November 17, 2015

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS–3321–NC  
Mail Stop C4–26–05  
7500 Security Boulevard  
Baltimore, MD 21244–1850

Re: Centers for Medicare and Medicaid Services 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.

Dear Acting Administrator Slavitt:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Request for Information (RFI) Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models.

The Medicare Access and CHIP Reauthorization Act (MACRA) has the potential to improve the delivery and outcome of care for Medicare patients. The ACR is committed to working collaboratively with the Centers for Medicare and Medicaid Services (CMS) 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.

General Comments

Radiologists are physicians trained in the diagnostic and/or therapeutic use of x-rays (radiography, fluoroscopy, computed tomography (CT), and radiation therapy), diagnostic ultrasound (US), magnetic resonance imaging (MRI) and radionuclides (nuclear medicine and radionuclide therapy), interventional
radiology, medical physics, and radiation biology. Radiologists train more extensively after medical school than most physicians. Specialization in radiology typically requires five to seven years of additional residency training and demonstrated proficiency in physics and advanced medical technology. The ACR and its members believe that the highest quality imaging care is delivered by radiologists certified by the American Board of Radiology practicing at accredited sites and supervising and interpreting imaging studies that meet appropriateness guidelines.

Radiologists are the experts in diagnostic imaging and have a long track record and ongoing commitment to developing and continuously improving the systems and scientific tools which facilitate efficient medical diagnosis, medical imaging, and patient care. Radiologists who practice at this level of quality do so with significant associated costs but the benefits to our patients are also extremely significant. We offer this definition so that CMS may understand the complexities of radiology which involve both patient facing and non-patient-facing activities, the contributions of diagnosis, and therapeutic services as well as many quality programs and data registries.

To help physicians, including radiologists transition to new care and delivery models and assure access to high-quality care for all patients, the emerging frameworks for MACRA’s alternative payment models (APMs) and the Merit-Based Incentive Payment System (MIPS) should do the following:

- **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 measurement and reporting systems.** Medicare’s 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 (MU) 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. Likewise payment models should have as one of their goals improved health equity for the patients served by these physicians.

• **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.

Moreover, when designing alternative payment models (APMs), imaging is a critical consideration because of its pivotal role in decision making during an episode of care. Imaging is often one of the first steps in evaluation of a patient’s condition and plays a central role in early accurate diagnosis. It aids in the choice of an appropriate and cost effective care pathway. The ACR is very interested in helping CMS accomplish its objective of designing APMs that achieve the Triple Aim of healthcare. Radiologists are a uniquely valuable resource to guide optimal use of imaging services given the opportunity. Our Imaging 3.0 initiative continues to demonstrate how radiologists can contribute, including through radiology specific episodes-of-care and team-based episode payment models.

To incentivize specialists to participate in Medicare alternative payment models, CMS should be fully transparent about how specialists would be paid, share in any savings, and be subject to adequate relevant and reportable quality measures. Currently, radiologists do not receive credit for contributing to cost savings and better care in CMMI models (i.e. Accountable Care Organizations (ACOs), Bundled Payments for Care Improvement (BPCI) demonstrations). Radiologists are typically referral based and paid on a fee-for-service basis, so not automatically included in the dialog around improving costs, patient care or assuming risk. Therefore, they are also not considered eligible to share in the resultant savings or losses. It is the ACR members’ experience that the conveners of ACO and BPCI projects are not typically sharing with the specialists upfront how any savings would be distributed if any were realized as a result of their demonstration project.
CMS should recognize that specialists are limited in their ability to participate in shared savings plans (risk contracts) because they do not typically have a defined pool of attributable beneficiaries. Specialists can participate in more than one ACO; there are instances where radiology practices are independent from hospitals or multi-specialty practices, such as free standing imaging centers. The lack of a defined attributable population will make participation in an APM particularly challenging for free standing imaging center practices.

The ACR supports cost effective, evidence-based care that aligns with the Triple Aim of better quality, lower costs and better care for patients. Therefore, for the quality of care to improve across the healthcare delivery system, CMS must ensure that the role of specialists and their non-physician providers in delivering that care is recognized and rewarded.

As CMS looks at the full spectrum of eligible providers and their staff, the ACR would like CMS to formally recognize the use of the registered radiologist assistant (RRA) as one of the types of non-physician providers that contributes to the quality of patient care in radiology practice. The RRAs are licensed professionals that assist the radiologist in providing care to their patients and provide many cost-saving, quality tasks that support the Triple Aim moving forward.

The ACR is developing several methods of controlling costs and improving patient care utilizing different models where radiologists can contribute at the time the study is ordered, as a bundle or in a team-based approach, which we describe later in this document.

**Defining Patient-Centered Care for Radiology (Imaging 3.0)**

The American College of Radiology launched a campaign called Imaging 3.0™ in 2012 to drive a culture change throughout the specialty. Imaging 1.0 describes the emergence of radiology as a medical specialty, while Imaging 2.0 recognizes the spectacular technological advances of the last 20 years. Imaging 3.0 refers to a new era in which radiologists use improved communication and information technology tools to ensure that only appropriate imaging is performed, re-engage with their referring physician colleagues, and more than ever before, connect with their patients.

Imaging 3.0 marries improved quality with reduced cost to deliver system-wide, patient-focused value. The first step, ACR Select™ or consultative clinical decision support, integrates and connects radiologists across institutions and business settings at the beginning of the care process when imaging is being considered by offering consultation and guidance through an evidence-based clinical decision support tool for referring physicians. Once a study has been ordered and the patient has been imaged, the second step occurs when the interpretation is delivered in a standardized and structured actionable radiology report. Structured reporting allows for quantitative measurement and data discovery supporting the determination of patient-specific value connected to actual outcomes. The third step is the ability for patients and referring physicians to have geography-independent web-based access to imaging and reports. Imaging 3.0 rests firmly on an information technology platform that has been developed by radiologists in partnership with industry and proven in clinical practice to ensure widespread interoperability and adoption.
Transforming Clinical Practice Initiative (R-SCAN)

The ACR is one of thirty-nine health care collaborative networks selected to participate in the Transforming Clinical Practice Initiative (TCPI) to provide technical assistance support to help prepare clinicians in the Radiology Support, Communication, and Alignment Network (R-SCAN) with tools, information, and network support needed to improve quality of care, increase patients’ access to information, and spend health care dollars more wisely.

