



November 17, 2015

The Honorable Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-3321-NC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models (CMS-3321-NC)

Dear Acting Administrator Slavitt:

The American College of Rheumatology, representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to respond to the Request for Information regarding the implementation of the Merit-Based Incentive Program and Alternative Payment Models under the Medicare Access and CHIP Reauthorization Act of 2015. We look forward to working with you and your team as MACRA is implemented.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise beyond that of primary care providers. Rheumatologists provide face-to-face, primarily non-procedure-based care, and serve patients with serious conditions that can be difficult to diagnose and treat including rheumatoid arthritis, systemic lupus erythematosus and other debilitating diseases. Early and appropriate treatment by rheumatologists slows disease progression, improves patient outcomes and reduces the need for costly downstream procedures and care that is complicated and made more expensive by advanced disease states.

Executive Summary

In general, the following principles drive our specific comments:

- In designing this and other reimbursement programs, reporting and quality measurements should be focused on promoting a high value health care system. Complex and overlapping requirements merely cause frustration and cost time and expenditures that should be directed to patient-centered care.
- Flexibility in the design of the programs and simplicity in implementation should drive the development of new programs.
- Appropriate notice on new requirements should be given in all instances to permit time to implement and validate new processes.
- Appropriate data and measurements should be used to develop these new programs to ensure there are no biases against certain patients and their physicians.
- Compliance options should be broad and not overly prescriptive.

Comments on Issues Contained in the Request for Information

Given the importance of the services provided by rheumatologists, which can be provided only by rheumatologists, the ACR is highly concerned about the growing shortage of providers with expertise in rheumatology. This shortage threatens access to high quality care for all affected individuals, and especially those who depend on Medicare. Therefore, in the months and years ahead, it will be critical that federal programs and policies assist and not hinder rheumatologists and rheumatology providers in their mission to deliver the highest possible quality of care to those Medicare beneficiaries unfortunate enough to suffer with rheumatic diseases.

Along those lines, **the ACR urges the Centers for Medicare and Medicaid Services to ensure that its systems and policies under MACRA are simple, efficient, transparent and provide genuine benefit for Medicare beneficiaries** with rheumatic diseases. We strongly urge CMS to not simply combine Medicare's existing reporting and quality measurement programs into a new and inevitably unwieldy MIPS program. Instead, existing reporting and quality programs should be redesigned and streamlined into a coherent, flexible and simple system that is truly relevant to high-value care. Above all, the MIPS program needs to be simpler and more meaningful than the current systems, and it must improve upon the current and separate quality and reporting systems which are complex and onerous. In particular, we request that CMS emphasize a *reduction in administrative burdens and streamlining of reporting tasks so that the delivery of patient-centered care is the principal focus in all clinical settings.*

Participation in an alternative payment model (APM) is one route by which some rheumatologists may succeed under MACRA and continue to provide high-quality care to Medicare beneficiaries. However, this course is untenable for a substantial portion of rheumatology providers because there are few existing APMs that are feasible for rheumatologists. Therefore workable alternatives must be developed and incorporated into MACRA if patient access to rheumatologists is to be preserved. We believe that participation in Qualified Clinical Data Registries (QCDRs) is a promising method by which providers can continuously monitor and improve quality of care. In order to incentivize participation and streamline the development of processes that favor quality improvement, **the ACR strongly recommends that providers who participate in QCDRs be granted credit towards their participation in the four MIPS categories.** Promoting practice improvement, based on provider-specific data and anonymized peer-to-peer comparisons, will be much more meaningful than a proliferation of generic measures and the inevitable burden on providers who already labor to keep up with reporting requirements. **Combining registry participation with participation in all four MIPS categories would allow providers to contribute to meaningful data collection and analysis, improve quality of the care and simultaneously reduce administrative burdens.**

A. The Merit-based Incentive Payment System

1. MIPS EP Identifier and Exclusions

The process for identifying MIPS eligible professionals (EPs) should be as simple and efficient as possible. The creation of a new MIPS identifier would only increase complexity and administrative burden on CMS and providers alike. **We do not recommend that CMS create a new MIPS identifier**, but rather use identifiers already in existence. CMS should update the current PECOS system annually and use a combination of TINs and NPIs to identify EP's. The assignment of

particular measures to TINs versus NPIs will prove to be a key element in the development of MIPS regulations and we look forward to participating with you in that process.

