

November 16, 2015

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

Dear Acting Administrator Slavitt:

Thank you for the opportunity to provide input to the Request for Information (RFI) regarding the implementation of Alternative Payment Models (APMs) and Merit-Based Incentive Programs (MIPS) under the Medicare Access and Chip Reauthorization Act (MACRA). We appreciate the Administration's willingness to prioritize the issues in the RFI that need to be addressed and to extend the comment period. Both of these adjustments will allow the physician community to provide the administration with more thoughtful input. We also appreciate that the Administration held listening sessions on these topics. We are hopeful that an ongoing dialogue with medicine will promote smooth and successful implementation of MIPS and APMs.

The physician community was deeply engaged while Congress drafted MACRA. We believe that, if properly implemented, the new physician payment framework will promote improvements in the delivery of care for Medicare patients. To help physicians make the transition to new care and delivery models and assure access to high-quality care for all patients, the undersigned organizations urge the Administration to carefully consider and adopt principles that:

- **Support delivery system improvements.** Constraints and limitations of current payment systems that obstruct physician-identified improvements in care must be eliminated. In addition, requirements for new models should be flexible enough to support different organizational arrangements and patient population needs so that innovation can flourish.
- **Avoid administrative and cost burdens for patients.** Patients should not be unduly burdened with hidden costs, administrative requirements or other obstacles that discourage them from seeking care or fulfilling their treatment plans.
- **Reduce administrative burdens for physicians.** Administrative burdens must be limited and reporting tasks streamlined so that the delivery of patient-centered care is the principal focus in all clinical settings.
- **Improve current quality and reporting systems.** Medicare's existing reporting and quality measurement programs cannot simply be combined to create the new MIPS program. These currently separate programs must be carefully assessed, revised, aligned, and streamlined into a

coherent and flexible system that is truly relevant to high-value care. In particular, the regulatory framework of the Meaningful Use program for electronic medical records must be revised to eliminate obstacles to technological innovation, enable interoperability, and improve usability to meet the needs of patient care and reduce the burden of excessive data collection requirements.

- **Recognize patient diversity.** Risk adjustment—for factors related to health status, stage of disease, genetic factors, local demographics and socioeconomic status--must be reflected in performance assessments to accommodate variations in patient need and the costs of care and to assure broad access to high value care.
- **Provide choice of payment models.** Physicians in all specialties, practice settings, and geographic areas should have the opportunity to choose from among the payment models available, based on what best accommodates their practice and the needs of their patients.
- **Be equitable.** No specialty or payment model should confront disproportionate requirements in order to succeed, nor should any specialty experience hardship because insufficient resources have been devoted to developing quality measures or other delivery model components that are relevant to their patients.
- **Be relevant and actionable.** Physicians should be held accountable only for those aspects of cost and quality that they can reasonably influence or control, and patient attribution methods must reflect these concerns. Timelines and deadlines must be realistic, significant policy changes should be phased-in, and feedback on individual performance and benchmarks must be accurate, timely and actionable.
- **Provide stability and resources.** Payment systems must provide adequate and predictable resources, and ensure that physicians have access to new tools they will need to redesign their practices to support the delivery of high-value care to all patients.
- **Be transparent.** Methodologies and performance assessment systems should be valid, scientifically tested, and transparent so that physicians have access to timely, accurate and actionable data for managing patient care. Medicare must provide claims and other performance data to physicians on the patient population covered by the delivery and payment model used in their practice.

Medicine is committed to working collaboratively and constructively with the Centers for Medicare and Medicaid Services and others to develop and share meaningful recommendations as regulations are prepared that will shape the delivery of health care services for years to come.

Sincerely,

American Medical Association
Advocacy Council of the American College of Allergy, Asthma and Immunology

AMDA – The Society for Post-Acute and Long-Term Care Medicine
American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
American Academy of Emergency Medicine
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Home Care Medicine
American Academy of Hospice and Palliative Medicine
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngic Allergy
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Pediatrics
American Association of Clinical Endocrinologists
American Association of Hip and Knee Surgeons
American Association of Neurological Surgeons
American Association of Neuromuscular & Electrodiagnostic Medicine
American Clinical Neurophysiology Society
American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Mohs Surgery
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Phlebology
American College of Physicians
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Geriatrics Society
American Medical Group Association
American Osteopathic Association
American Psychiatric Association
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Dermatopathology
American Society of Hematology
American Society of Neuroradiology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urogynecologic Society
American Urological Association

College of American Pathologists
Congress of Neurological Surgeons
Endocrine Society
Heart Rhythm Society
International Society for the Advancement of Spine Surgery
Medical Group Management Association
North American Neuro-Ophthalmology Society
North American Spine Society
Society for Vascular Surgery
Society of Critical Care Medicine
Society of Gynecologic Oncology
Spine Intervention Society
The Society of Thoracic Surgeons

Medical Association of the State of Alabama
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Nebraska Medical Association
Nevada State Medical Association
Medical Society of New Jersey
New Mexico Medical Society
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association

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South Dakota State Medical Association
Tennessee Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society



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November 17, 2015

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200 Independence Avenue, SW
Washington, DC 20201

Re: 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 Models (CMS-3321-NC)

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 Request for Information (RFI) on implementation of the Medicare Access and CHIP Reauthorization Act (MACRA). The AMA appreciates the listening sessions that CMS officials conducted in order to receive input from the physician community before the RFI was released. We also thank CMS for extending the RFI comment period and indicating which RFI topics have the highest priority. These adjustments have given us time to discuss the key RFI topics with national specialty and state medical societies so that the physician community can provide more thoughtful and cohesive perspectives in its responses to the RFI.

The AMA was deeply engaged in the legislative process that ultimately led to the enactment of MACRA. If properly implemented, the new physician payment framework in MACRA will facilitate and support significant improvements in the delivery of care for Medicare patients and more sustainable physician practices. We are hopeful that a true partnership and continuous dialogue between CMS and the physician community will not only promote smooth and successful implementation of this law, but will enable us to achieve better care for patients with judicious use of resources while preserving and strengthening high-quality medical practices.

Merit-Based Incentive Payment System (MIPS)

A key factor in medicine's support for MACRA was the law's promise to create a new Merit-Based Incentive Payment System that, unlike the programs it would replace, is truly value-based and meaningful to the majority of physicians and their patients. Initially at least, a large number of physicians will be participating in MIPS. The law encourages flexibility in the MIPS and the medical community would have serious objections to any proposal that merely moves the current incentive programs into the MIPS

without major modifications. In our view, changes in these programs should begin today and CMS must devote adequate time and resources to this effort, particularly if it intends—despite medicine’s longstanding objections—to maintain its policy of basing performance-related payment adjustments on two-year-old data. If current resources are not sufficient to improve the current programs and design a new MIPS program simultaneously, then the AMA would support CMS in requesting additional funding.

The current “one-size-fits-all” approach with its ever-expanding requirements, flawed methodologies, and insufficient measures has created a situation where many—perhaps most—physicians are judged at least in part on cost and/or quality measures that are largely irrelevant to their practice. Rather than adding more and more hoops with a bewildering array of titles, objectives, and rules that even CMS often has trouble explaining, the goal in the MIPS should be to create a new program with a limited set of requirements but with more options for meeting those requirements. Success should be counted in terms of how many physicians have an opportunity to participate in and be judged on initiatives that really matter, not how many can report on 9 marginally-relevant measures that have little bearing on the conditions they treat. More flexibility and significant methodological improvements will be needed to adjust for differences in specialty, site of service, type of practice, and patient mix.

As further discussed in the attached detailed comments, there is widespread agreement among physicians that:

- The current programs are so complex and CMS has done so little real outreach and education that many physicians, particularly those in small practices, have no idea why their payments have been adjusted or how to respond. Far more vigorous education efforts and much greater transparency and opportunity for physician input in policymaking will be required to ensure that the MIPS lives up to its promise. Web site postings and Open Door Forum calls are not an adequate forum for either consulting or informing physicians.
- An important component of quality improvement is learning from one’s mistakes. More analysis and sharing of current program data is needed to identify and respond to both methodological and process problems that have hampered the utility and equity of the existing programs. Widespread opposition to aggressive implementation of programs such as Meaningful Use should be viewed as a sign that something is not working, not as evidence of physician recalcitrance.
- CMS should also do more to address the problems that have already been uncovered. For example, confidential feedback report and Value-based Modifier (VM) data indicate that physicians treating the largest shares of the program’s sickest patients are most likely to incur penalties. It is also clear from these reports that the current attribution methods are holding many physicians accountable for costs they had no control over, while other physicians have no patients attributed and no way of calculating accurate scores.
- These problems will require numerous changes in the way that costs and quality are measured and compared across specialties, including better risk adjustment, more granular peer group comparisons, more sophisticated attribution methods, and recognition of additional cost influencing factors such as site of service. We are particularly concerned with claims-based cost and outcome measures and would view proposals to dictate the percentage of measures that must be based on outcomes rather than process as highly premature.

- CMS should recognize and adapt to diversity among physicians as well as patients. The MIPS will need to give physicians options so they can participate in quality, cost, and Clinical Practice Improvement (CPI) initiatives that differ depending on who, where, and what they treat. Wholesale incorporation of measures designed for hospitals with their larger, more heterogeneous patient populations is inappropriate.
- Even before there was a CMS, a Physician Quality Reporting System, a VM, or CPI, physicians were engaged in efforts to enhance quality, ensure competence, coordinate patient care, and make arrangements for their patients to receive needed care even outside normal office hours. Congress intended to recognize and give credit to those efforts in the new CPI category. This will work best if physicians can choose the initiatives most relevant to their practice. CMS should resist the temptation to load this category up with mandatory obligations and burdensome documentation requirements that fail to recognize the variation among physicians and patients.

Alternative Payment Models (APMs)

Many Medicare patients have the potential to benefit if MACRA is implemented in a way that enables their physicians to successfully participate in appropriate APMs. Through the establishment of the Physician-Focused Payment Models Technical Advisory Committee (PTAC), MACRA specifically encourages that APMs be *physician-focused*. Congress has recognized that there are many high-value physician services that would benefit patients and help reduce avoidable spending, which the Medicare program currently does not support. Many of these high-value approaches to care are identified as “opportunities” for new models to be supported by the CMS Innovation Center under section 1115A of the Affordable Care Act (ACA), including, for example:

- Utilizing geriatric assessments and comprehensive care plans to coordinate for patients with multiple chronic conditions and functional or cognitive impairment;
- Promoting care coordination between providers of services;
- Supporting care coordination for chronically ill patients at high risk of hospitalization through provider networks that include care coordinators, a chronic disease registry, and home telehealth technology;
- Varying physician payments for those who order advanced diagnostic imaging services in consultation with appropriate use criteria;
- Establishing community-based health teams to assist small medical home practices with chronic care management, including patient self-management; and
- Paying physicians for using patient decision-support tools to improve patient understanding of medical treatment options.

Five years after CMS was authorized to implement “new patient care models” in these areas, Medicare still does not enable the majority of physicians to pursue most of these opportunities to improve care in ways that could also reduce costs. Today, despite all the demonstration projects and other initiatives that Medicare has implemented, most physicians—in primary care and other specialties — still do not have access to Medicare payment models that provide the resources and flexibility they need to improve care for their Medicare patients. Consequently, most Medicare patients still are not benefiting from regular access to a full range of care coordination services, coordinated treatment planning by primary care and

specialist physicians, support for patient self-management of their chronic conditions, proactive outreach to ensure that high-risk patients get preventive care, or patient decision-support tools. As a result, the Medicare program is paying for hospitalizations and duplicative services that could have been avoided had physicians been able to deliver these high-value services.

The APM provisions in MACRA provide an important new opportunity to fix this problem. The AMA urges CMS to create a more welcoming environment for physician-defined payment models so that physicians in all specialties and communities will have access to qualified APMs. Moreover, we urge CMS to embrace physician-focused payment models designed to give physicians the resources and flexibility they need to implement specific improvements in care for their patients and to accept accountability for the specific elements of Medicare spending that they can influence or control. To that end, MACRA regulations and CMS administrative processes must establish a clear pathway for rapid approval and implementation of physician-focused APMs that are proposed by physician organizations, particularly if those APMs are recommended by the PTAC. For MACRA to succeed in reforming the delivery of care and improving value for patients and the Medicare Trust Funds, CMS must be willing to give serious consideration to proposed physician-focused APMs and support their implementation.

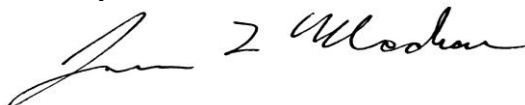
Physician-focused APMs should support innovative approaches that give physicians the flexibility to deliver high-value services and different approaches to care than those supported by the current payment system. CMS must avoid adding unnecessary and burdensome administrative requirements to APMs that cause the resources for additional payments to be spent on administrative costs rather than helping patients. There is widespread enthusiasm for APMs in the physician community, and many national specialty and state medical societies have been working to develop APM proposals that would qualify under MACRA. However, there is universal concern about whether CMS will implement the payment models that they are working hard to develop.