The R-SCAN program targets imaging exams highlighted in the widely embraced Choosing Wisely® campaign and aligns with the ACR Imaging 3.0 initiative in which radiologists help referring providers select the best imaging exam, help patients avoid unwarranted testing, reduce errors and improve quality and safety. As a Support and Alignment Network, the ACR will support at least 24,000 referring clinicians to expand their quality improvement capacity, learn from one another, and achieve common goals of improved care, better health, and reduced cost. R-SCAN will bring together radiologists, their referring physician colleagues, and patients in a collaboration to reduce unnecessary testing and procedures and to help participating clinicians meet the initiative’s phases of transformation and associated milestones, clinical and operational results.

These TCPI grant awards are part of a comprehensive strategy advanced by the Affordable Care Act that enables new levels of coordination, continuity and integration of care, while transitioning volume-driven systems to value-based, patient-centered, health care services. It builds upon successful models and programs such as the Hospital Value-Based Purchasing Organization Program, Partnership for Patients with Hospital Engagement Networks, Accountable Care Organizations and supports the Triple Aim of better quality, lower costs and better care for patients.

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

Major recommendations:

With the flexibility that MACRA offers, the ACR recognizes the magnitude of change that may need to occur.

Quality Measures and Domains

We recommend that CMS remove the requirement for reporting nine measures across three domains in the Quality category. It is an arbitrarily high standard that often results in reporting for the sake of reporting and may do little to improve patient care. Maintaining the 9 measure reporting requirement does not recognize the comprehensiveness of the four MIPS categories and increases the total reporting burden. With the inclusion of the new Clinical Practice Improvement (CPI) category, some or all of the activities captured though this category may be more meaningful and accurate representations of quality than the current set of Physician Quality Reporting System (PQRS) quality metrics.
CMS should allow measures to serve in multiple domains to ensure physicians within each specialty have an adequate suite of measures to meaningfully participate and comply with the program.

1) **EPs in Specialties with Few Measures/Non-patient facing/Other measures**

We recommend that CMS allow non-patient facing eligible providers (EPs) 1) the option of completing the standard requirements of the MIPS performance categories, 2) completing alternative pathways for any of the four categories that offer alternative measures, or 3) without alternative measures available eliminating the performance category entirely and optionally reweighting any remaining categories. For instance, appropriate use/efficiency and cost measures from the Quality category could count under Resource Use; or for the MU category measures not included formally in the MU program but that demonstrate use of technology such as image sharing measures included in the Quality category, or similar measures yet to be developed.

Rather than taking a one-size-fits-all approach, 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—and other facility-based specialties such as physicians who practice mainly in hospitals or in long-term care facilities and nursing homes. We recommend that CMS work with affected specialty societies to identify alternative measures and to determine methods to reweight categories when there are inadequate relevant measures.

**MIPS EP Identifier and Exclusions**

First and foremost, any changes to the process for identifying MIPS EPs should simplify, provide options and promote flexibility. CMS should not mandate use of a unique MIPS identifier, and must consider an individual EP’s freedom to designate or not participate under a 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 Qualified Clinical Data Registry (QCDR) that is much more relevant to their individual patient population and site-of-service.

And while the concept of a unique MIPS identifier would be a potential solution to problems that many radiologists face with the TIN/NPI combination currently used in PQRS (as described further below), the ACR does have concerns about creating yet another identifier for purposes of MIPS. We question whether CMS’ existing infrastructure can 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 additional field to the 1500 claims form.

We recommend that CMS perform an internal environmental scan to determine implication of creating a separate identifier and/or combining existing identifiers (TIN/NPI). The ACR recommends that CMS hold focus groups to include practice administrators and business managers to discuss and consider the administrative issues associated with all the options. We will gladly participate in such groups.
Issues with current TIN/NPI reporting structure:

- Many radiology group practices use multiple TINs by business lines, e.g. one TIN for breast imaging services, one for interventional radiology services, and a third for diagnostic services; or separate TINs for each facility where services are provided.
- Many NPIs may provide services under these multiple TINs but are members of the same group practice. Meeting reporting requirements under these TIN/NPI combinations is complex and burdensome and may result in payment adjustments due to confusion.

We do encourage CMS to consider a voluntary method for identifying a group practice that may cross TINs. The current GPRO registration process could be used in a slightly different way, so that a group practice (agnostic of TIN), registers as an entity and indicates which TINs and NPIs should be associated under that registration. This could be an “internal” identifier, solely for use by CMS.

The virtual group concept might serve to resolve this practice issue to some extent, but the 10 EP limit would not be a complete solution, as many group practices using multiple TINs could easily have unique TINs greater than 10 EPs.

**Virtual Groups**

Physicians, small practices, and other EPs should have maximum flexibility to form virtual groups.

No initial, annual, or other limits should be 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, might discourage EPs from pursuing this option. Such limitations could particularly harm the practices, many of which are providing care in rural settings, with limited resources and administrative support which would most benefit from being in a virtual group.

CMS expressed some concern with gaining experience on the virtual group mechanism, but it is unlikely a large number of virtual groups would initially register, as it may take time for smaller practices to learn about this option and take the actions necessary to form a virtual group.

It would be inappropriate 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-specialists from joining together in a virtual group.

Virtual groups should be allowed use of the same reporting mechanisms as do regular groups to meet reporting requirements.

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 (CPI) activities. However, there should be no requirement that all EPs within a virtual group practice 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.

**Quality Performance Category**

**Reporting Mechanisms Available for Quality Performance Category**

**Current PQRS Reporting Mechanisms and Criteria**

CMS should maintain all of the current PQRS reporting mechanisms to ensure flexibility for physicians with different needs. The initial transition to MIPS needs to be as seamless and as non-disruptive to clinical practice as possible. Continued support from CMS for QCDRs by minimizing administrative complexities for QCDR entities and encouraging their growth will enable greater strides towards meeting the National Quality Strategy aims. Examples of CMS support include GPROs to use QCDRs; potentially providing technical assistance as stipulated under MACRA to small or rural practices to participate in QCDRs; and also perhaps use of measure development funding for QCDR measure electronic specification, data transmission package development and electronic health record (EHR) vendor implementation.

As noted earlier, we urge CMS to reconsider the current PQRS requirement of nine measures across three domains, which is an arbitrarily high standard that often results in reporting for the sake of reporting and may do little to improve patient care.

