS is jumping ahead of itself and not finalizing key program requirements before it begins MIPS. We have also identified other complications with the January 1 start date, including the overlap with new participants in the MU program, which would require individuals to report twice in 2017, as discussed in more detail in the ACI section of our comment letter. CMS should recognize that these conflicting statutory deadlines strongly point to a later start date as the more appropriate timeframe for MACRA.

It is in the interest of patients, physicians, and the Medicare program that MACRA implementation goes smoothly. To do this, we strongly believe that a transitional period will help all of the stakeholders that are working towards implementing MACRA. In the past, CMS has used transitional periods at the start of new programs, providing accommodations for the first year as participants learn and adjust to new requirements. MACRA creates a similar challenge for practices that will require adjustments and a learning curve. We, therefore, urge CMS to create an initial transitional period for the MACRA program from July 1, 2017 – December 31, 2017.

Future program years

• Allow physicians to select a shorter reporting period

For both the MIPS and APM programs, CMS is proposing to use a full calendar year for the reporting period for measures that are not automatically calculated by CMS. A full calendar year requirement, however, can create significant administrative burden for practices and limits innovation while not necessarily improving the validity of the data. Instead, physicians should be able to select a shorter reporting period or use the full calendar year if they believe it is more appropriate for their practice.

The statutory language for the MIPS and APM categories does not require the use of a full calendar reporting period. The MIPS definition simply uses the term "performance period," avoiding the word "year" to allow CMS flexibility. Indeed, CMS recognizes this authority to set a shorter reporting period for the CPIA category and proposes a minimum 90-day reporting period. The APM statutory language also includes language noting that the reporting period "which may be less than a year." We urge CMS to take advantage of this flexibility and allow physicians to select a shorter reporting period for either the MIPS or APM programs.

The AMA acknowledges that performance may need to be calculated over a longer period of time in the resource use category in order to ensure its reliability and applicability to a significant number of practices. We believe that, if necessary, a distinction could be made between performance periods for programs where physician reporting is required versus those where CMS calculates measures using claims. To ensure that such a decision is evidence-based, CMS could conduct more detailed analysis of VBM data to determine the extent to which including data for a year rather than six or nine months improves reliability and expands applicability of resource measures. Under our proposal to restrict or eliminate the resource measures in 2017, there would be time for CMS to conduct this additional analysis and use it to inform decisions on the resource year performance period in 2018 and thereafter.

We understand that CMS' systems and processes may have challenges in using a shorter reporting period. We, however, urge the agency to work with physicians to develop options and a specific plan to provide accommodations where possible. We look forward to working with CMS to determine alternatives that will help ensure the future success of the MACRA programs.

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² Id. at § 1833(z).

<u>Impact on Small, Rural, Health Professional Shortage Areas (HPSAs) and Similarly Situated Practices</u>

The AMA is sensitive to the unique challenges that small, rural, HPSAs, and similarly situated physician practices face in trying to comply with Medicare and other payer requirements. These practices play a vital role in the care of their communities, including Medicare patients, and often have limited resources to devote to complex reporting programs. Accordingly, MACRA offers flexibility to build a program structure that ensures the viability of these practices in the future and should create programs that are feasible for physicians in every specialty and for practices of every size.

We recognize that the proposed rule's regulatory impact analysis included a table that was perceived to show that the MIPS program would negatively impact physicians in small practices. We, however, agree with CMS that the table does not present a clear picture of likely physician impacts under MIPS for a number of reasons: it does not reflect the accommodations in the proposed rule that are intended to provide flexibility to small practices; it only looks at quality and resource use and omits performance in the ACI and CPIA categories; it includes many non-physician health professionals, such as dentists and chiropractors, whose experience with Medicare quality reporting programs cannot be considered a good predictor of 2019 physician impacts; it includes specialties and practices that may be exempt from certain MIPS measures or categories; and it is based on 2014 data when physicians and other clinicians in many solo and small practices did not report their performance. Yet, while this information appears to be overly pessimistic, we continue to believe that CMS needs to provide additional accommodations for small, rural, HPSAs, and similarly situated practices.

Recommended Modifications:

Lower reporting burdens for small, rural, HPSAs, and similarly situated practices

CMS should provide explicit exemptions and lower thresholds throughout the proposed rule for physicians in small, rural, HPSAs, and similarly situated practices, incorporating specific accommodations into each of the four MIPS categories as well as APMs. For example, given reliability concerns of the resource use category, CMS should provide explicit exemptions not just for individual measures but to the entire category for certain small practices. Exemptions should also be included in the ACI category, where currently there are no accommodations based on practice size or resources. CMS should also consider the length of the reporting periods and the feasibility of shorter timeframes for these practices. Lastly, CMS should ensure that there are free or low cost reporting options within each MIPS category. Especially in the quality, ACI, and CPIA category, CMS should allow proposals for measures that could accommodate activities that do not require costly technology or interfaces that may create barriers for these practices.

Where possible, compare practices to their peers rather than more advanced and sophisticated entities

In areas where CMS is comparing performance of clinicians, CMS should take into account the size and resources a practice is able to devote to their MIPS performance. The scoring methodology should not provide distinct advantages for practices simply because they are large and should not penalize others for their size or unique patient population.

• Finalize the concept of virtual groups

The MACRA statute included the concept of virtual groups to help assist small practices; however, CMS proposes not to implement such groups until the 2018 performance period. In our November 17 comment letter on CMS' Request for Information (RFI), we noted that smaller practices will need time to learn about virtual groups, reducing the initial administrative burden on CMS and escalating the need for the agency to develop and disseminate information about this option. We strongly urge CMS to act on forming these groups as soon as possible. Without this assistance, we believe small practices may face even greater challenges when attempting to move into the MIPS program structure.

When developing virtual groups, CMS should offer significant flexibility—there should be no initial, annual, or other limits placed on the maximum number of groups approved each year or the required geographic proximity. Furthermore, there should be no requirement that all clinicians within a virtual group be within the same specialty. We refer CMS to our RFI comments for more details on these proposals.

Increase the low-volume reporting threshold

As outlined in more detail below, the low-volume threshold provides CMS with the flexibility to exempt small practices from the MIPS program. We encourage CMS to create a sufficient threshold so that physicians with small revenues and Medicare populations are not unduly burdened.

• Provide education, training, and technical assistance to these practices

Physicians participating in small and rural practices will need assistance to help them onboard to the new MACRA programs. This assistance should start as soon as possible and be readily accessible throughout the start of the MIPS and APM programs. In particular, CMS should not only provide educational information but have help desks and staff ready to assist physicians when they have questions about the program. The AMA is pleased to be a Support and Alignment Network grantee in the CMS Transforming Clinical Practice Initiative. This program is well positioned to serve this function, and we ask that CMS continue to highlight this and other opportunities for such practices.

Low-Volume Threshold

Since the release of the MACRA NPRM, many concerns have been voiced about the potential impact of MIPS on solo and small physician practices. To help mitigate adverse effects on small practices, CMS has proposed a low-volume threshold, exempting physicians with less than \$10,000 in Medicare allowed charges and fewer than 100 unique Medicare patients per year. An AMA analysis of the 2014 "Medicare Provider Utilization and Payment Data: Physician and Other Supplier" file, however, found that just 10 percent of physicians and 16 percent of all MIPS eligible clinicians would be exempt under the \$10,000/100 beneficiary proposal. These low-volume clinicians account for less than one percent of total Medicare allowed charges for Physician Fee Schedule services.

Recommended Modifications:

• Significantly raise the low-volume threshold

The AMA urges CMS to raise the low-volume threshold significantly from the proposed level, which would exempt only clinicians and groups with less than \$10,000 in Medicare allowed charges AND fewer than 100 unique Medicare patients per year. **Instead, the AMA recommends that clinicians with less**

than \$30,000 in Medicare allowed charges per year OR fewer than 100 unique Medicare patients be exempt from MIPS. The less than \$30,000 OR fewer than 100 patients threshold should apply to claims for each eligible clinician identified with a National Provider Identifier (NPI) and not be applied at the group level. In addition, physicians in small practices who are providing care to patients in rural areas and HPSAs should be provided opportunities to be exempt from MIPS.

By raising the threshold to \$30,000 in Medicare allowed charges OR fewer than 100 unique Medicare patients seen by the physician, and applying the threshold to each clinician, CMS would provide a better safety net for physicians in solo and small practices. This exemption would exclude less than 30 percent of physicians while still subjecting more than 93 percent of Medicare allowed spending to MIPS.

In addition, we believe changing the low-volume threshold is warranted based on several provisions of MACRA that were intended to assist small physicians but will not be finalized by the proposed start date. For example, MACRA outlined a requirement for virtual groups that would allow small practices to join together and be judged on aggregate data rather than individually under MIPS. CMS, however, has signaled that these groups will not be available for the proposed first performance year. Without this and other key assistance, we urge CMS to expand the low-volume threshold to avoid inadvertently penalizing small practices.

Finally, CMS' own data indicates that a \$30,000 threshold is more reasonable. Looking at the data from the 2015 and 2016 PQRS programs, over 25 percent of physicians with Medicare Part B charges less than \$40,000 were subject to a payment adjustment. In contrast, once physician Medicare revenues reach the \$40,000-\$100,000 range, physicians were considerably less likely to earn a penalty.

The low-volume threshold is an important tool for preventing adverse impacts from the MIPS program on patients' access to care. The NPRM estimates significant costs of participating in MIPS. Physicians with very small Medicare fee-for-service patient populations will have little likelihood of recovering these investments. If low-volume physicians are not exempted from MIPS, they may decide to further reduce their involvement with the Medicare program by seeing fewer Medicare patients, opting out of Medicare, or seeing only Medicare Advantage patients. Although these changes would have no real impact on Medicare allowed charges, they could worsen seniors' access to certain specialists who are already too few in number to serve the Medicare population, such as psychiatrists and addiction medicine specialists.

In addition, changing the patient threshold to be an alternative means of qualifying for the exemption instead of an additive means would help physicians who may provide very complex, high-cost treatments to a small number of Medicare patients. These physicians could exceed the \$30,000 threshold due to high-cost cases but could be seeing an average of fewer than two Medicare patients per week.

Feedback to Physicians

In past comment letters, 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. CMS and Congress need to update Medicare's antiquated systems. Physicians lack the data and the information used to arrive at the benchmarks and other calculations made under current reporting programs, which limits their ability to successfully participate. We, therefore, have asked CMS to make significant improvements in this area to the MIPS program but do not believe CMS' proposals address the majority of our concerns.

Recommended Modifications:

• Provide ongoing, real-time feedback on performance

We appreciate CMS' efforts to conduct MIPS user assessments but are concerned these efforts fall short and do not address the complexity of accessing feedback reports. We are also concerned with the timeliness of the release of feedback reports and benchmarking information. CMS should consult with stakeholder groups to determine the best presentation and most meaningful format for sharing ongoing, actionable performance feedback with physicians and practices. 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. While, Qualified Clinical Data Registries (QCDRs) have the ability to provide more timely and action information, the information they produce 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, including their composite score and not just with quality. At the very least, CMS must produce, at least quarterly reports on a physician's resource use/cost information compared to other MIPS eligible clinicians (ECs) since the information is based on claims submission.

Clearly outline methodologies used to calculate any benchmarks or attributed patients for a particular measure

This information must be clearly identified and easy to interpret. In addition, CMS should designate staff to help physicians and administrators interpret the reports, including understanding the various measure methodologies, attribution rules, scoring, and benchmarks. In cases where different attribution methods or other methodological variance creates mismatched data within a physician's report, the report should include an explanation rather than expecting physicians to search for and read detailed documents on the CMS web site.

Make available web-based, dashboard, and paper reports

The AMA believes that CMS should aim to display feedback and performance measurement information in graphic form with additional details displayed elsewhere. In addition, the reports should include high-level overall performance information and drill down tables with individual patient information. Finally, as the AMA has noted in previous comments, there have been ongoing problems with a physician's ability to access their feedback reports due to the overly complicated log-in process. We urge CMS to improve the log-in process for accessing reports to ensure it is simple and user-friendly. It should also be possible for individual physicians within a group practice to access their own reports directly rather than through a group.

Develop a fair and transparent process for physicians to appeal findings in the feedback reports and lengthen the review timeline to at least 90 days

Physicians must be provided adequate notice that feedback reports are available and given sufficient time to review their data. To expect physicians to access, review, and contest data in less than 90 days ignores the demands of patient care and competing priorities physicians face on a daily basis. Experience with earlier Quality and Resources Use Reports (QRURs) suggests that very few physicians are actually reviewing them. If the goal of MIPS is to improve care and prepare physicians to participate successfully in MIPS or transition to APMs, then CMS must take feedback report improvements seriously.

• Release feedback reports in a timely manner

We urge CMS to release the reports as early as possible so physicians are not well into the next reporting cycle before they learn of their MIPS results and performance and have the opportunity to institute workflow changes to ensure success under MIPS. Physicians should be able to choose if they want to receive more current information, such as MACRA's recommendation that data be available on a quarterly basis.

The Merit-Based Incentive Payment System (MIPS)

Overview

A key factor in medicine's support for MACRA was the law's promise to create a new Merit-Based Incentive Payment System that would be less complex and more meaningful to the majority of physicians and their patients. As highlighted in our comments to the MACRA RFI, CMS' overall goal in MIPS should be to create a more unified reporting program with greater choice and fewer requirements.

While we see several positive changes in the proposed rule, our main concern is that CMS continues to view the four MIPS components as separate programs, each with distinct measures, scoring methodologies, and requirements. MIPS is not proposed as a single unified program; rather, the four components operate alone and lack commonality in areas with significant overlap. **The AMA strongly urges CMS to work to establish a more holistic approach and not maintain the divide between different MIPS categories.** A holistic approach would transform MIPS from a continuation of four distinct compliance programs to one in which physicians can identify a purpose to the reporting activities. For example, if physicians can see the use of certified EHR technology (CEHRT) as something that will improve clinical performance and capture quality data, they will be more receptive to the idea that ACI is truly distinct from the MU program.

To create a more unified program, the AMA believes that CMS should identify clear connections across the four MIPS categories. Specific examples of how to initially transform MIPS into a more comprehensive approach include:

- Unifying definitions, such as small practice, across all MIPS categories.
 - As proposed, small practice generally means 15 or fewer clinicians; however, there is a variation in the quality component for the all-cause hospital readmission measure for practices with *fewer than 10 clinicians*. While CMS' reasoning for this exclusion is based on reliability and not merely an accommodation for practice size, few physicians will know or appreciate this difference, and participants will perceive that there are some accommodations for groups of one size and separate accommodations for groups of another. CMS should use the 15 or fewer clinician threshold, as defined in MACRA, throughout the rule.
- Streamlining scoring so that each category does not create a system that has multiple complex components and exceptions.
- Combining CPIAs and ACI measures. Proposed CPIAs such as closing the referral loop, timely
 communication of test results, and updating plans of care can utilize technology and could be
 used as part of both the ACI and CPIA scores. This synthesis could be expanded to incorporate
 quality and reduce duplicative data entry where appropriate.

- Implementing a call for new MIPS measures—CMS should expand the call for new quality measures to reach all other MIPS categories, allowing proposals for new ACI, CPIAs, or resource use measures and to promote a pathway towards APMs.
- Highlighting specialty designations in the quality component throughout the MIPS program to create specific pathways for specialties and subspecialties.

In the long-term, CMS should focus the program on the desirable outcomes we want to achieve. As we outlined in our <u>Quality Measure Development Plan comments</u>, CMS should start with a broad problem that needs to be solved, set targets for success, identify key roles for physicians as well as other stakeholders, and use measurement to guide us toward our targets (e.g., preventing diabetes, controlling blood pressure, or improving or managing another disease or condition). Then, based on feedback from relevant stakeholders, describe what is being asked of each entity. This process will more effectively allow CMS and stakeholders to create a measure to accompany each "ask."

Overall, physicians should feel that each MIPS category builds off of and mirrors the other categories. MIPS should then tie into APMs, creating a pathway for moving to more advanced models. This could be done by implementing the APM proposals for some of the MIPS categories. For example, the certified technology requirement for APMs requires a certain percentage of physicians to use certified EHRs but allows them to use the technology as they see fit. The ACI category could build up to this approach, creating a way for physicians to move towards using technology in this manner and becoming an APM. Similarly, the quality category of MIPS could build up to the same approach adopted for advanced APMs, which allows models to choose their own approach to measuring quality as long as they include at least one quality measure from the MIPS program. Our understanding is that the MACRA statute offers enough flexibility to implement this more comprehensive approach and will reduce the complexity found in the proposed program.

Since initially a large number of physicians will be participating in MIPS, we believe that the first perception of the program will be an important one to establish. The more streamlined and unified the MIPS program is, the more physicians will see it as one that can be accomplished and can be adopted into their practice.

While our focus is on creating a more unified version of MIPS, we also recognize that CMS has outlined specific proposals related to each of the MIPS components. The following highlights our comments on the different MIPS categories. We, however, urge CMS to address our recommended modifications in a way that creates greater alignment across MIPS.

Quality

Proposals the AMA Supports:

- Eliminate the domain requirement: Requiring physicians to report on specific domains overly complicates quality reporting. Removing this requirement will mitigate reporting data that is of little value.
- Allow flexibility in measure selection: Physicians should have the option to select individual measures or specialty specific measure sets, report via any reporting mechanism, and report as an individual or group.

• Eliminate pass/fail scoring: CMS should finalize its proposal to allow partial credit. Physicians should be able to earn points within the quality category even if they do not successfully report on a measure.

Recommended Modifications:

While the proposed quality category attempts to simplify reporting, it also creates new challenges. To simplify this category, we believe that several key changes should be made. Specifically, CMS should reduce the required number of measures, eliminate the outcome/high priority and cross-cutting measures requirements, and remove the three population health measures. Instead, reporting on outcome and cross-cutting measures should only count as bonus points and the population-based measures could be optional under the CPIA category.

Reporting Requirements

• Reduce the reporting threshold to 50 percent

CMS proposes to increase the threshold for successfully reporting on a measure from 50 percent to 80 percent via claims and 90 percent via EHR, clinical registry, QCDR, or web-interface. If a physician fails to meet the data completeness threshold they do not receive points for reporting on the measure. For example, if a physician reports 75 percent of their patients for a measure, they would fail to meet the threshold and would not earn any points for that measure.

The proposal is almost a two-fold increase in data completeness requirements compared to the current PQRS program. The AMA finds the proposed thresholds are not only unrealistic but incorrectly assume that a physician will not run into any administrative problems, and practices will be ready to begin reporting on a measure on day one of the reporting period. In reality, approximately three percent of claims have administrative issues that could affect a physician's success or inappropriately hold a physician accountable for a measure. Creating such high thresholds creates an environment with little room for error and will jeopardize the success of many participants.

As an example of this concern, physicians may perform a form of chart extraction where either a physician or third-party can submit the information to CMS after the close of the reporting period. When, however, a physician is reporting on an outcome measure, shared decision making measure, or patient reported outcome (PRO) measure, the physician or practice cannot go back in time to collect or document the information. For example, if an orthopedic surgeon chooses to report on the Total Knee Replacement Shared Decision Making measure, the orthopedic surgeon must discuss treatment options and document that discussion at the point of care with the patient. PRO measures and patient satisfaction are important aspects of care and sought after information by patients and other stakeholders, but, based on CMS' data completeness requirement, many of these measures would most likely not be calculated in a physician's quality score and potentially appear as if the physician provided poor care.

Such a high threshold will also create a disincentive from reporting on certain high priority measures due to the large administrative cost and burden with collecting information, especially when coupled with the new requirement of reporting on "all-payer" data using a QCDR, registry, EHR, or web-interface. CMS states that it wants to incentivize electronic reporting, especially registries and QCDRs; however, its proposal does the opposite—by placing the highest thresholds for these data submission methods, physicians will be deterred from using them and may prefer to stay with claims and other types of reporting mechanisms.

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³ 2013 National Health Insurer Report Card, American Medical Association. 2013.

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

If CMS is concerned that a 50 percent threshold lends itself to possible gaming then it is misinformed. A 50 percent threshold still requires reporting on a majority of patients and does not lend itself to cherry picking. Once physicians decide to institute a workflow change in their practice they continue to perform the function. They do not divert resources to deciding which patients to include for each measure. A 50 percent threshold is simply a more realistic reporting level that acknowledges potential problems, such as a vendor not updating measure specifications at the start of the reporting period, a practice switching EHR vendors, power outages, inaccurate coding or natural disaster. Therefore, we urge CMS to reduce the quality reporting threshold back to 50 percent.