Conclusion

The attachment to this letter provides detailed comments on the CMS priority topics in the MACRA RFI. The AMA worked with a number of national specialty and state medical societies to compile these comments. There is a great deal of common ground within organized medicine regarding the issues raised in the RFI, although each society has its own perspective. In particular, the AMA anticipates that comments submitted from individual societies will describe their specific experiences with and recommendations for APMs and MIPS.

The AMA appreciates the opportunity to provide comments and thanks you for considering our views.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD

Attachment

**CMS MACRA / MIPS / APM Request for Information
Detailed Comments of the American Medical Association
November 17, 2015**

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A. THE MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)

1. MIPS EP Identifier and Exclusions

- The Centers for Medicare & Medicaid Services (CMS) needs to perform an internal environmental scan to determine the implications with creating a separate identifier and/or combining existing identifiers, i.e., the tax identification number (TIN) and National Provider Identifier (NPI). As CMS works through this, organized medicine is happy to set up focus groups with practice administrators to think through the administrative issues and implications that may arise with maintaining the TIN/NPI identifier combination.
- CMS should establish a simple and flexible process for identifying MIPS eligible professionals (EPs). The best approach is maintaining identification by each EP's TIN/ NPI combination that is in place for the current physician quality programs.
- Requiring all EPs to register with CMS to create a new, distinct MIPS identifier would create a potentially insurmountable administrative burden for both EPs and for the agency. We are concerned with the ability of CMS' existing infrastructure to handle the creation of a new distinct MIPS identifier, especially ahead of the start of the MIPS reporting period and with enough lead time to allow ALL EPs to register. It is also not clear that CMS would be able to administer payments or penalties sufficiently through a new identifier separate from a TIN, and whether it would require an addition to the 1500 claims form.
- By not moving forward with a distinct identifier, CMS will not have to worry about "poor-performing" EPs deliberately switching their distinct identifier.
- It may be appropriate to create a new MIPS identifier for virtual groups because they will consist of separate practices with separate NPIs, TINs, and likely separate ownership structures. Virtual groups will have to work out a coordinated structure in order to comply with the program, so creating a distinct identifier could be part of the natural progression of entering into such an arrangement.
- If a TIN registers as a group, during the registration process the group can self-designate how they will use individual NPIs to differentiate the various EP specialties and/or departments and their desired way to participate/report. CMS should be aware that there may be other circumstances that may need to be addressed as the policy moves forward.
- CMS must consider an individual EP's freedom to designate (or not participate) under the group's MIPS election. For many EPs, there are more relevant reporting options than the larger group's election. For instance, many large groups participate under the Group Practice Reporting Option (GPRO) web-interface, but a specialist may want to participate and report through a QCDR that is much more relevant to their patient population and site of service.

2. Virtual Groups

- There should be maximum flexibility for physicians, small practices, and other EPs to form virtual groups.
- There should be no initial, annual, or other limits placed on the maximum number of virtual groups that could be approved each year. Setting limits on the establishment of virtual groups, including the maximum number of groups, minimum or maximum size, geographic proximity, or particular specialty, would have a chilling effect and discourage the EPs from pursuing this option. Such limitations could particularly harm the practices with limited resources and administrative support, which would most benefit from being in a virtual group.
- There is unlikely to be a flood of virtual groups signing up in the beginning, as smaller practices will likely take some time to learn about this option and take the actions necessary to form a virtual group. So this should not cause an undue administrative burden for CMS.
- It would not be appropriate to set arbitrary geographic limitations, including a 50-mile radius. This is unnecessary in a world where telemedicine and electronic communications are widely available. It also could hinder small groups of physician sub-specialties from joining together in a virtual group.
- EPs or small practices that practice in a certain specialty or sub-specialty may want to create a virtual group and report on the same quality measures and Clinical Practice Improvement activities. However, there should be no requirement that all EPs within a virtual group are within the same specialty.
- CMS may want to consider developing a separate identifier for each virtual group (especially virtual groups that do not already operate under a single TIN). This could be an “internal” identifier, solely for use by CMS, or an “external” identifier that the virtual group would also be required to use.
- EPs and small practices should be allowed to break away from larger TINs to form virtual groups. The remaining EPs within the TIN should be allowed to elect how they participate in MIPS or in APMs.

3. Quality Performance Category

a. Reporting Mechanisms Available for Quality Performance Category

Current PQRS Reporting Mechanisms and Criteria

- CMS needs to take advantage of this opportunity to fix things that are not working in the current quality reporting programs. At the same time, the initial transition to this new system needs to be as seamless and as non-disruptive to clinical practice as possible.
- At a minimum, CMS should maintain all of the current PQRS reporting mechanisms to ensure flexibility for physicians with different needs.

- We urge CMS to reconsider the current PQRS requirement of 9 measures across 3 domains, which is an arbitrarily high standard that often results in reporting for the sake of reporting and subsequent data that is of little value.
- Maintaining the 9 measure reporting requirement would also fail to recognize that the MIPS increases the total reporting burden of physicians with the addition of the new category of Clinical Practice Improvement (CPI) activities. CMS should keep in mind that for some physicians and specialties, some or all of the activities captured through this category may be more meaningful and accurate representations of quality than the current set of PQRS quality metrics. While organized medicine supports the goal of identifying national strategy domains, including the need to ensure a balanced national scorecard for quality, it is sometimes challenging to fit measures into these discrete boxes and ensure physicians within each specialty have an adequate suite of measures to meaningfully participate and comply with the program.
- The current domain assignment is very arbitrary and measures are moved from one domain to another from year to year. CMS needs to provide flexibility for a measure to satisfy multiple domains.
- We also believe that by adding the new category of Clinical Practice Improvement, CMS will inherently target a wider array of quality interventions that satisfy the goals of multiple domains.
- Consequently, we recommend that CMS consider doing away with the domain requirement and instead use domains to simply guide measuring national quality goals.
- Alternatively, if this is not possible, CMS should, at the very least, allow measures to be assigned and counted towards meeting multiple domains.
- We also would like to highlight that CMS' process of assigning domains and determining Measure Applicability Validation (MAV) clusters has historically occurred within a "black box." We urge CMS to give relevant stakeholders an opportunity to provide input into these determinations before domains and clusters are presented in proposed rules.

Quality Data Reported via Multiple Mechanisms

- A physician should not be allowed to report the same measure for the same patient across multiple mechanisms and have it count towards their score.
- However, there may be a need for a physician to report independent measures through multiple mechanisms and for those measures, in total, to count toward satisfying the quality measure reporting requirement. For example, an EP might identify a handful of clinically relevant electronically specified (e-specified) measures that can be reported through an electronic health record (EHR), but also might identify a few other relevant measures that are not yet e-specified and can only be reported through a registry. CMS should recognize the reporting of measures across multiple reporting mechanisms in order to promote meaningful engagement and to encourage EPs to experiment with different options.

- Combining methods would also enable multi-specialty groups to use multiple registries to satisfy reporting.

Quality Measure Types and Weighting

- Moving to more “high value” measures or “measures that matter” are important goals of the house of medicine. However, there is not uniform agreement on which measures have the greatest (or incrementally more) value in driving results. Measures considered “high value” may differ by specialty or patient, as well as varying depending upon the intended purpose.
- Valid and reliable outcome measures could potentially lead to more direct measures of quality and their development by medical specialties should be encouraged and funded. However, we also recognize that certain types of measures might be more appropriate for certain specialties and practice settings than for others. Furthermore, process measures that are evidence-based can be integral to improved outcomes and in some specialties, this foundational step must first be addressed before moving on to outcome measures.
- There are a number of methodological issues that must be addressed by CMS before moving to assigning more weight to outcome measures, including risk adjustment and attribution.
- Outcome measures at the physician level can also be particularly challenging to construct for two primary reasons—small sample sizes and the difficulty of identifying outcomes for which the physician can and should be held accountable (i.e., outcomes that are largely dependent on the quality of care received, not other factors).
- Infrastructure challenges may also prevent measure developers from developing outcome measures. These can involve problems with capturing patient reported or experience of care measures in the EHR as well as interoperability issues that interfere with the exchange of needed information, and the inability to do longitudinal tracking due to the lack of uniform patient identifiers.
- Therefore, CMS should maintain flexibility by not requiring the use of any specific type of measure in the initial years of the program. A flexible approach is critical to ensuring that relevant measures are available to as many physicians as possible.
- We are opposed to requiring that a minimum number of measures be outcomes-based and/or weighing outcome measures more heavily. CMS is assuming that individual physicians can wield sufficient influence on which measures are developed and available to meet the needs of their patient population. Holding physicians accountable for something that is not necessarily within their direct control would be imprudent. It also ignores infrastructure issues that may prevent the development or incorporation of appropriate outcome measures into CMS programs.
- In view of this challenge, we strongly advise CMS not to push forward with the development and maintenance of administrative claims based outcome measures, which are typically poorly designed, under- or over-capture clinical information, and often have attribution issues.

- Instead, CMS should encourage physicians to report on clinician-led and evidence-based outcome measures by recognizing and compensating for the increased effort required to report on patient outcomes. For example, if a physician reports on an outcome measure, CMS could consider eliminating or reducing other requirements such as reporting on 9 measures.

Data Stratification

- Stratifying data by demographic factors such as race, ethnicity, and gender is important to ensure equivalent quality and access to care among diverse patient populations. Documentation of these factors will result in more accurate measurements and more precise accounting for risk and other factors that can influence performance. However, the proposed set of demographic data included in the 2016 Physician Fee Schedule proposed rule provides a basic set of data elements to form the foundation of risk stratification efforts. In order for demographic data to be used and analyzed, it has to be collected for a substantial period of time to be significant. At the same time, CMS must recognize the additional burden this could pose to the reporting physician and to the entities collecting this data, e.g., qualified clinical data registries (QCDRs). CMS must streamline the collection of these demographic data. The AMA also encourages the MIPS program to be streamlined with requirements put forth in the ONC's 2015 Edition Health IT Certification Criteria and with MU program requirements. Streamlining requirements allows for meaningful collection of demographic data, ensures uniform capture of information and eases reporting burden.
- CMS should consider *directly* providing QCDR entities with more open access to CMS claims and EHR data so they can easily gather this information. As it is, many EPs and health entities are hesitant to participate in clinical data registries, even for quality improvement, due to fears of breaching the security or privacy of protected patient health data. Stratifying the data will also reduce sample sizes, creating further issues of validity and statistical significance.
- Furthermore, physician requirements in the Meaningful Use program are too heavily focused on the act of data collection and documentation for program compliance. Most providers participating in MU are subjected to tedious data entry demands. This is viewed by physicians and other health care professionals as a primary drain on productivity. Physicians participating in MIPS should not be required to collect ancillary data sets unless they are necessary for quality measurement or are deemed by the physician as having direct use in patient care. The MU program should optimize the reuse of data and requirements in MU to reduce the burden on physician documentation. Documentation should be the product of care delivery. Data that are necessary to be collected should facilitate a "collect once, reuse many times" structure. As much as possible, secondary and tertiary data uses should be leveraged from clinically necessary data. The AMA is participating in activities to support tightly-mapped ontological structures that will provide pathways for better data collection and analytics.
- AMA-PCPI developed measures, as well as electronic clinical quality measures (eCQMs) in federal programs, include supplemental data elements of race, ethnicity, "administrative sex," and payer. The code sets used to capture administrative sex and payers are "ONC Administrative Sex" and "Source of Payment Typology," respectively. Race and ethnicity data elements are specified using the Centers for Disease Control and Prevention (CDC) Race and Ethnicity codes, the standards recommended by the Health Information Technology (HIT) Standards Committee in 2011. The

AMA supports the expansion of these code sets to allow for greater granularity, as proposed in the ONC 2015 Edition HIT Certification Criteria, and urges CMS to make these categories consistent across all programs. In our experience, the collection of demographic data has not been problematic. However, these data may not be captured in a uniform fashion across sites. Standardization in the collection of these elements will be essential to ensure meaningful comparisons across providers and sites.

- Regarding the collection and reporting of disability status, we anticipate challenges in consistent definition and collection of these data elements. Education and training will be required to ensure that cultural bias does not influence the collection of these data. In addition, we support the standardization of disability codes to reflect more granularity and encourage harmonization of code sets across all CMS programs. CMS should look to EPs and any other vendors for additional insight. The National Quality Registry Network (NQRN) is uniquely positioned to serve as the convener of these essential stakeholders to achieve consensus around the definitional and operational challenges associated with the collection of these demographic data, including disability status.
- If all data elements are captured electronically, and harmonization across all programs supports the needed level of granularity, then we do not think a phased approach to collection of the information is necessary. However, we do support a timeline that adequately gives EPs, CMS, registries, and health IT vendors the opportunity to build the elements into their workflow and perform testing to ensure that the data collected are valid and reliable. There also needs to be sufficient time to achieve agreement on a single standard for reporting (Office of Management and Budget (OMB) versus CDC categories) and educate the community of EHR and registry users. The OMB uses OMB categories plus a separate category for “other.” The CDC value set, captured as supplemental data elements, is aligned with the OMB categories. Therefore, we suggest that CMS use “CDC” as this is how the supplemental data elements are recommended from the workgroup that developed them.