While the purpose and goal of the National Quality Strategy is recognized as valuable, the requirement of reporting across three domains has been a substantial increased burden for many physicians, even those with well above nine measures available to report. This is particularly true for radiology where many measures, both QCDR and PQRS, have been categorized in the patient safety or care coordination domains and many are sub-specialty or imaging modality specific. Although the measure applicability validation (MAV) process enables physicians with less than three domains to avoid the penalty when reporting through claims or traditional registry, there is no MAV for QCDRs and meeting the 3 domain requirement prevented a number of ACR QCDR participants from fully meeting PQRS requirements in 2014; this situation will persist in 2015.

Additionally, it is often challenging and at times arbitrary to assign one domain to a measure; measures have been moved across domains from year to year. The assignment to domains has not been completely transparent. CMS should allow stakeholder input into domain determinations; at the very minimum, the measure steward should make recommendations. CMS should allow measures to serve in multiple domains to ensure physicians within each specialty have an adequate suite of measures to meaningfully participate and comply with the program.
Maintaining the nine measure reporting requirement would also fail to recognize that the MIPS increases the total reporting burden of physicians with the addition of reporting in the new category of CPI activities. CMS should keep in mind that for many physicians and specialties, some or all of the activities captured though this category may be more meaningful and accurate representations of quality than the current set of PQRS quality metrics.

We also believe that by adding the new category of CPI, 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.

**Quality Data Reported via Multiple Mechanisms**

*CMS inquires about selecting among MIPS quality data submitted by various methods, and avoiding multiple counting of the patient data reported multiple times.*

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. CMS should recognize the reporting of measures across multiple reporting mechanisms to promote meaningful engagement and to encourage EPs to try and gain experience with different options. Combining methods would also enable multi-specialty groups to use multiple registries to satisfy reporting and allow a broader spectrum of quality improvement across the group.

**Quality Measure Types and Weighting**

*CMS asks if it should require reporting of certain types of measures such as outcomes-based measures, and whether those should be assigned more weight.*

It is important to pursue an increase in the number of “high value” measures. 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, and may vary depending upon the intended purpose. To this end, when considering outcomes measures as “high value”, the definition of “outcome” should remain broad as with CMS’ current definition. This strategy allows measures that assess an intermediate or distal outcome to be considered. That possibility should be maintained. Valid and reliable outcome measures potentially could provide a more direct impact on quality; 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. Improving processes support better outcomes, so there remains a place for those.

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 beneficiary 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 difficulties can involve problems with capturing patient reported or experience of care measures in the EHR, as well as interoperability issues that interfere with exchange of needed information, and inability to do longitudinal tracking due to the lack of uniform patient identifiers. Thus, CMS should maintain flexibility by not requiring the use of any specific type of measure in the initial years of the program, and then considering revisions carefully after a certain point in time. 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 outcomes measures more heavily than other non-outcomes measures. 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. Inclusion of appropriate outcome measures equitably across all types of clinician specialties is hampered by feasibility of data collection, ability to cause change, and infrastructure limitations.

Instead, CMS should encourage physicians to report on clinician-led, patient-valued 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**

*CMS asks whether reporting mechanisms should be required to be able to stratify the data by demographic characteristics such as race, ethnicity, and gender.*

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. 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., QCDRs).

Requiring EHRs to track race and ethnicity can eventually allow stratification by those and other demographic characteristics, but it is premature to make this mandatory. Additionally, this is no longer a requirement in the MU program. And conversely, many commercial carriers stopped collecting information “not related to health” on claim forms many years ago. EHRs, systems or institutions purposefully no longer collect such demographic characteristic data because of concerns that it may increase disparity in patient access or care, particularly in some regions of the country. This information is difficult to collect in practice.

**The Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey**

*CMS questions whether the “CAHPS for PQRS” survey should be part of quality or Clinical Practice Improvement (CPI) activities, how to implement CAHPS for all practice sizes, and how to leverage current reporting of the CAHPS by physician groups.*
We support the use of patient satisfaction surveys as one way of participating in the CPI category. However, CMS should also allow for other types of patient-centric measures, not just Clinician Group-CAHPS and non-CAHPS “experience of care” measures and surveys, to count under the CPI category. Radiologists and other typically non-patient facing professionals may deliver services that factor significantly in the patient experience or care as well as ultimate clinical outcome. Surveys, measures or other means to improve patient experience should be considered for professionals who demonstrate better outcomes from: providing consultative care that leads to shared decision making about imaging utilization, delivering patient-centric reports or providing access via their websites to patient-empowerment resources, e.g., radiologyinfo.org, and offer guidance on non-radiology health-related conditions such as smoking cessation and weight management as part of their care.

**EPs in Specialties with Few Quality Measures**

CMS inquires how to assess quality performance for EPs in specialties with too few measures to meet defined criteria, and how to identify which EPs should receive adjusted performance requirements.

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 issues and concerns with the current MU program and the cost measures in the Value Modifier program we do not recommend automatically adding weight to the Meaningful Use (MU) or Resource Use categories.

CMS should maintain the “MAV” process for the MIPS Quality category, inclusive of all reporting mechanisms. CMS should also consider a similar process for all four MIPS categories, or alternatively, allow the option for EPs to select category re-weighting, when inadequate relevant measures exist in other categories.

We recommend that CMS work with affected specialty societies to identify how to reweight categories when there are inadequate relevant measures.

The CPI category may provide the most flexibility and seems most reasonable to which weight should be added, and would allow 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.

Again, we reiterate that 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**

CMS inquires as to potential barriers for successful performance in the MIPS Quality category.
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, nor are QCDRs yet available for measures other than for the Quality category. Additionally, clinical data registry implementation for facility based specialties such as radiology may be especially problematic where the radiology group is reliant on and must coordinate with the hospitals in which they provide services to obtain data. This has proven prohibitive for some radiology practices or required exceptionally long timeframe for implementation. A radiology group practicing at multiple facilities may experience smooth implementation at one and the opposite at another, but both are required for complete reporting.

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, and that a portion of those funds be used to support measure developers in electronic measure specification development and creation of interoperable electronic data transmission services across vendor systems. 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. nine measures across three NQS domains) that force physicians to report on measures that are marginally relevant to their practice simply for the sake of reporting.

Data Accuracy

Testing

*CMS asks what testing should be required to assure the integrity of data submitted via QCDRs and other registries and via EHRs.*

To enhance data integrity, CMS should provide validation on calculated reporting and performance rates as data are 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 by CMS, but not required. Also, the current testing only checks for data formats and does not offer data validation in the test environment, such as checking for numerator less than denominator or calculated rates not matching submitted rates.

