March 1, 2016

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC  20201

Re: CMS Quality Measure Development Plan

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 CMS Quality Measure Development Plan as required by Section 102 of the Medicare Access and CHIP Reauthorization Act (MACRA).

The AMA was deeply engaged in the legislative process that ultimately led to the enactment of MACRA and believes physicians will need a strategic quality framework that supports innovation, improves care delivery for patients, and leads to more sustainable physician practices for this new law to be successful. We understand that this is the first opportunity to provide comments on the draft plan, and that CMS intends to update it annually. Thus, the AMA and physician specialty organizations welcome the opportunity to actively engage and offer feedback on the development of this initial plan as well as future modifications. A participatory process is critical to assuring practicing physicians that quality measures within the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) will be clinically relevant and meaningful for their practice and setting of care, as well as administratively actionable and helpful in providing better care and value for patients.

The AMA strongly urges CMS to improve upon the current quality programs by ensuring that MIPS and APMs take into consideration the various physician specialties and sub-specialties so that all physicians can effectively and successfully participate. At the same time, we urge CMS to avoid adopting the one-size-fits-all approach as currently constructed under the Value-Based Modifier (VBM) and Meaningful Use (MU) programs, which have diverted physician efforts and resources away from participating in activities that truly have a positive impact on patient care.
As outlined in more detail below, we believe that the Quality Measure Development Plan must:

- Call on CMS and payers to re-think the design of quality programs for Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) to take into consideration the varying specialties within medicine. We encourage CMS to take a new view that uses measurement more as a guide to address broad problems;
- Provide more timely data and feedback to physicians so programs are based on intrinsic motivation rather than narrowly focusing on penalties and rewards; and
- Develop measures in a transparent process through physician-led organizations to ensure that the measures are meaningful to users, uphold national standards, and harmonize with clinical data registries.

I. **Strategic Vision of the Measure Development Plan**

A key factor in medicine’s support for MACRA was the law’s promise to create a new MIPS program that, unlike the existing quality programs, is truly value-based and meaningful to the majority of physicians and their patients. The law encourages flexibility and a chance to redesign and overcome existing problems. Consequently, the medical community would have serious objections to a new MIPS program that merely moves the current incentive programs without major modifications. Leading quality experts are also calling on CMS and payers to re-think the design of quality programs.¹,² The AMA is therefore concerned that the Measure Development Plan lacks acknowledgement of this change and provides no plans of blending all of the components into a more comprehensive design. Instead, the plan follows the same piecemeal approach to measurement, where each CMS quality program operates in a silo. In our view, CMS must devote adequate time and resources to moving to a more holistic structure. If CMS believes its current resources are insufficient to make these needed changes, then the AMA would support an agency request for additional funding.

To move to more unified quality reporting, we recommend that CMS provide timely and usable data to physicians so that they can improve care instead of narrowly focusing on penalties and rewards. Current timeframes for the release of reports are too long, as CMS typically provides feedback reports, often fraught with errors, nine months after the close of the reporting period. This delay means that physicians are already well into the next reporting cycle and have no opportunity to change their behavior before they are penalized again. Evidence shows that physicians respond to real time, high quality data feedback due to their intrinsic motivation. A study published in the *American Economic Review* found that “information on performance that was new to surgeons and unrelated to patient demand led to an intrinsic response four times larger than a surgeon’s response to a profit incentive.”³ While qualified clinical data registries (QCDRs) hold promise in providing information to physicians, the demands and constraints put on them by CMS stifle their ability to satisfy the needs of physicians as they move to MIPS.

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In light of the opportunities MIPS and APMs provide, we encourage CMS to take a new view on measurement that takes into consideration the varying specialties within medicine. CMS should start with a broad problem that needs to be solved, sets targets for success, identifies key roles for physicians as well as other stakeholders, and use measurement to guide us toward our targets, as described below:

- Select a topic of great importance to a large number of citizens and that is or builds on a current focus of the federal government. For example, preventing diabetes, controlling blood pressure, or improving or managing another disease or condition.