The CAHPS Survey

- We support making the use of patient satisfaction surveys one way of satisfying the CPI category. However, CMS should also allow for other types of CAHPS (Consumer Assessment of Healthcare Providers and Systems) surveys, not just the CG-CAHPS (Clinician and Group CAHPS) and non-CAHPS “experience of care” measures and surveys, to count under the CPI category. We do not believe that patient experience and patient satisfaction should be categorized as a Quality metric since these measures and surveys include factors outside the control of the physician (e.g., physician wait times in a hospital setting).
- 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 or stop smoking, or limits pain medications, is likely to receive a low “performance” score even when these are clinically indicated.

EPs in Specialties with Few Quality Measures

- For specialties that may not have enough measures, CMS should use its authority to re-adjust the weights of the other MIPS categories.

- Due to serious flaws in the current Meaningful Use (MU) and Value Modifier programs, we caution against automatically adding weight to the MU or Resource Use categories.
- The CPI category may provide the most flexibility for many physicians to receive recognition for the quality improvement activities that are most relevant to their practice. This category was also given the least amount of weight under MACRA. Therefore, we believe that when a specialty does not have enough measures, CMS should give more weight to a properly constructed CPI category, developed in cooperation with the affected specialties and sub-specialties.
- Alternatively, CMS could allow specialties to select which other category or categories they would like to count more. We recommend that CMS customize the performance requirements for those EPs and work with the affected specialty and the related specialty society/societies to set requirements that are appropriate for the unique nature of that particular specialty.
- Rather than taking a one-size-fits-all approach as it has with the current MU program, CMS must consider the varying practice patterns of specialties and sub-specialties, as well as the site-of-service in which a physician practices. This is particularly important for radiologists, anesthesiologists, and pathologists—as well as facility-based specialties such as physicians who practice largely in the hospital or in long-term care facilities and nursing homes.

Barriers to Successful Quality Performance

- The greatest barriers to success for many physicians are not having a sufficient set of relevant measures to choose from, or having too few patients to meet minimum standards for a statistically significant sample. And while QCDRs have allowed for the development of more diverse measures, this reporting mechanism is not yet accessible to everyone.
- CMS must continue to address measurement gaps and to improve the existing set of measures. We reiterate our concern that CMS has not yet allocated MACRA-authorized funding toward this effort, and we urge the agency to do so as expeditiously as possible. (We also remind CMS of the importance of ensuring that measure development is evidence-based and clinician-led.)
- Furthermore, we reiterate our concern about arbitrarily high reporting thresholds (e.g., 9 measures across 3 NQS domains) that force physicians to report on measures that are marginally relevant to their practice, simply for the sake of reporting.

b. Data Accuracy

Testing

- 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 CMS flagging any errors on both format and values as data is submitted. Ongoing validation and auditing are also needed.

- To avoid data integrity problems such as those CMS encountered with 2014 data collected via QCDRs and EHRs, CMS should require these entities to complete preliminary CMS-sponsored submission testing. Currently this is highly encouraged, but not required.
- CMS and its contractors should 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.

Standards

- QCDR XML (Extensible Markup Language) and QRDA (Quality Reporting Data Architecture) are formats currently allowed by CMS for PQRS reporting. CMS should initially consider that using any method of electronic capture and transmission of quality data meets the intent of interoperability. It should not be required that certified EHR technology (CEHRT) uses only QRDA for capturing and transmitting data. Requiring CEHRT or clinical quality data registries (QCDRs) to only use QRDA will require time and resources to put this in place.
- That said, the 2015 Edition Certification requires that all health information IT modules used for the submission of clinical quality measure (CQM) data must at least be certified to the QRDA standard. While there are still concerns with the QRDA format—including EHR vendor compliance and testing—issues do arise when health IT products attempt to accommodate multiple standards.
- Transitioning to QRDA could help reduce vendor interface costs for physicians who are already using CEHRT and desire to participate in registry reporting. As a starting point, CMS should provide ample notification, testing periods, and conversion guidelines to allow for previous users (whether QCDRs or others) who report data in the XML format to transition towards QRDA I or III formats in order to remain in programmatic compliance.
- We also believe that CMS should work with registries and other stakeholders to identify emerging standards that support a more scalable and flexible data reporting format.

Review and Qualification

- It will require substantial effort by each QCDR to ensure its file transmissions meet the form and manner of CMS specifications. However, it would be beneficial for a QCDR to know at the start that its file format is accurate. To accomplish this, CMS should provide specifications and access to the testing portal to QCDRs for testing within a reasonable time period and prior to the CMS approval date (currently May). During that time, QCDRs should be able to test data for validity, as well as for data format.
- One problem with the current file format is that the standardized, one-form-fits-all does not always translate seamlessly for each QCDR. When developing formats for data submission, it is critical that CMS work with registries to ensure that CMS can accept formats which allow each registry to demonstrate the unique features of its data, such as embedded risk adjustment.

- We are also aware that testing tools used for “form and manner” compliance have in the past been delayed, error-prone, or had multiple versions for use in testing vendor products. Health IT systems rely on these tools to validate their quality reporting system and any issues with these tools can promulgate errors down the development time-line or into the production environment.

Feedback during Testing

- It would be helpful for CMS to inform stakeholders of calculation errors and anything that does not comply with specifications, such as zero rates.
- If testing requires any type of practice audit or request for information from practices for data validation purposes, CMS should inform vendors of any communication to practices so that vendors can work with CMS to ensure that practices understand the purpose of the validation request.
- In advance of, or concurrent with, updates to quality measures, CMS should clearly identify a timeline when testing tools will be available and at what point the version will be “static.” Suggested milestones should be made available so that health IT vendors can incorporate measure testing into their product’s timeline.

Thresholds for Data Integrity

- The overall goal of CMS should be to collect data that is as accurate as possible, and not be punitive to the EPs for inadequacies of the QCDR, the EHR, and/or CMS’ process. Therefore, we recommend that these types of issues around accuracy, completeness, and reliability should be validated during testing. However, it may not always be possible to validate a calculation rate for things such as continuous variables. Asking for calculated rate and elements provides a second order check, so it is important to have both.
- If a QCDR or EHR vendor is alerted to errors and does not make corrections in a reasonable period of time, it would be appropriate for CMS to discard the records where validation is not feasible or results in inconsistencies.
- In an attempt to reduce the design burden around measure calculation and to help normalize reporting variations between health IT products, CMS should work with developers to establish a “black box” calculation system. This software module would be agnostic to vendors’ products and could be hosted outside the health IT product or available as a plug-in through an application programming interface (API). It could be used (not required by CMS) as an alternative calculation application to help standardize reporting, reduce inconsistencies that originate due to product design, or help better align with data integrity standards.

Non-Compliant Data Reporting Mechanisms

- If adequate opportunities for initial testing, validation, and data correction are available and a QCDR, qualified registry, or EHR vendor is still not adequately submitting correct and valid data, then the vendor should be placed on a corrective action plan. If after the probationary period the

vendor is still not adequately submitting data, the vendor should be excluded from future performance periods until it shows through testing that it is able to submit valid data.

- To help resolve potential and ongoing issues, CMS should develop a root cause analysis toolkit that vendors could use to help self-identify issues. This analysis should be conducted before corrective actions are initiated. This would help inform CMS and other vendors about new issues or ones that may become systemic.
- If a vendor is found incapable of submitting accurate data, then EPs who used that vendor should be held harmless from any penalties. CMS must also recognize that there may be instances where the problem may reside with CMS and not just the vendor, such as a vendor not submitting complete information because CMS failed to provide necessary and/or timely information. In these instances, CMS should also hold physicians harmless from any penalties.
- We also urge CMS to consider developing a fair process or methodology to deal with future situations where the physician makes the good faith effort to comply, but the data is deemed invalid and unreliable. For example, why should physicians who received high performance scores in the past be labelled as “average” just because a CMS error prevented them from having a valid report in the current year?
- We also strongly encourage CMS to notify through written mail any affected physicians and group practices when data are deemed invalid. The notification process to date has been essentially non-existent and grossly inadequate, which will become an even larger problem after MIPS takes effect and CMS quality programs are no longer just pay-for-reporting, but pay-for-performance.

c. Use of Certified EHR Technology (CEHRT) under the Quality Performance Category

- We support the current policy of allowing physicians to report quality measures through certified EHR systems to fulfill the clinical quality measure component of Meaningful Use. We also recommend that QCDR reporting count towards satisfying MU quality.
- CEHRT should only adhere to standards conformity and be tested for compliance. The use of CEHRT should not be proscribed beyond the constraints of the certification program of the Office of the National Coordinator for Health Information Technology (ONC), nor should it be limited to process objectives established by CMS. These requirements currently limit the utility of CEHRT by constraining the functionality of health IT to accommodate thresholds, measure calculation, and numerator/denominators.

Standards for Data Capture and Transmission

- QCDR XML and QRDA are formats currently allowed by CMS for PQRS reporting. CMS should initially consider that using any method of electronic capture and transmission of quality data meets the intent of interoperability. It should not be required that CEHRT use only QRDA for capturing and transmitting data. Requiring CEHRT or QCDRs to only use QRDA will require time and resources to put in place.

- That said, the 2015 Edition Certification requires that all health IT modules used for the submission of CQM data must at least be certified to the QRDA standard. While there are still concerns with the QRDA format—including EHR vendor compliance and testing—issues do arise when health IT products attempt to accommodate multiple standards. We appreciate CMS’ attempt to lessen the reporting burden on physicians by moving certification to the QRDA Category I and II standards and the optional CMS “form and manner” guidance. While this is intended for future health IT seeking the 2015 Edition of CEHRT, we are concerned with the continued variances in implementation guides (IGs) between QRDA I & III, consolidated clinical document architecture (C-CDA), and CMS’ form and manner requirements.
- We are aware that EHR vendors who wish to support both QRDA and C-CDA standards must establish concurrent technical methods to accommodate differences between the way patient data are managed when applied to the QRDA for CMS quality reporting, and the C-CDA standard for data exchange between physicians. Part of the issue can be attributed to the variability between the timing of Health Level Seven (HL7) balloting for QRDA I & III, C-CDA, and CMS’ form and manner guidance updates. We understand that the process of update publication, balloting, and comment resolution is necessary for the right consensus among standards development organization members. This process can be lengthy and serves to improve the draft standard over time. However, vendors must support data exchange with a variety of health IT products using the C-CDA draft standard as part of the CEHRT requirement. There are already well documented issues with variability between vendors implementing C-CDA IGs (e.g., for things like summaries of care) and the resulting lack of functional interoperability we see today. In addition, we feel it is necessary to point out that there is also significant concern with the effort to support CMS’ form and manner requirements in addition to HL7’s QRDA IGs and the resulting data discrepancies that may lead to patient safety issues.
- For vendors to support data exchange and CMS quality reporting, they often must rely on CMS’ IGs to explain methods and workarounds so that data may be bifurcated for both purposes. However, we have heard that this fork in the data pathway may not always be correctly reconciled. EHRs may need to report quality data in the format that CMS stipulates for reporting and in a separate format for care summaries and exchange. However, the difference between C-CDA conformance and CMS’ QRDA IGs means that data adjusted to comply with the CMS version of the QRDA report is less likely to be properly structured in the C-CDA and may not be present in routine transfers of clinical care. As an example, clinically significant reasons for an exception in a patient’s treatment should be available to other providers also caring for that patient. However, this information may not come across if the original data are manipulated for QRDA formatting. If the data are managed by the EHR in different ways to support two different formats, the EHR may be reported to CMS correctly, but C-CDA conformant summaries of care sent to other physicians may not include the exception reasoning. Thus, other physicians may not be aware of the exception and might mistakenly and incorrectly treat the patient without knowing why the referring physician avoided that treatment in the first place.
- Requiring C-CDA, QRDA, and CMS’ form and manner conformance is excessive for vendors and variations in IGs means that information has to be modeled differently for reporting and direct patient care. While CMS’ intent may be to simplify reporting, the proposed approach could lead to patient safety issues. We therefore recommend that CMS and HL7 should align standards before

further programmatic requirements are finalized. We recommend that CMS embrace the spirit of interoperability and only establish requirements that both QRDA and C-CDAs can handle without complex IGs or workarounds. We further recommend that ONC's health IT certification process expressly test for tight conformance to any standard required by CMS.

- Transitioning to QRDA could help reduce vendor interface costs for physicians who are already using CEHRT and desire to participate in registry reporting. As a starting point, CMS should provide ample notification, testing periods, and conversion guidelines to allow for previous users (whether QCRDs or others) who report data in the XML format to transition towards QRDA I or III formats in order to remain in programmatic compliance.
- We also believe that CMS should work with registries and other stakeholders to identify emerging standards that support a more scalable and flexible data reporting format.

4. Resource Use Performance Category

Current Measures

- The RFI implies that CMS may keep all the current Value-based Modifier (VM) cost measures and then expand upon them. The current measures have no clinical relevance for many physicians. Some have no costs attributed to them. Others are tagged with costs for services they had no opportunity to control. As can be seen in CMS' QRURs (Quality and Resource Use Reports) and VM experience reports, the current cost and outcome measures also discriminate against physicians with high numbers of chronically ill and high risk patients.
- There are many reasons for this, including an inadequate risk adjuster and cost of care measures that punish physicians repeatedly for the same high cost patients with multiple chronic conditions. Many of the measures were developed for hospitals and are inappropriate for physician practices, which do not have Medicare patient populations that are large enough or heterogeneous enough to produce an accurate picture of their resource use.
- Congress understood that the VM methodology is seriously flawed. That is why this category is worth only 10 points initially. We agree with that decision. We also agree with the MACRA's authors that improving the current episode-based measures and attribution process are critical to a fair and successful MIPS program and look forward to offering additional input as CMS complies with this mandate. CMS needs to devote significant data analysis and resources to this effort in order to *replace*, not *expand*, the current VM cost measures.