• Reduce the number of required quality measures

The AMA is pleased to see that CMS has eliminated the domain requirement and reduced the number of required quality measures to achieve the maximum points under the quality category compared to the PQRS program. We continue to be concerned, however, that the requirements CMS has put forward are overly restrictive and emphasize compliance over quality improvement. We are troubled that there is a misperception by CMS that a physician must be overly measured in order to demonstrate value and care improvement.

To allow physicians to focus on improvement efforts that better suit their area of practice and patient population, physicians should be able to choose a few measures that will have a high impact on care improvements, such as controlling blood pressure. Yet, under the quality proposal, a physician's time will still be consumed with finding relevant measures. In addition to the six quality measures, a physician will also potentially be assessed on three population health measures (acute and chronic composites and all-cause hospital readmission measure), and will be held accountable for the various activities under the three other MIPS categories.

The six random measures a physician or group must report on may not meet the needs of a physician's practice to achieve the maximum potential points under the quality category. **Therefore, we recommend that CMS further reduce the number of required quality measures to four.** Allowing for such flexibility will reduce administrative burden and provide time for physicians to focus on quality improvement. It will also lend itself to more accurate measurement and a better snapshot of quality.

• Eliminate the outcome and cross-cutting measure requirement

The proposed rule adds complexity by mandating that physicians report on an outcome measure and cross-cutting measure. If an outcome measure is not available then a practice must report on at least one "high priority" measure. We believe this proposal may disadvantage certain specialties as well as small or rural physician practices.

In particular, and as discussed in more detail in the data submission section of these comments, the outcome and cross-cutting measure requirement poses challenges for QCDRs. Some approved QCDRs

⁴ Implementing Team Based Care Module. *STEPSforward*. American Medical Association. 2016. Web-Module. https://www.stepsforward.org/modules/team-based-care#section-references. Accessed June 16, 2016.

do not incorporate value codes in their data collection process. QCDRs are different from traditional registries and are not complete EHR systems. This was the intended purpose of the QCDR—to allow providers and certain CMS-approved quality improvement registries to select measures from the registry to focus on quality reporting purposes. Furthermore, a specialized registry collects data addressing specific aspects of care (a condition or a specific procedure). Accordingly, there will be Medicare patients eligible for the denominator of cross-cutting measures, but the data would not necessarily be captured in the registry because it may be outside the registry's scope of the condition or procedure (unrelated office visit for example). This not only is counter to the purpose of QCDRs, it makes the 90 percent reporting threshold for QCDRs nearly impossible to meet. Thus, we urge CMS to remove this cross-cutting measure requirement.

Instead, CMS should recognize the importance of these measures through bonus points rather than a mandate on all participants. As the AMA highlighted in our MACRA RFI comments, there are a number of methodological issues that must be addressed by CMS before requiring the reporting on outcome measures, such as risk-adjustment for socio-economic (SES) and demographic status (SDS) and attribution (particularly for reporting on cross-cutting measures and population health measures/administrative claims measures). In addition, infrastructure challenges may prevent physicians from having the ability to report on outcomes measures, such as having the appropriate data elements in the EHR as well as interoperability issues that may interfere with the exchange of needed information, and the inability to do longitudinal tracking due to the lack of uniform patient identifiers. CMS should maintain flexibility by not requiring the use of any specific type of measures in the initial years of the program. Our recommendation maintains flexibility in the design of the category and ensures success by all physician specialties regardless of practice size or patient population. It also takes into consideration the lack of relevant outcome measures or high priority measures available by specialty and reporting mechanism, and simplifies the overall calculation for scoring quality.

• Provide clarification on specialty measure sets

We appreciate the flexibility offered by allowing physicians to select measures either from the individual quality measure list or specialty specific measure set. We are, however, concerned that the creation of specialty measure sets may cause confusion given many sets have less than the required six measures and do not include an outcome or high priority measure. We request that CMS clarify how scoring will work in these instances.

We recognize the need to assist physicians and steer them to appropriate measures based on their specialty, but the sets are initially much better suited as educational materials. Many of the sets are categorized by general specialty and not broken down by sub-specialization. The sets, therefore, may not be applicable for sub-specialists. In addition, many specialties do not have a listed specialty measure set. For example, there is no neurosurgery measure set. Is it CMS' intent for a neurosurgeon to report on the surgical measure set? What about specialists within neurosurgery, such as spine, cerebrovascular and endovascular, neuro-oncology, pain, etc. In addition, within each set, the number of applicable measures may further be reduced by the available reporting/submission mechanism. For example, the urology specialty set only includes one EHR based measure. Therefore, we seek clarification as to whether a urologist who reports the one electronic clinical quality measure (eCQM) in the set (PQRS 50: Urinary Incontinence: Assessment of Presence or Absence Plan of Care for Urinary Incontinence in Women) is only accountable for the one eCQM and not accountable for reporting on an outcome or high priority measure.

Make global and population-based measures optional

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' proposal to merely move three problematic VBM measures into the MIPS quality category. Reclassifying these measures as "population health measures" under the quality category does not fix any of the inherent problems with these measures and avoids creating an improved 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. In light of this flexibility and, due to the reasons and concerns we outline below, we urge CMS to institute discretion and not include the three population health measures in the quality category. Instead, they should be optional under the CPIA category. This recommendation is similar to a previous PQRS reporting option where practices had the option to self-designate whether they wanted CMS to calculate administrative claims measures on their behalf.

As proposed, CMS plans to assess and incorporate into a physician's or group's quality score the following three administrative claims population health measures:

- Acute Composite
- Chronic Composite
- All-Cause Hospital Readmission (only applicable in groups with 10+ (EC))

The AMA is concerned with the incorporation of the acute and chronic condition composite measures as they were intended to be implemented and reported at the metropolitan area or county level (per 100,000) and have been endorsed as such by the National Quality Forum (NQF) with the exception of Prevention Quality Indicator (PQI 8 Heart Failure), which is at the health plan/integrated delivery system level.

A similar concern exists for the All-Cause Hospital Readmission measure. The measure was developed for use at the hospital/acute care facility level and not for the population to which CMS proposes to apply it in the MIPS program—groups of 10 or more clinicians with at least 200 cases. Applying measures that are intended for a different level of measurement is inappropriate without sufficient testing and rigorous assessment of appropriate sample sizes and risk adjustment models. The information on the reliability rates achieved by group and patient sample size must be transparent. In addition, the risk adjustment approach must ensure appropriate representation of clinical and sociodemographic factors and be vetted by the physician community and others before widespread implementation.

CMS states in the rule that based on the VBM program, the acute and chronic composites had an average reliability range of 0.64-0.79 for groups and individuals. Yet, it is unclear how CMS determined reliability, and the existing measure specifications lack information to ensure physician performance is accurately represented. CMS should provide information on how this testing was conducted. Testing performed for NQF evaluation, as mentioned above, occurred at the county level with the exception of one measure that is endorsed at the facility level (PQI 8- Heart Failure). Also, the Agency for Healthcare Research and Quality (AHRQ) testing submitted to NQF on the PQIs demonstrate that risk adjustment is needed, particularly around SDS factors. AHRQ's testing and risk models endorsed by NQF included poverty level. Therefore, before the measures are implemented in an accountability program and for purposes of transparency, CMS must test the AHRQ risk-model at the physician-level and allow an opportunity for review and comment.

We also remain concerned about the reliability rates of applying the all-cause hospital readmission measure to physicians in practices of 10 or more ECs. We are unclear how CMS determined reliability for the readmission measure at the physician level, and there is not enough information in the rule or

QRUR experience reports to ensure that physician performance is accurately represented, even when applied only to practices of 10 or more ECs.

If CMS insists on moving forward with the three population health measures and does not make them optional under CPIA, as we recommended earlier, **physician performance on any administrative claims measure should not be used for 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.** 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 profiling measures that have suboptimal reliability scores, recognizing that doing so could be misleading.

• Reporting Consumer Assessment of Healthcare Providers & Systems (CAHPS) for MIPS should be voluntary and counted as a high-weight CPIA

The AMA continues to oppose any mandatory reporting of CAHPS to be considered successful under MIPS, whether a group of 1-99 or, as CMS proposes in future years, for groups of 100 or more MIPS ECs. Instead, reporting CAHPS should be voluntary and, to encourage and recognize the cost associated with administering CAHPS, should count as a high-weight CPIA. Requiring CAHPS for MIPS practices with 100 or more ECs lacks recognition of the diversity of large practices. Not all such practices are multi-specialty or have an internal medicine focus in the traditional office setting. CAHPS was designed for use by primary care and/or internal medicine practices in the ambulatory setting and is not applicable to other specialties, particularly surgical specialties or physicians who practice in settings outside of the office. In addition, patient satisfaction, while important, does not always correlate with better clinical outcomes and may even conflict with clinically indicated treatments. For example, a physician who recommends that a patient lose weight, stop smoking, or limit pain medications, is likely to receive a low "performance" score, even when these are clinically indicated. Therefore, tying CAHPS scores to publicly reported ratings and accountability can be problematic, as CAHPS often depends more on patient perceptions than on good medicine.⁸

If CMS moves forward with the proposed quality requirements and bonus points for reporting on a patient experience measure, we seek clarification whether CAHPS would automatically provide two bonus points or would count as the one required high priority measure that all clinicians must report before bonus points are counted. If the physician or group receives bonus points for reporting on CAHPS, must they still report on another high priority measure as part of their remaining five measures? It appears, based on CMS' proposal, specialists are at a disadvantage and not being offered the same opportunity as primary care physicians to earn the maximum number of points in the quality category due to the lack of relevancy of CAHPS, especially for specialists such as surgeons, anesthesiologists, pathologists or radiologists. CAHPS seems to be the only "patient experience" measure being offered in the traditional MIPS quality measure set. Therefore, if patient experience measures are allocated two

http://web.stanford.edu/dept/SUSE/SEAL/Reports Papers/ReliabCoefsGTheoryHdbk.pdf

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⁵ 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.

⁶ Del, Siegle. Instrument Reliability. Educational Research Basics. University of Connecticut. Accessed 06/13/2016. http://researchbasics.education.uconn.edu/instrument_reliability/

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

⁸ Alexandra Junewicz and Stuart J. Younger, "Patient-Satisfaction Surveys on a Scale of 0 to 10: Improving Health Care, or Leading It Astray?" Hastings Center Report 45, no. 3 (2015): 43-51. DOI: 10.1002/hast.453.

points, versus one, this could put specialists at a disadvantage. To simplify the program and ensure specialists have the same opportunity as primary care practices, we recommend that reporting on CAHPS should instead count as a high-weight CPIA.

Selection of Quality Measures for Individuals and Groups

Provide a three-year phase out period for any new measures being proposed for removal

The AMA remains concerned with the number of measures CMS has proposed for removal under MIPS, and believes it is premature and short-sighted to continue to remove measures considered "topped out," especially since reporting rates within PQRS are quite low and there remains a lack of relevant measures for specialists, particularly sub-specialists. The AMA does support the removal of measures when clinical evidence has changed, but we are concerned with the growing gap that has been created in the measure portfolio due to the number of measures CMS has removed over the last few years and the measures slated for removal in 2017. We are also concerned with the high bar CMS has now set for physicians who are new entrants to reporting on quality, given the increasing complexity of the measures left in the program.

Going forward, we once again urge CMS to provide a three-year phase out period for any new measures being proposed for removal to allow for the submission of new measures within the current Call for Measures timeframe. Under the current process for incorporating new measures into physician quality programs, CMS requires a measure developer to submit measures almost two years prior to the start of the program year. For example, a measure submitted prior to June 1, 2016 will not be incorporated into the program until 2018.

CMS should provide measure owners with more detailed analysis on the use of their measures. Such data can allow them to work to develop the next generation of measures and/or improve performance with measures. Aside from what is published in the PQRS Experience Reports (last released for the 2014 program) and any information a measure owner might receive from CMS for the purposes of NQF submission, measure owners are not provided any more detailed information about their measures in the PQRS program. The Experience Report also does not provide measure stewards or specialty societies with enough detail to help determine the utilization and usefulness of the measures. Therefore, we ask that CMS provide stewards and specialty societies with information on average performance rate, percentage of measure reported on by specialty and site of service, standard deviation, quintiles, etc., at a minimum.

• Do not significantly reduce the number of available Clinical Quality Measures

We are concerned with the number of eCQMs and claims quality measures CMS has proposed for removal and the unintended consequences this will have on small practices to succeed and find the quality category meaningful under MIPS. These reporting options are the most popular options and ones that small practices depend upon. As CMS highlights in the 2014 PQRS Experience Report, EHR reporting nearly doubled between 2013 and 2014 to over 50,000 eligible professionals.

The proposal to reduce the number of available eCQMs from over 60 to about 40 also appears short-sighted since the law encourages the use of reporting through electronic means, specifically CEHRT. Based on the number of eCQMs left in the program, the relevancy of the EHR reporting option is further diminished, especially if CMS maintains the current structure for achieving maximum points under quality. A major selling point for a physician, particularly a small practice, to adopt an EHR is the ability

⁹ Centers for Medicare & Medicaid Services. 2014 PQRS Reporting Experience- Including Trends (2007-2014). April 15, 2016.

to report, capture, and submit quality data from the EHR. The majority of solo and small practices do not have the resources to invest in another reporting tool outside of the EHR system, such as a clinical registry or QCDR. Consequently, if it is CMS' goal is to have physicians embrace EHRs, then it should re-instate the eCQMs it has proposed for removal.

• Reinstate measures group reporting as an option

We are unclear of CMS' reasoning to eliminate measures group reporting. Measures groups are designed to provide an overall picture of patient care for a particular condition or set of services. The design of a measures group is also more in line with providing a holistic approach to evaluating quality and similar to the calls physician health policy experts have made on how to design a relevant and value-driven MIPS program. For example, the cataracts measures group addresses surgical complications rates, clinical outcomes, patient-reported outcomes, and patient satisfaction to provide a comprehensive picture of surgical care. The measures that are included in a measures group undergo a deliberate process with the intent of the measures group in mind. Often if a measure is intended as a group it is cited as such as it undergoes NQF evaluation so the consensus development process understands the intent and end goal of the measure.

Allowing physicians to report on a measures group for a sampling of their patients is a less burdensome yet meaningful way for a physician or practice to meet their quality reporting requirements and encourages the use of the harder, more resource intensive outcome measures. This reporting option also provides smaller practices and individual physicians without an EHR a less costly and administratively burdensome reporting option. By removing these measures groups, CMS has skewed quality reporting policy to favor large group practices given that the majority report through the GPRO web-interface that allows for and requires reporting on a sampling of patients.

While measures group reporting may not have been the most popular option for some specialties, it did have a high success rate. For instance, only about five percent of ophthalmologists who participated in 2014 PQRS program reported a measures group, but the option had an over 94 percent success rate. ¹² In addition, based on data from the American Academy of Ophthalmology's Intelligent Research in Sight (IRIS®) registry, over 1,261 ophthalmologists reported the cataracts measures group through their IRIS® registry in 2015, compared to a little over 800 in 2014—a 57.6 percent increase in one year.

CMS' overall low reporting rate may have more to do with changes to the measures group requirements over the last few years, making it a less realistic and viable option for many specialties. Specifically, CMS changed the requirements from allowing measures groups to be reported via claims and registry to only registry and increased the number of required measures from three to nine. In many instances, the measures CMS added to the group were arbitrary and did not make the most clinical sense to a physician who may have, in earlier PQRS program years, reported on the measures group. We still believe measures group reporting provides benefits to physicians and should remain in the MIPS program.

¹² Centers for Medicare & Medicaid Services. 2014 PQRS Reporting Experience- Including Trends (2007-2014). April 15, 2016.

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¹⁰ Berenson RA. If You Can't Measure Performance, Can You Improve It? JAMA. 2016;315(7):645-646. http://jama.jamanetwork.com/article.aspx?articleid=2491628. Accessed February 23, 2016.

¹¹ Halamka, John. Rethinking MACRA, a follow up. May 11, 2016. Available at: http://geekdoctor.blogspot.com/2016/05/rethinking-macra-follow-up.html. Accessed June 13, 2016.

Provide funding for measure testing in addition to measure development

We are pleased with the MACRA provision that provides funding for quality measure development, a long-term objective of medicine. We are particularly encouraged that this will expand CMS' ability to support the development of meaningful measures used by physicians who participate in new payment and delivery models designed to improve the quality and efficiency of care. A portfolio of appropriate quality measures that meets the needs of the various physician specialties will be key to achieving the legislation's goals. Part of the commitment by CMS to move towards improving the quality of care must also include the funding of measure testing, not just funding measure development. Measure testing allows for measure developers to not just test for validity and reliability, but to take into consideration real-world experience when developing and refining a measure.

• Provide funding to physician-led organizations

The AMA continues to be concerned about the lack of expediency by CMS with distributing the \$75 million over five years to fund the development of physician quality measures for use in MIPS. Specifically, we are concerned with the entities CMS may enter into contracts with as the funding was intended to go to physician-led organizations that have devoted substantial time and resources to developing and refining quality improvement and/or measure development activities. Developing measures through and with physician-led organizations, such as the Physician Consortium for Performance Improvement (PCPI®), will also enhance physician engagement and trust in the process and assist with the successful implementation of the MIPS program. A preference for measure development by organizations such as PCPI and specialty societies will further enhance that new measures are harmonized with specialty societies' clinical data registry activities, a reporting mechanism encouraged by MACRA. It will allow the profession to prioritize measurement efforts, coordinate activities, and ensure an inclusive process.

In contrast, the AMA is becoming increasingly concerned with potential influence from the pharmaceutical, medical device, and biotechnology industry through their financial support of measure development. We do not think that use of industry-funded or backed measures should be allowed within Medicare and other CMS programs. The potential of a conflict of interest is too great. If real, such conflicts could result in measurement benefitting industry, not patients.

To maintain the integrity of the MIPS program and avoid potential, real, or perceived conflicts of interest, the AMA believes that any entities receiving funding for measure development should not be involved in endorsing quality measures. Measure evaluation and endorsement should remain impartial and kept completely separate from measure development. This ensures the integrity of the measure endorsement process and avoids the concern of having a single entity responsible for implementing all domains of the quality agenda, from measure development to measure endorsement. We refer CMS to the AMA's Measure Development Comments for a more detailed outline of our concerns and priorities around measure development funding.

Furthermore, the recently released Measure Development Plan appears particularly biased towards maintaining existing funding patterns and streams as well as the NQF Incubator. We remind CMS that MACRA requires the Measure Development Plan and CMS to take into account how clinical practice guidelines and best practices can be used in the development of quality measures. To follow the intent of the law, **the AMA recommends that CMS work directly with physician-led organizations with broad and deep experience authoring guidelines.** Medical specialty societies are among those most able to interpret changes in scientific evidence. Many specialty societies align guideline development and updates with their plans for quality measure development and maintenance. Notably, the PCPI

membership model ensures that it routinely works in conjunction with and across multiple specialty societies and guideline developers.

• Consult with relevant eligible clinician organizations and other relevant stakeholders

We remind CMS that section 1848(q)(2)(D)(viii) of MACRA does not require CMS to utilize the Measure Application Partnership (MAP) to provide guidance into the pre-rulemaking process on the selection of MIPS quality measures, but requires the Secretary to consult with relevant EC organizations, including state and national medical societies. We recommend that CMS address the following issues to strengthen the pre-rulemaking process:

- Voting options on individual measures do not correspond with the early state of the vast majority of measures under review;
- The MAP treats measures undergoing maintenance/updates as if they are under development, despite the fact that CMS has data about and experience with the measure, which, if shared, could lead to a more focused and meaningful discussion;
- Stakeholders often only have one week to 30 days to comment on MAP recommendations—depriving stakeholders of a thorough review and constructive feedback;
- The deliberations of the MAP coordinating committee and workgroups are highly dependent upon who has a seat at the table. If a measure within a particular specialty area is being reviewed, and that specialty is not represented on the committee or workgroup, legitimate issues may be overlooked and measure review may be inadequate; and
- Notices for measure developers or stakeholders to publicly comment are sometimes inadequate. Agendas are all too often unavailable until or close to the day of a MAP meeting. The order of review of items on the agenda frequently deviates from the published schedule, making it difficult for those not present, including clinicians and the public, to participate or provide comments.

The lack of reliable processes leads to unpredictable MAP proceedings, inadequate review of the measures—especially in the context of considering appropriateness based on program requirements—and reports issued with limited time to comment. We remind CMS that requiring measure developers to propose measures to the MAP for use in CMS programs introduces another time-consuming step in the measure development cycle. MACRA, however, provides CMS the flexibility in terms of how it uses the MAP.