CMS and its contractors should work with QCDR and EHR vendors in their early stages 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

*CMS inquires whether it should require certain standards for submitting registry/QCDR/EHR data, such as the Quality Reporting Document Architecture (QRDA) standard.*
QRDA should not be required by registries or QCDRs. A standardized format such as Health Level 7 (HL7) or XML should be allowed.

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 Certified EHR Technology (CEHRT) use only QRDA for capturing and transmitting data. A requirement of CEHRT or QCDRs to only use QRDA will require time and resources for implementation.

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**

*CMS asks if it should require all registries, QCDRs, and health IT systems to undergo “review and qualification” to ensure they meet the “form and manner” requirements for data submission.*

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 from inception 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 timeline or into the production environment.

**Feedback During Testing**

*CMS asks what feedback during testing would be beneficial to stakeholders.*

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**

*CMS poses several questions regarding thresholds for data integrity (accuracy, completeness, and reliability) including when problematic data should be re-calculated or discarded, and whether to require submitted data to include calculated performance rates.*

The overall goal of CMS should be to collect as much accurate data as possible and not be punitive to the EPs for inadequacies of the QCDR, 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 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 programing 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**

*CMS asks about appropriate consequences and scoring for EPs, group practices, and virtual groups whose data reporting mechanism does not meet CMS data integrity standards – and the consequences as well for the QCDR, qualified registry, or EHR vendor (including possible disqualification for future performance periods).*

If adequate opportunities for initial testing and validation as well as for correcting data issues are available and a QCDR, qualified registry or EHR vendor is still not submitting correct and valid data, then the QCDR should be placed on a corrective action plan. If after the probationary period the QCDR is still not adequately submitting data, the QCDR should be excluded from future performance periods until such time that it can show through testing that it is able to submit valid data.

To help resolve potential and on-going 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 those 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.

**Use of CEHRT under the Quality Performance Category**

*CMS asks under the MIPS, what should constitute use of CEHRT for purposes of reporting quality data?*

We support the current policy of allowing physicians to report quality measures through certified EHR systems to fulfill the clinical quality measure component of MU. We also recommend that QCDR reporting count towards satisfying the quality elements of MU.

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 Office of the National Coordinator (ONC)’s certification program, 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.

*Instead of requiring that the EHR be utilized to transmit the data, should it be sufficient to use the EHR to capture and/or calculate the quality data? What standards should apply for data capture and transmission?*

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. Although 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 recommend that CQM reporting using a QCDR should constitute use of CEHRT for purposes of reporting quality data under MIPS. This would increase the applicability of the CQM reporting requirements to specialist EPs, promote participation in QCDRs, and encourage more specialized registries to seek QCDR status.

**Resource Use Performance Category**

**Current Measures**

The RFI implies that CMS may retain all the current value-based modifier (VM) cost measures and perhaps expand upon them. The current measures have limited clinical relevance for many physicians. Some physicians have no costs attributed to their work. Other physicians are associated with costs for services they currently have no opportunity to control. As an example, due to the attribution methods for the per capita cost measures, the only current VM cost measure that conceivably could be attributed to radiology groups is the Medicare Spending per Beneficiary (MSPB) measure, but only for those groups with 125 attributed beneficiaries. For this measure to be attributed to radiologists, the costs during the index hospital
admission associated with the radiology group should be for directly controlled imaging services. Although the radiologist has some responsibility for ensuring appropriate imaging is provided, an order placed by a referring physician is usually executed by the radiologist. With the measure attributed to the radiology group, that group is then within a peer group of non-radiology groups for comparison. This current methodology is inequitable.

The resource use category is important to radiology so we encourage use of actionable, meaningful measures for radiologists. We believe there are relevant, valid resource metrics for radiology but currently there is no way to attribute costs effectively, while addressing Medicare Part A and B costs.

However, we believe that valuable metrics can be identified to improve use of resources in the following areas in particular, but will need time (2-4 years) for development and to identify benchmarks:

- Appropriate imaging recommendations for “incidentalomas” (over-diagnosis) (too many, too often)
- Use of prior images to avoid duplicative exams
- Imaging appropriateness (actionable when done as a team with referring physicians, e.g. appropriate use of CT for headache in concert with neurologists using a similar measure, or in a facility setting)

Optional methods for calculating performance for radiology in this category could be:

- Use of hospital value based programs measures such as Imaging Efficiency measures in the Hospital Outpatient Quality Reporting (HOQR) program.
- Optional use of other program measure performance.
- Before having a hospital performance score attributed to a radiology group, an initial discovery/team-building period would be required with the hospital to understand how the radiology group could make positive change prior to selecting use of these measures. Community practice radiologists would likely require a discovery period more than academic practice radiologists that are predominantly in ACOs. Likewise, hospital-employed radiologists would likely have built relationships that would facilitate a joint effort. Allowing use of hospital measures as an option would enable this discovery period.

We also strongly urge CMS to consider the option of counting quality measures designated in the efficiency/cost domain to serve also as measures under the Resource Use category. Examples are: 1) mammography/lung cancer screening abnormal interpretation rate or 2) appropriate use measures such as the 2016 PQRS measures on appropriate follow up imaging recommendations for incidentally found abdominal and thyroid lesions.

Congress understood that the VM methodology is seriously flawed and demonstrated this by weighting this category lower than the other three categories. Improving upon and adding to the current episode-based measures and attribution process are critical to a fair and successful MIPS program. The ACR very much looks forward to offering creative solutions as CMS complies with this mandate. CMS needs to devote significant data analysis and resources to this effort to replace or enhance, not expand, the current VM cost measures.
**Measures Based on Potential Harm and/or Overuse**

Medicine supports physician use of evidence-based clinical decision support systems. 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 in the Protecting Access to Medicare Act 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. The ACR TCPI SAN (R-SCAN) illustrates radiology’s effort to further this dialogue among patients, referring physicians and radiologists.

Neither AUC nor Choosing Wisely™ recommendations 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 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’s 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 a physician’s resource use based on AUC or Choosing Wisely guidelines. Instead, physicians who use them should be given credit under the practice improvement category.

Individual specialties might decide to use AUC or Choosing Wisely guidelines in the creation of resource measures applicable to their members. In these cases CMS could then consider adoption of any measures 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 data typically under or over captures “overuse”.