Measures Based on Potential Harm and/or Overuse

- Medicine supports the use by physicians of evidence-based clinical decision support systems to help guide their choice of treatment for particular conditions or patients. A growing number of specialties have developed and continue to expand and refine clinical guidelines and appropriateness use criteria (AUC). Also, as directed by Congress, CMS is currently developing a program that would require consultation of such guidelines for advanced imaging services and potentially others as well.

- The “Choosing Wisely” campaign is a related but different activity which was intended to promote a dialogue between patients and providers around potentially unnecessary tests, treatments and procedures.
- Neither of these concepts should be considered absolute recommendations regarding the appropriateness of a given test, treatment or procedure. Presented with the general Choosing Wisely guidelines, a physician or patient may conclude that a particular recommendation is not appropriate in a given circumstance. Similarly, due to the nature of their practice, some physicians may conclude that particular AUC recommendations do not apply to a subset of their patients.
- As a result, some legitimate variation in adherence to AUC and therefore average costs is to be expected. In addition, CMS’ current attribution methods frequently hold the wrong physician accountable for the cost of a given service.
- Until such issues are resolved, it would be premature to judge physicians’ resource use based on AUC or Choosing Wisely guidelines. Instead, physicians who use these should be given credit under the Clinical Practice Improvement category.
- However, individual specialties might decide to use AUC or “Choosing Wisely” guidelines in the creation of resource use measures applicable to their members. In these cases, CMS could then consider adoption of any that have a solid evidence base and were developed through a multi-specialty, clinician-led process. All specialties that provide the service in question would need to be consulted prior to adoption.
- Furthermore, we do not believe that measures based on Choosing Wisely recommendations should be calculated from administrative claims data. Administrative claims data typically under- or over-capture overuse.

Physicians/Practitioners without Applicable Measures

- CMS should consult with specialties without enough measures to cover all of their members, about how to redistribute points from this category. For example, how points should be redistributed will likely depend on which, if any, other MIPS categories have measures or activities that are more applicable for physicians without applicable resource use measures.

Physicians/Practitioners without Enough Data

- A related question addressed in another section of the RFI involves the question of how to deal with physicians and practices that do not have large enough Medicare populations to compute reliable scores.
- Even with a low-bar minimum case threshold of 20 patients, more than 40 percent of groups with 25 or more practitioners did not have enough data to create scores for the 2012 QRURs. Under current VM policy, CMS simply declares that these practices have “average” costs. This protects the practice from cost-related VM penalties but it also precludes a practice from using a good score on the cost side to offset a bad score on the quality side.

- CMS should modify this policy to ensure that no practice is disadvantaged by the “small numbers” data issue. Alternatives are to call practices without enough data to calculate either a resource or quality score “average” on both categories or exempt them from mandatory tiering if that is retained in MIPS.

Episode-Based Cost Measures

- In addition to their other flaws, VM measures today are irrelevant for many physicians—either because no patients get attributed to them or because they had little to no opportunity to influence the costs that are attributed to them. Shortcomings in the attribution and risk adjustment methodology exacerbate the problem. If properly selected and designed, measures tied to episodes of care could increase the relevance, reliability, and applicability of resource use measures and make physician feedback reports more actionable. This would also offer an opportunity to adapt risk adjustment and attribution methodologies to the individual condition or service being measured.
- Transparency and physician involvement in the development of these measures and the accompanying methodological decisions are critical. We strongly believe that CMS should create a process that provides an opportunity for thorough input from practicing physicians throughout the process. Posting episodes developed by a contractor working with a handful of “experts” on a web site will not be sufficient. We appreciate the work that CMS has done in testing episode measures through the QRURs.

Aligning Measures

- The first order of business should be to ensure that measures used in individual MIPS categories are valid, reliable, relevant, and actionable.
- Episode measures potentially could include both costs and outcomes. This would require the identification of specific outcomes related to the condition or service being measured, rather than some general measure such as All Cause Readmissions.
- Alignment with measures in other parts of Medicare will need to be determined on a case-by-case basis with relevant specialties, taking into consideration their site of service. Wholesale incorporation of other providers’ cost measures into MIPS should be approached with caution and only after testing and re-specification of the measure.

Peer Groups

- Due to the diversity of physician practices even within the same specialty, making accurate comparisons of their performance will require far more detailed delineation—of specialty, sub-specialty, area(s) of expertise and/or site(s) of practice—than is currently conducted by either Medicare or private payers. While we appreciate CMS’ efforts to adjust for a physician’s specialty in the VM program, more work is needed.

- A means of recognizing sub-specialization, either due to training, services provided, or site of service, will need to be developed and implemented.
- Site of service should also be used to make adjustments for physicians whose practices focus on hospital or nursing home patients, whose care is typically more complex and more costly than patients outside a facility.

5. Clinical Practice Improvement (CPI) Activities Performance Category

Types of Qualifying Activities

- CMS should allow for the broadest interpretation of CPI activities possible. The selection of activities should be optional. No category should be mandatory.
- Physicians and other eligible professionals should be given credit for CPI activities in which they are currently engaged, including those that are mandated or encouraged by Medicare and other government programs. This would include a long list of activities such as:
 - Participation in a Qualified Clinical Data Registry and in registries run by other government agencies such as the Food and Drug Administration, or private entities such as a hospital, or medical specialty.
 - Certain quality measures from other provider types such as the safe surgery checklist and flu vaccination measures for the Ambulatory Surgery Center Quality Reporting Program.
 - Compliance with a coming requirement for consulting Appropriate Use Criteria for advanced imaging services.
 - Participation in CMS' Million Hearts Campaign, Cardiovascular Disease Risk Reduction Model, Oncology Care Model, and/or Transforming Clinical Practice Initiative.
 - Participation in relevant practice improvement activities facilitated by each state's Quality Improvement Organization.
- Other activities associated with the six CPI categories Congress specifically called for in MACRA include the following types of activities:
 - Expanded practice access: Same day appointments for urgent needs; after-hours clinician advice – using secured messaging, patients can ask questions of their provider that is well documented in the patient record; remote monitoring of chronic conditions; establishing policy allowing patients with emergencies to walk-in during certain established hours; Saturday and expanded hours for clinics to increase access; use of satellite offices to bring services to patients; and serving on call in an emergency department.
 - Care coordination: Timely communication of test results; ability of a practice to receive and act upon fax or email from a referring doctor; ability to provide patients with printed copies of test results; and billing chronic care management or transitional care management codes.
 - Beneficiary engagement: Practices providing patients with the option to download or have mailed medical history forms to fill out prior to a first appointment; training of patients in appropriate administration of medications and proper use and maintenance of durable medical equipment and various remote monitoring devices and home testing

products; use of decision trees and questionnaires to engage patients in shared decision making on their medical care; patient flyers for specific conditions; and nutritional counseling.

- Various activities of organizations representing physicians and medical groups should also be recognized as practice improvement. This would include accredited continuing medical education, board-certification-related activities, and other initiatives aimed at improving clinical practice, such as opioid prescriber training and the provision of medication-assisted treatment of opioid use disorders.
- For example, completion of the AMA's STEPS Forward™ modules should qualify as CPI activities. The AMA launched STEPS Forward in June 2015 to drive physician internal practice improvement. The modules will offer continuing medical education (CME) credit, and new modules are being developed for rollout in March 2016 on specific payment models. STEPS Forward will be enhanced with the recent award of a CMS TCPI grant to provide practice transformation resources for physicians. The modules, available at <https://www.stepsforward.org/>, currently include:
 - Medication Adherence;
 - Panel Management;
 - Preventing Type-2 Diabetes in At-Risk Patients;
 - Improving Blood Pressure Control;
 - Preparing Your Practice for Change;
 - Adopting Telemedicine in Practice;
 - Behavioral Health Integration in Ambulatory Practice ;
 - Building an Intensive Primary Care Practice;
 - Implementing Team-Based Care;
 - EHR Implementation; and
 - Select Sustainable Change Initiatives.
- Administration of CAHPS or other patient experience and satisfaction surveys should be considered as a CPI activity rather than a quality measure.
- Participation in designated private payer clinical practice improvement activities should also count toward the CPI category.
- Physicians and other EPs should have the freedom to choose the CPI activities that are most beneficial and appropriate for their type of practice and patient population, regardless of subcategory domain. Subcategories should only serve as a guide for defining CPI activities.
- Activities aimed at reducing disparities in care or furthering other socially desirable goals should be completely voluntary and equally weighted with other activities.
- We would strongly oppose any efforts to use the CPI portion of MIPS as a backdoor way of forcing physicians to participate in various federal health programs such as Medicaid or the federal exchanges.

Attestation and Reporting of CPI Activities

- Physicians should be able to demonstrate their performance of CPI activities through a simple attestation process. Attestation should occur annually.
- The attestation process would be best facilitated through a web portal that is simple to access and use.
- Transmission of CPI activity results also should be permitted but not required through EHRs and QCDRs, when and where the capabilities exist.
- The physician or other EP should generally be responsible for documenting CPI activities. Participation in some activities could be reported on and/or collected from claims.
- Organizations and other entities that sponsor CPI activities should be required to maintain records for up to a certain period of time that can be used to verify physician or other eligible professional participation in a CPI activity.
- Some CPI activities (e.g., a certification) may be granted by the certifying organization for more than a one-year period. In such cases, physicians and other EPs should be allowed to attest to that activity for each of the years until the certification expires. After the initial year, the physician or other EP should not have to demonstrate anything additional in subsequent attestations until the certification expires, unless additional actions are required by the certifying organization.
- Where applicable, there should be an option of having participation in a CPI activity reported by the certifying agency rather than individual physicians. An APM Entity should be allowed to provide participation rates for physicians in the APM.

Thresholds and Quantifying Activities

- CPI activity performance should be based on completion *or ongoing participation* in a specified number of clinical improvement activities, rather than hours.
- CPI activities should include those in which an individual physician or other EP can participate or complete, *or* activities in which participation or completion occurs at the group practice level.
- Initially, the number of required CPI activities should be based on practice size.

Weighting of Various Activities

- At least initially, all CPI activities should be weighted equally.
- All CPI activities, regardless of subcategories, should be weighted equally while experience with the program is gained.

- Physicians should not be required to attest to a CPI activity in every subcategory or any specific subcategory or activity. They should be able to pick and choose, so these would have to be weighted equally.

APM Participation

- The subcategory of participation in an APM should not be limited to qualified APMs. The definition of the APM subcategory under MIPS should include physician or other EP's participation in an APM "sponsored" by a commercial payer or Medicaid.

Small and Rural Practices

- Allowing for the broadest definition of CPI activities and least burdensome requirements will be needed to ensure that physicians and other EPs in small or rural practices are able to participate.
- Ensuring that there are options which are free or low cost is also crucial. For example, many physicians issue disease and population-specific notifications and perform other activities without the use of a certified electronic medical record, and this should be counted as CPI.

Best Practices

- Initially, CMS should allow for the broadest definition of CPI activities and, simultaneously, work with stakeholders to identify best practices based upon community and population needs.

6. Meaningful Use of Certified EHR Technology Performance Category

- The intent of the Meaningful Use (MU) program has been achieved—over 80 percent of physicians and hospitals have adopted and use electronic health records (EHRs). CMS should now shift the focus away from measures that mandate data entry and reorient MU objectives toward high-quality care that supports the MIPS program.
- Given the scale of our previous comments, the AMA was surprised that the Stage 3 final rule repurposed the previous stages' measures and failed to provide a glide path to the new MIPS program.
- Since MU is a significant component of MIPS, it is extremely important that, prior to its implementation, CMS change the MU program to ensure it is achievable and meaningful for all physicians, including specialists.
- In particular, the process-oriented MU objectives continue to support a fee-for-service environment where measures are tied to specific services or treatments. Measure thresholds have inadvertently stalled technical innovation. Instead of supporting an outcome, EHRs are now designed to direct users down a narrow path to track how an activity was accomplished.

- MU has also been the driving factor in EHR design for the past six years. Current systems are focused on data entry, threshold measurement, and numerator/denominator calculations, rather than usability and interoperability for patients and physicians.
- We believe that the structure of the MU program has forced health IT vendors to count clicks and capture check-the-box process measures. This is not reflective of medicine, which is a dynamic environment where physician-patient narratives, medical summaries, care plans, patients' access to information, and interoperability should not be diluted.
- We believe that a glide path, utilizing use cases that are widely applicable across care settings, is an appropriate place to start and could help EHR vendors prioritize the development of high-impact functionality into their systems.
- (CMS should therefore reopen MU Stage 3 to realign the program with MIPS and APMs.) The current structure jeopardizes physicians' transition to MIPS and their ability to participate in APMs.