Scoring the Quality Performance Category

• Ensure quality scoring does not favor large practices

The AMA is concerned that CMS' proposed quality scoring favors large practices that report through the Group Practice Reporting Option (GPRO) Web-Interface—this method is a one stop quality shop that has built in bonus points. ECs who have the option to report through this mechanism will automatically achieve all of the requirements (plus bonus points) to potentially earn maximum points. While the GPRO Web-Interface requires reporting on more measures, reporting is more evenly distributed throughout a large practice due to economy of scale, and ECs only have to report on a sampling of patients versus the high percentage of patients for other data submission methods. We ask that CMS consider this impact and refer to our suggestion on reducing quality thresholds.

• Simplify the scoring methodology

MACRA requires that CMS develop performance standards for each quality measure that take into consideration historical performance standards and improvement. To accomplish this, CMS proposes to assign one to 10 points to each quality measure based on how a MIPS EC's performance compares to measure benchmarks. In order for the measure to be scored, it must have the required case minimum. If a MIPS EC fails to submit a measure required under the quality performance category criteria, then the clinician would receive zero points for that measure.

Given that the benchmarking methodology for each quality measure is a new, complicated scoring calculation, we ask that CMS keep the scoring of the remainder of the quality category as simple and straightforward as possible. Specifically, the quality scoring is overly complex as requirements vary based on group size. An EC may or may not be scored on the three additional measures. For example, a physician in a practice of 10 or more ECs is scored on 90 points versus a physician in a practice of nine or fewer ECs is scored on 80 points. We, therefore, ask that CMS remove the "population health" measures we cited above and avoid creating different scoring subcategories. Furthermore, creating subcategories for physicians in practices of nine or fewer appears to create different definitions of "small practices" throughout the MIPS program. Physicians will not understand the subtlety of why certain practice sizes have fewer measures than others and will simply see this as another added complexity when trying to figure out what requirements they need to meet. At a minimum, CMS should provide accommodations based on the statute's definition of a small practice, meaning 15 or fewer professionals.

• Do not automatically attribute an institution's score to an EC

In future years, CMS proposes to consider an option for facility-based MIPS ECs to elect to use their institution's performance rate as a proxy for the MIPS EC's quality and resource use score. We support this option; however, CMS must allow the individual EC to designate (or not participate) under the group. Attribution should not be automatic and an individual EC, practice, or department should have an opt-in choice. Based upon experience with the incorporation of hospital measures into existing physician incentive programs, we have serious reservations about a widespread application of other provider groups' measures to MIPS. In some circumstances the use of another provider's measures, once they have been re-specified, tested, and validated for use by physicians, could potentially be an appropriate for certain specialties. If an EC practices in multiple facilities they should still have the choice of which facility they would like to attribute their score to or whether they would like to participate in MIPS as an individual or part of a group. We recommend that CMS work with facility-based specialties and related specialty societies to determine the appropriate type of measures to attribute to a facility-based EC. CMS must also recognize what is appropriate to attribute given the nature and the diversity of institutional practice settings.

• Develop population health measure benchmarks by specialty and region

If CMS maintains its proposal to calculate the three population health measures, it must create separate benchmarks by specialty and region to ensure more accurate comparisons for these measures. It is inappropriate for a cardiologist to be compared to a primary care physician given the differences in clinical severity among their patients. Similarly, it would be inappropriate to compare a cardiologist in New York to a cardiologist in Oregon due to their varying patient populations. MACRA includes language about the specialties that can potentially have facility/hospital-based measures attributed to them. However, we do not believe the law precludes CMS from considering specialties that practice in other sites of services, such as nursing homes, assisted living, or home health and treating them in a different manner. Given the different patient populations these specialties treat, it is inappropriate to assume they can be compared to other internal medicine/family physicians that practice in the ambulatory

settings. The costs, resources, and quality for treating these patients are different, with different outcomes and expectations and often higher associated costs and more clinically severe patients. In addition, the quality measures are often inappropriate and do not match the patient population they serve. From a patient perspective, it would be more helpful to understand how your physician compares to other physicians in that specialty within your region. This approach would help facilitate such comparisons and improve the relevance of information for patients.

Adopt standards and mapping tools

For the quality performance category, CMS proposes that the performance standard is a measure-specific benchmark and that benchmarks are set within a measure based on the reporting mechanism. For example, several eCQMs have specifications that are different than the corresponding measures from registries. To resolve this issue, CMS proposes to develop separate benchmarks for EHRs, claims, QCDRs, and clinical registry submission options.

While the AMA is generally supportive of this proposed policy, we would like to highlight that EHRs do not uniformly calculate eCQMs measures across different vendors and practices due to the lack of specificity within CMS' Implementation Guides. Incorporation of data requires the development, maintenance, and refinement of administrative code sets such as the International Classification of Diseases (ICD), Current Procedural Terminology (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 urge CMS to incorporate this work into its implementation guides to ensure eCQM calculations and benchmarks are accurate and that different EHRs are more accurately capturing eCQMs.

• Expand protections for reporting on new measures

To encourage reporting on new measures and help mitigate potential unintended consequences, CMS should create protections for reporting on new and innovative measures. **Therefore, we support CMS' alternative proposal to not score a MIPS EC lower than three points when reporting on a new measure**. This policy should also apply to physicians who change reporting mechanisms. Furthermore, the proposal should not only be applicable to the first year the measure is available in MIPS but should apply to the first time the physician reports on the measure.

• Remove point limits on "topped out" measures

We are concerned with CMS' proposal for scoring measures it considers "topped out." Based on the proposal, CMS is essentially punishing high achievers by limiting the maximum 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 would be considered "topped out," raising the concern that most physicians will be less likely to achieve the highest scores possible in the Quality component of MIPS, especially since this category has the greatest weight (50 percent).

A physician may not have the option to report on alternative measures that have lower success rates. Many specialties, particularly sub-specialists, have a limited number of applicable measures and are constrained to a small set of measures that may be in the topped out range compared to other specialties. CMS is also making the blanket assumption that, when a measure is reported in the 95 percent range, that it is a negative as opposed to a positive. Instead of encouraging physicians to be striving towards providing the best possible care and rewarding top quality, CMS is overly scrutinizing physicians and

arbitrarily assigning a poor quality designation when a difference may be less than one percent. The proposal also adds complexity to the quality scoring system. Therefore, we urge CMS to abandon its proposal of creating truncated coefficient benchmarks and instead treat all measures equally.

Alternatively, if CMS does not move forward with our primary recommendation, we urge that CMS utilize the Shared Savings Program (SSP) approach over the Hospital Value Based Purchasing (HVBP) proposal. Based on the example CMS outlines in the rule, physicians who still score well below 95 percent could potentially lose more than 50 percent of the points they could have earned on another measure. This could prove very discouraging and limit success.

Decile	Sample Quality Measure Benchmarks	Possible Points
Benchmark Decile 1	0%-74.9%	1.0-1.9
Benchmark Decile 2	75%-79.9%	2.0-2.9
Benchmark Decile 3	80%-84.9%	3.0-3.9
Benchmark Decile 4	85%-94.9%	4.0-4.9
Benchmark Decile 5	95%-99.9%	5.0-5.9
Benchmark Deciles 6-10	100%	Midpoint value = 8.5 points

TABLE 18: Example of Using Benchmarks for Topped Out Measures

The flat percentages approach used in the SSP allows those with high scores to earn maximum or near maximum quality points while allowing room for improvement and rewarding that improvement in subsequent years. This approach, while still complex, is more reasonable since physicians who achieve the same high level of performance would receive the same points, as opposed to the alternative proposed in the HVBP benchmarking approach. We also do not support limiting the number of topped out measures upon which a physician could report since not all specialties and sub-specialties have a broad set of available measures.

• Ensure administrative claims measures meet a reliability threshold as opposed to minimum case number

With regards to appropriate minimum patient samples and thresholds for reliability, CMS should keep in mind that these thresholds may vary across measures and even across specialties. It is better to focus on ensuring that a specific reliability score is obtained, rather than focusing on minimum sample sizes. The number of patients or cases required will vary based upon the measure, the population included, and whether the measures are focused on an outcome or process. Because of the large number of medical specialties and diverse patient populations, developing a minimum number of patients for everyone is not optimal. As recommended earlier, we urge that, for ALL administrative claims measures, including the population health measures, CMS ensure the measures meet a reliability threshold of 0.8 at the individual physician level before holding a physician accountable on the measure. A lack of reliability in the data and minimal variations in care can lead to incorrectly categorizing and penalizing physician performance.

• Ensure data is accurate

The AMA is glad to see CMS considers how to handle scoring when a measure's reliability or validity may be compromised due to unforeseen circumstances, such as data collection problems. CMS' overall goal should be to collect data that is as accurate as possible and not be punitive to ECs for inadequacies of vendors or CMS' process. As CMS is aware, in 2014 the PQRS program experienced massive data

collection issues that prohibited CMS from considering EHR and registry data. To prevent similar problems in the MIPS program, we are supportive of CMS' proposal to recognize the measure as being submitted and not disadvantage the MIPS EC by assigning them zero points for a non-reported measure.

In the future, if a data collection or vendor submission issue arises, we strongly encourage CMS to notify any affected physicians and group practices through the mail. The notification process to date has been essentially non-existent and grossly inadequate, which will become an even larger problem as we transition away from just a pay-for-reporting program and into a pay-for-performance program, such as MIPS.

As highlighted to the AMA through our conversations with EHR vendors, we are seriously concerned about the lack of time for health IT vendors to develop and test their products. In discussing the proposed MIPS start date, developers have highlighted that, before they can support any new or updated eCQMs, they must test their products' ability to capture, calculate, and report on each measure. While this process is time and resource intensive, it is essential that all EHR components are rigorously tested before they are used in patient care. A major component in eCQM testing is the use of testing tools that allow EHR developers to catch and correct issues in the quality measure logic. However, these tools will only be developed *after* the final list of quality measures is released. CMS has until November 1, 2016 to finalize the rule—providing only two months for developers to prepare their products for the quality component in MIPS. Even if the final rule is released prior to November 1, 2016, CMS contractors and developers will not have enough time to create the tools, nor will EHR vendors have enough time to do adequate testing of their systems.

We already know that CMS and the EHR vendors are struggling to capture and report process measures that have been in place for several years. To resolve some of these challenges, CMS needs an administrative process to ensure that vendors update their systems to incorporate new data elements as well as to ensure eCQMs can be captured and calculated within the EHR. This process will almost certainly require more than two or three months. It is unclear to us why something as critical as measuring quality must be rushed. Again, we urge CMS to reconsider the January 1, 2017 start date to help address this issue.

• Develop a transparent Measure Applicability Validation (MAV) process

CMS states that it intends to develop a validation process to review and validate a MIPS EC's inability to report on the quality performance requirements, and that the process will function similarly to the MAV process. CMS should consult with the AMA and other physician stakeholders as it develops the new validation process. We have had previous concerns related to the MAV, including the lack of clarity in how the MAV actually functions. The MAV clusters have historically occurred within a black box and often physicians are inappropriately held accountable for measures. Before CMS holds a physician accountable for reporting on fewer than the required number of measures, CMS must build a process that includes a case minimum requirement. The case minimum requirement should be the same as what CMS finalizes for setting benchmarks for a particular measure.

• Reward high priority measures with bonus points

Moving to high priority measures is an important goal, and physicians should be recognized and compensated for this increased effort. As we have repeatedly stated throughout our comments, we do not support CMS' proposal that requires the reporting of outcome/high priority measures to achieve maximum potential quality category points. Alternatively, we support using bonus points for these measures; however, we are concerned that this could favor large practices over small practices given the Web-Interface includes several high priority measures. To ensure equity, CMS may need to cap the

number of bonus points Web-Interface reporters can earn and move the patient experience measures under the CPIA category. As we stated earlier, CAHPS for MIPS is the only eligible patient experience measure, which is not applicable to many specialties or physicians in small practices.

There are a limited number of available high priority measures, specifically via the EHR or claims submission options, and lack of data in the rule outlining how bonus points may mask poor performance. Therefore, it is premature for the AMA to recommend a specific cap tied to bonus points. We request that CMS share modeling data demonstrating how a cap might be necessary for assigning bonus points to a measure before finalizing any option. Our general view is that to encourage reporting on high priority measures, the more points a physician can achieve, the better. However, there must also be a balance to ensure parity between specialties and group size that might not have the option to report on high priority measures or as many high priority measures.

• Make incentives to use CEHRT more flexible

To encourage the use of CEHRT for quality improvement, CMS proposes to allow one bonus point up to a maximum of five percent of the denominator of the quality performance category if a physician meets CMS' "end-to-end electronic reporting" standard when reporting on an individual measure. The bonus would be 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 understand awarding a bonus point to encourage electronic reporting, however, given the high costs and limitations of today's EHRs, we are highly concerned that CMS is missing the mark and undervalues the usefulness of registries. Many registries still rely on both automated and manual data entry. Most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection. 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 where it makes sense, and using alternative methods when they are more efficient. We caution CMS from incentivizing end-to-end reporting simply because it bypasses a sometimes necessary 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 if it is completely "electronic" from end-to-end.

• Release additional information on measuring improvement

At this time, CMS does not provide enough information in the rule in terms of the three methodologies it is considering for assessing a physician's MIPS improvement scores. The AMA would be happy to have further conversations with CMS to discuss this issue. Before finalizing any proposal, we request CMS release an RFI outlining in detail the three options and provide modeling data in terms of how the various methodologies would work in practice. No methodology should be finalized without testing and significant outreach to and input from the medical community, to ensure physicians understand and trust what they are being scored on.

CMS is required to disclose what benchmarks are prior to the start of a performance period. As such, generous education and outreach must be used in concert with performance standards education so that groups and providers know exactly who their peers are and how they will be assessed.

Resource Use

The AMA believes the proposed resource use category of MIPS carries over many of the problematic areas of the VBM, including measures that we know are inappropriate. The proposal also fails to make needed improvements in several key areas, such as attribution and risk adjustment, which are necessary to make this category valid for physicians. Furthermore, the addition of new episodes measures appears premature and CMS has not yet developed needed patient condition groups and patient relationship categories nor established the creation of the virtual group option. In light of these significant concerns, we believe that CMS should allow physicians to be exempt from the resource use category if they so choose and offer a pilot program for those who want to be evaluated on resource use of specific episode groups.

Recommended Modifications:

Resource Use Measures

Remove the Per Capita Cost and Medicare Spending Per Beneficiary (MSPB) measures

In determining which resource measures it would use in the MIPS resource section, CMS said it will eliminate four condition-specific per capita cost measures because physicians saw them as irrelevant. On the other hand, the agency intends to retain a total per capita cost measure and a Medicare spending measure that most physicians also view as irrelevant and unfair. While the AMA supports elimination of the condition-specific measures, we strongly believe that the agency should remove the other two general cost measures as well.

It is inappropriate to use broad measures such as total per capita costs and MSPB to evaluate the resource use of individual physicians. Many Medicare beneficiaries have multiple health problems, and in most cases, those different health problems are treated by multiple physicians and other providers. QRURs consistently show that the services delivered by an individual physician represent a tiny fraction of the total cost of care for their patients. Moreover, under Medicare rules, beneficiaries have the freedom to see any physicians they wish to obtain treatment from for their health problems. Even if each of the individual physicians whom a patient sees is "efficient" in the services they deliver and order, the overall spending on the patient's care may be higher than for other patients because of the number and types of physicians and other providers the patient chooses to use.

In most communities, these choices are also constrained by what care is actually available. For example, in a community with a shortage of rehabilitation units, patients and physicians may have little or no ability to influence the cost and quality of post-acute care. Hospital stays may also be extended as patients wait for availability of post-acute care. In other cases, costs may depend on CMS policy and methodological decisions and whether or not a patient is treated in one of the special cancer, psychiatric or rehabilitation facilities that CMS has excluded in the calculation of certain cost and quality measures. Clearly, the fact that a particular physician is "attributed" all of the spending for a patient based on a CMS statistical formula does not mean that the physician had any ability to change the total amount of spending in any significant way. Moreover, the current risk adjustment methodologies used by CMS for these measures fail to adequately compensate for the appropriate variation in spending associated with patients who have higher needs, particularly needs that go beyond what is recorded on health care claims forms. Also, as CMS knows very well, for most beneficiaries who are hospitalized, the biggest variation in the

MSPB measure occurs in the post-acute care phase, not the hospitalization itself. While there are cases where post-acute care is strongly associated with a particular type of physician service and, therefore, might be appropriately included in a bundled payment that a physician group chooses to manage, this is a very different situation than simply tagging a physician who happened to have provided the most expensive services during a hospitalization with the entire cost of hospitalization and post-acute care.

There is widespread recognition that Medicare spending and resource use measures are penalizing both physicians and hospitals that care for lower income and more challenged patient populations. CMS acknowledges in the preamble to the proposed rule that physicians treating the largest shares of Medicare's sickest patients are most likely to be penalized under the current VBM program. There is a serious risk that continuing to penalize physicians using these problematic measures under the MIPS program could force them to avoid caring for patients who have the greatest needs. Incorporating them in MIPS before CMS has made and tested significant improvements, such as accounting for sociodemographic factors in the risk adjuster, would be a serious error in judgment. In the preamble, CMS acknowledges the extensive comments it has received describing the many problems with these measures, but the agency then proposes to continue using them with modifications that do not address and may even exacerbate the underlying flaws. **Instead, we recommend that both measures be removed entirely and replaced with better measures as they become available**.

• Do not institute technical changes to the MSPB Measure

CMS proposes two "technical changes" and a related policy modification in the MSPB measure:

- One technical change is to remove the specialty adjustment. CMS says "it is unclear that the
 current additional adjustment for physician specialty improves the accounting for case-mix
 differences for acute care patients, and thus, may not be needed." However, if it is "unclear"
 whether the adjustment improves the measure, it is presumably also unclear whether removing it
 would be harmful, especially in view of the fact that CMS previously has said that the specialty
 adjustment improves reliability of the measure.
- The second change is to calculate observed-to-expected ratios for each individual case and then average them, rather than summing the observed and expected costs and dividing the totals.
- In addition, CMS is proposing to reduce the minimum number of cases necessary to have this measure included in the resource score from the current 125 to 20 or fewer. This is a reversal of CMS' decision in the 2016 payment rule to increase the 20 case minimum for the MSPB to 125 in order to improve its reliability when used in conjunction with a specialty adjustment.

CMS states that its analysis of 2013 claims data indicates that the two proposed technical changes "would improve the MSPB measure's ability to calculate costs and the accuracy with which it can be used to make clinician-level performance calculations." Yet, it appears the reason for the change is to simply apply the resource use category to more physicians. In the 2013 analysis, CMS concluded that the MSPB measure met "moderate" reliability standards (0.4) for all practices. This analysis did not adjust for specialty, however, and when another "more appropriate methodology" including a specialty adjustment was employed, with a 20 case minimum threshold, only 18 percent of solo practices and 40 percent of all practices met the 0.4 percent standard. This led the agency to raise the MSPB threshold to 125 cases in last year's final rule, thereby reducing the number of practices subject to the measure by nearly two-thirds.

In returning to a 20 case minimum, CMS states that if the specialty adjustment is eliminated, the measure is moderately reliable across all group sizes and for 88 percent of practices. CMS says this "slight decrease" in the number of practices meeting a "moderate" reliability score is justified by the need to

increase "participation" of MIPS-eligible clinicians. It further proposes to use a 0.4 reliability standard with a 20 case minimum as the general policy in MIPS.

The AMA strongly disagrees with the general proposal as well as its specific application in the MSPB. In most disciplines a 0.4 percent reliability standard would be viewed as unacceptable, and many in the health care field believe that a standard of at least 0.8 should be required. Rather than focusing on expanding the application of these measures, we believe CMS must concentrate on improving reliability first. We are concerned that the policies and modifications being proposed in this rule will heighten physician cynicism and increase the risk of MIPS-related penalties for practices that are small, rural, and/or have high levels of poor and/or frail patients. **CMS should remove these measures, at least for the time being, and make a detailed analysis of the impact of all cost measures publicly available so that patients and physicians can more effectively comment on the proposed changes.**

• Use of untested episode measures is premature

We agree with the many comments cited by CMS that it would be more appropriate for CMS to use measures of resource use based on episodes of care than broad measures such as total per capita costs and MSPB. However, it is important to note that those who supported use of episode measures supported the use of "properly selected and designed" episode measures that would be used instead of, not in addition to, the existing cost measures.