**Physicians/Practitioners without Applicable Measures**

CMS should consult with specialties without enough measures applicable to 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 resource measures.

We recommend that CMS work with affected specialty societies to identify how to reweight categories when there are inadequate relevant measures or consider a methodology such that these physicians are held harmless from a negative payment adjustment.
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 Quality Resource Use Reports (QRUR). 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 prevents a practice from obtaining credit for lowering cost while they continue to strive for improved quality. This does not incent practices to try to improve across their activities.

CMS should modify this policy to ensure that no practice is disadvantaged by the issue of inadequate sample size. As with physicians who do not have adequate applicable measures, CMS should consider a methodology such that these physicians are held harmless from a negative payment adjustment.

Episode-Based Cost Measures

In addition to their other flaws, VM measures today are irrelevant for many physicians—either because no patients are attributed to them or 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 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 and inclusive input from practicing physicians throughout the process.

Aligning Measures

The primary goal of this effort 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. 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 of practice—than is currently conducted by either Medicare or private payers. Although we appreciate CMS’ efforts to adjust for specialty in the VM program, more work is needed.

A means of recognizing sub-specialization either due to training or services provided should be developed and implemented.

Site of service could also be used to make adjustments for physicians whose practices focus on hospital or nursing home patients, whose care is typically more complex and costly than that of patients outside of such a facility.

Clinical Practice Improvement Activities Performance Category

Types of Qualifying Activities

CMS should allow for the broadest interpretation of CPI activities possible. Choice 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. These may also include activities recommended by a certifying medical specialty board as quality improvement activities for Maintenance of Certification Part 4. This would include a long list of activities such as:

- Participation in a QCDR and registries run by other government agencies such as FDA or private entities such as a hospital, or medical specialty.
- Stewardship to promote imaging appropriateness among ordering physicians
- Leadership and participation in protocol optimization and management
- Participation in survey for Diagnostic Imaging Center of Excellence (DICOE) Program, or stewardship of group to attain DICOE status
- Participation in relevant practice improvement activities facilitated by each state’s Quality Improvement Organization.
- Leadership or participation in a local clinical quality improvement activity
- R-SCAN

Other activities associated with the six practice improvement categories Congress specifically called for in the 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 are well documented in the patient record; establish 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, serving on call in an emergency department.

- **Care coordination**: Timely communication of test results; ability of practice to receive and act upon fax or email from referring doctor; ability to provide patients with printed copy of test results; billing chronic care management or transitional care management codes.

- **Beneficiary engagement**: Practice provides patients with option to download or have mailed information about the imaging exam and medical history forms to fill out prior to first appointment; training of patients in appropriate preparation, understanding and choice of imaging exams. Use of decision trees and questionnaires to engage patients in shared decision making on their medical care. Patient flyers for specific conditions. Counseling for healthy behaviors such as smoking cessation.

Other activities that should be considered:

- Activities that develop infrastructure for the performance of accountability measures, such as collaborating with an EHR vendor to enable participation in a QCDR.
- Participation in designated private payer CPI activities.
- 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 practice.
- Administration of CAHPS or other patient experience and satisfaction surveys should be considered as a CPI activity rather than a quality measure.

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 disparity in care or furthering other socially desirable goals should be completely voluntary and equally weighted with other activities.

**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 should be permitted but not required through EHRs and QCDRs when and where the capabilities exist.

The physician or other EP should 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 eligible professionals should be allowed to attest to that activity in each subsequent year until the certification expires. After the initial year, the physician or other eligible professional should not have to demonstrate anything further in subsequent attestations until the certification expires unless additional actions are required by certifying organization.

Where applicable, there should be an option for participation in a practice improvement 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**

Initially, CPI activities should be based on completion or ongoing participation in a specified number of clinical improvement activities. Some activities may require a certain number of hours to be considered complete.

CPI activities should be considered at the individual EP level as well as at the group level.

**Weighting of Various Activities**

At least initially, all CPI activities should be weighted equally. There should be a way to accommodate higher credit for activities that follow a quality improvement cycle, such as Plan-Do-Study-Act (PDSA). This may be accomplished by weighting or considering a completed PDSA activity as two CPI activities.

All CPI activities, regardless of subcategories, should be weighted equally while experience with the program is gained.

Providers should not be required to attest to a practice improvement activity in every subcategory or any specific subcategory or activity. Providers should be able to choose CPI activities that are most relevant to their practice and patient base, with equal weighting.

**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 eligible professional participation in an APM “sponsored” by a commercial payer or Medicaid.

**Small and Rural Practices**

The broadest definition of CPI activities and least burdensome requirements will be needed to ensure that physicians and other eligible professionals in small or rural practices are able to participate.

Ensuring that there are options that are free or low cost is also key. For example, many physicians perform disease and population-specific notifications and other activities without the use of a certified electronic medical record; this type of care should be counted as clinical improvement.
**Best Practices**

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

The CPI activities should be used as an opportunity to encourage and empower the many local quality improvement activities used by practices all over the country.

**MU of CEHRT Performance Category**

The performance score for the MU of CEHRT performance category should not require full satisfaction of all MU requirements. The ACR recommends that CMS eliminate the comprehensive, all-or-nothing approach to successful participation in the EHR Incentive Program. Instead, successfully meeting measures or exclusions under the MU Stage 3 objectives should accumulate toward an EP’s 25% of the composite score for the MU performance category. This way, if the EP fails a single measure and does not qualify for an exclusion from that particular measure, a relatively small portion of the EP’s total composite score for MU would be adjusted, and not the full 25%.

Furthermore, CMS should not use a tiered methodology for determining levels of achievement in this performance category that would allow EPs to receive a higher or lower score based on their performance relative to the thresholds established in the Medicare EHR Incentive program’s MU objectives and measures. Using a threshold performance-based/tiered methodology would unfairly penalize certain participants based on circumstances and variables largely outside their control, such as subspecialty/scope of practice, location/setting, health information exchange (HIE) network availability, business environment/competition, and patient population, among others. Additionally, it would weigh percentage-based measures more favorably than the equally important non-percentage-based measures. Most importantly, it would not take into consideration the use of exclusions from measures which enable many specialist EPs to comply with the program’s primary care-oriented requirements. The exclusions allow MU’s single list of participation requirements to account for scope of practice differences and other variations, and thus need to be scored the same as fully satisfying the corresponding measures.