Redesigning Stage 3

- CMS should return to the statutory intent of the Health Information Technology for Economic and Clinical Health (HITECH) Act and focus Stage 3 on the three categories outlined in the law: 1) electronic prescribing; 2) information exchange; and 3) quality reporting.
- Functional interoperability—or the seamless exchange of relevant medical information, the incorporation of data, and its use in providing knowledge to the end user—should be a central theme in every aspect of MU.
- A fundamental rethinking of MU should support the reuse of data to reduce the burden on documentation. Data that are necessary to be collected should facilitate a “collect once, reuse many times” structure. The AMA is participating in activities to support tightly-mapped ontological structures that will provide pathways for better data collection and analytics.
- Specific measures must also be broadened to reflect changes in technology and new innovations. Specifically, patient engagement measures should be broader to allow more choice and reflect diverse patient populations. More attention must also be paid to the electronic prescription of controlled substances (EPCS) to reduce the burden on physicians and to increase the uptake of EPCS.

Use Cases

- MU measures should be redesigned to focus on outcomes and use cases rather than processes and data entry.
- For example, a use case could be built around referral management. This requires a tightly integrated feedback loop where each participant in the care team has the right information when they need it. The ability to close the information loop spans tasks such as referrals, diagnostic orders, prescriptions, interventions, and follow-up care. Many activities like referral priority, office or lab

visit scheduling, and visit completion could be included. Communication channels between pharmacies, physical therapy centers, post-acute care, and telemedicine visits could also be included.

- Another use case could be tied to patient choice and consent. This information should seamlessly follow the individual as they transition between care settings.
- Instead of the traditional MU counting approach of measuring physician process actions, use cases could be measured by evaluating interoperability, data availability, usability, task efficiency, user satisfaction, or if a goal was achieved.
- The measurement of a use case should not be limited to just the traditional thresholds of MU. Rather, the ultimate goal should be that an outcome was achieved or multiple tasks were completed successfully; not necessarily how or what individual steps were used to get there.
- A shift to use cases, evaluating outcomes, and measuring interoperability will require the creation of new metrics. The AMA supports the Office of the National Coordinator's (ONC's) call to action for physicians to participate in developing these metrics. This process will require simple rules, clear goals, and less of a federal top-down structure as medical societies should be the primary architects for both use case development and performance metrics. While medical societies should lead use case design, use cases should also incorporate patients and other care professionals.
- Given the complex data exchange requirements of high-value use cases functional interoperability will be a natural outcropping of this type of MU program. As these use cases will be closely coupled with the needs of patients and physicians the demands of the end user will directly influence the design of health IT. We foresee data fluidity, access, and product usability becoming forefront design principles as the business case for health IT vendors shift from program compliance to functionality.

Pilots

- The current MU program fails to provide an avenue for innovation or ensure that all care providers can participate. CMS should therefore collaborate with national specialty societies to develop alternatives or pilots that could be optionally used to satisfy the MU component of the composite score. Radiologists, for example, should be given the option to participate in MU Stage 3 or satisfy an alternative pathway that could be comprised of elements of MU, such as clinical data registry participation, data security/HIPAA checks and updates, and implementing clinical decision support functionality and leveraging advancements in picture archiving technology.
- Participants in these pilots should be allowed some flexibility from full MIPS satisfaction. For a limited amount of time participants in these pilots should have greater flexibility to test and experiment in incorporating social determinants of health in patient or population care, utilize emerging technologies in innovative ways, participate in other larger pilots, or evaluate how initiatives, such as precision medicine, could be incorporated into their workflows. In addition, those looking to move to APMs could pilot alternatives to the MU program that assist in moving to new payment and delivery models.

- Reimbursement for pilot participants may need to be based on previous performance in their existing payment models. However, CMS or a medical society could collect and analyze “lessons learned” and route findings back to others, including physicians, medical societies, researchers, private payers, or institutions. This feedback loop could help inform other APM proposals or MU use cases design going forward.
- CMS could also implement additional health IT-enabled activities outside the scope of the current MU requirements such as imaging data-sharing, structured reporting, enabling electronic orders, etc. ONC, in collaboration with health IT vendors and standards bodies, could establish pilot or optional health IT certification criteria for IT functionality that supports these alternative actions.
- Given the need for flexibility these criteria should be based primarily on outcomes, rather than specific standards or processes. Appropriate safeguards would need to be in place to so that innovative approaches and emerging technologies could be tested in production environments using clinical data. A learning environment should be established where piloted health IT lessons could be shared among stakeholders. CMS and ONC would need to work closely with the national specialty societies to appropriately plan and implement these alternative pathways.

Methods for Credit in Meaningful Use

- A rethinking of MU should move away from the pass-fail approach and allow physicians to meet a mixture of measures, goals, and outcomes based on their patient population and specialty.
- MU performance should be based on a variety of goal and use case metrics. MU should have little to do with measuring the number of steps or processes involved.
- Factors that could be included in the MU composite score:
 - Methods identifying functional interoperability, including a physician’s level of satisfaction with their health IT product, should contribute positively to the score.
 - Methods for MU scoring should not be limited to just one-on-one direct patient care. MU has the potential to be a step in care transformation, and therefore should also count steps physicians take to improve the care and wellness of their patient population.
 - Workflow evaluations based on data captured in health IT could be one method for receiving MU credit. The use of data to improve a medical practice—and therefore better support the care team—could also be used as credit for meeting MU.
- MU must also accommodate varying situations. Meeting a certain percentage of a measure, possibly based on a combination of metrics and goal achievement, should be an option for physicians to get credit for the percentage they were able to complete.
- **We highly encourage CMS to move to our suggested Stage 3 redesign though the incorporation of use case and pilots, however, if CMS continues to maintain the current Stage 3 structure of threshold measurement the following must occur.**

- Stage 3 objectives should score in an accumulative fashion toward the 25 percent of the MU category in MIPS. In other words, if a physician fails to satisfy an individual measure or use case, and does not meet the prerequisites of any available exclusion(s) from the failed measure, that physician should only lose a smaller, proportional percentage.
- There should, however, be an opportunity for physicians to use high performance in some areas as one method for accommodating less than optimal performance in others. Many aspects of patient wellness are outside the hands of physicians.
- The AMA is, however, against a tiered approach based on performance of other physicians. Using a performance-based/tiered methodology for the MU component of the composite score would unfairly penalize certain participants based on circumstances largely outside their control—such as subspecialty/scope of practice, location/setting, HIE network availability, business environment/competition, and patient population, among others.

Moreover, many MU participants satisfy the requirements of the program, in part, through meeting the prerequisites of available exclusions from certain measures rather than satisfying the measures themselves. The exclusions exist to allow MU's single list of participation requirements to account for scope of practice differences and other variations. Exclusions should qualify as fully meeting the measure and not result in a lower score for the MU component.

Interoperability

- While some benefits have been gained through the use of EHRs, the lack of on-demand access to pertinent medical information still drives duplicative testing and forces both patients and physicians to routinely reenter data.
- Medical information continues to be siloed in large repositories. Excessive costs and proprietary technology limits the flow of medical information. While many document-centric exchanges based on C-CDAs and other standards occur, the incorporation and use of this data is not consistently applied across EHRs.
- Without a firm commitment to eliminate barriers in data exchange by health IT vendors and more targeted federal interoperability policy, momentum around interoperability will stall and patients and physicians will continue to be left shouldering the burden.
- CMS must first resolve basic cornerstones necessary for data exchange such as: patient matching; provider directories; standardized vocabularies; and improved privacy and security. These cornerstones are fundamental aspects to interoperability and are keys to successful MIPS and APM programs. CMS and ONC do not need to be directly responsible for the development of technology or governance for these cornerstones; however, the agencies should actively monitor and coordinate the work being done by other stakeholders.
- Concurrently, work must be done to resolve well-documented issues with certain tasks, such as sharing summaries of care, before physicians are held accountable for these actions. The current method of exchanging static documents between physicians is not ideal; however, EHRs built to

facilitate document-centric exchange are already in place. Moving to functional interoperability is a goal, but health IT vendors must work with their customers today to optimize technology already in production environments. CMS also must take into consideration the time and resources necessary for this to happen.

- Issues with interoperability extend beyond EHR-to-EHR data exchange. Registries are playing a key role in the development of new medical knowledge and can serve as a core component in the creation of advanced clinical quality measures. CMS should acknowledge physicians participating in registry reporting and deem their participation as satisfying any MU quality measurements.
- Data standards required by CMS for PQRS participation are not well-synchronized with other data exchange standards. Implementation guidance and testing tools provided by CMS must be consistent with other tools and products health IT vendors need to develop their systems. The ONC, CMS, the National Institute of Standards and Technology (NIST), and other standards organizations should work together in close collaboration to ensure guidance and tools are robust, functional, and do not add undue complexity and cost to system design. The AMA has provided further comments in the data quality section of this document.

Certification

- The AMA appreciates some aspects of ONC's updated certification program, including conformance testing and health IT vendor transparency. We are, however, concerned that providing CMS or other agencies with the authority to establish health IT requirements without fully understanding the complexities, costs, requirements on vendors, burden on physicians, capability of technology, design timelines, and safety and security concerns, may hinder program goals and create unattainable reporting requirements for many program participants.
- We are also concerned that ONC has not sufficiently reengineered its testing requirements and improved oversight of certification bodies and testing laboratories. The AMA and 36 other medical societies previously submitted a sign on letter in January 2015 asking ONC to reevaluate its health IT certification program and focus testing on health IT product performance, usability, interoperability, and safety.
- While ONC has taken some small steps in this direction, our concerns are still relevant. Since CMS now establishes what constitutes CEHRT, we are very concerned that physicians will once again be required to purchase EHRs that were tested for MU compliance and not product interoperability performance. We feel this will negatively affect a physician's ability to perform in MIPS, and to a greater extent, they may lack the tools necessary to advance to an APM.
- We understand that ONC seeks to set a low-bar in its certification program that encourages vendors to go above and beyond; however, many health IT vendors create products that only "teach to the test" when attempting to pass certification.
- CMS should work closely with ONC when establishing requirements for health IT. In this vein, ONC should also explore ways to reduce unnecessary criteria through possible deeming and to shed

costly and time-consuming aspects of the current certification program. This will free up resources and allow ONC to refocus on functionality and interoperability testing.

- As many certification criteria are designed specifically for MU Stage 3, CMS can play a major role in reducing the complexity in health IT certification. By restructuring Stage 3 to disregard prescriptive measures and threshold calculations health IT vendors will have more freedom to innovate around functional outcomes and interoperability.
- A restructuring of Stage 3 would therefore provide ONC more flexibility to transition certification from a process-oriented approach to a program focused on interoperability testing. This would also allow ONC to further promote increased transparency around the function capabilities of certified products.

Hardship Exceptions

- There should be significant flexibility in the type of hardship exceptions that are offered for Meaningful Use. Many physicians face unique situations that may not fall into an established hardship exception category, but cause the provider to be unable to meet MU requirements.
- Physicians should not be punished or penalized for taking a hardship exception. If a physician chooses to file a hardship exception, they should not be penalized in the MU performance category and should have options on how to reweight the other MIPS categories.
- Many physicians are forced to take a hardship exemption through no fault of their own (e.g., EHR vendor delays, inaccurate information, faulty software, etc.) These physicians should not be penalized for the inability of their EHR software to complete MU, and therefore, affect their MIPS composite score.
- Hardship exceptions should not be capped at five years since many practices simply cannot participate due to their specialty or patient population.

Measure Concerns

The AMA strongly encourages CMS to redesign MU under the use case and pilot framework we have proposed. If CMS chooses to stay with the current Stage 3 objectives and measurement threshold structure, CMS must address the following concerns:

- CMS should work with specialty societies and other stakeholders to reduce the required thresholds to more reasonable levels and develop measures that are appropriate and meaningful.
 - The relevance to all specialties and the conditions they treat;
 - The cost-benefit analysis, including the cost of lost productivity; and
 - Whether actions are controlled by the physician and not by patients, technology, or other factors over which providers have little influence.

- Measure example: That 10 percent of all patients view, download, or transmit their health information or access their information through an API, or a combination of the two. CMS addressed this in the MU Modifications rule – and lowered the initial 5 percent requirement – but now has increased it, making it even more difficult to meet. It is counterintuitive for CMS to revert back to an increased threshold for this measure.
- Another measure example: That in more than 50 percent of transitions of care and referrals, the EP creates a summary of care and electronically exchanges the summary of care record. Many EPs are located in areas where the doctors they refer patients to and receive patients from do not have EHRs. Therefore, it is impossible for EPs in these areas to meet this measure, and they should not be penalized for the inaction of others in their area to adopt EHRs.
- Furthermore, any objective new to MU (not currently in MU Modifications) should, at least for the initial reporting period, not be tied to any thresholds. The objective should only be enabled and provide time for both physicians and patients to maximize the measure's utility without being burdened by measurement.
- CMS should allow physicians to select a six-month minimum reporting period at least during early years/transition.
- **Overall, providers who are attempting to attest to Meaningful Use should not be penalized for actions they cannot control. CMS should ensure that each measure required for Meaningful Use is one that providers are able to attest to without relying on the actions of other individuals (patients, technology, or other providers).**

7. Other Measures

- 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 the 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 option for certain specialties, particularly those that practice largely within a facility. However, the use of other system measures should not be mandatory.
- CMS should also allow for the optional attribution of the facility-based score to EPs who practice in or are employed by that facility, and compare it to the national average for similar facilities as the benchmark.
- The 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 setting. The costs and resources for treating these patients are different and often higher. In addition, the quality measures are often inappropriate and do not match the patient population they serve.