Many of the episode-based measures listed in Tables 4 and 5 have only recently been developed and/or made widely known to practicing physicians. More time is needed to fine-tune and test the proposed episodes and to consider potential alternatives that relevant specialties believe would be more appropriate and better aligned with episodes being used or developed by other payers such as Medicaid. **To maintain credibility with the physician community and engender confidence in the measures, CMS must solicit and incorporate input from practicing physicians and the professional organizations that represent them.** The proposed rule refers to evaluation of the episodes by CMS and an outside contractor, but makes no mention of input from physician specialties either during the development process or a comment period that concluded earlier this year. Some physicians have invested substantial time and effort to help CMS come up with relevant and valid episode groups. That these efforts did not warrant a mention in the rule is discouraging to say the least.

It is also inappropriate to begin using these episodes for MIPS in ways that could potentially penalize physicians before CMS has provided additional information needed to evaluate their suitability. Although CMS has released lists of the diagnosis and procedure codes used to define these episode measures, to achieve true transparency and facilitate insightful input, additional information must be made available. Rather than just a generic discussion of the risk adjustment methodology, for example, CMS must release the actual variables, coefficients, and equations used for the risk adjustment process, as well as the predictive accuracy of the methodology.

Assurances regarding CMS and an outside contractor's "detailed and rigorous evaluation" of the episodes are also insufficient when the agency has not released the results of those evaluations and reviews or any information on the validity and reliability of the episode groups. One half of the proposed measures in Tables 4 and 5 have not been reported in the QRURs, so physicians have no experience with them, and, given the difficulty in accessing and analyzing QRURS at the individual clinician's level, physicians' experience with the remainder also is extremely limited.

The AMA recognizes that Congress directed CMS to move to episode measurement, and we support this approach if it is done right. However, Congress also clearly recognized the serious problems with the retrospective, claims-based resource measures, attribution methodologies, and risk adjustment systems

that CMS has been using. MACRA addresses those concerns by setting the initial weight of the resource category at "no more than ten percent" and requiring CMS to develop codes for new Care Episode Groups, Patient Condition Categories, and Patient Relationship Categories. These new groups and categories are intended to enable physicians to directly provide the information needed to determine what type of episode a particular service supported, what characteristics of a patient affected the number and types of services the patient received, and what role the individual physician played. MACRA requires these new codes to be developed and implemented by 2018. **This means that any episode measures implemented in 2017 could be obsolete by the end of the year.**

MACRA specifically requires that measures of resource use "shall include results from the methodology [to develop Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories]." It also gives CMS the option of setting the weight for this category at anything from 0 to 10 percent, creating the opportunity for the agency to take time to get the measures right before they are imposed on hundreds of thousands of physicians. We strongly urge CMS to use this opportunity to work with medical specialties to identify and refine those episodes that seem most promising and then pilot them with groups or individual physicians who volunteer to have their MIPS score tied to performance under applicable episodes. Exact details of this approach could vary. No resource use measures should be mandated until Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories have been developed and gained support from the professional societies whose members treat the majority of patients falling into a particular episode.

• Quality and resource use measures should be paired

CMS states in the preamble that "measuring resource use is an integral part of measuring value." The AMA believes that quality and resources use must be considered together. Several of the proposed episode measures, such as cholecystitis, cholecystectomy, diverticulitis, and spinal fusion have no quality measures specifically directed at those conditions or procedures, and, for others, it is not clear whether the quality measures being used in MIPS address the most important areas where patients could be at risk from efforts to control costs.

Just as the "Triple Aim" was intended to convey the notion that quality and cost should be improved simultaneously, it is inappropriate to put physicians in the position of being penalized for higher spending but not rewarded for higher quality and vice versa. No episode measures should be used in MIPS unless there are also appropriate quality measures available that avoid creating financial rewards for under-treatment of patients.

• Improve attribution methods for episode measures

CMS has proposed attributing an acute condition episode to all eligible MIPS clinicians that bill at least 30 percent of inpatient evaluation and management (E&M) visits during the initial treatment because they are "likely to have been responsible for the oversight of care for the beneficiary during the episode." There is no indication that CMS has conducted any research to determine whether this attribution method and threshold are appropriate and are valid for the proposed episode measures. It seems unlikely that the same attribution threshold would be appropriate for the wide range of episode measures listed in Tables 4 and 5. We are also concerned with CMS' suggestions that more than one MIPS eligible clinician could be attributed a single episode. The purpose behind episode measures is to ensure that physicians are held accountable for the costs they can control but not for costs they cannot. Reliance on a single attribution method that assigns total costs to individual physicians regardless of their contribution to those costs, as CMS is proposing here, is what episodes were intended to move away from.

Some specific questions/issues raised by the proposed attribution method include:

- What happens with surgical procedures or other services where most or all E&M services provided by the "lead" physician are part of a global code and therefore will not be reflected as a separate service on the claim form?
- What if the physician who is responsible for an infection or other complication that leads to large expenditures for services provided by other physicians does not meet the 30 percent threshold or is not MIPS-eligible? Is it fair to assign accountability and potential penalties to the physicians who responded to the problem rather than the physician who created them?
- Why should two, or possibly even three, physicians all be held responsible and potentially penalized for all the costs within a particular episode? Does CMS have an idea of how often this will happen? The current system penalizes one physician for all the costs associated with very high risk patients. Will this proposal penalize two or three physicians for treating the same high risk patient? Should not each physician be accountable only for the portion of the costs that they could control?
- If CMS intends to hold individual physicians responsible for an entire episode of care, is it really possible to set up a single rule about whether costs should be assigned at a group or individual level? We can think of circumstances where group attribution would hold a practice accountable for services of several physicians who might not have met the 30 percent threshold individually. If these three physicians were largely responsible for the patient's care, this would be entirely appropriate. If another physician in another group largely generated the costs but did not hit the threshold, individual attribution would be more equitable.

These types of problems are inherent in the kind of retrospective, overarching statistical attribution formulas CMS is using in these episode measures. The appropriate solution is to construct episodes that reflect the type of care that is being delivered, accurately depict which physicians are accountable for which costs, and make adjustments for the patient differences that lead to justifiable variation in costs. That cannot be done without the active assistance of practicing physicians, and it will also require new tools, including those Congress required in MACRA. CMS should implement the Patient Relationship Categories and codes as required by MACRA and then use them to appropriately assign responsibility for episodes, portions of episodes, and individual services within episodes to the physicians who delivered or ordered those services. Implementation of resource use measures except in a voluntary pilot program should be delayed until after these new codes are available.

• Develop a pilot program for the resource use category rather than using flawed measures to judge resource use

MACRA specifically provides for how to deal with situations in which "there are not sufficient measures...applicable and available." Yet CMS indicates that it will use resource use measures that have reliability levels as low as 0.4 for the MIPS program simply because it considers "high participation...to be an important programmatic objective." If a measure has a reliability of only 0.4, it means essentially that differences in the resource use scores of two physicians are more likely due to random or unadjusted-for differences in the patients those physicians treat than to systematic differences in the spending associated with the ways the two physicians deliver care.

CMS indicates that it is uncertain how many of these measures to include in the final rule. As previously noted, we recommend that none of the measures be mandated for use in 2017. Those selected for a pilot that is voluntary for participating physicians should be judged by the following criteria:

- The measures have high reliability (at least 0.8 percent) in measuring differences in physician performance and high reliability in classifying performance over time;
- The physicians who would be attributed responsibility for the episode would have the ability to control most of the types of spending that occur within the episode;
- The risk adjustment system that is used adequately adjusts for all key differences in patients that would result in differences in the services they need; and
- There are a sufficient number of quality measures to accompany the resource use measure for the episode to avoid creating financial rewards for under-treatment of patients.

In addition, CMS requests comments on whether to specialty-adjust the episode-based measures. It is impossible to provide meaningful comments without seeing the results of the analyses conducted to evaluate the reliability of the measures. Accordingly, CMS should release the results of its evaluations of the episode measures.

• Do not incorporate Part D or Part B dug costs into resource use measures

CMS' current resource measures are nowhere near ideal and adding prescription drugs into the mix will only exacerbate current inequities in the program. In fact, we strongly believe that, rather than incorporating Part D drugs into the resource category, CMS should remove Part B drugs, which are already counted. The physicians who administer these expensive but life-changing drugs already face a greater than average risk of Medicare payment penalties due to persistent methodological flaws in CMS resource measures. We are also concerned that the Administration's controversial Part B drug demonstration proposal could lead to erroneous comparisons of physicians depending on whether or not they practice in an area where drug reimbursement rates are reduced by the demonstration. In this scenario, expenditures in the demo areas would look lower than average for physicians administering expensive drugs and higher than average for physicians administering low cost drugs. Comparisons would be even murkier when the next phase of the demonstration takes effect and creates additional locality-specific payment differences that would be hard to disentangle.

Scoring the Resource Use Performance Category

• Do not base benchmarks on the performance period

It is inappropriate for CMS to define resource use benchmarks based on the performance period rather than a baseline period prior to the performance period. As CMS indicates, it is important for physicians to know in advance how they would be scored under MIPS, but the proposed approach would not allow for physicians to know the resource use benchmarks. Telling physicians the methodology for calculating their resource use score but not providing them the actual data to determine what level of performance needs to be achieved does not enable them to determine whether or how much they need to improve or give them sufficient time to make the changes needed to succeed.

CMS indicates that it is "challenging" to compare resource use in a performance period with an historical baseline period, but it can also be challenging to compare quality measures with a baseline period, particularly if the gap between the two periods is long. Because the resource use measures are based on claims data, benchmarks can and should be established using a baseline period that is prior to but close to the performance period, and, because the benchmarks are based on all physicians' performance, not an individual physician's performance, they can be established using a time period shorter than a year. Since the benchmarks would already be based on "standardized payment data," it should be feasible for CMS to also adjust for any changes in payment rates and methodologies

that occur between the baseline period and the performance period in ways that ensure physicians are not unfairly penalized.

CMS indicates that the benefits of earlier benchmarks are "more limited" for resource use measures because physicians "would not be able to track their daily progress because they would not have all the necessary information to determine the attribution, price standardization, and otherwise adjust the measures." This is a problem that CMS needs to solve because it is unreasonable to expect that physicians can improve on any measure without having timely, detailed feedback on their progress. Our discussion on feedback to physicians discusses this issue in more detail. Moreover, as discussed earlier, resource use measures should be defined in ways in which differences in physicians' performance result from differences in how they manage care and how they deliver and order services, not based on attribution rules or price adjustments. Attribution rules and other methodological features should also be clear enough that the average physician can understand and apply them.

Do not define benchmarks based solely on deciles

The AMA has reservations about CMS' proposal to assign points to physicians based on where their measured resource use falls among the deciles of resource use distribution by all physicians. We note that in Table 21, CMS provides an example that has spending on patients in the lowest cost quintile for the measure at \$15,000 versus \$100,000 for those in the highest spending quintile. It is difficult to imagine how a properly risk-adjusted measure of actual spending on comparable patients could have such a large spending spread and raises real questions about the potential impact of moving forward with such an approach before resource use measurement tools are improved and physicians can have more confidence that comparisons are based on cost variation that physicians can control rather than other factors such as patient mix and community resources that CMS has not adjusted for.

Awarding the maximum points to physicians in the lowest-spending decile in a distribution like this would raise serious questions as to whether CMS was rewarding physicians for undertreating patients or encouraging physicians to focus their care on patients whose low treatment needs were not accurately reflected in the risk adjustment methodology for the measure.

MACRA requires the Secretary to "establish performance standards" for resource use measures. The distribution shown in Table 21 is not a "performance standard," but is merely a report on the actual spending on the measure in a prior period. The implicit assumption is that the best performance is spending that is \$15,000 or less. If CMS believes lowest cost should define its performance standards, then the agency should provide evidence for each measure that the physicians who are delivering care at that level of spending are doing so with high quality and for patients with an average risk profile. Experience under the VBM does not support that conclusion, however. Notably, in both of the first two years of the VBM, no practice was found to be both low cost and high quality and practices that did not treat many high-risk patients tended to fare better than those that did.

Judging performance based on the current methodologies is premature and, as noted earlier, the AMA does not believe that CMS should score this category in the initial performance year. Ultimately, the goal must be to identify an appropriate spending or resource level and then **evaluate an individual physician's performance against that standard.** If the variation in the measure is high and/or the reliability of the measure is low, then only the physicians who differ from the standard by large amounts will be able to be classified as above or below the standard. The remaining physicians should be determined to have met the standard, and they should be awarded the corresponding number of points for doing so.

• Reward improvement in resource use

MACRA clearly states that in measuring a physician's performance on resource use, the Secretary "shall take into account the improvement of the professional." Yet, the proposed rule has no methodology for assessing improvement or for rewarding a provider who has reduced spending. The methodology for scoring resource use should be based in part on the change in resource use from the prior year, not just on the average resource use in the current year.

• Allow alternatives to reweighting

CMS should acknowledge that not all categories must be reweighted simply because there are insufficient measures. Specifically, MACRA allows the resource use category to "account for *no more than* 10 percent" of the composite score. Yet, CMS has proposed that if there are no applicable resource measures for a physician, a resource use performance category score would not be calculated and the weights for the other MIPS categories should be increased. We believe this is inappropriate as MACRA states that if there are no sufficient measures applicable and available the Secretary shall assign "different scoring weights (including a weight of zero)." The law permits, but does not require, a score of zero. The most appropriate action when resource use cannot be calculated for a physician would be to score the physician as "meets resource use standard." The assumption in MIPS should be that physicians are practicing effectively unless data show otherwise, and those data should come from a balance of categories, as required by Congress, not from simply a few where measures happen to be available.

Advancing Care Information (ACI)

Proposals the AMA Supports:

- Remove duplicative clinical quality measurement: The AMA agrees with the proposal to remove separate clinical quality measures from the ACI category, recognizing that the quality component of MIPS already serves this function. This will help streamline reporting, avoid unnecessary overlap, and sharpen the focus of each MIPS category.
- Improve EHR usability: Eliminating the Computerized Provider Order Entry (CPOE) and Clinical Decision Support (CDS) measures will improve the usability of EHRs as these measures have resulted in additional data entry and pop-up alerts that interfere with clinical workflow. CMS should finalize its primary proposal which removes these measures.
- Simplify public health and clinical data registry reporting: MU challenged physicians by including numerous registry reporting measures that were often not relevant to specific specialties or required timelines that were infeasible. The AMA supports CMS' solution to this problem by allowing clinicians to report only on the Immunization Registry Reporting measure. We furthermore support the proposal that physicians receive a bonus point for reporting to multiple public health and clinical data registries, creating clear incentives to use these tools to improve health. However, CMS should award points for each registry to which a physician reports, rather than limiting it to one point as proposed.

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¹³ MACRA § 1848(q)(5)(E)(II)(bb) (emphasis added).

¹⁴ Id at § 1848(q)(5)(F).

• Ease reporting processes: CMS should finalize its proposals to ease reporting burden by allowing group data submission and performance assessment at either the individual or group levels.

Recommended Modifications:

Prior to the release of the proposed MACRA rule, CMS recognized that many physicians and patients were frustrated with the current state of EHRs as well as the MU program and announced that the proposed rule would make a course correction to refocus the program. CMS statements, however, does not align with what it is proposing in the rule. In many instances the ACI category is largely unchanged from MU Stage 3—for example, it remains a pass-fail program and retains the same prescriptive measures. The AMA, many other medical societies, and health information technology (health IT) experts hold firm that CMS current health IT measures and Office of the National Coordinator for Health Information Technology (ONC's) certification requirements miss the mark, limit innovation, and create administrative burdens. CMS is a considerable of the National Coordinator for Health Information Technology (ONC's) certification requirements miss the mark, limit innovation, and create administrative burdens.

Furthermore, many in the physician community find the ACI performance category to be confusing and compliance-driven rather than physician and patient-centric. CMS should, therefore, take immediate action to reduce the overall complexity of the ACI category while also establishing a clear path away from process-oriented measures. To that end, we recommend the following significant changes to the ACI category.

Base Score

• Grant credit for each reported measure under the base score

As proposed, the base score carries over the problematic all-or-nothing structure of the current MU program: if a physician fails to report/attest to just one requirement, the physician earns a zero for not only the base category, but the *entire* ACI category. Missing one base measure earns a zero score regardless of whether that physician achieved 100 percent on every other ACI requirement. CMS' justification for retaining this approach is that the base score only requires simple yes/no or one patient reporting for each measure. Yet, by using this scoring, CMS maintains a structure where failure to report does not simply harm your performance but renders all of your other efforts meaningless. The potential for complete failure due to inadvertent error or mistake continues to dominate the program and the incentive to try is diminished.

To remedy this problem, CMS should award credit for each measure reported under the base score and make clear that a physician will not fail the entire ACI category if they fail to report all base measures. This allows the base score to reflect a physician's actual success in achieving requirements, rather than simply awarding zero or 50 points with no differentiation. We urge CMS to not add to the complexity of the base score but maintain its intent—to show functionality or the capability of doing each measure. The score should continue to use yes/no or one patient reporting and measures should be equally weighted across the base score so that physicians do not become confused or burdened by an intricate system of points and weights.

¹⁵ Andy Slavitt and Karen DeSalvo. EHR Incentive Programs: Where We Go Next. January 19, 2016. https://blog.cms.gov/2016/01/19/ehr-incentive-programs-where-we-go-next/

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¹⁶ Interoperability sign-on letter addressed to Andy Slavitt and Karen DeSalvo. June 3, 2016. https://download.ama-assn.org/resources/doc/washington/interoperability-onc-cms-sign-on-letter-03june2016.pdf

¹⁷ John Halamka. Making a Difference. Accessed on June 9, 2016 from http://geekdoctor.blogspot.com/2016/06/making-difference.html

Reweight the base score to 75 percent of the total ACI category

CMS proposes to divide the ACI category into two components—a base and performance score—which each account for 50 percent of the total ACI score. While this even divide appears to be simple, it places too much emphasis on the performance of new and untested measures as well as a scoring construct that, as discussed in more detail below, will be very challenging for physicians. The base score represents the foundation of the ACI category, requiring physicians initially complete each measure at least once. The performance category builds off of the base score to then assess how physicians actually perform in each measure across their patient population. It, therefore, makes sense that CMS first seek to ensure MIPS participants are focused on and working to fulfill the base score requirements before moving on to the performance score. A 75 percent weighting of the base score would highlight the importance of the base requirements before evaluating the more complex performance component. We emphasize that greater weighting of the base score should only occur if CMS also moves away from the pass-fail approach to scoring this section, as described above. We do not support a greater base score weight if CMS maintains the proposed pass-fail scoring approach.

Performance Score

The AMA believes the proposed performance score is extremely complex and creates significant barriers to achieving CMS' goals of a program that is simplified, allows flexibility in selecting measures, and encourages innovation. As such, we believe this portion of the ACI category requires significant changes and should not be finalized in its current form.

• Success in performance scoring should include a physician's improvement from year to year

The performance score is problematic because it forces physician practices of varying size, resources, and manpower to compete against one another for percentage points, rather than encouraging physicians to compete against themselves and improve from year to year. Whereas there exists accommodations for small practices in the quality and CPIA categories of the proposed rule, the ACI category does not include similar accommodations. This lack of modification places small practices, new users of health IT, and those first trying an ACI measure at a disadvantage. These participants will most likely score lower than those who have implemented and previously adopted the tasks required by an ACI measure. Knowing that they will likely earn only one to two points for a new performance measure, clinicians may simply maintain their current activities and not try to adopt new tasks.

To remedy this perverse incentive, the AMA believes the performance score must take into account a physician's improvement. We propose that CMS allow participants to use the first performance period to measure their current levels of performance and receive full credit in the performance score for this level-setting. Subsequently, CMS will consider whether the physician has improved his or her performance compared to the previous reporting year. **If a physician achieves a minimum one percent increase in their adoption of a performance measure, CMS should award the full 10 points for that measure.** For example, a physician first reports in 2017 that she meets the secure messaging requirement for five percent of her patients. In 2018, the physician meets the secure messaging requirement for 10 percent of her patients. In 2019, the physician again shows improvement and provides secure messaging for eleven percent of her patients. Under our proposal, the physician is showing improvement and would earn the full 10 points for the 2018 and 2019 reporting periods. We believe this scoring process, unlike the current proposal, rewards improvement, creates incentives for physicians to try, and promotes the adoption of new technology.

• Performance should measure a majority of patients rather than the total patient population

While the proposed performance score removes the arbitrary thresholds of the MU program, it now requires physicians to report on their total patient population. This approach fails to recognize the many valid reasons why a patient or physician may not perform an ACI measure. For example, a patient may prefer to not have their health information shared on a patient portal for privacy concerns. Yet, under the current proposal, respecting this patient request will negatively impact the physician's performance score.