Finally, the ACR recommends that EPs who obtain significant hardship exceptions from the EHR Incentive Program should be awarded the full 25% score for the MU category for the year(s) in question. Providing a smaller percentage would unfairly penalize physicians who were unable to comply with the EHR Incentive Program for a given year due to significant hardship.

**Non-Patient Facing Eligible Professionals**

Non-patient-facing EPs should have the option of completing the same requirements of the MIPS performance categories as patient-facing EPs, completing alternatives, or eliminating the performance category entirely and reweighting any remaining categories accordingly.

For the MU performance category, ACR recommends that non-patient-facing EPs each year have the option to choose one of the following:
1) Scoring using the same methodologies as patient-facing professionals (i.e., MU compliance);
2) Actively engaging with a minimum number of specialized/clinical data registries appropriate to the non-patient-facing EP’s scope of practice as an alternative pathway to the 25% for the MU performance category; or,
3) Excluding the performance category entirely and reweighing the remaining categories to enable reaching 100% of the composite score.

**Other Measures**

CMS should 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.

We acknowledge there should be a certain minimum percentage of services performed at a facility, for an EP to use that facility score. We recommend that CMS perform some internal analytics to determine the typical practice patterns of facility-based specialties and work with relevant specialty societies before proposing a recommended percentage, 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 pathways for any of the four categories that offer alternative measures. For instance, appropriate use/efficiency and cost measures from the Quality category could count under Resource Use. For the MU category, measures not included formally in the Meaningful Use program but that demonstrate use of technology, such as imaging sharing measures included in the Quality category (i.e. Optimizing Patient Exposure to Ionizing Radiation image sharing), or similar measures yet to be developed, should count towards the MU score.

If CMS will not consider optional alternative pathways, we recommend that CMS weigh 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.

**Development of Performance Standards**

The RFI appears to suggest that CMS will continue to base payment adjustments on a performance period two years prior to the payment period, e.g. 2019 being used to adjust payments in 2021. This forces the agency to truncate development of policies and hinders timely modifications in the program. It also means that physicians have little understanding of comparison benchmarks. We strongly urge CMS to make every effort to reduce the gap between the performance 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.

Development of standards that differ according to size and other practice features is 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 made very clear and highly transparent so that physicians can understand them and be successful in MIPS.

Based on the legislative language describing the new CPI category, we do not believe that Congress intended for CMS to somehow measure whether a particular activity improved care. For example, 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 challenging.

**Defining and Incorporating Improvement:**

CMS is required to disclose benchmarks prior to the start of a performance period. As such, intensive education and outreach must be used in concert with performance standards development so that groups and providers know exactly who are their peers and where their goals will be set. Improvement should be defined as year over year improvement; however, CMS should not introduce methodologies that are untested. Rather, we encourage outreach to and input from the medical community to ensure physicians understand and trust on what they are being scored. We caution CMS against using a composite measure of improvement. Success in one category does not mean success in another category; likewise, failure in one category does not indicate failure in another category.

In the Hospital Value-Based Purchasing program, participants can earn points for improvement compared to the baseline and additional points for achievement as compared to performance from the prior year. We question how this could work in a care environment 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.
**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 it is not possible to attribute resource use to some physicians in a specialty, then physicians in this specialty would need flexibility regarding their resource use score. Or 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 MU of EHRs, should not be held accountable for that activity.

CMS should consider a “MAV”-like process for all four MIPS categories, or alternatively, allow the option for EPs to select category re-weighting, when inadequate relevant measures exist in other categories. We recommend that CMS work with affected specialty societies to identify how to reweight categories when there are inadequate relevant measures.

**MIPS Composite Performance Score and Performance Threshold**

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

**Public Reporting**

**Minimum Threshold**

MACRA provides a great deal of flexibility in how MIPS is implemented. This offers a real opportunity to learn from mistakes and build on the successes of the current value-based programs. We would suggest that CMS first work on carefully designing the MIPS; 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 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. 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.

The number of patients or cases required for validation will vary based upon the measure, the population included, physician specialty, 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 all measures is not optimal. There is increased potential for CMS to inadvertently 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. 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 process of determining whether measures are ready for public reporting should occur in a transparent manner and should rely heavily on relevant clinical expert input. The current process is opaque. For example, 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 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 medical societies for internal analysis. These societies have significant expertise in identifying shortcomings with measure calculations and data.

**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 may need to be addressed with systems-level measures, not measures that are reported at the level of the individual practitioner.

**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. Web-based reports as well as dashboards and paper reports should be made available.
CMS must be forthcoming in any feedback reports in regard to the methodologies used to calculate any benchmarks or attribute patients for a particular measure. For example, it would be useful to know what other services the patient had with which providers as well as pharmacy and admission data to help physicians understand cost data. This information must be clearly identified and easy to interpret. Current feedback reports lack key details to guide 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 all parties involved.

Where appropriate, CMS should aim to display feedback and performance measurement information in graphic form with additional details displayed elsewhere. Reports should contain high-level overall performance information as well as tables with functionality that drills down to individual patient information.

Feedback reports should be accessible to physicians and practice administrators/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 an 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 available staff 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

Payment Incentive for APM Participation

To ensure that the physicians participating in APMs 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 regardless of whether the APM entity is a physician-owned organization. There are various arrangements that could comprise an APM entity including, 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, it should be required to provide a means for physicians to influence the governing policies of the organization through significant physician representation on the governing board.

CMS should allow flexibility for proposed APMs to outline different organizational structures, such as solo practice, multiple practices, a hospital or home health agency, and other medical arrangements to serve as an APM entity while preserving different pathways by which revenues can flow through the APM entity. The methodology that an APM entity uses to distribute APM revenues to physicians and other health professionals participating in the APM should foster collaboration among the team, not present a barrier to it. Proposals submitted for qualified APMs should explain how revenues will be distributed rather than CMS establishing the requirements. Specialists, such as radiologists, participate in multiple APMs and
therefore, should be able to aggregate their APM participation.

**Patient Approach**

MACRA provides that either the percentage of patients or percentage of payments may be used to determine whether an eligible professional is a qualified professional or a partially qualified professional; it is important to delineate that physicians in an APM could be contributing to the patient’s care and the goals of the APM in other ways in addition to face-to-face encounters and procedures. Non-patient-facing specialists, such as radiologists contribute to the overall diagnosis, treatment, and management for many patients in the population served by an APM although they may not physically see the patient. Therefore, it is important to note that APMs may involve multiple physicians, each of whom could potentially attribute the patient to themselves. 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.