- We acknowledge there must be a certain minimum percentage of services performed at the “facility,” but there is not enough information in the RFI to provide a recommendation on an exact number. Therefore, CMS should perform some internal analytics to determine the typical practice patterns of facility-based specialties before proposing a recommended number, and then provide an opportunity for stakeholder comments. As part of the analytics, CMS should also consider situations where physicians practice in multiple facilities.
- We recommend that CMS allow non-patient facing EPs the option of completing the standard requirements of the MIPS performance categories or completing alternative pathways for any of the four categories that offer alternative measures.
- If CMS will not consider *optional* alternative pathways, we recommend that CMS weight the CPI category higher for non-patient facing and facility-based physicians, to allow for a broader scope of activities that realistically reflect their actual practice patterns and patient populations.

8. Development of Performance Standards

The comments that follow offer some brief and preliminary thoughts that our group plans to refine in the future.

- The RFI appears to take for granted that CMS will continue to base payment adjustments upon a performance period that occurred two years earlier. This forces the agency to truncate development of policies and hinders timely modifications in the program. It also means that physicians have little or no idea of what Medicare is judging them on. We strongly urge CMS to make every effort to reduce the gap between the performance period and the payment year.
- Physicians and groups need to know who they are being compared to, what their thresholds are, and what precisely they are working toward. We urge CMS to prioritize outreach and education to empower providers and groups to operate with clarity in MIPS.
- Performance standards should not change periodically, as CMS suggests in the RFI. Rather, the standards for one performance year should remain the standards throughout the entire performance year.

Historical Performance Standards:

- Although the law requires CMS to “*consider*” historical performance standards, it stops short of requiring the agency to “*use*” historical standards. Given the imperfect and still changing nature of the current incentive programs, it is preferable to use some future year as the basis for determining historical performance.
- In the interim, CMS should consult with medical organizations to identify potential sources of data, including QCDRs, for historical performance standards.

- Since a very large percentage of physicians will have VM scores that are not based on actual data and many others will have scores that bear little relevance to their own performance, the VM would be an ill-conceived foundation of performance under MIPS.
- The development of standards that differ according to size and other practice features seems worthy of investigation and could be better evaluated through an analysis of QRUR and VM data.
- In addition, CMS should refine the VM specialty mix adjustments to ensure that performance comparisons are applied to groups of similar characteristics. These calculations should be very clear and highly transparent, so that physicians can understand them and be successful in MIPS.
- Based upon the legislative language describing the new CPI category, we do not believe that Congress intended for CMS to somehow measure whether or not a particular activity “improved” care. The logistics of measuring how many patients took advantage of after-hours care, e-mailed a doctor, or utilized other services visualized in the law, are mind-boggling.

Defining and Incorporating Improvement

- The MIPS is not designed to be a tournament-style program, as 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 development so that groups and providers know exactly who their peers are and what their goals will be.
- Improvement should be defined as year over year improvement. However, CMS should not introduce methodologies that are untested, at least without significant outreach to and input from the medical community, to ensure physicians understand and trust what they are being scored on.
- In the Hospital Value-Based Purchasing program, participants can win points for improvement as compared to the baseline, and additional points for achievement as compared to performance from the prior year. We question how this could work in the physician world where thousands of group practices operate in a fluid environment of recruitment, acquisition, expansion, and reduction. If a particular group improves one year but the payment adjustment is applied two years later, the providers or groups responsible for positive results may no longer be part of the group and may never see any reward for their achievements. Conversely, those who achieved success somewhere else and then moved to a group with low performance two years earlier will be penalized instead of rewarded for their efforts.
- We caution CMS against using a composite measure of improvement. Success in one category does not mean success in another. Likewise, failure in one category does not indicate failure in another category.

9. Flexibility in Weighting Performance Categories

- There clearly are situations where certain EPs could not be assessed at all for purposes of a particular performance category. For example, if there are no measures specific to the conditions that a particular specialty treats and the type of care they provide, then physicians in this specialty would

need flexibility regarding their quality component score. Quality activity needs to be meaningful and related to the actual services a physician personally delivers. General primary care measures should not be viewed as fulfilling the need for specialty-based measures.

- Also, hospital-based specialists, who weren't eligible for incentives related to the Meaningful Use of EHRs, should not be held accountable for that activity.
- To account for the percentage weight that would have been applicable to the quality where performance measures are lacking, CMS should work with affected medical societies to determine how the percentage weight should be re-distributed and whether CPI activities could have their weight increased to make up for the lack of quality measures.
- To identify the types of practitioners where insufficient measures justify flexibility in the weighting, CMS could establish a process for pre-review whereby each practitioner could submit the measures and activities they believe are available to them. CMS would then give them a "pre-determination" regarding whether these would be sufficient for the given years' MIPS index. In the event that CMS found that the EP had not submitted all the existing activities available, CMS would provide them with a report as part of this pre-determination process.
- As part of this pre-determination process, CMS would use the difference between the percentage of activities available to a practitioner versus 100 percent, to re-weight the other categories.
- CMS should also set up an appeals and communication process with EPs after they receive their quarterly feedback forms to ensure their progress towards 100 percent.
- Reweighting determinations should be based on specialty or sub-specialty rather than applied at the measure or activity level. The ability to be successful should be determined based on the measures and activities that are available for each EP in that given specialty or sub-specialty.
- As has been demonstrated in the Value-based Modifier program, the appropriate threshold will vary depending on the measure involved. There is no single threshold that is applicable for all measures within a category. CMS should keep in mind that measures developed for hospitals often require the use of minimum thresholds that make them inappropriate for use with most physician practices.

10. MIPS Composite Performance Score and Performance Threshold

- Additional detail and analysis are needed in order to answer the questions in this section. We look forward to providing further input going forward.

11. Public Reporting

Minimum Threshold

- The MIPS is essentially an opportunity to press the reset button and to learn from mistakes made in the past, including rushed and sometimes imprudent implementation of certain policies. We would suggest that CMS first work on carefully designing the MIPS system; accrue a minimum foundation

of data using the new system (e.g., at least 2 years of data); confidentially share that data with practicing physicians via clear, easy to understand feedback reports; and simultaneously conduct research into what information and reporting formats are most valuable to consumers and physicians. Only after this work is complete should CMS transition to the public reporting of physician performance data.

- Similar to current programs, such as the Physician Quality Reporting System (PQRS), the early years of the MIPS could include the public reporting of data which indicates whether an EP satisfied the reporting requirements for the multiple components of MIPS. But we believe that attempting to accurately calculate and showcase performance data for public consumption is an unrealistic goal for the initial years of this new program. There are currently too many unresolved problems related to risk adjustment, attribution, appropriate sample sizes, and even the ongoing lack of relevant measures for certain specialties. In addition, CMS currently lacks the ability to provide timely, accurate, and actionable feedback to physicians for any type of benchmarking or public display of information, which directly conflicts with CMS' contention that public reporting leads to quality improvement at the individual physician or group-level. Providing physicians and groups with feedback 6 months after the close of the reporting period and well into the next reporting cycle does not allow any physician or practice to make actionable improvement. Therefore, the public reporting of performance data, in many instances, would be premature.
- When making decisions about whether a measure is ready for public reporting, CMS should continue to adhere to its current policy of selecting only those measures which prove to be valid, reliable, and accurate upon analysis; are deemed statistically comparable; meet a minimum sample size of patients; are not first-year measures; and have proven, through concept testing, to be of value to consumers.
- With regard to appropriate minimum patient thresholds, CMS should keep in mind that these thresholds may vary across measures and even across specialties. It is perhaps better to focus on ensuring that a specific reliability score is obtained, such as 0.70, 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 measure is focused on an outcome or process. Because of the large number of medical specialties, patient populations, and mix of measures, selecting one minimum number of patients for everyone is not optimal. There is increased potential for CMS to incorrectly categorize and potentially penalize physician performance when the issue is due to a lack of reliability in the data, and not true variations in care.
- The process of determining whether measures are ready for public reporting should occur in as transparent of a manner as possible and should rely heavily on relevant clinical expert input. The current process is opaque as there is no opportunity to comment on the Physician Compare Technical Expert Panel recommendations.
- We also caution against using raw file downloadable databases to present data to the public that is not quite ready for posting on physician profile pages. We are concerned that such data could be misleading, misinterpreted, or misused by the public. We recommend that CMS first make the data

available, confidentially, to professional societies for internal analysis. Professional societies have significant expertise in identifying shortcomings with measure calculations and data, and can develop tools and resources to assist physicians with performance improvement.

Stratification of Data

- All patients deserve equal access to high quality care, and stratifying data might help to identify and reduce disparities in care. Nevertheless, CMS first needs to address more foundational challenges related to public reporting (e.g., appropriate sample sizes, accurate attribution, and meaningful formats). Attempting to stratify data before these foundational issues are addressed would only further complicate the endeavor and produce potentially inaccurate, more confusing, and less actionable data for physicians and the public.
- Targeting health disparities at the individual physician level may not be practical due to small sample sizes and other methodological issues that might result in misleading and confusing information for the public. Targeting disparities is a larger system goal that might need to be addressed with systems-level measures, not measures that are reported at the level of the individual practitioner.

12. Feedback Reports

- CMS must provide ongoing, real-time feedback on performance and should consult stakeholder groups continuously to determine the best presentation and most meaningful format for sharing ongoing, actionable performance feedback information with physicians and practices.
- As technology is constantly changing, it will be critical for CMS to take an ongoing approach to improving the way performance information is disseminated to physicians and practices. Stakeholders must be included in this process so that feedback can be provided in a format that works best for physicians and is meaningful to their practice's ongoing improvement activities.
- CMS must be forthcoming in any feedback reports in regard to the methodologies used to comprise any benchmarks or attribute patients for a particular measure. This information must be clearly identified and easy to interpret.
- Current feedback reports lack key details to understanding the methodologies used to arrive at the benchmarks and other calculations made. This creates frustration and distrust, and must be avoided going forward. A successful payer-provider relationship stems from mutual trust and understanding between both parties involved.
- Where appropriate, CMS should aim to display feedback and performance measurement information in graphic form with additional details displayed elsewhere.
- Detailed information should be provided in feedback reports, including the ability to see high-level, overall performance information, as well as drill down tables with individual patient information. CMS must continually consult with stakeholders to ensure displayed data is relevant and meaningful, and understood by the intended audience.

- Web-based reports as well as dashboards and paper reports should be made available.
- Feedback reports should be accessible to physicians, practice administrators, and related officials. The log-in process for accessing reports must be simple and user-friendly. There have been ongoing problems with accessing reports due to the overly complicated log-in process and cumbersome password requirements which reset at very short intervals, complicating the log-in process and ultimately limiting access to these reports. CMS should make staff available to help physicians and administrators interpret the reports.
- CMS must provide a fair and transparent process for providers to appeal findings in feedback reports, and should lengthen the appeals process to at least 90 days.

B. ALTERNATIVE PAYMENT MODELS (APMs)

Physician-Focused Payment Models

The RFI contains a section on “physician-focused” payment models (PFPMs) separate from the questions pertaining to APMs. The priority issue identified in the RFI extension announcement is what criteria should be used by the Physician-focused Payment Model Technical Advisory Committee (PTAC) for assessing proposals submitted by stakeholders.

- The RFI notes that PFPMs proposed to the PTAC and recommended to HHS need not meet the same criteria that MACRA establishes for APMs, but CMS encourages proposals that will allow physicians to earn incentive payments available to participants in qualified APMs. The physician community strongly agrees with this view.
- **It is critical that the MACRA regulations establish a clear pathway for physician-focused payment models, particularly those that are proposed to the PTAC and recommended by the PTAC to HHS, to be implemented by CMS as qualified APMs.**
- In presentation materials for its webinars on MACRA implementation, CMS has stated that it has no obligation to test models that are recommended by the PTAC. We strongly disagree with this extremely narrow perspective. For MACRA to succeed in reforming the delivery of care and improving value for patients and the Medicare Trust Funds, CMS must be willing to give serious consideration to proposed PFPMs that come through the PTAC and support their implementation.
- In presentation materials for the Health Care Payment Learning and Action Network, CMS indicates that the incentive payments for physicians participating in qualified APMs will only be made to “those in the most highly advanced APMs.” This statement, and accompanying graphics that depict only a small percentage of APM participants receiving MACRA’s lump sum bonus payments, represent a serious misrepresentation of the MACRA statute and the intent of Congress. The MACRA provides two pathways for physicians to choose: MIPS or alternative payment models. It does not say anything about advanced payment models, nor does it restrict incentive payment to physicians in “the most highly advanced APMs.”