In addition, past experience with the MU program shows that physicians are still in the process of adopting technology measures and are nowhere near reporting on the majority of their patients, let alone all of their patients. As shown in the following chart, physicians are currently reporting on closer to 20 percent of their patients for most of the performance score measures. Stage 3 also adds two entirely new measures—patient generated health data and integration of a patient care record—that we believe will further challenge physician success in this category.

ACI Performance based on Attestation Data^

Objectives	Patient Electronic Access		Coordination of Care Through Patient Engagement			Health Information Exchange (HIE)		
Measures	Patient Access	Patient- Specific Education	VDT	Secure Messaging	Patient generated health data*	Patient Care Record Exchanged	Request/Accept Patient Care Record*	Clinical Information Reconciliation
	95%	95%						
core								
te S								
Performance Rate Score								
			20%	22%		19%	19%	19%
					10%			
Percentage Points Earned	9.5	9.5	2	2.2	1	1.9	1.9	1.9
Performance Score			2014 1		29.9			

[^]Based on CMS Medicare Incentive Program 2014 data

The chart shows that measuring physicians on all of their patients results in low scores across most of the performance measures. This result compels physicians to report on *all* of the performance measures, thereby negating the flexibility CMS highlights that would permit physicians to select measures within the performance score. Even when reporting on all of the measures, physicians are still likely to only receive approximately 30 out of the 80 possible performance points.

For these reasons, we do not believe that CMS should evaluate performance using 100 percent of the physician's patients. Instead, we urge CMS to focus on a majority of a physician's patients—allowing physicians to earn the full 10 points per performance measure when they report on at least 50 percent of their patients. This approach more readily reflects the current status of physician adoption of ACI measures while ensuring that physicians use technology for most of their patients. It also allows physicians to have the flexibility CMS intended in selecting relevant ACI measures in the performance score. Finally, it is consistent with our proposed approach to the quality performance category, creating symmetry across the different MIPS categories.

^{*}New Measures (projected performance based on prior experience with new measures)

• Encourage alternative ACI measures

As proposed, the ACI category adopts the same flawed Stage 3 measures opposed by the majority of physician societies and does not provide a clear path away from process measures. EHR developers will continue to rely on these requirements as a roadmap for product design, hindering usability, and certain specialties will continue to have no relevant technology measures for their practice. CMS has acknowledged the need for a use-case approach to health IT; however, there are currently no formal methods of gathering feedback from physicians on the utility and success of existing measures to support such an approach. Physicians are unable to identify how systems designed to meet proposed ACI measures will be able to support their needs as they transition to new payment models.

Time constraints should not have barred CMS from considering new measures, as we and other stakeholders have highlighted key changes and alternative measure options in previous comment letters. Furthermore, clinicians are already using their systems in innovative ways that go beyond the current MU measures. Yet, the MU program—and ACI, as proposed—simply do not count or recognize these actions. The AMA has repeatedly asked that these measures be overhauled and refocused on outcomes (noting that MACRA emphasizes the importance of moving from process toward outcome-based measures). For example, we have highlighted that CMS could broaden its patient engagement measures to account for actions such as the Open Notes program, appointment reminders, and other actions that are already being conducted through EHRs. In the short-term, we urge CMS to incorporate this broadened approach to health IT measurement. While we recognize limitations in changing CEHRT, these functions are already part of many systems and could be readily incorporated into EHRs. Not adopting these broader measures limits innovation and signals to vendors that the current state of technology is acceptable and sustainable.

To better position ACI and the greater MIPS program for success in the long-term, CMS should allow proposals for more relevant measures and count these measures as part of the performance category. Mirroring the quality category, specialties could identify a group of ACI measures that are more relevant for their practices. CMS could also leverage the proposed CPIAs and utilize existing but relevant ACI measures or adopt new ones to facilitate reporting on these activities, including activities related to closing the referral loop, timely communication of test results, and updating plans of care. This would not only improve the relevance of measures but would help bridge the different MIPS components, creating a more integrated program. For example:

- 1) A physician could select a CPIA, such as engaging patients in a plan of care. The physician would report this selection to CMS via attestation, which would satisfy the CPIA scoring component. Note, that the CPIA should not require the use of CEHRT or a specific technology—this should be an option that the physicians chooses if they want to also earn credit in the ACI category.
- 2) The physician would carry out the activities associated with a plan of care for the patient, such as referring a diabetic patient for an eye exam, collecting the patient's blood glucose levels over time, and coordinating with the patient's nutritionist. The physician may find it helpful to utilize CEHRT and other non-certified health IT to carry out these activities; for instance, the physician could collect patient generated health data to monitor the patient's blood glucose levels and answer questions from the patient about his condition through secure messaging. The use of CEHRT functions would be registered automatically by the EHR (including a numerator/denominator calculation) and could be associated with the selected CPIA.
- 3) At the end of the reporting period, data on the use of EHRs could be provided to CMS in a number of ways. For example, physicians could use a Physician Satisfaction Survey, answering questions such as, "Which CEHRT functionality did you find most useful to accomplish your CPIA?" This would provide CMS with quantitative feedback on how CEHRT functions helped

them accomplish the selected CPIAs. The survey could also provide not only CMS, but also ONC and health IT developers with qualitative data on how various EHR functions facilitate interoperability, clinical practice improvement, utility of health IT, and better patient outcomes over time. Data could also be pulled directly from the EHR and provided to CMS.

CMS could score this category in a number of ways. For example, the physician could earn credit in the ACI performance score for each of the activities he or she completes as described above. The approach could later be expanded into the quality realm to help integrate the four separate MIPS components into one program. It will help physicians identify a patient goal and how they can leverage the technology they have in place rather than simply checking a box.

In addition, MACRA provides CMS with the flexibility to support alternative and less prescriptive approaches to the use of CEHRT. Indeed, the proposed APM track requires only that 50 percent of the APM's clinicians use CEHRT to "document and communicate clinical care information." The flexible standard for the use of CEHRT in APMs should also be incorporated in the MIPS track to allow physicians and medical specialties to use CEHRT in a way that best serves their patients.

We understand that this approach is a major shift from the proposed ACI structure. At a minimum, we request that CMS outline a process for considering new ACI measures. In every other MIPS category, CMS has defined a way for stakeholders to propose new measures or activities to include in future years; yet, this opportunity is completely missing from the ACI category. This is especially surprising given that the ACI category is premised on innovation and harnessing new ways to use technology—it should have the most flexibility to incorporate new activities. We suggest that CMS implement a call for new ACI measures that is similar to the proposal for developing new CPIAs. Such a call for new measures should focus on improving usability, emphasizing how vendors can implement user-centered design principles, improve user experience, and reduce cognitive workload. This will signal to physicians that the program is flexible and that new technology and other care innovations can be incorporated in the future. It also provides consistency across the different MIPS categories. Without this process, we believe physicians will not see a difference in the ACI category, beyond its name, and will report on measures that are still process-based and irrelevant to their practices.

Certified Technology

• Provide accommodations for 2014 CEHRT

CMS recognized in its proposed rule that most physicians in 2017 will still be using 2014 CEHRT or may be using a combination of 2014 and 2015 edition CEHRT. To accommodate the 2014 edition technology, CMS proposes allowing the modified Stage 2 objectives and measures rather than the Stage 3 measures but will require all physicians to use 2015 edition technology starting in 2018. While we appreciate this proposal, we remain concerned that the 2015 edition technology will not be ready on time. Currently, there is almost no software that has met the 2015 edition criteria. In addition, vendors should be focusing on incorporating the new MIPS measures to ensure physicians can report through these tools. We, therefore, believe that CMS should allow physicians to continue to use the 2014 edition technology, or a combination of technology, until it confirms that 2015 edition technology is readily available.

In addition, even with CMS' proposed accommodations for 2014 CEHRT, there remains a problem with the performance score that could negatively impact physicians using the earlier version of their EHRs. Physicians using 2014 CEHRT will have two fewer measures in the performance score section on which they can report—patient generated health data and integration of a patient care record —due to the constraints of their technology. Accordingly, they have only six measures to choose from and fewer opportunities to earn performance points. **To avoid this detriment on 2014 edition users, we**

recommend that CMS increase the weight of the available six measures in the performance score for those using 2014 CEHRT. To be equitable, each measure must be worth 13.33 points instead of 10 points.

Scoring the ACI Performance Category

• Maintain existing measure exclusions and hardships

CMS proposes to maintain only the exclusions for the electronic prescribing and immunization registry measures and limits the available hardship categories. We strongly disagree with this significant change in the program. The measure exclusions and hardship categories were established to recognize that different practices and specialties may be unable to report on specific measures and those certain measures may not be relevant to all practices. Indeed, MU participants actively called for additional, not fewer, exclusions and hardship categories. Because CMS has chosen not to change the measures, or make them more inclusive and practical for physicians, the exclusions and hardships should also be maintained.

CMS suggests that the MIPS low-volume threshold and flexibility in the ACI performance score eliminates the need for such accommodations. We strongly disagree since the low-volume threshold has no explicit correlation with the ACI measures. For example, the low-volume threshold is unlikely to exclude all physicians who do not transfer or refer patients. Without an exclusion, these physicians will now need to provide a summary of care document despite this being irrelevant to their practice. In addition, as described above, the flexibility highlighted by CMS in the performance category is doubtful—most physicians will continue to report on all of the measures in the performance score and remain far from achieving more than 30 points.

• Re-weight the ACI category

MACRA provides the Secretary the authority to re-weight the ACI component of MIPS from 25 percent down to 15 percent if at least 75 percent of eligible professionals are meaningful EHR users. CMS proposes two methods to estimate the proportion of physicians that are meaningful EHR users. The primary proposal would establish a physician as a meaningful EHR user if they score a total of 75 points (50 in base and 25 or more in performance) in the ACI category. An alternative approach would lower the required point value for a meaningful EHR user down to 50 points (50 points in base).

As stated throughout this letter, we urge CMS to consider various approaches that would reduce the complexity of the program and provide physicians in all practice sizes an equal opportunity to score well in MIPS. Accordingly, we support CMS' alternative approach to establishing a meaningful EHR user at the 50 point level. CMS should then reduce the applicable percentage weight of the ACI category in the MIPS composite score and reassign it to the CPIA category. We reiterate that CPIA activities are more in line with patient goals and provide physicians greater flexibility when using health IT.

• Establish a 90-day ACI reporting period

For the 2014 and 2015 reporting periods, the MU program has operated on a 90-day reporting period, rather than a full calendar year, to accommodate many issues with the program. In particular, this shorter reporting period permitted necessary technology updates, system downtime, accommodations to improve usability, and facilitated physician's transition to new health IT measures. As we have discussed in past comment letters, reporting the MU/ACI measures for an entire year can hinder efforts to test new technology or ensure the security of systems.

Accordingly, we recommend that CMS maintain the 90-day reporting period for the ACI category. Physicians will need to devote time and resources to understanding the new MIPS program, which includes new reporting mechanisms, measures, and a new scoring system. We also want to encourage physicians to improve interoperability with other practices and ensure that systems remain protected while implementing these changes. A shorter reporting period enables physicians to adopt innovative uses of technology as they make this transition and permits them to test new health IT solutions.

The MACRA statute provides CMS with the authority to create a shorter reporting period. In fact, CMS used this flexibility in proposing a 90-day CPIA performance period. We, therefore, recommend that the ACI category follow this same approach. A 90-day period would not create confusion but would align the periods of both the CPIA and ACI categories, which already have significant cross-over in certain measures, as explained in our performance score comments above.

Allow exceptions for group reporting

We support CMS' proposal to permit group reporting of the ACI category; however, we are unclear if CMS will exclude from the group score members that normally would receive a hardship exception or have their ACI performance re-weighted to zero. Without this accommodation, there exist instances in which group scores will be weighed down by clinicians who may be unable to report on certain measures. For example, multi-specialty practices with both patient-facing and non-patient-facing clinicians should not have the non-patient facing clinicians count as part of their score. We urge CMS to include language in the final rule reflecting that any applicable exemptions or exclusions apply to the individual within the group, so that the group's overall score is not negatively impacted by those clinicians unable to report on ACI measures. At a minimum, CMS should revise its non-patient-facing clinician definition to the following: an eligible clinician or group that, on average, bills 25 or fewer patient-facing encounters during a performance period.

• Avoid duplicate EHR reporting in 2017

Under the proposed rule, the first MIPS performance period is 2017. This timeframe creates a conflict for physicians who are new to the MU program in 2017. To avoid the 2018 MU payment adjustment, these new participants will need to report on both MIPS and the MU 2017 criteria, despite the significant overlap between these two program. This small group of clinicians essentially will be required to report EHR information for 2017 twice under different programs, each with different standards of success. This will cause significant confusion and is likely to lead to mistakes and inadvertent errors.

We strongly urge CMS to create an accommodation for these physicians, such as an exemption from the 2017 MU reporting requirements. Those who are participating in MU for the first time in 2017 should be focused on preparing for MIPS and should not have to try and worry about previous reporting requirements. Making these physicians report twice, doubles the burden for those who are just beginning to learn and use EHRs. We think that without a solution, physicians will see this double reporting as contrary to the intent of MACRA, and it will complicate the launch of the new MIPS program.

Clinical Practice Improvement Activity (CPIA)

Proposals the AMA Supports:

- Offering choice: The AMA supports the broad list of CPIAs included in the proposed rule and is pleased that physicians can select from any of the identified activities. This allows physicians to customize CPIAs to best reflect their region, specialty, patients, and practice needs.
- **90-day reporting period:** Recognizing that CPIA is a new category, we support a shorter performance period that will allow physicians to become accustomed to reporting on these activities.
- **Promoting medical homes and APMs**: The AMA strongly agrees that physicians practicing in medical homes and APMs should receive credit for this effort as part of the CPIA category.
- **Providing accommodations for small, rural, and non-patient facing physicians:** We support allowing physicians with particular challenges to meet a lower reporting threshold.
- Ensuring a simple reporting process: We agree that physicians should report CPIA activities generally through attestation and not be required to comply with lengthy documentation or other reporting requirements that will increase administrative burden. Any additional guidance on how to report CPIAs should focus on how to facilitate reporting, such as allowing organizations, APMs, or other entities that sponsor CPIAs to maintain and submit participation records on behalf of physicians. In addition, CMS should not require physicians to resubmit documents if the CPIA is granted for more than a one-year period (e.g., certification).

Recommended Modifications:

CPIA Reporting Requirements

• Decrease the number of required CPIAs

Under the proposed rule, physicians would be required to report on as many as six different activities in order to receive the full CPIA score. While the activities vary in their time and cost burden, the resources involved in meeting six different activities can quickly add up and create new challenges for physicians. Instead, the AMA recommends that physicians should report on either two high-weighted (20 points each) or four medium-weighted (10 points each) CPIAs, or some combination, to achieve a total of 40 points. We believe this reduction is warranted given that CPIA is an entirely new category for physician reporting and will take time for physicians to learn. Furthermore, the CPIA category will typically only count for 15 percent of the overall MIPS composite score and should not require the same level of reporting (e.g., six measures) as the quality component, which is weighted at a much higher 50 percent.

The AMA also fully supports the accommodations made for small, rural, and non-patient facing clinicians or groups within the CPIA category. To retain the exceptions for these practices, the AMA would suggest that CMS adjust its proposal to allow those entities who report on two medium-weighted CPIAs or one high-weighted CPIA to achieve the full credit in this category. Accordingly, those providers who report on one medium-weighted CPIA activity would achieve a 50 percent score. This provides flexibility for these entities, while still encouraging them to select relevant practice improvement activities and incentivizing them to select high-weighted activities.

• Increase the credit for participation in an APM

Section 1848(q)(5)(C)(ii) of MACRA requires that APM participation earns *a minimum* one half of the highest potential score for the CPIA performance category (emphasis added). This reflects that many APMs already include requirements that mirror the activities listed as CPIAs, and that this category may be redundant for APM participants. Furthermore, CMS acknowledges the connection between APMs and CPIA, stating practice improvement activities "drive movement toward delivery system reform principles and APMs." Accordingly, the statute provides CMS with the authority to grant those participating in APMs anywhere from half to full credit for the CPIA category.

Yet, CMS proposes the lowest possible threshold—providing only 50 percent of the total CPIA score for APM participation, regardless of the model or activities already being performed by the APM. Especially in light of the difficult qualifications that CMS requires for APMs to be categorized as Advanced APMs, we believe APM participation covers many CPIA-related activities and should receive more than half credit. We urge CMS to provide full CPIA credit to APMs. At a minimum, CMS should provide sufficient credit so that APMs would only be required to perform one additional CPIA of any weight to earn the full category score.

• Increase the recognized accreditation entities for medical homes

We recommend that CMS expand the recognized certification entities for medical homes and similar specialty recognition programs. CMS currently proposes to recognize one of four national accreditation organizations to certify medical homes. In addition, CMS only accepts the National Committee for Quality Assurance (NCQA) accreditation for certification in the comparable specialty recognition program. We do not believe physicians should be required to pay a third-party accrediting body to receive recognition as a patient-centered medical home or similar specialty group. CMS should include programs that accredit medical homes and specialty groups based on the advanced primary care functions, including state-based, payer sponsored, and regional medical home recognition programs. The agency should also consider an attestation approach for the key functions of a patient-centered medical home, similar to the type of attestation process used in the Comprehensive Primary Care Initiative (CPCI).

It is not clear to the AMA why CMS has limited comparable specialty practices to NCQA designation given that many of the same national accreditation organizations, in addition to state-based, payer sponsored, or regional recognition programs, have comparable specialty designation programs. For example, the Blue Cross Blue Shield plans have many specialty designation programs that are comparable to NCQA designation. CMS should recognize these accreditation programs for medical homes.

Proposed CPIAs

• Expand "high-weighted" activities

While the AMA is generally pleased with CMS' broad proposal for the CPIA category, we are concerned that the agency identifies only 11 out of the more than 90 listed CPIAs as "high-weighted." This categorizes certain high quality patient activities as only "medium," ignoring the potentially significant patient benefit and care improvements associated with certain activities. In particular, listing activities as "medium" and not "high" may deter physicians from selecting these measures. For example, there are no "high-weighted" measures for the emergency response and preparedness CPIA subcategory, which creates a perverse incentive for physicians to not select any of these important care activities. In addition, CMS ignores the time commitment, cost, and effort to implement and complete many of the medium-

weighted measures. To better reflect the benefit and burden associated with certain CPIAs, the AMA believes the following activities are more appropriately categorized as "high-weighted" and encourages CMS to seek the advice of specialty and state societies on how to evaluate other CPIAs:

Subcategory	Activity
Expanded Practice Access	Use of telehealth services and analysis of data for quality improvement, such as participation in remote specialty care consults, or teleaudiology pilots that assess ability to still deliver quality care to patients.
Population Management	Participation in Center for Medicare & Medicaid Innovation (CMMI) models such as Million Hearts Campaign.
Care Coordination	Performance of regulator practices that include providing specialist reports back to the referring MIPS eligible clinician or group to close the referral loop or where the referring MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the certified EHR technology.
Care Coordination	Implementation of practices/processes to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s).
Care Coordination	Implementation of practices/processes for care transition that include documentation of how a MIPS eligible clinician or group carried out a patient-centered action plan for first 30 days following a discharge (e.g., staff involved, phone calls conducted in support of transition, accompaniments, navigation actions, home visits, patient information access, etc.).
Care Coordination	 Establish effective care coordination and active referral management that could include one or more of the following: Establish care coordination agreements with frequently used consultants that set expectations for documented flow of information and MIPS eligible clinician or MIPS eligible clinician group expectations between settings. Provide patients with information that sets their expectations consistently with the care coordination agreements; Track patients referred to specialist through the entire process; and/or Systematically integrate information from referrals into the plan of care.
Beneficiary Engagement	Engage patients, family, and caregivers in developing a plan of care and prioritizing their goals for action, documented in the certified EHR technology.
Beneficiary Engagement	Incorporate evidence-based techniques to promote self-management into usual care, using techniques such as goal setting with structured follow-up, teach back, action planning or motivational interviewing.
Beneficiary Engagement	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
Patient Safety and Practice Assessment	Completion of training and obtaining an approved waiver for provision of medication-assisted treatment of opioid use disorders

Subcategory	Activity
	using buprenorphine.
Patient Safety and Practice Assessment	Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice (noting that activities simply involving registration are not sufficient and that MIPS eligible clinicians and groups must participate for a minimum of six months).
Patient Safety and Practice Assessment	 Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following: Train all staff in quality improvement methods; Integrate practice change/quality improvement into staff duties; Engage all staff in identifying and testing practices changes; Designate regular team meetings to review data and plan improvement cycles; Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families.
Achieving Health Equity	Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food, security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.
Emergency Response and Preparedness	Participation in Disaster Medical Assistance Teams, or Community Medium Response and Emergency Responder Teams (noting that activities that simply involve registration are not sufficient and that MIPS eligible clinicians and groups must be registered for a minimum of 6 months as a volunteer for domestic or international humanitarian volunteer work).
Emergency Response and Preparedness	Participation in domestic or international humanitarian volunteer work (noting that activities that simply involve registration are not sufficient and that MIPS eligible clinicians and groups must be registered for a minimum of 6 months as a volunteer for domestic or international humanitarian volunteer work).