- Review the data on prevalence, demographics, and the evidence (e.g., diabetes prevention programs (DPPs) recognized by the Centers for Disease Control and Prevention result in weight loss, preventing progression to diabetes). In addition, review data on the return on investment through targeted interventions and evaluations. With this information, and after feedback from relevant stakeholders, describe the ask of each entity, for example:
  - **Physicians:** Test patients for prediabetes and refer those at risk to DPPs; follow-up with patients to support their efforts and assess progress.
  - **Electronic Health Record (EHR) Vendors:** Enable every practice/EHR installation to retrieve a registry of patients in prediabetes range, stratified by race and ethnicity. With such readily available data, physicians and teams can design their own approach to referral, which becomes intrinsic to the practice.
  - **Employer & Private Health Plans:** Health benefits plans cover HbA1c testing for everyone per United States Preventative Services Task Force recommendations and cover DPPs per community task force recommendations.
  - **State Public Health Departments:** Ensure an adequate supply of DPPs to support populations.
  - **Individuals:** Complete DPPs and provide feedback about your satisfaction with the program and results.

This process will more effectively allow CMS and stakeholders to create a measure to accompany each “ask.” A similar framework could work for hypertension. Even with this more comprehensive approach, initial coordinated measure sets will not be relevant for every physician or every plan. Rather, a portfolio of meaningful and high impact measures will be created over time and can be reviewed and evaluated to expand upon as appropriate. Pilot studies designed to address our nation’s most pressing health related needs could be tested and refined under the auspices of the Center for Medicare and Medicaid Innovation.

**Institute of Medicine (IOM) Report, Vital Signs: Core Metrics for Health and Health Care Progress**

The recent IOM Report, *Vital Signs: Core Metrics for Health and Health Care Progress* addresses quality challenges with recommendations to rethink measurement. The AMA believes the IOM report should be seen as a roadmap for the redesign of how health care is measured. Our experience with measurement is consistent with the report’s findings that the resources required for measure development, maintenance, and updates have become too great and take too long to deliver work product. They are also consistent with the second joint AMA-RAND study released in 2015, which examined physician experiences with new models of health care delivery and payment, described by some as a measurement
“tsunami.” The AMA also shares the concern expressed by the IOM Committee that meaningful and effective measurement requires engagement by many stakeholders, including, patients, insurers, EHR vendors, and others, encompassing all state and local jurisdictions.

We are, however, concerned that CMS has narrowly applied the IOM Committee’s thinking in the proposed Measure Development Plan by focusing its own recommendations to the Population Health domain and attempting to fit the recommendations into existing quality “boxes,” as opposed to refining how we think about measurement to achieve large scale results. We also remind CMS that the goals of the IOM report can only be achieved if accountability is also assigned to the parties (e.g., vendors) who control what is being required of the eligible professionals whose performance is being measured. Accomplishing this will require significant investments in infrastructure to ensure data are collected seamlessly and in ways that do not interfere with normal workflow. The current circumstances, in which those providing care have accountability without tools, must change. CMS must also ensure that the policies put in place do not stifle innovation, dampen intrinsic motivation, or deter the redesign of the EHR user interface, as highlighted by the first joint AMA-RAND study, issued October 2013.

Recognizing the AMA and IOM’s recommendations on re-shaping measurement will take some time, the AMA offers the following comments related to the plan.

**Measure Integration to Support MIPS and APMs**

The selection of quality measures for an APM should be based on the goals and design of the APMs—quality measures are not a goal unto themselves. The first question to ask when speaking with specialty societies about developing an APM is whether there are ways that care could be improved for patients that would also help lower spending. **Quality measures in an APM should help demonstrate that the APM is achieving its goals for care improvement and that it is not doing so by stinting on care.** Experience to date with APMs, such as a joint replacement model in Wisconsin, has found that APM measures are more likely to be based on outcomes of care, such as complication, readmission, and reoperation rates, instead of typical Physician Quality Reporting System (PQRS) measures.

If there are any MIPS measures related to the condition or disease that is managed within the APM, the APM entity should consider whether or not use of those measures is appropriate. Similarly, if a medical society has a clinical data registry, then physician participation in the registry could be used for MIPS reporting and for an APM. **Quality measure reporting for an APM should be no more burdensome than under MIPS, and CMS should harmonize measures so that there are not different ways to measure an item under MIPS versus another APM, or one method for Medicare versus other payers.**

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II. Operational Requirements of the Quality Measure Development Plan

Measure Development Funding

We are pleased with the provision that adds new subsection(s) to section 1848 of the Social Security Act (42 U.S.C. § 1395w–4(s)), which 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.