- As long as they meet the three statutory criteria, physicians participating in all Medicare Shared Savings Program accountable care organizations (ACOs) should be able to qualify for APM incentive payments under the regulations implementing MACRA, as should those participating in all models implemented under Section 1115A (except for the Health Care Innovation Challenge Awards that are excluded by the law).
- Within the MACRA law, establishment of the PTAC is under the title, “Promoting Alternative Payment Models.” The PTAC subsection’s purpose is stated as “increasing transparency of physician-focused payment models.” This legislative language makes it clear that Congress intended for PFPMs to provide an alternative, more transparent avenue for the development of qualified APMs than the existing CMS process. It did not intend for PTAC-recommended models to receive comments from CMS and never be implemented.
- The forthcoming regulations should establish an easy pathway for PFPMs to be adopted as qualified APMs. CMS should outline clear criteria that will be used to evaluate PFPM proposals. CMS and the PTAC should work collaboratively with medical societies and others developing proposals, provide feedback on drafts, and provide data up-front to help in modeling impacts.
- The regulations also should make it clear that PFPMs that are recommended by the PTAC will be accepted by CMS. Although it is reasonable to have a subsequent application phase to work out the implementation details, stakeholders should not have to go through a separate proposal process to first have their proposed PFPMs adopted by the PTAC, and then to have them accepted by CMS. HHS needs to organize a reasonable process that will allow it to get good ideas for PFPMs from specialty societies and other organizations, ensure that they meet criteria that are known up-front to those preparing proposals, and then provide pathways for implementation that will allow participating physicians to earn MACRA incentive payments.
- Implementation pathways should not be limited to small tests in a few communities nor should they be subject to lengthy testing requirements prior to implementation. The APM incentive payments available under MACRA are for services furnished through an eligible APM entity during a six-year period only: 2019 through 2024. Physicians in all specialties and all geographic areas should have a meaningful opportunity to choose the APM pathway by having PFPMs available to them. In transmitting PTAC recommendations to CMS, HHS should direct CMS in how to implement recommended PFPMs. There needs to be a process in place for PTAC recommendations to be implemented quickly so that PFPMs are available to physicians in an expeditious manner, with sufficient time for physicians to adopt and participate in such models within the short window of 2019 through 2024.
- The AMA recommends that CMS commit to review PFPM proposals and either approve or reject them within 90 days. If a proposal is rejected, CMS should provide a detailed explanation of the reasons for rejection and recommendations for the types of revisions which could be made that would enable it to be approved. If a rejected proposal is resubmitted with revisions that address the reasons for previous rejection, CMS should re-review it and approve it, or reject it with specific recommendations for the improvements needed to obtain approval, within 30 days.

- Any physician practice in any part of the country that feels it can successfully implement an approved APM should be permitted to do so. Applications for physicians to participate in an approved APM should be made available within 90 days of the APM's approval by CMS, and physicians should be able to apply to participate in approved APMs at least twice per year. APM participation applications should be reviewed and approved or rejected within 60 days; if an application is rejected, CMS should indicate the reasons for rejection and methods of correction.
- PFPMs should support innovative approaches that give physicians the flexibility to deliver high-value services that the existing payment system does not support. They should also ensure that the PFPM does not have so many administrative requirements that additional payments are all spent on administrative costs rather than helping patients.
- National medical specialty societies have been working to develop PFPM proposals that would qualify as APMs under MACRA. There is enthusiasm for APMs in the physician community since the passage of MACRA and many specialties are forming committees and holding workshops to figure out the best way forward. As these comments underscore, the specialties' biggest concern is whether CMS will implement the payment models they develop.
- In developing criteria for assessing PFPMs, MACRA specifically directs the establishment of criteria for PFPMs for specialist physicians. Today, specialists have very few models available beyond the existing system so models for specialists should be an important focus of MACRA implementation efforts.

Seven Physician-Focused Payment Model Designs

- There are many high-value physician services that would benefit patients and help reduce avoidable spending, but the current system generally does not provide payment for them:
 - Responding to a patient's phone call about a symptom or problem, even though that could help the patient avoid the need for far more expensive services, such as an emergency department visit;
 - Communications between primary care physicians and other specialists to coordinate care, even though that can avoid ordering duplicate tests and prescribing conflicting medications;
 - Communications between community physicians and emergency physicians, and short-term treatment and discharge planning in emergency departments, even though that could enable patients to be safely discharged without admission;
 - Time spent by a physician serving as the leader of a multi-physician care team for patients with complex conditions;
 - Providing proactive telephone outreach to high-risk patients to ensure they get preventive care, even though that could prevent serious health problems or identify them at earlier stages when they can be treated more successfully;
 - Spending time in a shared decision-making process with patients and family members when there are multiple treatment options, even though that has been shown to reduce the frequency of invasive procedures and the use of low-value treatments;

- Hiring nurses and other staff to provide education and self-management support to patients and family members, even though that could help them manage their health problems more effectively and avoid hospitalizations for exacerbations;
 - Providing palliative care for patients in conjunction with treatment, even though that can improve quality of life for patients and reduce the use of expensive treatments; and
 - Providing auxiliary services (such as transportation) to help patients access physicians, even if it would avoid having them taken by ambulance to an emergency department.
- To be successful, APMs need to fix these problems. A well-designed APM will pay adequately for high-value services and avoid financially penalizing physicians when they reduce avoidable services and prevent complications. Physicians need the flexibility to use payments in different ways than they can under the current system in order to improve care and reduce overall spending.
 - APMs do not need to be rocket science with complex rules. Some specialties are designing new models that simply pay physicians for specific high-value services in return for a commitment from the physicians to manage specific types of avoidable spending such as hospital admissions.
 - In developing proposed rules and criteria for PFPs, CMS should take a similar approach. Proposals should describe the opportunity to improve patient care, barriers to implementing those improvements under the current payment system, and how the proposed model would overcome these barriers allow physicians to improve care for the condition or episode.
 - With regard to the APM criteria in MACRA, CMS should ask what costs the model participants are likely to incur in order to participate in the model, what savings the model is likely to achieve for Medicare, what accountability measures should be used to judge whether the model is meeting its targets for costs savings and care quality, and how to hold participants accountable for these measures. For example, monthly payments to model participants could be adjusted up or down depending on performance on the measures, or participants could be prevented from continuing in the model.
 - No single APM will work for all physicians or their patients. Different medical specialties treat different kinds of health problems, and the opportunities to improve quality and reduce costs differ for the different types of health problems addressed by physicians within each specialty and subspecialty. Moreover, the care delivery changes that are needed to address these opportunities also differ by specialty, as do the barriers in the current payment system that need to be overcome for physicians to redesign care delivery for their patients.
 - This means there will need to be multiple types of APMs in order for physicians in all specialties to participate and for all patients to benefit. A good APM will overcome the specific payment system barriers a physician practice faces in pursuing the specific kinds of improvement opportunities available for the conditions the physicians in that practice treat.
 - There is no need for complex and expensive changes in payment structures if simple changes will address the barriers. If paying for a new service code could enable a physician to deliver significantly better care while reducing avoidable costs, there is no need to force the practice to find ways to manage a complex bundled payment. On the other hand, if much more extensive changes in

care delivery are needed that involve multiple providers, an entirely new type of bundled payment may be needed to provide sufficient flexibility and accountability to support those changes in care, and a practice may need to work collaboratively with other physician practices and other types of providers to manage that payment in order to deliver the improved care.

- Seven different types of APMs are described in the following section that can be used to address the most common types of opportunities and barriers. All of them could allow the participating physicians to qualify for MACRA APM incentive payments. Additional information about these APMs, as well as examples of conditions or episodes that are appropriate for each APM, is available in the report, “[A Guide to Physician-Focused Alternative Payment Models](#),” developed by the AMA and the Center for Healthcare Quality & Payment Reform, available at www.ama-assn.org/go/apm.
 1. Payment for a High-Value Service: A physician practice would be paid for delivering one or more high-value services that are not currently billable, and the practice would take accountability for controlling the use of other, avoidable services for their patients. In addition to billing for current Medicare Fee Schedule (MFS) services, physicians could also be paid for specific services that are not currently eligible for MFS payment. One or more other services would also be identified that the physician agrees can be avoided or managed with use of the newly-payable service(s). The practice’s rate of avoidable utilization would be compared to a target level. If the practice’s rate of avoidable utilization and quality is close to the target, the physician receives the standard payment amount for the new code, but if it is significantly lower or higher, the payment rate for the service(s) would be increased or decreased.
 2. Condition-Based Payment for Physician Services: A physician practice would have the flexibility to use the diagnostic or treatment options that address a patient’s condition most efficiently and effectively without concern that using lower-cost options would damage the practice’s operating margin. The physician could be paid for treating or managing the care of patients with a specific health condition, rather than having payment tied to the delivery of specific services or treatments. The APM would provide flexibility to support both services that are currently billable as well as high-value services that are not currently billable. For patients with the relevant health condition that is covered by the APM, the physician would no longer bill for individual services that are related to management of the condition. Quality of care for the condition would be measured and compared to benchmarks, and condition-based payment amounts would be reduced if quality measures were significantly below benchmark levels.
 3. Multi-Physician Bundled Payment: Two or more physician practices that are providing complementary diagnostic or treatment services to a patient would have the flexibility to redesign those services in ways that would enable high-quality care to be delivered as efficiently as possible. A single payment would cover the services delivered by two or more physicians to diagnose a patient’s condition or deliver a specific treatment for a diagnosed health problem. The physicians would have the flexibility to use the bundled payment for services that are not currently eligible for payment as well as for services which are currently separately payable, and they could also divide the payment differently than what they would receive under the current system. In order to receive the benefits of the more coordinated and flexible care, the patient would need to agree to use only the physicians on the team for all services covered by the bundled payment. The participating practices would designate an organizational entity to receive

the bundled payment, which would meet the MACRA requirement for an “Alternative Payment Entity.” The practices could agree to take accountability for reducing avoidable utilization and costs of certain services by, for example, reducing a type of complication associated with the condition. The bundled payment amount would be reduced if the avoidable utilization was not reduced, or if the physicians did not meet alternative measures of quality, outcomes, or appropriate use.

4. Physician-Facility Procedure Bundle: A physician who delivers a procedure at a hospital or other facility would have the flexibility to choose the most appropriate facility for the treatment and to work with the facility to deliver the procedure in the most efficient and high-quality way. This APM is similar to the multi-physician bundled payment, except it bundles the payment for the facility in addition to the physician services. Since many treatments can be delivered in various sites (e.g., hospital inpatient or outpatient, ambulatory surgery center, physician office), the bundle could either be “facility-independent,” such that the payment would be the same regardless of the site of service, or “facility-specific,” with the payment amount differing depending on the site of service.
5. Warranted Payment for Physician Services: A physician would have the flexibility and accountability to deliver care with as few complications as possible. This APM differs from the previous APMs by using a single bundled payment to cover the costs of unplanned physician services to treat complications in addition to the costs of services that are planned as part of a patient’s treatment. The physician practice would receive a higher payment than they would under the current system for delivering the same type of service without a warranty. The practice would be responsible both for delivering the initial service and any additional physician services needed to treat complications included in the warranty. Services to treat the complications would no longer be separately billable.
6. Episode Payment for a Procedure: A physician who is delivering a particular procedure would be able to work collaboratively with the other providers delivering services related to the procedure (e.g., the facility where the procedure is performed, other physicians who are involved in the procedure, physicians and facilities who are involved in the patient’s recovery or in treating complications of the procedure, etc.) in order to improve outcomes and control the total spending associated with the procedure.
7. Condition-Based Payment: A physician practice would have the flexibility to use the diagnosis or treatment options that address a particular health condition (or combination of conditions) most efficiently and effectively and to work collaboratively with other providers that deliver services for the patient’s condition in order to improve outcomes and control the total spending associated with care for the condition.

Nominal Financial Risk

CMS has also assigned priority to the issue of financial risk. It asks what types of “financial risk” should be considered for an eligible APM entity, and what is the appropriate level of financial risk “in excess of a nominal amount” to be considered an eligible APM entity.

- To date, CMS has typically measured the financial risk associated with an APM using one yardstick: the total cost of care for a patient population. Currently, an ACO or other APM that does not have to pay CMS if its patients' total costs of care exceed a CMS-developed financial benchmark is considered by the agency to be upside only and is not recognized as being accountable for financial risk.
- There are many financial risks that can be more than nominal that this typical CMS approach overlooks, however, including: start-up costs to get the APM off the ground such as data analysis and establishing procedures for coordinating care and sharing information; ongoing costs for new employees such as care managers; and foregone revenue from billable services that are reduced under an APM due to use of appropriateness guidelines and efforts to reduce exacerbations of patients' conditions requiring emergency department visits and hospitalizations. The practice 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.
- An APM could be viewed as a product line being provided by a physician practice or other organization. The practice or APM Entity will incur costs associated with the product line and receive revenues from it. The financial risk to the practice or APM Entity is that the revenue from the APM may not cover the costs of participating in it. An APM that involves physicians taking the time to jointly develop treatment plans, reducing complications, improving the appropriateness of test ordering, hiring care managers, and participating in a clinical data registry may experience reduced MFS revenues because they are providing high-value services which are not payable under the MFS and providing fewer or less expensive billable services.
- The financial risk to the practice is that the payments from the APM will not be enough to cover these reduced MFS revenues. The practice could be saving money for Medicare by reducing hospital admissions and expensive tests and procedures, but still be losing money for the practice. The definition of more than nominal financial risk should not be based on the relative gain or loss to the Medicare Trust Fund, but on how much the physician practice or APM Entity gains or loses.
- Under this approach, all Medicare ACOs, including those in Track 1, should qualify as APMs under MACRA. Physicians participating in Medicare ACOs, including Track 1 ACOs, at the threshold levels set by MACRA, should qualify to earn the annual 5 percent incentive payments for APM participation and be exempt from MIPS.
- Physicians will be much more willing to take accountability for costs that they can affect through their own performance, such as the costs of preventable complications, than they are to take on risk for the total cost of care for a large patient population. "More than nominal financial risk" should be defined in a way that allows physicians to take accountability for the services they can truly influence instead of requiring physicians to take responsibility for total Medicare spending on every health problem and service their patients get. Also, it is important that CMS allow sufficient time to achieve savings goals and not expect them to be reached in year one.
- An additional issue, besides what types of costs count as financial risk, is what level of financial risk should be considered more than nominal. As a benchmark for what could be considered "more than

nominal,” the AMA recommends that physicians choosing the qualified APM pathway be required to accept no more risk than they would face if they instead had chosen the MIPS pathway. The maximum penalty a physician faces in 2019 from MIPS participation is 4 percent; therefore, an APM that involves financial risk to the participating physicians’ equivalent to 4 percent of their Medicare payments for professional services should meet the requirement for more than nominal financial risk.