• Include additional activities

The AMA believes that the list of qualifying CPIAs is robust and would like to see all of the activities in the proposed rule included in the final regulation. We especially thank the agency for including the AMA's STEPSforward TM program as one of the qualifying CPIAs. After consultation with different state and specialty societies there are a number of additional activities that the agency should also include under this MIPS category.

First, we would like CMS to add accredited continuing medical education (CME) and board-certification-related activities to the list of CPIAs. These activities take up considerable time for physicians but ensure patient care is of the highest quality and reflects the latest medical knowledge and innovations. While

some proposed CPIA activities could be satisfied through CME, we believe a more explicit recognition would help physicians understand whether all CME will count under the CPIA component of MIPS.

In addition, we encourage CMS to adopt the following additional CPIA and designate it as "medium-weighted" in the emergency response and preparedness subcategory: Participation in public health emergency disease (e.g., Zika, swine flu, Ebola) outbreak control efforts. Activities could include participating in mass vaccination campaigns, community education, and staff training on how to screen patients for disease.

We also urge CMS to adopt CPIAs that address physician satisfaction. Higher levels of physician satisfaction can lead to improved patient care and a more sustainable and effective healthcare system. Factors influencing physician satisfaction include whether practice leadership is supportive of quality improvement ideas, if payers cover medically necessary services, and whether EHR functionality is user-friendly or includes time-consuming data entry. ¹⁸ CPIAs that address these factors and others affecting physician satisfaction should be included.

CMS should also seek to expand activities that are relevant to unique care settings, such as physicians who treat patients in nursing facilities or home health centers. For example, CMS could include facility projects, such as the Improving Dementia Care Initiative or the Quality Assurance and Performance Improvement (QAPI), on the CPIA list to ensure these physicians have relevant activities for their practices and patients.

Finally, we would like CMS to clarify the scope of some of the CPIAs but recommend that this be done through more flexible sub-regulatory guidance that can be readily updated and modified. In particular, CMS should highlight that the population management subcategory includes a broad array of activities related to prediabetes, diabetes, and hypertension. The AMA believes that Centers for Disease Control and Prevention (CDC) recognized diabetes prevention programs and the AMA-American Heart Association Target Blood Pressure (BP)TM initiative to improve blood pressure control should be included activities in this subcategory. Likewise, the AMA would like to provide additional guidance on the relevant modules for the STEPSforward TM program. We urge CMS to work with stakeholders to provide this additional information as soon as possible so that practices can prepare to report on these activities.

• Allow practices to maintain CPIA activities over time

CMS proposes that in future years, the CPIA scoring will continue to have more stringent requirements, and may limit MIPS participants from reporting on the same activity over several performance periods. We strongly oppose these proposals and believe them to be contrary to the purpose of this category.

CMS should use the CPIA category to incentivize practices to adopt activities that benefit patients and improve quality of care in the long-term. By placing limitations on whether a physician can report a CPIA for multiple periods, CMS is encouraging practices to implement temporary instead of permanent improvements and risks creating short-lived activities that lack consistency across time. This temporary approach is not beneficial to patients and is confusing and disruptive to physician workflows. We strongly urge CMS to avoid this approach in future years.

Finally, CMS should permit MIPS participants to select from a wide range of CPIAs, allow participants to perform them in a way that is effective and reasonable for both the participants and their patient population, and refrain from imposing restrictive specifications regarding how participants document and

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¹⁸ Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. RAND Health and The AMA. 2013.

report their activities. We, therefore, urge CMS to keep the broad list of CPIAs and publish additional detail through non-binding clarification or guidance, rather than in regulatory text, which may limit innovation and flexibility.

MIPS Composite Performance Score

The complexity of the rule becomes quickly apparent when trying to understand how the composite score is calculated. We believe that most physicians will not be able to understand the numerous point systems, how they interrelate with one another to result in a final score, and what this final score actually means in terms of their Medicare reimbursement. For example, the quality performance category by itself has four different point calculations for the measures, ranging from 80 to 210 points. Physicians then must further understand how bonus points are determined within the quality component and then factor in how benchmarks impact this final quality score (which vary based on how the data is submitted). Understanding this process is not only difficult but becomes extremely challenging when you consider that this is only one of the four categories that a clinician must understand to comprehend their final MIPS score. To reduce confusion, we recommend the following:

Recommended Modifications:

• Focus on a single total score rather than creating multiple scoring subcomponents

Currently, the four categories are broken down into subcategories with different scoring methodologies, which only add to the complexity of the overall program. Where possible, CMS should try to create a straightforward scoring process that has the fewest number of different point categories.

 Provide information about score calculations in advance of the performance period so that physician can anticipate what is required under MIPS

The MACRA statute explicitly states that thresholds should be published prior to the performance period, providing transparency to participants. Yet, CMS highlights several instances where this information will not be available under the current proposal. First, benchmarks for certain new quality measures would not be published until after the performance period. Second, by proposing to create benchmarks for the resource use measures based on the performance period, CMS would not be able to publish the actual numerical benchmarks in advance of the performance period. Without this information, we believe it will be exceptionally hard for physicians to prepare for and succeed under the MIPS program. CMS acknowledges this and makes accommodations for the new quality measures but does not provide any similar relief in the resource use category. Accordingly, we believe CMS must improve the information it provides to physicians before scoring them.

• Wait to evaluate overall MIPS improvement

Section 1848(q)(3)(B) of MACRA requires the Secretary to consider improvement in establishing performance standards. While we recognize this requirement for MIPS, we believe that it is far too soon for CMS to incorporate improvement into the composite scoring methodology at this time. MIPS is an entirely new reporting program, with new measures, new requirements, and new categories that will take significant education for physicians and other participants to understand. Indeed, the statute recognizes that it may take time before accounting for improvement in MIPS— it notes that improvement should not factor into scoring until the second year and caveats this requirements by saying "if data sufficient to measure improvement is available." We, therefore, believe that CMS should work on securing a successful launch of the program and encouraging participation before it begins to evaluate future improvement.

Re-weighting

MACRA offers flexibility by allowing the Secretary to reweight the MIPS components if there are not sufficient measures and activities applicable and available to a participant. CMS' proposal, however, focuses predominantly on moving any missing category into the weight of the quality performance category. Given that the quality category is already worth 50 percent of the total MIPS score for the first year, we believe this proposal could overemphasize the quality component and make the other three categories immaterial. CMS also creates an overemphasis on the ACI category for MIPS APMs. For these entities that do not submit quality data through the CMS Web Interface, CMS proposes their ACI score will account for 75 percent of their total score. Again, we think this creates too much of an emphasis on a single category and limits the ability for a clinician to average performance across the different MIPS components. Instead, we recommend the following:

• Work with affected physicians and medical societies to determine how the percentage weight should be re-distributed across the MIPS categories

To accommodate differences in practices, specialties, regions, and patients, re-weighting should not be done in a single, across-the board manner. There will be situations in which it is appropriate to proportionally redistribute the category weights, while at other times it may be more appropriate to place the full weight in one category. CMS should allow this flexibility. In our comments to the MACRA RFI we proposed how CMS could identify the practitioners with insufficient measures and a process whereby the agency could provide a "pre-determination" on categories that need to be re-weighted. We refer CMS to these comments for further detail on this approach.

Increase the CPIA category weight to make up for the lack of quality or other measures

CMS itself states that "we envision that all MIPS eligible clinicians would have sufficient activities applicable and available and do not propose any scenario where a MIPS eligible clinician would not receive a CPIA performance category score." CMS should therefore leverage the breadth of the CPIA category when it does need to re-weight the MIPS components.

Performance Thresholds

• Set the performance threshold by using a range of scores

The MACRA statute outlines most of the requirements for the MIPS performance thresholds; however, we are unclear if CMS intends to use a single numerical threshold or a range of scores to determine the MIPS adjustment factors. We believe that using a single numerical number as the performance threshold (e.g., 60, as used in the example in the proposed rule) is too limiting and will create arbitrary cutoffs for the physicians that cluster around the mean or median performance level. Instead, CMS should set the performance threshold by using a range of scores (e.g., 55-75). Those above the performance threshold would still receive a positive adjustment factor and those below would receive a negative adjustment factor, as outlined in the statute; however, the cluster of physicians around the mean/median would 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.

• Clarify how CMS plans to calculate the performance threshold for the 2019 payment year

CMS notes that it will primarily be based on 2014 and 2015 data from previous reporting programs; however, there is no detail about the "sensitivity analyses" used to account for the CPIA category. This methodology should be published and include a public comment period prior to the start of MIPS.

Finally, we disagree with CMS' alternative proposal that would require a physician to earn a minimum number of points above the threshold before receiving a positive adjustment factor. We think that physicians who are performing above the established threshold have shown a high level of performance and should be able to immediately begin earning incentives.

Targeted Review and Auditing

Because MIPS is a new program, we strongly recommend that CMS provide significant education to physicians about how the program operates, including the review and auditing procedures. Physicians and groups simply need to know who they are being compared to, what their thresholds are, and what precisely they are working toward before they begin participating and reporting. This will not only improve success in the program but will reduce requests for targeted review of the MIPS score. In addition, we offer the following recommendations.

Proposals the AMA Supports:

• Streamline auditing: The AMA strongly supports the proposal that CMS will only use one set of auditing requirements for the MIPS program. This will reduce administrative burden and aligns with our request that CMS view MIPS as a unified approach rather than four separate components.

Recommended Modifications:

• Broaden timelines

We recognize that the MACRA statute limited the circumstances in which a clinician can seek a review of their MIPS adjustment factor; however, we urge CMS to broaden the proposed timelines for this process. 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. This will allow time for physicians to adequately asses if a mistake occurred and may prevent erroneous requests for a review. Similarly, the 10 calendar day timeframe for providing supporting information is extremely challenging, especially because the lack of clear guidance on what must be maintained. We, therefore, recommend at least 20 business days for submission of additional information and exceptions be allowed where this timeline may not be feasible.

CMS has noted that the deadlines for appealing a MIPS adjustment factor can create barriers when trying to implement a later start date. Given this concern and our proposal for an initial transition period starting on July 1, 2017, we recognize that CMS may not be able to broaden these timelines for the first performance period. We, however, ask CMS to consider if other program modifications, such as lowering the data submission thresholds, removing certain problematic measures, assessing the number of appeals, and streamlining program requirements, will help reduce the number of and delays in processing

requests for targeted review. We also ask that CMS work with us to identify ways to improve the timeliness of the review process, by automating processes, providing additional guidance, and seeking additional resources if necessary.

Publish clear guidance on what documentation must be maintained by a physician or group to comply with a MIPS audit

In the past, physicians have been confused by the different requests for documentation, and many have felt they were unfairly penalized due to insufficient notice about the documentation that needed to be maintained and provided to the agency. CMS should clarify whether it or another entity will be the primary lead on data validation and auditing and the specific documents and data that must be available to pass an audit. CMS should also have sufficient resources to staff a help desk and develop support materials to guide physicians through the review and audit process.

• Audits and reviews should encourage education and the ability to learn from past mistakes rather than penalizing and recouping incentives

Overall, we urge CMS to take into consideration that this will be the start of a new program. By initially taking an educational as opposed to a punitive approach, CMS can collect and analyze "common errors" and publish "lessons learned" about the MIPS program. The agency can then route findings back to physicians, medical societies, and others to improve the chances of success under MACRA.

Third Party Data Submission

Recommended Modifications:

• Require testing and provide data validation and reporting

To enhance data integrity, CMS should provide validation on calculated reporting and performance rates as data is submitted by EHRs and QCDRs to CMS, including flagging any errors on both format and values as data is submitted. Ongoing validation and auditing are also needed. To avoid data integrity problems similar to the ones CMS encountered with 2014 data, CMS should require these entities to complete preliminary CMS-sponsored submission testing. Currently, such testing is highly encouraged, but not required. CMS and its contractors should also work with QCDR and EHR vendors in their early stages in order to integrate processes for ongoing data testing. For instance, discussions on processes for system testing should occur once a QCDR self-nominates and submits its data validation plan.

Provide adequate time for QCDRs, registries, and vendors to adopt changes

CMS must recognize that changes to QCDRs, registries, and EHRs require significant financial resources and time to plan, incorporate, and test. This time-lag limitation becomes very challenging when CMS makes annual changes to quality reporting and technology functionality. In addition, annual changes are administratively burdensome and do not allow sufficient time for implementation. These entities are faced with a dilemma of moving forward with incorporating proposed requirements that may not be included in the final regulation, or waiting until the final rule comes out and then having little time to adopt these changes before the reporting year begins.

There must be ample notice in the rulemaking process for QCDRs, registries, and vendors to plan and adequately meet these changes. As highlighted in our comments on the performance period, it is unrealistic to expect that these changes can be easily adopted by the 2017 performance period following

publication of the MACRA final rule. We refer CMS to our MACRA RFI comments for more details on this issue as well as our Revised Stage 3 Meaningful Use comments.

• Provide flexibility for QCDRs

As CMS recognizes in this proposed rule, Congress required in MACRA for the Secretary to encourage the use of QCDRs for the quality component of MIPS. We appreciate CMS' proposals to foster the growing acceptance of QCDRs in clinical care, not only to meet the maximum allowable points in the quality component, but also to help ECs and groups meet other components of MIPS, such as ACI and CPIA. Yet, we can only achieve this shared goal of greater QCDR participation if CMS recognizes that QCDRs need the flexibility to incorporate measures into the registry as each specialty sees fit.

QCDRs have experienced tremendous growth and success in improving quality because physicians recognize that QCDR measures are meaningful to their profession and patient care. In contrast, CMS proposes to require QCDRs to report on measures that may not be relevant or applicable to the data that they were designed to collect, especially cross-cutting measures. Accordingly, we urge the agency to err on the side of flexibility with respect to this requirement, as originally envisioned by Congress.

In fact, we believe CMS is not following the statutory intent of section 1848(q)(2)(D)(vi) of MACRA that allows flexibility with the measures QCDRs report. Based on statute, QCDRs are not subject to certain requirements, such as inclusion of measures on the annual final list of quality measures, publication in peer-reviewed journals, and endorsement by a consensus based entity. In addition, QCDR measures are exempt from the consideration of whether measures address measure gaps and the priority given to outcome, patient experience, care coordination, and appropriate use measures. This reflects the intent to allow specialties to develop and select QCDR measures outside the prescriptive process used to develop and choose general quality reporting measures. CMS, however, is proposing to require physicians to report on one cross-cutting measure that must be chosen from the list of general quality measures. Accordingly, physicians reporting via a QCDR will be forced to select a measure outside their specialty-specific QCDR measure list. We again urge CMS to remove this requirement.

CMS further notes in this proposed rule that if a QCDR wants to use a non-MIPS measure for inclusion in the MIPS program, such measures would go through a "rigorous CMS approval process" during the QCDR self-nomination period. Once the measures are analyzed, the QCDR would be notified of which measures are approved for implementation. This "rigorous" review process will help ensure that each measure within a respective QCDR is not only meaningful for that specialty but also rooted in science and medical literature. Thus, it is unclear why CMS is proposing to measure requirements that may not be relevant to the data the registry collects, especially when QCDR measures will be held to such a high threshold of review. It is also unrealistic to expect that these changes can be easily adopted once CMS finalizes its review of a QCDR.

Notify physicians when a third-party data submission entity is on probation

We generally support CMS' proposal for placing third-party intermediaries on probation if CMS continues to see data inaccuracies. However, CMS must put in place a process to notify physicians well ahead of CMS terminating a reporting mechanism. Physicians must have ample opportunity ahead of a new performance period to research alternative submission mechanisms and vendors. If the termination occurs mid-performance period, CMS must also ensure it does not penalize a physician for a third-party intermediary compliance issue.

We also remain concerned with the final publication timeline of approved QCDRs. For instance, for the 2016 PQRS program, CMS did not publish the final 2016 QCDR approved list until May 2016 (midreporting period). This delay could prevent a physician from finding an appropriate data submission method and successfully report. This problem would have been exacerbated if CMS terminated the approval of the QCDR or the measures changed to such an extent that the QCDR was no longer relevant to the physician. Many specialties only have one viable QCDR option to choose from. In instances such as the one mentioned, CMS must ensure a physician is not penalized due to the late publication of the OCDR list.

Alternative Payment Models (APMs)

MACRA specifies that physicians for whom a minimum percentage of revenues or patients are supported by one or more APMs qualify for five percent lump sum incentive payments for a six-year period and are exempt from MIPS. Eligible APM entities must tie payments to MIPS-comparable quality measures, require use of CEHRT, and, except for certain medical home models, must assume more than nominal financial risk for monetary losses. The NPRM labels those APMs that enable physicians to qualify for the five percent payments as "Advanced APMs," although this term is not used in MACRA. Physicians who participate in APMs that do not meet these criteria, or who do not have a sufficient proportion of their revenues or patients in Advanced APMs can receive credit for their participation in calculating their MIPS composite scores.

The AMA appreciates the flexibility provided to APMs in several of the NPRM proposed policies. Other policies, especially the definition of financial risk requirements and the lack of a clear process and timeline for approving additional APMs, are a serious concern and must be changed if the APM pathway outlined in the MACRA legislation is to be a meaningful option for more than a handful of physicians.

Proposals the AMA Supports:

• Retain flexibility in quality measurement

The final rule should retain the flexibility that is proposed for Advanced APMs to choose their own approach to measuring quality, with the requirement to choose at least one quality measure from the various categories of MIPS-comparable quality measures listed in the proposed rule. The AMA does not agree with the proposal that payments under an APM need to explicitly vary based on quality measures in order to meet the requirements of MACRA. An APM which establishes a minimum quality standard for continued participation should also be considered as meeting the requirement in MACRA that an APM "provides for payment...based on quality measures." Broadening the view of how payments can be based on quality measures would allow more APMs to qualify under MACRA, including the existing models developed by CMMI. For example, although payment amounts under the Bundled Payment for Care Initiative (BPCI) are not directly tied to quality measures, the CMS fact sheet states that the agency "is committed to ensuring that beneficiaries receiving care from providers participating in BPCI receive high quality care. To that end, CMS is actively monitoring the quality of the care beneficiaries receive. CMS is analyzing quality information available from claims and quality reporting from the Awardees, as well

as surveys and patient assessment tools to assess care experience and health outcomes." This would certainly seem to meet the requirement in MACRA that the APM "provides for payment based on quality measures." The fact that the payments do not explicitly vary based on quality measures does not mean that physicians will continue to be paid under BPCI if quality deteriorates. In fact, the Patient Protection and Affordable Care Act (ACA) explicitly indicates that payment models under section 1115A authorize models that "reduce spending without reducing the quality of care;" it does not require that every model must improve quality.

• Require 50 percent of participating clinicians to use CEHRT

The proposal that Advanced APMs require 50 percent of participating clinicians to use CEHRT to "document and/or communicate clinical care to their patients or other health care providers" should be finalized. APM entities should be permitted to exclude from calculations of the 50 percent any clinicians who would have had their MIPS ACI component weight reduced to zero, for example, due to being hospital-based or lacking face-to-face patient interaction. CMS should maintain the 50 percent minimum into the future as more experience is gained with the new MACRA programs, and should not raise it to 75 percent in the second performance period.

CMS should also allow the type of flexibility that is proposed for use of CEHRT in Advanced APMs to be applied to other aspects of MACRA, such as the ACI and CPIA components of MIPS. If an Advanced APM can meet the CEHRT use requirement by having half of its participating clinicians using CEHRT to document and/or communicate clinical care, then a medical practice participating in MIPS should be able to meet the ACI requirements using a similar approach.

Finally, the point that existing CMMI models such as BPCI and Comprehensive Care for Joint Replacement do not explicitly require the use of CEHRT should not preclude participants from being considered to be part of an Advanced APM. If the hospitals participating in these bundled payment models are using CEHRT, and physicians involved in the models are doing so as well, then the hospitals and physicians would automatically qualify if there were an explicit requirement to use CEHRT. Consequently, it should be a simple matter to allow hospitals and physicians that confirm they are using CEHRT to qualify as participants in an Advanced APM.