MACRA specifically authorizes $15 million per year for each of fiscal years 2015 through 2019, for a total of $75 million, to fund the development of physician quality measures for use in the MIPS. MACRA also states that the “Secretary shall enter into contracts or other arrangements with entities for the purpose of developing, improving, updating, or expanding in accordance with the plan under paragraph (1) quality measures for application under the applicable provisions. Such entities shall include organizations with quality measure development expertise.”

We believe the appropriate “organizations with quality measure development expertise” are physician-led organizations that have devoted substantial time and resources to developing and refining quality improvement and/or measure development activities. These include the PCPI Foundation® (PCPI®) and the medical specialty societies. We also believe that preference should be given to organizations that meet the following prerequisites:

- Quality measures are developed through a transparent process, which may include soliciting feedback from various stakeholders on measures under development;
- Measure information is shared with CMS as part of the QCDR reporting process;
- Measure descriptions and information on the measures are available to the public;
- Measure developers have experience and expertise with clinical quality measure standards currently in use (e.g., Quality Data Model, HL7, HQMF, eMeasure); and
- Developers are involved in or have deep knowledge of national efforts related to health care standards, such as clinical practice guidelines.

We believe these requirements will help earn the trust of all stakeholders, most of all patients and clinicians. Measure development initiatives should also adhere to certain processes to ensure that the measures are meaningful to users, uphold national standards, and can be harmonized with measures already in widespread use. Developing measures through and with physician-led multi-stakeholder organizations, such as the 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 ensure 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. PCPI’s new membership model, which now includes patients, consumers, physicians, non-physician clinicians, health systems, health plans, payers, licensing and accrediting organizations, and others, recognizes the numerous stakeholders involved in performance measurement and quality improvement.

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. It is for this very reason that PCPI does not consult with or accept funds from the above mentioned industries.

Furthermore, the Department of Health and Human Services is currently under contract with an outside entity that endorses measures, identifies measure development priorities, and measure gaps pursuant to section 1890 of the Social Security Act (42 U.S.C. § 1395aaa). 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. Such a construct would inhibit engagement by other stakeholders, including physicians. In addition, it might limit access to a wide range of ideas, clinical and practical perspectives, and discourage the innovation that is truly needed for a successful program.

Based on our review of the Measure Development Plan, we are also concerned CMS may dedicate a significant portion of the measure development funds to building or supporting infrastructure, specifically related to Health Information Technology (HIT). This could reduce available funding for actual measure development, which is concerning given that we believe current amounts may be insufficient. Again, if CMS believes it needs additional funding to build the HIT infrastructure, the AMA would support CMS in such a request.

**Clinical Practice Guidelines**

MACRA requires the Measure Development Plan 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 are aligning 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 guidelines developers.

**Domains and Priorities**

CMS should reconsider the current quality requirements within PQRS, MU, and the VBM as MACRA does not require physicians to report on measures within all of the quality domains, rather they are
intended to serve as a guide. While the AMA supports the goal of identifying national strategy domains, including the need to ensure a balanced national scorecard for quality, fitting measures into these discrete boxes and ensuring physicians within each specialty have an adequate suite of measures to meaningfully participate and comply with the program is challenging. The current domain assignment CMS utilizes for PQRS is arbitrary and measures are moved from one domain to another from year-to-year. **Instead, we recommend that CMS eliminates the domain requirement and use domains to guide measuring national quality goals, which will ensure a flexible MIPS design, especially in the initial program years. A flexible approach is critical to ensuring that relevant measures are available to as many physicians as possible.**

**Clinical Practice Improvement (CPI) Activities**

CMS should allow for the broadest interpretation of CPI activities as possible to ensure program flexibility and innovation. Physicians and practices should be able to select from among many activities and options relevant to the areas of greatest need. No CPI category or type of activity should be mandatory. The categories specified in MACRA are suggestions for activities that should count but should not limit the options for patients and physicians. Rather, physicians should have the freedom to choose the activities that are most beneficial and appropriate for their practice and patient population, regardless of subcategory domain. CMS should also allow physicians to demonstrate their performance of CPI activities through a simple annual attestation process. Physicians should earn credit for CPI activities in which they are currently engaged, including those that are mandated or encouraged by Medicare and other government programs. Such activities could include, but are not limited to:

- Participation in a QCDR or in other clinical registries such as those maintained by a hospital or medical specialty;
- Tracking certain quality measures from other provider types/settings such as the safe surgery checklist for the Ambulatory Surgery Center Quality Reporting Program;
- Compliance with upcoming requirements for consulting Appropriate Use Criteria (AUC) for advanced imaging services;
- Participation in CMS’ Million Hearts Campaign, Cardiovascular Disease Risk Reduction Model, Oncology Care Model, and/or transforming Clinical Practice Initiative; and
- Participation in relevant practice improvement activities facilitated by each state’s Quality Improvement Organization.

Reporting of CPI activity results should be permitted but not required via EHRs and QCDRs, when and where such capabilities exist. Sponsors of CPI activities should be required to maintain records of participation for no less than the period of time during which verification can be requested. For more detailed comments and recommendations for designing CPI activities, we refer CMS to our response to the Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Model comments.
III. Challenges in Quality Measure Development and Potential Strategic Approaches

Shortening the Timeframe for Measure Development

While CMS may have reduced the time required to develop measures by incorporating Lean principles into the workflow, the AMA remains concerned that the time to develop, propose for use, and implement a measure into a program is still too long. Multiple stages in the measure development timeline and lifecycle are not clearly streamlined or examined. We recommend that CMS routinely track the time it takes to develop a measure from beginning (CMS issues measure development funding) to end (first year a physician may report on the measure) to determine where delays occur. The time tracking process must also include the time required to test, certify, and re-certify electronic clinical quality measures.

Peer-Reviewed Journal Submission: MACRA requires new measures to be submitted to a peer-review journal prior to use in MIPS. The process CMS establishes related to this requirement, however, should not further extend the measure proposal timeline. The existing timeline is already a challenge and requires developers to propose measures to CMS almost two years prior to use within a program. We offer the following suggestions and encourage CMS to further consult with specialty societies and measure developers before setting a requirement:

- First map and outline the measure development and review cycle to determine the best time for peer-review journal submission; and
- Implement time tracking to determine how long the review cycle takes with and without taking into consideration journal submission timelines and deadlines.

Measure Application Partnership (MAP): The MAP process adds value by providing multi-stakeholder input for CMS programs. Yet, requiring that measure developers propose measures to the MAP for use in CMS programs introduces another time-consuming step in the measure development cycle. MACRA provides CMS some flexibility in how it uses the MAP. The AMA believes that the MAP process would be strengthened by addressing the following issues:

- 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 and the programs 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 of opportunities 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 inadequate review of the measures—especially in the context of considering appropriateness based on program requirements—and unpredictable MAP proceedings and reports issued with limited time to comment.

Streamlining Data Acquisition for Measure Testing

Based on the AMA’s experience with developing measures through the PCPI, the AMA supports the creation of a National Testing Collaborative. The AMA and PCPI have recommended for years that measure developers have access to “reusable” testing platforms, but recognize this is not something any one entity can do alone. Securing data sources, particularly locating clinical (“real-world”) sites that are willing and able to engage in measure testing, is time and resource intensive. The AMA and PCPI would strongly support efforts by CMS to establish such a collaborative.

Developing Patient Reported Outcomes Measures (PROMs) and Appropriate Use Measures

We agree with the Development Plan’s assessment that there is a need to create a portfolio of PROMs and alternatives to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys to measure patient experience. The AMA has long advocated for alternatives to CAHPS. We understand there is a difference between patient experience and satisfaction, but the definition and difference are not well understood. There is a growing body of evidence, as highlighted in a recent Hastings Center Report, that patient experience surveys can have repercussions that impede rather than enhance the quality of care. While patient-satisfaction surveys have a valuable place in evaluating health care, the Hastings Report highlights that, “there are significant dangers in tying them to publicly reported ratings and accountability, as they often depend more on patient perceptions that are subject to potential manipulation than on good medicine.”