**Nominal Financial Risk**

Most participants in ACO and CMMI demonstrations are participating in one-sided risk. There is little experience with two-sided risk. Therefore most ACO participants are not recognized as being accountable for financial risk. 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 receive. The financial risk should be proportionate to the amount of control a specialty has over utilization of its services. Physicians should not be held accountable for financial risk and decisions made by hospitals and other contracted entities under which they have no input or control. Referral-based specialties, such as radiology, are at risk if held responsible for the volume of their services ordered by others.

There are many financial risks that can be more than nominal and should be considered by CMS, including risks associated with the Merit-Based Incentive Payment System (MIPS) downside risk of +/-4 to +/-9% or the APM financial risk associated with the current ACO and BPCI demonstrations. Nominal financial risks should initially be set low and also be associated with start-up costs, data analysis, establishing procedures for care coordination and hiring additional staff. A radiology practice may incur these costs with the goal of recouping the costs through savings on other services, however if the savings are not achieved, the radiology practice will incur losses. Moreover, the reduction in volume and the foregone revenue from billable services by radiologists that are reduced due to the use of clinical decision support (CDS) should be considered as financial risks that can be more than nominal. CMS should also consider risk adjusting based on socio-economic factors of the population to account for a higher-risk population versus lower.

**Regarding EAPM Entity Requirements**

APM entities could include physician practices, independent practice associations, physician-hospital organizations, and other organizations. In most cases, it seems likely that payments under an APM will be
made to an entity rather than directly to an eligible physician. To ensure that the physicians participating in the APM can 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. The ACR emphasized the importance of this in response to the proposed and final rules on ACOs. We firmly believe that physician representation on governing boards where physicians are held accountable for reporting measures, lowering costs, improving patient care, and taking on financial risk is essential to the success of any EAPM.

Different APM designs will require different types of APM entities. CMS should 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 these existing 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.

A key issue for APM entities will be determining the methods for establishing whether physicians participating in an APM have 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 eligibility application.

Claims for Medicare physician services are generally submitted by an organization with a TIN comprising one or more physicians that are separately identified through their 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.

**Information Regarding Physician-Focused Payment Models**

The ACR supports CMS’ efforts to establish criteria for Physician-Focused Payment Models (PFPMs), especially for specialist physicians. The ACR supports radiologists who are eligible professionals to become qualified professionals and participate in APMs for Medicare and private payer patient populations.

In our response to the previous RFI on Specialty Practitioner Payment Model Opportunities, the ACR described a number of potential APMs in which we believe radiologists could play a major role. We present them again here.
Radiology Episode-Based Payment Models

Lung Cancer

Lung cancer is the leading cause of cancer death in the United States for both men and women. Screening for lung cancer in high risk older adults who are current and former smokers with low-dose computed tomography (LDCT) is the only method proven to reduce lung cancer mortality and is cost effective. The United States Preventive Services Task Force (USPSTF)’s decision to give lung cancer screening with low dose CT scanning a Grade B recommendation represents an important opportunity to improve population health and one to which radiologists will contribute in a critically important way. The ACR is considering the development of payment models that will align incentives and optimize follow up for both incidentally detected pulmonary nodules as well as for those patients screened with CT. We have developed an ACR-Designated Lung Cancer Screening Center program that encompasses all aspects of a quality based program from patient selection to outcomes tracking.

Breast Cancer

The ACR has extensive experience with screening for breast cancer under the Mammography Quality Standards Act (MQSA) program. The ACR believes that considerable cost saving could take place in the Medicare program if more of the patient population were screened and cancers detected at an early stage. To that end, the ACR is exploring ways that screening mammography studies could be provided to a population under a bundled-payment model.

The ACR’s Neiman Health Policy Institute is currently developing such a model. Within this model, a radiology practice would negotiate with a payer to provide annual screening services that included not only initial mammography screening, but additional recall services such as diagnostic mammography and ultrasound for a defined patient population. This approach can align incentives and allow practices to implement and use technology as appropriate for an individual patient according to best practice guidelines. It also could reduce co-payments for patients who are recalled for additional imaging since the provisions of the Affordable Care Act that make screening tests available without cost sharing do not apply to the recall imaging.

Team-based Episodes-of-Care

The ACR is actively looking at ways in which radiologists can contribute to the Triple Aim of higher value care and better patient experience at lower cost. We have identified several areas of interest based on relative spending in the inpatient environment. The acute management of stroke appears to offer opportunities for optimizing the use of imaging and positively influencing care pathways. ACR’s initial work involved looking at stroke-related DRGs, which showed that the contribution of radiology services to the entire DRG was quite high (>75%). Stroke is also known to be a big expense in the Medicare program.

The ACR has been in discussions with the American Association of Neurology (AAN) as well as other medical specialty societies to determine how we can be involved in the development of a team-based episode-of-care focusing on stroke. For stroke patients, imaging is a key step in the acute phase and can change the management of the patient’s condition. The ACR believes there are opportunities to incentivize
appropriate use of imaging in stroke to streamline care and reduce the time to eventual diagnosis and treatment through payment by using clinical decision support tools. A precedent has already been set for team-based episodes including radiology. For example, radiologists are participating on various efforts including the joint CMS/AMA PACES (Patient-Centered Episodes of Care) project. As imaging is integral to care in many disease management or procedural episodes, ACR representation covers six PACES workgroups to date: cardiac, critical care, endocrine, musculoskeletal, neurology and respiratory.

**Clinical Decision Support (CDS) with Radiologist Consultation**

As a leader in promoting evidence-based imaging care, the ACR agrees with the Institute of Medicine’s (IOM) *Improving Diagnosis in Health Care* report highlighting the important role of radiologists as integral members of the diagnostic team. The report emphasizes the importance of inter-professional collaboration among primary care clinicians and various specialists, including radiologists. The IOM recognizes that enhanced collaboration among radiologists and treating health care professionals is critical to diagnosis and has the potential to improve diagnostic testing. CDS at the point of care, as well as direct consultations with radiologists, are methods for improving imaging test selection.

Health systems should leverage informatics to provide providers with the latest evidence-based practice through CDS systems embedded in the clinical workflow. CDS for ordering imaging examinations will guide referring physicians, help patients avoid unwarranted testing and ensure that patients receive the correct exam for their health condition. The implementation of CDS in association with direct consultations with radiologists can aid in eliminating unnecessary imaging, increase patient safety and quality and result in lowering overall healthcare costs. As previously noted, the reduction in volume and the foregone revenue from billable services by radiologists that are reduced under an APM due to use of CDS should be considered as financial risks that can be more than nominal.