• Meeting APM participation thresholds

MACRA outlines threshold levels of participation in Advanced APMs that physicians must meet to qualify and partially qualify for the annual five percent incentive payments. These thresholds begin with 25 percent of participating physicians' Medicare revenues coming through an Advanced APM in order to receive the 2019 incentive payment and grow to 75 percent of revenues coming through a combination of Medicare and Other Payer Advanced APMs for payments in 2023 and later years. Physicians who do not meet the level of revenues needed to be a qualifying participant (QP) can be partial QPs if they have 20 percent of their revenues coming through an Advanced APM for 2019 and 50 percent for 2023 and later. Partial QPs do not receive the APM incentive payments, but they can choose to be exempt from MIPS. The NPRM contains several policies that would facilitate physicians' ability to reach these thresholds that should be finalized:

• Patient thresholds: As an alternative to achieving the necessary revenue thresholds, MACRA provides another approach to measuring physicians' participation in Advanced APMs by the proportion of their patients in the APM. CMS should finalize its proposal to set the patient threshold percentages for QPs and partial QPs well below the revenue thresholds. QPs would need to have 20 percent of their patients in the Advanced APM for 2019 and 2020, 35 percent for 2021 and 2022, and 50 percent for 2023 and later years.

Partial QPs would need to have 10 percent of their patients in an Advanced APM for 2019 and 2020, 25 percent for 2021 and 2022, and 35 percent for 2023 and later years. In the later years, when physicians can qualify with a mix of Medicare and Other Payer APMs, QPs would need to have at least 20 percent and partial QPs at least 10 percent of their Medicare patients in an APM. It is notable that MACRA states that determinations of whether the QP and partial QP thresholds have been met are to be based on "the most recent period for which data are available (which may be less than a year)." The AMA urges CMS to provide as much flexibility as possible for APM participants to meet these thresholds so that they may achieve the participation levels closer to the time that each year's APM incentive payments are made. Physicians who are participating in an Advanced APM in 2018, for example, but do not reach a 25 percent level of participation until early 2019, still should be able to get the mid-2020 APM incentive payment.

- Assessing Participation Level: The AMA recommends that CMS finalize its proposed approach to calculating the percentages of revenues or patients for purposes of making QP or partial QP determinations. For this purpose, CMS proposes a methodology for calculating the ratio of payments for "attributed" patients to payments for "attribution-eligible" patients. As we understand it, this means that for an APM targeting patients with a particular disease, condition or episode, the denominator would be payments for Medicare Part B professional services provided to all the patients seen by participants in the APM entity group with that disease, condition or episode, and the numerator would be Part B professional services payments for all the patients with the disease, condition or episode who were actually attributed to the APM. If this interpretation is incorrect, however, we urge CMS to finalize an approach reflecting the methodology described herein.
- Assessment at Entity Level: CMS should finalize its proposal to make determinations of QP and partial QP status for all of participants in an Advanced APM entity group as a whole, instead of making separate determinations for each practice participating in an APM entity. CMS should also finalize its proposal to sum an individual physician's participation levels across multiple APM entities to allow the physician to achieve QP or partial QP status even if none of the APM entities in which the physician participates is able to achieve QP status for its participant group as a whole. At least in the early years to assist with transitioning to APMs, CMS should also consider whether it would be possible for a participating medical practice that meets the thresholds to achieve QP status even if its APM entity as a whole falls short.

• MIPS APM scoring

Several approaches to re-weighting and assessing performance of physicians participating in MIPS APMs are described in the NPRM that aim to minimize redundant reporting by APMs and their participating physicians, help physicians avoid having to meet requirements for both APMs and MIPS, and offer advantages to APM participants in calculation of their MIPS composite scores. **These proposals are a major step in the right direction, especially for Medicare SSP and Next Generation Accountable Care Organizations (ACO) participants.** The AMA recommends that the 10 percent weight that would otherwise go to resource use be added to CPIA, instead of being divided between CPIA and ACI. Also, the proposal for other MIPS APM participants should not assign a weight of 75 percent to the ACI component of MIPS. Component weights that need to be reassigned should be reassigned to CPIA, or the participants could be given an "average" score on the missing components so that they are not penalized.

The AMA recommends that CMS consider an alternative approach that would go further in avoiding the potential for physicians in MIPS APMs having to fulfill requirements for two different programs. As

CMS notes, many existing APMs are already designed to support performance improvement on quality measures and/or resource use. In addition, many existing APMs are using health IT in innovative ways to achieve their performance improvement goals, and MACRA provides for APM participation to count as CPIA. The AMA recommends, therefore, that MIPS APM participants have the option of having the APM serve as the basis for their entire MIPS composite score. As CMS has proposed, resource use would be weighted at zero, and then the APM, such as a qualified medical home or ACO, would provide all the information needed for CMS to compute its participants' quality, use of CEHRT, and CPIA. Furthermore, we recommend in the CPIA section of this letter that APM participants' CPIA be scored higher than the minimum 50 percent requirement in MACRA.

Physician Focused Payment Model (PFPM) criteria

The criteria that are proposed for PFPMs should be finalized. The criterion that PFPM proposals address is an issue that broadens and expands the APM portfolio; however, it should be revised to clarify that the availability of current APMs addressing a disease, condition, or episode does not preclude other PFPM proposals that address the same disease, condition, or episode with different payment models. Instead, PFPMs should generate a diversity of APMs with multiple designs and approaches. The AMA also encourages CMS to support the following types of technical assistance for physician practices and other physician organizations, such as specialty societies, that are working to develop and implement APMs:

- Designing and utilizing a team approach that divides responsibilities among physicians and supporting allied health professionals;
- Obtaining the data and analysis needed to monitor and improve performance;
- Forming partnerships and alliances to achieve economies of scale and to share tools, resources, and data without the need to consolidate organizationally;
- Obtaining the financial resources needed to transition to new payment models and to manage fluctuations in revenues and costs; and
- Obtaining deemed status for APMs that are replicable, and implementing APMs that have deemed status in other practice settings and specialties.

Recommended Modifications:

Nominal Risk

• Modify definition of "more than nominal risk" for advanced APMs

In outlining the principles that formed the basis for the Advanced APM policies in the NPRM, CMS states that "our goals...are to expand the opportunities for participation in APMs, maximize participation in current and future Advanced APMs, create clear and attainable standards for incentives, promote the continued flexibility in the design of APMs, and support multi-payer initiatives across the health care market." The AMA agrees that the standards for incentives should be clear and attainable, but the proposed definition of "more than nominal risk" falls far short of meeting this goal. The AMA recommends that the financial risk requirements for Advanced APMs be modified in five key ways:

1. <u>Simplify the definition</u> With multiple components that include total risk, marginal risk, and minimum loss rate, it would be difficult for physicians contemplating participation in Advanced APMs to understand the magnitude of their financial risks and to design care in ways that would avoid losses. Physicians in solo, small, or large medical practices who are thinking of participating in an Advanced APM need to be able to know how much money they should set aside in the event that repayments or reductions are required. Although physicians should have the option to participate in

more complicated financial arrangements in an Advanced APM if they so choose, the minimum requirement for financial risk in the regulations needs to be established as a known percentage or dollar amount that physicians can calculate and set aside.

2. Base the risk requirements on physician practice revenues instead of Medicare expenditures MACRA does not require that risk be defined solely in terms of CMS losses. A physician practice will "bear financial risk for monetary losses in excess of a nominal amount" if the cost of participating in the APM or the amount by which the practice's payments could vary represent a large proportion of the practice's revenues, regardless of how large or small the loss is to CMS. Under one-sided shared savings models, physician practices could experience significant financial losses even if CMS saves money. Although the term "APM benchmark" is not defined in the proposed regulations, the requirement that financial risk be linked to the APM benchmark or episode target price means that the risk to which physicians would be subject could be tied to the total costs of care for the patients treated under the APM, and this likely includes inpatient and outpatient hospital, post-acute care, drug, and other costs that are beyond physicians' control.

To use a \$1,000,000 benchmark example, similar to those in Table 29, since physicians' professional services represent 19 percent of Part A and B spending, on average, of the \$1,000,000, about \$190,000 would likely be for physician services. Total risk of four percent of the benchmark would be \$40,000, but this \$40,000 is 21 percent of physician services revenue. For many physicians, being at risk for 4 percent of Medicare spending could eliminate the physician's revenue. It is not reasonable to interpret the statutory phrase "more than nominal" in a way that can result in a physician being at risk for 20 percent, 50 percent, or more of their revenues. The NPRM states that "the APM Incentive Payment added by the MACRA primarily incentivizes participation in Advanced APMs that involve covered professional services under Medicare Part B." The AMA agrees. Linking risk requirements to an organization's revenues, therefore, as currently proposed for medical homes, would be a much more appropriate standard. For APMs composed of medical practices that only receive revenues for Part B professional services, total risk would be a percentage of their professional services revenues. For APMs involving more integrated organizations such as hospitals and other facilities, the organization's revenue would include a percentage of these other services.

Unless certain drug costs are explicitly and voluntarily included in the accountability standards for a stakeholder-proposed PFPM, calculations of revenues or expenditures for purposes of meeting APM risk requirements should exclude all Part B and D drug costs. It is not appropriate to hold physicians accountable for these costs as they have no control over the prices set by pharmaceutical manufacturers and pharmacy benefit managers.

3. Reduce the amount of losses defined as "more than nominal" The Regulatory Impact Analysis states that "losses in excess of three percent of revenues" is the Health and Human Services "standard for determining whether an economic effect is 'significant." It continues that, "because there are so many affected eligible clinicians, even if only a small proportion is significantly adversely affected, the number could be 'substantial." Defining "more than nominal" as four percent of Medicare expenditures rather than a percentage of the practice's revenues means that "more than nominal" financial risk would be greater than what U.S. Department of Health and Human Services (HHS) has defined as "significant" risk. Instead, final regulations should define "more than nominal financial risk" for all Advanced APMs similar to the NPRM's initial risk standard for primary care medical homes, which is 2.5 percent of Medicare Part A and B revenues. This change would set the "more than nominal" definition below the definition of "significant" losses. CMS also states that, "[a]s reference points to anchor the proposed values, we used the percentage amounts of MIPS adjustments in the MACRA...." A physician participating in MIPS in the first performance period faces a maximum penalty of four percent of Part B professional services revenue in 2019. Congress intended

for MACRA to incentivize participation in APMs, so physicians considering an Advanced APM should not be required to assume financial risk in excess of this MIPS penalty.

- 4. Count physicians' uncompensated costs as potential financial losses The AMA urges CMS to count costs that APM participants incur for APM participation and for delivering APM patients' care that are not paid for directly as potential losses to the physician practice under the APM. The costs of redesigning care delivery to improve outcomes can be significant. Physicians choosing to participate in an APM often need to hire care coordinators and patient and family educators whose services cannot be billed under the Medicare Fee Schedule. Existing staff need to be trained in the new way of delivering care. It is expensive to conduct ongoing data analysis to determine which patients need to be proactively scheduled for a visit or test, to communicate with patients by phone about selfmanagement to control their symptoms or properly take medications, and to reengineer scheduling systems, hire extra staff, and leave appointment slots open to provide rapid access for high risk patients, as well as after-hours access. Care redesign can also require practices to provide additional clinical services to reduce the likelihood of complications that could lead to emergency visits, such as hydrating cancer patients undergoing chemotherapy. In addition, physicians in an APM frequently engage in development of treatment plans, organize multidisciplinary teams to improve care coordination and quality, supervise care managers, communicate frequently by phone and other technology with other professionals and patients, and similar services, none of which can be billed under the Fee Schedule. A new survey by the National Association of Accountable Care Organizations (NAACOs) found that these and similar operating costs average \$1.6 million annually. CMS has recognized these types of costs in some of the existing APMs. For example, the ACO Investment Model Request for Applications states: "ACOs need a sustainable business model as they transition to payment arrangements that reward outcomes rather than volume. Given the time lag between when ACOs begin making investments and when they can realistically expect to receive sufficient shared savings to recoup their investments, organizations with less access to capital may be less likely to enter or sustain participation in Medicare ACO initiatives." CMS should similarly recognize these costs as a financial risk that physicians face under Advanced APMs.
- 5. Count loss of guaranteed payments as losses for all APMs The ability to count the potential loss of part or all of otherwise guaranteed payments as a financial risk under the "more than nominal risk" standard should apply to all Advanced APMs, not just medical homes. Although MACRA exempts a medical home model expanded under section 1115A(c) from the need to meet financial risk criteria, the legislation does not require that CMS set a higher definition of nominal risk for other APMs that are not an expanded medical home model. Most organizations involved in the development of APMs recognize that physicians participating in the APM will need to engage in new or expanded activities in order for the APM to meet its quality and financial goals, and that many of these services and activities are not eligible for payment under the current fee schedule. Consequently, many APMs, including the CMS Oncology Care Model, compensate physicians for these services through new payments, such as monthly care management payments. If the APM is designed to reduce this payment if the physician and/or APM do not achieve their goals, the physician will experience a financial loss because the payments will be less than the costs they have incurred. Consequently, the loss of such payments should be considered a financial loss to any physician practice, not just primary care practices.

Statements by CMS about some of the problems with the financial model for the original Comprehensive Primary Care (CPC) model provide further support for this package of recommendations for modifying the proposed definition of more than nominal financial risk. In a Frequently Asked Questions document, for example, CMS notes that "(1) individual practice control over the likelihood of a shared savings payment is attenuated because spending is aggregated at the regional level; (2) total cost of care may be challenging for small primary care practices to control ...;

and (3) the amount of any shared savings payments is unknown in advance and the complexity of the regionally aggregated formula and paucity of actionable cost data leaves practices doubtful of achieving any return." CMS then describes how it has addressed these problems in its design for the CPC+ model: "The incentive design is stronger because it can be more closely measured at the practice level, will incorporate measures that primary care practices can directly impact, and will be more easily understood by practice leaders." The CPC+ incentive design holds physicians accountable for meeting metrics of avoidable hospital admissions and other utilization that drives growth in the total costs of care, but practices that are unable to achieve these metrics would have to repay performance-based payments, not repay the costs of hospital and post-acute care for which the practices do not receive any revenue.

Unlike its current proposal for Advanced APMs, the CMS statements on the CPC+ model also recognizes some of the costs of participating in the APM as potential losses: "Participation in the model is a significant amount of work for practices (e.g., work flow changes, staff hiring, learning activities, reporting, monitoring, and auditing requirements) and, if they do not adequately complete the work, they are at risk for termination from the program and the loss of resources needed to retain hired staff."

These CMS observations are true, but the same issues arise with many APMs, not just small primary care practices participating in CPC or CPC+. Participants in the Oncology Care Model (OCM) will face similar requirements for redesigning care, problems controlling total costs of care, and risk of termination from the program if they do not meet targets for spending reductions. Under the current CMS approach, however, OCM program termination from what is referred to as the "one-sided" model or having to lose or repay part or all of their monthly payments from CMS would not be counted as a risk of financial loss.

• Statutory authority to modify nominal risk definition

The eligible APM entity definition in MACRA gives CMS discretion in defining what it means to "bear financial risk for monetary losses under an alternative payment model that are in excess of a nominal amount." This is made clear by the decision of Congress to provide no statutory details on what is meant by a "nominal" amount of financial risk despite the depth of experience Congress has had with APMs in general. For example, ACOs are among the types of APMs that are covered by the APM entity definition, and Congress has a wealth of knowledge on this type of APM. The ACO program was established by section 3032 of the ACA, and the ACO regulations at sections 425.600 through 425.610 of title 42, Code of Federal Regulations, expressly provides for three approaches: Track 1, which does not require that an ACO share losses with the Medicare program (referred to as the one-sided model); Track 2, which does require an ACO to share in such losses (referred to as the two-sided model); and Track 3, which is a two-sided model with the potential for receiving a greater share of savings and paying a greater share of losses than with Track 2.

Congress would have built the concept of two-sided risk into the eligible APM entity definition had that been its intent, but Congress did not do so. It recognized the principle from the ACO authorizing statute that one of the purposes of providing for the creation of ACOs is to "encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery." That investment—the cost of switching to a fundamentally different approach to patient care—is in and of itself a substantial risk. The practices creating the APM may incur these costs with the goal of recovering them through savings on other services, but if the savings are not achieved elsewhere, the practice will incur losses. That can be a significant financial risk to the practice even if the practice is not required to make a payment to CMS. Practices that choose to make these changes in their operations face the

financial risk that the payments the APM receives from the Medicare program will not be enough to cover their expenses.

The ACO statutory language does not emphasize payment models that involve responsibility for financial losses (the relevant provision is in subsection (i)(2)(A) of section 1899), but CMS has moved forcefully to shift ACOs to the two-sided model by limiting the number of years for which an ACO may operate under the one-sided model. The fact that Congress *did not* expressly include any language on two-sided risk in establishing the nominal risk standard makes clear that Congress did not intend to require CMS to impose the two-sided risk model on all eligible APM entities under MACRA.

Another important point as to the intent of Congress is that the Other Payer APM part of the QP definition also deals with the nominal risk issue but includes a specific requirement that "the eligible professional participates in an entity that…bears more than nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures." In omitting the actual-to-expected expenditures comparison from the eligible APM entity requirement, Congress provides more discretion for Medicare APMs than it does for the Other Payer APM definition.

This omission in the eligible APM entity version cannot be considered a mistake by Congress. The two versions are too close to each other in section 1833(z) for the difference to be a mistake. Finally, it must be taken into account that Congress was very specific on a type of entity that is not subject to the nominal risk standard—medical homes expanded under SSA section 1115A(c). Congress knows how to provide specific details to make its policies clear. The nominal risk language and the medical homes language are both in the same short provision—sub-clause (ii) of section 1833(z)(3)(D). The decision by Congress not to provide any details on the nominal risk standard was a deliberate and careful decision. Congress clearly intended to give CMS greater flexibility in defining the "more than nominal risk" standard than simply repeating the way CMS has defined risk for two-sided risk ACOs.

• Medical Homes

As described above, the AMA recommends that CMS set the more than nominal risk requirements for all Advanced APMs to be like its proposal for risk in medical homes. In addition to the reasons cited above, having two different approaches to defining nominal risk adds unnecessary complexity. The AMA also urges CMS to withdraw its proposal to have the total loss rate for medical homes escalate from 2.5 to 5 percent over four years. Under CMS' current proposal, despite years of experience all over the country with patient-centered primary care medical home models, the only Medicare medical home program that will qualify as an Advanced APM is the CPCI Plus model announced in April, which has not yet been implemented and will be limited to a small number of practices.

CMS states its belief that "the meaning of 'nominal' is, as plain language implies, minimal in magnitude." Although we agree with CMS that Congress did not intend for "one dollar of risk to be more than nominal," we also do not believe it intended "more than nominal" to mean "significant," or it would have said so in the law. As noted previously, however, because HHS has for many years defined three percent of revenues as "significant," it is certainly reasonable to view 2.5 percent of revenues as "more than nominal." The idea behind MACRA is to provide incentives for physicians to move into payment models that will improve patient care while lowering growth in Medicare spending. The six years that the five percent incentive payments for Advanced APM participants are available should be viewed as a transition period. CMS should not lock escalating financial risk requirements into regulations before there has been any experience at all with the program.

The AMA also urges CMS to withdraw its proposal that medical homes be limited to organizations with fewer than 50 clinicians and be limited to those that focus on provision of primary care. In discussing

CPIA credit, for example, MACRA refers to "a practice that is certified as a patient-centered medical home or comparable specialty practice," but the NPRM makes no provision for specialty medical homes to qualify as Advanced APMs. The 50-clinician limit seems arbitrary and does not provide a meaningful distinction in the type or quality of care that patients would receive. The fact that there are more clinicians in a group does not mean they are any better able to take risk for total Medicare spending on their patients; indeed, the larger the practice, the more patients they will have and the more Medicare spending will be associated with those patients, so the risk is constant in percentage terms, not lower.

We also recommend that CMS expand the means that are available for medical homes to be certified. CMS currently proposes that medical homes be certified by one of four national accreditation organizations. Physicians should not be required to pay a third-party accrediting body to receive recognition as a patient-centered medical home and they should not be forced to implement expensive, non-evidence-based requirements simply because they have been imposed by an accrediting body. Recognition or certification of a practice by an accrediting body may not accurately capture actual advanced primary care functionality. CMS should also recognize programs that accredit medical homes based on the advanced primary care functions, including state-based, payer sponsored, and regional medical home recognition programs. The agency should also consider an attestation approach for the key functions of a patient-centered medical home, similar to the type of attestation process used in the CPCI.