- For nearly 20 years, CMS [regulations](#) have defined “substantial financial risk” for physician’s participating in a Medicare Advantage plan as 25 percent of a physician’s revenue from patient care. If 25 percent represents “substantial” financial risk, then “nominal” financial risk should be a far lower percentage. CMS discourages Medicare managed care plans from placing physicians at substantial financial risk so it certainly should not ask APMs to do so.

Payment Incentive for APM Participation

A priority question that CMS asks in the original RFI and the extension announcement is how it should define “services furnished under this part through an EAPM entity.”

- In most cases, it seems likely that payments under an APM will be made to an entity rather than directly to an eligible physician. For example, Medicare ACO shared savings payments are paid to the ACO, not to the individual physicians or group practices participating in the ACO. Medicare ACOs should be recognized as eligible APM Entities.
- In order to ensure that the physicians participating in the APM are able to influence the governance policies of the APM Entity, CMS should require such entities to provide for meaningful participation in governance by physicians whether or not the APM Entity is a physician-owned organization. APM Entities could include physician practices, independent practice associations, physician-hospital organizations and other organizations. If the organization is a hospital or other entity that is not physician-owned, then it should be required to provide a means for physicians to influence the governing policies of the organization, such as through significant practicing physician representation on the governing board.
- It is important for CMS to allow flexibility for proposed APMs to outline different organizational structures to serve as APM Entities and different pathways by which revenues might flow through the APM Entity. CMS should not require all APM Entities to be organized the same way, nor should it require every physician participating in an APM to obtain a new APM identification number. There could be different tiers depending on the number of different physicians and organizations involved and the extent to which participation in the APM is consistent with existing organizational structures. In some cases an APM may involve a medical practice, and in others it may include multiple practices, a hospital or home health agency, and other facilities or providers. Different APM designs will require different types of APM Entities.
- A key issue for APM Entities will be determining the methods for establishing that physicians participating in an APM have or have not met the MACRA participation thresholds to qualify for the lump sum incentive payments. These methodologies should be left to the discretion of the APM Entities, but they should be required to describe the method they will use when they submit an APM proposal or an application to participate in an APM. For example, an APM that involves revenues

for physician and professional services only will likely use a different method for determining revenue thresholds for the participating physicians than would an APM that involves revenues for hospital and post-acute care services.

- Claims for Medicare physician services are generally submitted by an organization with a taxpayer identification number (TIN) comprising one or more physicians that are separately identified through their National Provider Identifier (NPI). If Medicare makes payments to a TIN for an APM involving multiple physicians, then the APM Entity should be allowed to take responsibility for providing information to CMS on the revenue shares attributable to each APM physician. This approach has several advantages:
 - An APM Entity that is paying participating physicians for high-value services that are either not covered or not separately payable by Medicare's current payment systems can count these services in its calculations of each physician's revenue or patient shares under the APM.
 - An APM Entity can determine the best way to attribute revenue or patient shares to different participating physicians if physicians participating in the APM are not being paid on a fee-for-service basis.
 - If some of the physicians who bill for MFS services through a TIN are APM participants and some are MIPS participants, due to different programs being available for physicians in different specialties, for example, the APM Entity can sort out the reporting requirements for the different programs.
- There is likely to be a great deal of variation in how this issue is approached. For example, emergency physicians are responsible for a small proportion of the overall care that any one patient receives, but, if an emergency medicine practice is participating in one or more APMs, then these physicians should have the ability to meet the MACRA thresholds. In an ACO, there may be many physicians participating and seeing the ACO patients. The APM Entity may wish to determine the average revenue proportion for all members of the medical group that participates in the ACO, or it may develop a method for determining revenue thresholds for each individual physician.
- A fundamental principle of all APMs is that they will advance teamwork among those involved in providing health care to a patient population. The methods that an APM Entity uses to distribute APM revenues to the physicians and other health professionals participating in the APM should foster collaboration among the team, not present a barrier to it. Proposals that are submitted for qualified APMs should explain how revenues will be distributed instead of CMS establishing uniform requirements.

Patient Approach

*A related priority question that CMS asks is what methodologies could be used to attribute and count **patients** in lieu of using **payments** to determine whether a physician has met the threshold to be a qualifying or partial qualifying APM participant.*

- Eligible physicians should not be required to use either the patient or payments approach. They should retain the option to use the patient approach to calculating the share of their Medicare “business” that is attributable to one or more APMs instead of the revenue approach.
- Most physicians manage certain proportions of patients with one of several different conditions. Assuming that episode- and condition-based payment models are approved as qualifying APMs, the models will be applicable to some proportion of the patient population that each physician manages who has the conditions or episodes of care. Reporting the proportion of patients who are being managed within an APM may be a more patient-centered approach than summing up revenues from the services physicians provide. In some cases, it may be simpler to determine what proportion of a physician’s patient population has conditions or episodes covered by APMs than to calculate revenues attributable to APMs. APMs may be designed around higher-cost conditions; however, so some physicians may be more likely to meet the MACRA thresholds using the revenue approach.
- A related issue is what the minimum threshold of involvement in a patient’s care should be in order for an APM physician to include a patient in their count. The attribution method used in the Medicare Shared Savings Program assigns patients to physicians if they have provided at least one primary care service to the patient. Physicians in an APM could be contributing to the patient’s care and the goals of the APM in other ways, however, besides face-to-face visits and procedures for patients. Psychiatrists, neurologists and other specialists could be consulting with primary care physicians on how to manage patients with substance use disorders, depression, Alzheimer’s or diabetes, for example, without seeing the patients themselves. Radiologists and pathologists could help achieve correct diagnoses for patients and emergency physicians could help prevent hospital admissions. Diagnosis, treatment, and management for many patients in the population served by an APM may involve multiple physicians, each of whom could potentially legitimately count the patient as their patient. CMS should require those proposing qualifying APMs to describe how patients would be counted for purposes of establishing whether physicians are qualifying or partially qualifying APM participants.

Calculating the Revenue Threshold

One of the priority questions that CMS asks is what types of data and information physicians can submit to CMS for purposes of determining whether they meet the non-Medicare share of the combination all-payer and Medicare payment threshold set by MACRA.

- CMS currently has a multi-payer APM, the Comprehensive Primary Care Initiative, for which it collects information on the share of each participating physician practice’s revenues that is attributable to each of the non-Medicare payers participating in the model. Similar approaches could be used to collect the needed data for multi-payer APMs under MACRA.
- Some states, such as Wisconsin, have all-payer claims databases that could be used to collect this information. The regional health improvement collaboratives, particularly those that also serve as Medicare Qualified Entities, could also assist in reporting this information. Some clinical data registries also collect information from multiple payers which could be used for this purpose.
- The process for submitting this information should not add administrative burdens to APM participants. Using the data sources above or another source, physicians should be able to attest to

the revenues they receive from non-Medicare payers associated with the APM.

- Proposals that are submitted for multi-payer APMs should be required to state how the physicians participating in these APMs will be able to satisfy the MACRA requirement to meet a combined revenue or patient threshold for Medicare and other payers APM participation.
- A related and fundamental issue that CMS needs to consider is how multi-payer models can be approved as qualified APMs. MACRA does not outline a specific process for models outside of Medicare to be classified as APMs.

Use of Electronic Health Record Technology

CMS has assigned priority to the question of how the agency should define “use” of certified EHR technology (CEHRT) by APM participants.

- The construct and use of CEHRT in APMs should follow a functional outcomes approach, rather than one that is tied to process measures and “counting clicks” to meet thresholds. The “use” of CEHRT should be outlined within the APM proposal. As many proposals for new APMs will be developed by stakeholders, not CMS, the traditional concept of CEHRT must be adjusted to allow the development of specialized health IT modules that support the goals of APMs.
- To date, the intent of CEHRT has been to accommodate the needs of the Meaningful Use (MU) program. Throughout Stage 1 and 2, regulations issued by the Office of the National Coordinator (ONC) established the definition of what constituted CEHRT. While MU is a component of MIPS, its structure is primarily based on process measures and threshold achievement. Current generation EHRs are built on the prescriptive requirements established by ONC to reflect the needs of the MU program.
- ONC’s newly established 2015 Edition certification program removes the direct tie to MU and has established a list of criteria from which health IT products can be built. These criteria still mirror the basic functions of MU; however, ONC no longer establishes the definition of CEHRT—that is now the responsibility of CMS.
- As various specialties could be involved in an APM, it is appropriate to allow some individuals participating in patient care to utilize technology outside certification as long as enough others in the APM utilize CEHRT to meet the needs and goals of the APM. For example, many radiologists and pathologists use advanced medical information technology, not certified by ONC, to support the high-quality care of their patients. These specialties, and others like them, should not be required to purchase additional technology only to participate in an APM.

Quality Measures for MIPS and APMs

An additional question that CMS has asked is what criteria could be used to evaluate “comparability” to MIPS of quality measures used by an eligible APM entity.

- As with use of CEHRT, selection of quality measures for an APM should be based on the goals and design of the APM.

- 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 to use those measures. For example, 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.
- It is important that quality measure reporting for an APM be no more burdensome than under MIPS. It is also important to focus on harmonizing measures so that there are not different ways of measuring the same thing that must be used for MIPS versus APMs and for Medicare versus other payers.
- 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 PQRS measures.

Medicaid Medical Home Models

CMS asks what criteria could be used to determine comparability of state Medicaid medical home models to medical home models expanded by CMS.

- There is much that CMS can learn from patient-centered medical home models in state Medicaid programs that can help shape expansion of the medical home model for Medicare and other payers. The medical home model was initially developed by the American Academy of Pediatrics (AAP) and has been adopted by many states for their Medicaid populations. A 2012 Commonwealth Fund study found that half of states had implemented medical home programs in Medicaid at that time.
- In [AMA comments](#) on the 2016 physician payment proposed rule, the AMA addressed potential expansion of the Comprehensive Primary Care Initiative. The AMA recommended that as CMS considers potential expansion of this model, it should seek to: reduce administrative burdens associated with the current model; offer an expanded array of model designs with increased physician flexibility to redesign the delivery of primary care services; and link cost accountability to costs that primary care physicians can influence. The AMA comments also recommended that CMS provide flexibility to allow physicians in specialties other than those that Medicare defines as primary care to participate in an expanded medical home model.
- Major health conditions that are being addressed through alternative delivery models in Medicaid, such as medical homes, include asthma, substance use disorders, pregnancy prevention, and maternity care. Several of the APMs described in the Physician-Focused Payment Models section of this letter are appropriate for addressing these conditions. For example, APM #2, condition-based payment for a physician's services, could be used to provide monthly payment to a primary care or specialty practice that is helping patients manage asthma, opioid use disorder, or other chronic conditions.
- The AMA has adopted the Joint Principles for the medical home that were defined by the AAP, American Academy of Family Physicians, American College of Physicians, and the American Osteopathic Association, stating that the following characteristics are essential, and these characteristics should therefore be present in Medicaid medical homes:

- Personal physician - each patient has an ongoing relationship with a personal physician trained to provide first contact, continuous and comprehensive care.
 - Physician directed medical practice – the personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients.
 - Whole person orientation – the personal physician is responsible for providing for all the patient’s health care needs or taking responsibility for appropriately arranging care with other qualified professionals. This includes care for all stages of life; acute care, chronic care, preventive services, and end of life care.
 - Care is coordinated and/or integrated across all elements of the complex health care system and the patient’s community.
 - Quality and safety are hallmarks of the medical home.
 - Enhanced access to care is available through systems such as open scheduling, expanded hours and new options for communication between patients, their personal physician, and practice staff.
 - Payment appropriately recognizes the added value provided to patients who have a patient-centered medical home.
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- In its guidance to states, the AAP urges that medical home legislation not be so prescriptive as to limit flexibility in designing the medical home project, or make it difficult for practices to participate. The AAP also recommends that states establish multi-stakeholder medical home advisory committees to provide input and counsel to the creation, ongoing implementation, and evaluation of the state medical home project. The AMA recommends that these policies also be applied to expanded Medicare medical home models.