**Criteria for Physician-focused Payment Models**

Traditionally, about half of the radiologists in the US provide services to multiple sites-of-service in both the office and hospital settings. The ACR strongly believes that radiologists should be allowed and encouraged to participate in as many new APMs as possible. Most radiology groups will be new to the process and will start out slowly, but we anticipate that their success will allow them to expand into further models as encouraged by MACRA. The ACR also believes that participation in existing APMs through ACOs, Medicaid, and CMMI demonstrations should also count towards participating in an EAPM.

CMS should establish a clear pathway in the MACRA regulations as to how models are to be proposed to the physician-focused payment model technical advisory committee (PTAC), the process for review, and how CMS will evaluate the PTAC recommendations for APMs moving forward.

The MACRA mandate establishes the PTAC under the title, “Promoting Alternative Payment Models.” The PTAC subsection’s purpose is stated as “increasing transparency of physician-focused payment models.” In the spirit of this purpose, CMS and the PTAC should work collaboratively with medical societies and other organizations to promote APMs that will move forward successfully with the goal of CMS and other payers acceptance for implementation. This should include transparency and guidance in
developing proposals, providing feedback on drafts, and making data available up-front to help in modeling impacts.

Proposals should describe the opportunity to improve patient care, reduce costs to the program, disclose any perceived barriers to implementing those improvements under the current payment system, and make recommendations as to how CMS and the specialty can overcome these barriers and meet the stated goals. For example, there are Medicare regulations to be followed under the current fee-for-service payment system that would be barriers to fully implementing some proposed APMs.

Proposals should also describe how the model will affect disparities among beneficiaries by race, and ethnicity, gender, beneficiaries with disabilities, and low income areas and how the applicant intends to monitor changes in disparities during the model implementation. In addition, CMS should ensure that implementation of an accepted PFPM does not have so many administrative requirements that they discourage participation when additional payments are fully spent on administrative costs rather reducing total costs within the model and to the Medicare Trust Fund.

Definition of Physician-focused Payment Models

To date CMS’ main focus on the development of APMs has been on ACOs, bundled payments for hospital-based episodes, and patient-centered primary care medical homes. None of these efforts have been focused on or examples of how specialty physicians contribute in the care team to lower costs and contribute to higher quality patient care. CMS’ definition of an APM should make it clear how specialty physicians can contribute in a meaningful way and be held accountable for their contributions. A physician should not be held accountable for being part of an EAPM where they do not have a role to contribute. Specialty physicians should also be rewarded for cost savings and improved care to which they contribute and also be adjusted for risk when goals are not met. The definitions and criteria moving forward should be clear as to how the process will work for specialty physicians. Transparency of information shared in a timely manner and flexibility to work within models to find the most innovative ways to meet the Triple Aim goals should also be a considered.

National medical specialty societies have been working to develop PFPM prior to the implementation and in anticipation of the MACRA legislation. These models take a long time to develop, pilot test, and implement and therefore should qualify as APMs under MACRA. CMS’ regulations should establish a clear means for PFPM proposals to be approved for implementation as qualified APMs.

Required Information on Model Design

The ACR reviewed the model design factors that are used by the CMMI. Many of these factors seem reasonable, however, if CMS should decide to move forward with these criteria, CMS should not require that all of the criteria be met in order to qualify. Also, CMS should provide a more detailed explanation of how the established criteria could be met in a proposal. For example, when reviewing the criteria, we believe that there are a few areas that would be difficult to answer:
3. **Strength of evidence base:** CMMI’s purpose is to fund new interventions. ACR strongly supports pilot testing but if the PTAC were to only consider interventions that have been previously tried elsewhere, this would be difficult for most APMs to demonstrate.

8. **Potential for cost savings:** In some cases this may be difficult to predict with accuracy. For example, increased use in a preventive service will increase patient participation and early detection of cancers by radiology; however, the cost reduction may primarily exist in the reduction of unnecessary downstream tests and therapeutic interventions. In addition, the cost savings associated with preventive services may require considerable time to accrue.

17. **Waiver authority:** We believe more clarification is needed to explain how an APM proposal would disclose a waiver of authority.

**Technical Assistance to Small Practices and Practices in Health Professional Shortage Areas**

The ACR would appreciate any guidance CMS offers to MIPS EPs and QPs in practices of 15 or fewer professionals with priority given to such practices located in rural areas, Health Professional Shortage Areas, medically underserved areas, and practices with low composite scores. The ACR has a Commission on General, Small, and Rural Practice that has been in place for many years that helps to address concerns of the radiology membership on these types of issues.

The ACR believes that small and rural practices should be allowed to thrive in the transition and not be forced into employment by health systems. We believe this could compromise access to and choice of quality imaging for patients. Small and rural radiology practices should have the option to contract and work cooperatively with health systems as independent providers of professional services or in co-management agreements that align incentives around the provision of patient-centered high-value imaging care. Physicians in all specialties and all geographic areas should have a meaningful opportunity to choose the MIPS and/or APM pathway by having these options directly available to them.

The concepts of MIPS and APMs are difficult for the average physician practice to understand or interpret how their practice may transition to these new models. As stated above, the ACR believes radiologists should be eligible to report measures in all of the MIPS categories; however, this ability will need to evolve over time. We believe that CMS should offer technical guidance on a continuous basis and some flexibility in the reporting requirements as we move towards full implementation. Many of our members will be slow to adapt to this transformational change and any educational materials, webinars, and other assistance would be welcomed. The ACR’s Imaging 3.0 case study series available to members and the public on our web site deliver real-world examples of radiologists adapting to change in the health care. ACR is providing its diverse membership with many examples of how to contribute to the Triple Aim and demonstrate their full value in a new payment system. The ACR is ready to assist in getting the word out to our members, especially those in small, rural, and underserved areas.

The ACR believes that the most effective solutions for health care of the future will come from physicians and that collaboration across specialties will generate the most innovative and robust ideas. We are very interested in working with CMS on MIPS and APMs as outlined in MACRA.
The ACR looks forward to continued dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues please contact Pam Kassing at 800-227-5463 ext. 4544 or via email at pkassing@acr.org.

Respectfully Submitted,

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