The AMA encourages CMS to partner with PCPI on the development of PROMs. PCPI has delineated best practices for developers and has created a toolkit for outcome measures, making it well situated to work and lead in this space. In addition, PCPI’s new membership model ensures that patients and consumers will be central participants in any PROMs. Absent funding, PROM development will be limited and slow.

CMS also proposes to emphasize the concepts in the Choosing Wisely campaign through the development of appropriate use measures. While the AMA supports the concept of appropriate use measures to ensure patients are not receiving unnecessary services, we remind CMS that many of the Choosing Wisely recommendations are not well suited for measurement. As clearly highlighted on the Choosing Wisely website, the recommendations do not represent a “standard of care,” nor are they

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6 Id.
intended as fixed treatment protocols. The recommendations are designed to function as a guide and should not be used for the denial of treatment and services, which will occur when tied to measurement in an accountability program, such as MIPS. The goal of Choosing Wisely is to encourage a discussion of issues between physicians and patients, encourage active patient participation in health care decision-making, and foster greater mutual understanding.\(^7\)

As CMS balances measures of overuse of some services with measures protecting patients from underuse of other services, it must work to avoid unintended consequences. CMS would be well advised to not create measures that imply that some services are simply either good or bad, as this would thwart achievement of the goal to promote shared decision making.

Similarly, due to the nature of a practice’s population, some physicians may conclude that particular AUC recommendations do not apply to a subset of their patients. Developers of AUC recognize that there are patients and circumstances in which deviations from AUC are justifiable and that variation is to be expected. It is for this reason that organizations such as the American College of Cardiology with the American Heart Association no longer designate low value procedures as “inappropriate,” instead using the term “rarely appropriate.” As with all other measures, those based on the Choosing Wisely program must be updated as new evidence becomes available. In addition, CMS’ current attribution methods frequently hold the wrong physician accountable for the given service. Until attribution issues are resolved and/or CMS does not design a program where the requirement to “pass” is 100 percent, it would be premature to judge a physician’s resource use or quality based on AUC or Choosing Wisely guidelines. Instead, physicians who use these could be given credit under the Clinical Practice Improvement category.

Furthermore, we do not believe that measures based on Choosing Wisely recommendations or AUC should be calculated from administrative claims data. Most AUC require some kind of clinical information that is not found in claims data.\(^8\) If CMS moves forward with appropriate use measures it must ensure the measures are aligned and correspond with the AUC program CMS is developing, per Section 218 (b) of Public Law 113-93, entitled the Protecting Access to Medicare Act (PAMA). PAMA requires CMS to have a program in place to address appropriate use of services by January 1, 2017.

**Risk-Adjustment**

For CMS to design a fair and equitable MIPS program, it must expand its risk adjustment methodology to incorporate race, income, and community features to avoid inaccurate conclusions about quality and performance measurement that could unfairly penalize physicians who treat socio-disadvantaged patients. While case mix may not play a role in certain structure and process measures, risk adjustment is required to fairly measure outcomes that are not fully within the physician’s control. When factors such as patients’ socioeconomic and socio-demographic situations are ignored, this may lead to the erroneous conclusion that physicians and practices serving low-income patients provide lower quality care than those serving predominantly high-income patients. Observed differences in

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measured outcomes may be due to differences in patient mix, rather than differences or deficiencies in the quality of care provided. CMS’ contractor, Acumen, encountered this problem when testing the Diabetes Mellitus (DM) measure composite now part of the GPRO web-interface. When Acumen tested the DM composite using an expanded risk adjustment model that included demographic and regional characteristics (i.e., race, region, region type, household income, and home value), the results differed from the original performance assessment. The AMA recommends that CMS expeditiously expand, test, and improve its risk-adjustment methodology so that the performance of physicians who treat frail and socioeconomic challenged patients is measured fairly. This will ensure that inadequate risk adjustment does not reduce their access to care because physicians are worried that their performance will be unfairly assessed.

IV. Conclusion

The AMA appreciates the opportunity to provide our comments on this important issue. If you should have any questions regarding this letter, please feel free to contact Koryn Rubin, Assistant Director for Federal Affairs, at koryn.rubin@ama-assn.org or 202-789-7408.

Sincerely,

James L. Madara, MD