Finally, the definition of Other Payer Advanced APM medical homes needs to be revised to ensure that medical homes serving vulnerable populations, such as children covered by Medicaid, are not forced to assume financial risks that would jeopardize patients' access to care. CMS proposes a nominal amount standard for Medicaid medical homes of four percent of the APM entity's total Medicare Parts A and B revenue in 2019 and five percent in 2020 and thereafter. Medical practices should be encouraged to serve Medicaid and dual eligible patients, but this risk requirement is likely to have the opposite effect. Simply providing care to Medicaid and dual eligible patients would be considered by most physicians to involve more than nominal risk of financial losses due to the very low payment rates in most Medicaid programs.

Creating Additional APMs

• Modifying existing APMs

There needs to be a straightforward means of both (a) modifying existing APMs so that they can qualify as MIPS APMs or Advanced APMs, and (b) allowing participating physicians to sign supplemental agreements with CMS to meet the qualifications under the rule. The statute authorizing CMMI directs the Secretary to "focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title." Consistent with the law, the Bundled Payments for Care Initiative and several other CMMI models listed in Table 32 of the NPRM have been implemented including means of measuring quality and provision for dropping participants if quality problems appear. The fact that the models' payment amounts do not explicitly vary based on quality differences does not mean that payments are not "based on quality measures." Likewise, the Comprehensive Care for Joint Replacement model was developed after MACRA was enacted, so it should have been structured to meet the requirements for an Advanced APM. NAACOs is working on proposals for a new Medicare SSP track that would be subject to a more than nominal degree of financial risk but not have risk requirements as steep as the current two-sided risk track ACOs. The AMA urges CMS to give rapid and serious consideration to the NAACOs proposal so that the new track will be available to physicians participating in Track 1 ACOs who wish to be in an Advanced APM.

Concerns have also been raised about the NPRM's required "participant lists." The AMA recommends that CMS apply the same flexibility to identifying participants in MIPS APMs as it proposes for

Advanced APMs. For Advanced APMs, in addition to those on a regular participant list, CMS proposes to use affiliated practitioners and eligible clinicians who are in a contractual relationship with an Advanced APM Entity based at least in part on supporting the Advanced APM entity's quality or cost goals under the APM.

We furthermore recommend that CMS eliminate the requirement that MIPS APM entities base payment incentives on quality performance. The CMS rationale for incorporating this requirement for Advanced APMs is that MACRA requires it as a basis for making incentive payments to QPs. MIPS APMs should simply be required to report measures of quality and have methodologies for achieving cost and utilization objectives.

Whether there is a need for a participant list, a quality measure, or some measurable financial risk, there should be an expeditious means of modifying the agreements between existing APM entities and CMS to allow more APMs (or physician practices that are participating in an APM) to qualify as MIPS or Advanced APMs.

• APMs for specialists

The final rule needs to provide more opportunities for specialists who are not primary care physicians to participate in MIPS APMs and Advanced APMs. Based on the APMs listed in Table 32 that would currently qualify as MIPS or Advanced APMs, the only specialist physicians who would have access to an eligible APM are the subset of oncologists and nephrologists who have applied for and been approved to participate in the CMS oncology and ESRD models.

Review of PFPMs

We urge CMS to provide a clear pathway for models recommended by PTAC to be implemented as APMs under MACRA. We commend the efforts of the PTAC to put in place a timely and predictable review process for stakeholder models, but remain very concerned that CMS is unwilling to do the same. Congress clearly foresaw MACRA providing for development of a robust array of PFPMs that could help improve care for patients with Medicare and other insurance. Many specialty societies that have been working to develop PFPM proposals are alarmed by comments from CMS officials indicating that even after these proposals have been recommended by the PTAC to the Secretary, they would still need to go through a separate, potentially years-long CMS process before they could be implemented and qualify as APMs under MACRA.

• More APMs are needed

CMS needs to develop a pathway and provide assistance to organizations that wish to develop and/or become participants in MACRA APMs. There also needs to be a pathway to help MIPS APMs transition to become Advanced APMs. Those involved in the development of MACRA did not contemplate three separate categories for participation: MIPS, Advanced APMs, and MIPS APMs. The appropriate role for MIPS APMs is as a transitional step to Advanced APMs, but no one has a vision of what that transition looks like. Discussing the Advanced APM financial risk requirements, CMS comments in the NPRM that its proposal "reflects our belief that more and more APMs will meet this high bar over time." With just one percent of Medicare ACOs in Track 2 and four percent in Track 3, the AMA does not see any justification for the agency's belief. Assistance and Medicare data need to be provided to organizations developing APM proposals to help them design APMs that will qualify as Advanced APMs.

If CMS maintains its current approach to defining more than nominal financial risk and fails to illuminate a path to guide the development and implementation of physician-focused APMs, it will preclude many

promising APMs that are under development from qualifying under MACRA. The table below provides examples of work currently underway by many specialty societies to develop APMs for a number of important patient conditions such as cancer and diabetes. In addition, the American College of Surgeons is leading a multispecialty effort to develop a methodology that would allow APMs to group together claims from physicians in multiple practices into a comprehensive episode of care for more than 100 procedural and condition based episodes, as well as supporting episodes such as anesthesiology and pathology. Without significant changes from the APM policies proposed in the NPRM, it will be difficult for these proposals to be implemented and for Medicare patients to benefit from these care improvements.

Condition	Specialties Involved	Opportunities to Improve Care and Reduce Spending
Angina (Stable)	Cardiology Primary Care	 Help patients quickly and accurately determine causes of chest pain and risk of heart attack Reduce unnecessary stress tests and cardiac imaging Reduce unnecessary invasive cardiac tests and procedures Reduce risk of heart attacks
Diabetes	 Endocrinology Primary Care	 Reduce complications and associated hospitalizations Prevent or slow progression from pre-diabetes to diabetes Slow disease progression Improve patient understanding and self-management of their condition
Ovarian and Endometrial Cancer	• Gynecologic Oncology	 Improve outcomes of cancer treatment through more accurate diagnosis and appropriate treatment Reduce repeat surgeries and readmissions Avoid unnecessarily invasive surgery and reduce complications of surgery
Epilepsy	Neurology	 Improve accuracy of diagnosis Reduce frequency and severity of seizures Reduce injuries and complications requiring emergency visits and hospitalizations
Stroke	NeurologyRadiologyPhysiatryPrimary CareVascular Surgery	 Get rapid and accurate diagnosis Improve coordination and reduce fragmentation Return patients to maximum functionality Use the most cost-effective facilities and services for rehabilitation Prevent additional strokes
Pregnancy	Obstetrics and Gynecology	 Reduce elective early deliveries and use of elective C-sections Reduce low birthweight deliveries and need for neonatal ICU Reduce complications of delivery Deliver babies in lower-cost settings
Cancer	Medical OncologyPathologyRadiation OncologySurgical Oncology	 Improve cancer outcomes through accurate diagnosis and staging, appropriate utilization of treatments, and joint treatment plans Help cancer patients and families in managing psychological, physical, and financial challenges of their disease Reduce nausea, vomiting, pain, dehydration, and other complications of cancer Reduce complications requiring emergency visits and hospital admissions Improve appropriateness of imaging during surveillance for

		progression and recurrence of disease
Asthma	Allergy and Immunology	 Improve diagnostic accuracy, treatment planning, and medication adherence Reduce work and school absenteeism, and increase productivity Reduce emergency visits and hospitalizations due to asthma exacerbations
Chronic Kidney Disease	NephrologyVascular Surgery	 Slow progression to end stage renal disease and improve treatment planning Plan ahead for hemodialysis patients' vascular access to create and maintain arteriovenous fistula and avoid use of multiple catheters Avoid emergency visits and hospitalizations
Opioid Use Disorder	AddictionMedicinePrimary Care	 Increase patient access to comprehensive treatment for opioid use disorder including medication-assisted treatment (MAT) Support primary care physicians providing MAT with access to addiction specialists and rapid access for unstable patients Improve financial model for addiction treatment to support counseling, patient education, and other services needed for comprehensive treatment and long-term stability

Other APM Issues

• Start date for APM participation

With a start date for APM participation of January 1, 2017, physicians would need to already be participating in an APM before the final regulations are published defining whether the APM would qualify as an APM under MACRA, either as a MIPS or Advanced APM. Especially as the identification of APM participating physicians will be based on participant lists as of December 31, 2017, there is no justification for requiring that eligible APMs be implemented and physicians be participating in them on January 1, 2017. The first Advanced APM incentive payment to QPs will not be made until mid-2019, two and half years after physicians will have been required to be participating in an APM. Very few APMs qualify as Advanced or MIPS APMs under the proposed rule, which makes it impossible for all but a handful of physicians to meet the proposed January 2017 deadline. We are hopeful that CMS will work closely with the PTAC and move quickly to implement additional APMs during 2017 that meet the requirements of the law and rule so that as many physicians as possible have the option to participate in APMs as soon as possible, which is what Congress intended in MACRA.

• Changes in APM status

We recognize that there may be scenarios in which MIPS eligible clinicians may change taxpayer identifier numbers (TINs), use more than one TIN for billing Medicare, change their APM participation status, and/or change other practice affiliations during a performance period. Therefore, we are concerned with CMS' proposal to require a physician who leaves an APM Entity, the APM is no longer approved by CMS, or folds mid-reporting period to have to submit data to MIPS and have their performance assessed either as individual MIPS EC or as a group for all four categories. Depending upon the timing, it most likely is not realistic for such a physician to meet the MIPS requirements. The policy CMS proposes essentially penalizes physicians for trying to transition into an APM and will disincentivize physicians or groups from joining an APM entity. To avoid this problem, CMS should institute its CMMI waiver authority (section 1115A) that authorizes CMS to waive statutory

provisions related to MIPS reporting and scoring. Based on that authority, we recommend that CMS develop a policy that, during this transition period, a physician is not held to MIPS performance standards but assessed as satisfying MIPS. If the goal is to have the APM entity focus on the APM-specific requirements, physicians should not need to turn their attention to satisfy alternative requirements that might be contradictory to the APM's goals and focus.

The problem is further exacerbated based on the proposed MIPS requirements. For instance, under the quality category a physician reporting on a measure through an EHR must report on 90 percent of their denominator eligible patients, which makes it impossible for a physician to score well under the quality category if they are no longer part of an APM entity mid-reporting period. Alternatively, we are aware of instances under the current programs where physicians attempted to participate in the SSP but the SSP folded mid-year. Under this scenario, the physicians remained on CMS' SSP list and could not submit data to PQRS because they were still listed as an SSP participating physician, causing CMS to reject the PQRS data. The physicians made good faith efforts to adopt a new program but were penalized for trying to do so. CMS should avoid creating a similar perverse incentive when finalizing its APM proposals.

• Treatment of non-fee-for-service payments

CMS should withdraw its proposal to decide on a case-by-case basis whether to exclude many payments made to physicians that are not traditional Medicare Physician Fee Schedule payments from calculations of the five percent lump sum payments to participants in Advanced APMs. It is completely inappropriate to declare that "financial risk payments" should not count as physician payments for services, since under CMS shared savings models, this is the only way that physicians can be compensated for services delivered that are not directly paid under the fee schedule. These payments are not "incentives," they are compensation contingent on performance. It is also inappropriate to indicate that monthly payments for patient care are merely "cash flow mechanisms," when in most cases, they are flexible payments designed to enable physicians to deliver a range of services, including services that are not directly paid for under the fee schedule. This proposal adds unnecessary complexity and uncertainty to the calculations and could provide a disincentive for physicians who want to transition away from a fee-for-service approach.

Additional Issues

Physician Compare

Proposals the AMA Supports:

- **Public reporting:** The AMA supports public reporting of physician data when it is valid, reliable, and meaningful to both consumers and physicians. Recognizing the statute requires increased public reporting on the Physician Compare website, we want to continue to work with CMS to ensure information is accurate and presented in a format consumers can understand and use appropriately.
- **Reliability threshold**: We support moving from a minimum sample size of 20 patients to a reliability threshold to determine whether performance data is included on the Physician Compare website. Section 10331 of the ACA requires any public reporting of performance information to be statistically valid. Therefore, CMS should select a high reliability threshold to ensure data is only posted when it is sufficient to make a statistically valid comparison.

Recommended Modifications:

• 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, especially when there have been numerous inaccuracies in previous data sets CMS has released. **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 publicly 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.

• 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 on the Physician Compare website given the major problems that have occurred previously with the accuracy of published data. MIPS is a new program that includes new data sets and significant changes to reporting in each performance category. We believe there is still significant testing and evaluation of MIPS performance data that must be completed. We also believe there are problems with the comparison of practices that report the same measures through different reporting methods. In addition, we continue to have concerns regarding risk adjustment and the lack of timely feedback CMS is able to provide to physicians. Given these limitations, we believe CMS should be cautious and thoughtful before expanding information included on the Physician Compare website.

Allow physicians three years to report on measures prior to public reporting

Currently, CMS does not publicly report first year measures that have been in use for less than one year. We believe CMS should 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.

• Limit public reporting to composite score and performance category participation

Section 1848(q)(9)(A) of MACRA requires that CMS include on the Physician Compare website the composite scores for each MIPS physician and the performance of each MIPS physician on each performance category. The section also states that CMS *may* include the performance of each MIPS physician with respect to each measure in each performance category (emphasis added). CMS proposes to publicly report not only the composite score and performance category of each physician, but also performance on all quality and resource use measures. Within the ACI performance category, CMS proposes to include indicators identifying if a physician scores highly in the patient access, care coordination, patient engagement or health information exchange.

We have concerns that many of the ACI and resource use measures, such as patient-generated health data measure and episode groups, have never been tested. Given MIPS is a new program for both CMS and physicians, we believe CMS should not publicly report physicians' performance on any specific measures within any of the performance categories at this early time. Instead, the AMA recommends that CMS indicate whether a physician satisfied the reporting requirements for each of the performance categories with a green check mark, as it has done previously for the EHR Incentive Program. For

example, if a physician reported six quality measures, received a base score in ACI, or reported the required number of CPIA measures, they would receive a green check mark for those performance categories.

Alternatively, even if CMS moves forward with posting individual quality measure performance, it should continue to designate physician performance in the ACI category with a green check mark. Under MIPS, physicians have the option to use either 2014 or 2015 Edition CEHRT to report on either Stage 3 or Modified Stage 2 objectives and measures. Therefore, the measures each physician is reporting under the ACI category will be different, and it would be extremely challenging for a consumer to make meaningful comparisons of measure performance. In addition, the Stage 3 measures include entirely new requirements, such as patient generated health information. As discussed above, we do not believe these new measures should be publicly reported until physicians gain experience with these measures and CMS understands the validity of these measures. Similarly, the CPIA category is entirely new and should not have individual measure performance posted at this early date.

CMS should use the first few years of the MIPS program to accrue data under the new system, and share data with physicians via clear feedback. Only after that work is complete, should CMS consider transitioning to public reporting of physician performance data on quality, resource use, ACI, or CPIA. The AMA urges CMS to limit initial public reporting on MIPS physicians to their composite score and performance category participation.

• Emphasize the limitations of Medicare utilization and payment data

Section 104 of MACRA requires CMS to make available, in an easily understood format, information similar to the type of information included in the Medicare Provider and Utilization and Payment Data File. Recognizing the statute requires CMS to post Medicare utilization and payment data, we urge CMS to publish the data in a format that is easily understandable and useful for consumers. The AMA supports providing consumers with information that will help them make informed decisions about their health care. Unfortunately, the Medicare utilization and payment data can be misleading and confusing for consumers. The AMA has concerns with the accuracy of utilization data and has repeatedly provided CMS with recommendations to improve the validity and accuracy of Medicare utilization data. Given these issues, CMS should include a detailed disclaimer highlighting the limitations of the utilization data, including that the information may not be representative of a physician's entire patient population and are not risk adjusted. In addition, CMS should make clear that the number and cost of services may be misleading to the average Medicare consumer and explain that billed charges are not the same as payment to a physician. Finally, CMS should inform consumers that there have historically been accuracy issues with this type of data. The AMA urges CMS to educate consumers on the limitations of the Medicare utilization and payment data before it is made publicly available.

Surveillance and Information Blocking Attestations

Recommended Modifications:

• Reissue surveillance attestation proposal

CMS proposes to require physicians participating in MU, MIPS, or APMs to attest that they have cooperated with the surveillance of CEHRT under the ONC Health IT Certification Program. In the 2015 Edition Health IT Certification Criteria, ONC took steps to strengthen the oversight of health IT products once they are deployed in medical offices and hospitals. In addition, ONC published a proposed rule in early March 2016, seeking authority to conduct in-the-field surveillance and directly review and evaluate

the performance of CEHRT. The AMA supported the strengthened oversight in the 2015 Edition requirements and submitted comments on ONC's proposed rule. 19,20

Physicians agree that CEHRT must function and perform as designed and marketed, and can play a key role in identifying problems with health IT in a clinical setting. However, the extent to which a physician must support and cooperate with in-the-field surveillance activities must be balanced against demands on the physician's time and potential disruptions to the physician's practice. Many physicians find that time with their patients is already limited and their resources increasingly stretched due to a myriad of existing compliance requirements.

While we support these efforts to improve oversight, at the time of this letter, ONC has not yet finalized the rule containing its proposed surveillance activities. Accordingly, CMS' proposal that physicians cooperate with such activities is vague and overbroad. We have significant concerns regarding how such attestations might be audited and the consequences of a physician's failure to fully accommodate the request. Therefore, the AMA asks that CMS reissue this aspect of the proposed rule after ONC's proposed surveillance activities are finalized to allow informed stakeholder comment on this proposal.

• Simplify the information blocking attestation requirement

MACRA requires that an eligible physician demonstrate their CEHRT was connected, supported the exchange of information, and the physician did not knowingly or willfully take action to block or limit interoperability. The AMA has commented numerous times on the need for interoperability and views the seamless exchange of useful information as a key component in improving quality, enabling care coordination, and achieving patient goals. In particular, the AMA joined ONC's Interoperability pledge to not engage in information blocking and ensure electronic access for consumers. More recently, the AMA and 36 other medical societies sent a letter to ONC and CMS highlighting that, "interoperability means the usefulness, timeliness, correctness, and completeness of data, as well as the ease and cost of information access." The letter also identifies the misconstrued view that "interoperability" equates to the exchange of static documents. Physicians are often bombarded with unnecessary and unstructured data, resulting in a lack of meaningful health information.

We understand that MACRA requires physicians to demonstrate they are not inhibiting interoperability, and we believe a simple attestation is an appropriate mechanism to do so. However, CMS' proposal outlines three separate attestation components, which encompass complex health IT issues with which most physicians will not be familiar or fully understand. Specifically, CMS proposes that physicians attest to the implementation of health IT standards and validate that EHRs are "implemented in a manner that allows for the timely, secure, and bi-directional exchange of structured electronic health information." Not only is the technical implementation of health IT outside the control of most physicians, but more importantly, health IT vendors themselves have yet to establish secure and bi-directional exchanges between their own systems. Asking physicians to attest that they understand and comply with these requirements is well outside the scope of their medical training, and forces them to inappropriately and needlessly assume risk.

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¹⁹ AMA comment letter to ONC on the 2015 Edition Health IT Certification Criteria proposed rule. May 29, 2015. https://download.ama-assn.org/resources/doc/washington/x-pub/cert-comment-letter-29may2015.pdf

AMA comment letter to ONC on the Enhanced Oversight and Accountability proposed rule. May 2, 2016. https://download.ama-assn.org/resources/doc/washington/ehr-onc-oversight-accountability-letter-02may2016.pdf

²¹ Interoperability Pledge. https://www.healthit.gov/commitment

²² Sign-on letter to CMS and ONC on measuring interoperability. June 3, 2016. https://download.ama-assn.org/resources/doc/washington/interoperability-onc-cms-sign-on-letter-03june2016.pdf

We also note that physicians participating in MU, MIPS, and APMs must already utilize CEHRT, which by definition must support application programing interfaces (APIs) that provide access to patient data. Furthermore, participation in MIPS will, through the base score of ACI, require physicians to attest they have enabled and used all data exchange functions within their EHRs. For these reasons, the AMA opposes CMS' proposal and requests that a far more constrained attestation requirement be finalized.

Interim Final Rule

The AMA recognizes that we have recommended significant changes to the proposed rule, many of which will require additional discussions among CMS, medical societies, physicians, and other participants. In light of this, we strongly urge CMS to adopt an interim final rule rather than a final MACRA rule. Also, we encourage CMS to continue the open dialogue with MACRA stakeholders to provide feedback and identify needed program adjustments that may not become apparent until the MIPS and APM programs begin to be implemented. Accordingly, an interim final rule will provide this flexibility and allow for a smoother and more successful implementation.