2. Virtual Groups

MACRA includes a provision allowing individual physicians and physician groups to unite for purposes of performance assessment even if they do not share a TIN. CMS seeks comments on the parameters for creating these “virtual” groups. Barriers to forming virtual groups should be minimized and there should be no limit to the number of virtual groups that can be formed. Groups should be allowed to include members from multiple specialties and subspecialties. Additionally, there should be no arbitrary geographic restriction on group formation, such as a 50-mile radius. Such a restriction would prevent physicians in many areas of the country from joining together even though they share patients and otherwise interact in meaningful ways.

3. Quality Performance Category

a. Reporting Mechanisms Available for Quality Performance Category

Each November CMS must publish proposed quality measures from which MIPS participants may choose for performance assessment for the upcoming year. CMS seeks comments on the reporting mechanisms and criteria to be used and how the MIPS quality performance category should be applied to physicians in specialties with too few quality measures to meet minimum criteria.

The ACR recommends that any and all measures be meaningful to patients and simple for providers to implement. Available NQF process measures represent a reasonable starting point and outcome measures should follow. However, the process of adopting new measures must ensure arrival at a consensus on difficult issues such as sample size, attribution, and risk adjustment. The development of high quality outcome measures requires a long and rigorous process and it is important that CMS appropriately encourage the development and implementation of outcome measures without pushing too aggressively before it is feasible. The timeline for high quality outcome measures will vary considerably by specialty. It is also important for CMS to account for the fact that some specialties do not have clinically meaningful performance measures that are endorsed through the NQF. It is important for CMS to preserve and expand on the flexibility of allowing specialty-developed measures in QCDRs and other mechanisms.

For specialties with too few quality performance measures, CMS should allow for a re-adjustment of the weights of the other MIPS categories. For example, the Clinical Practice Improvement (CPI) category may provide a path for some rheumatologists to demonstrate quality improvement activities relevant to their practice. Unfortunately, this category was given the least weight under MACRA. In contrast, due to serious flaws in the current Meaningful Use (MU) and Value Modifier programs, weight should not be indiscriminately added to the MU or Resource Use categories. Again, flexibility is key. Given the tremendous variation in patient populations and practice models adopted by providers to accommodate those patients, flexibility in the choice of quality measures and their relative weights will be paramount to building a system that incentivizes and rewards movement toward best practices.

One way to achieve flexibility and maintain high standards would be to create a points system. As an example, under such a points system, if all available MIPS programs were worth a total of 150 points, then an individual provider or group might fulfill MIPS requirements by participating in

activities most relevant to their scope of practice while achieving the required 100 points. Minimum requirements for points from specific categories would preserve the goal that quality improvement activities span a range of domains. Exceptions must be allowed for subspecialties with too few measures in a given category. The basic principle we endorse is that there should be more points available than the required threshold, such that providers can leverage some flexibility. We encourage CMS to continue to work closely with specialty societies and their members in the establishment of quality measures and weights assignments so as to avoid one-size-fits-all errors and the creation of rules that inadvertently disfavor valuable, if less common, practice models.

- Should CMS maintain the same or similar reporting criteria under MIPS as under PQRS?

CMS should take advantage of this opportunity to improve upon reporting criteria and not simply repurpose PQRS criteria for MIPS. In the process, CMS should increase flexibility and provider choice, and reduce burdens by making available an expanded menu of options to fulfill MIPS reporting requirements. As above, this should include the option of participating in a QCDR to fulfill reporting criteria. As a rule, the menu of options constituting reporting criteria should be designed to be more efficient and less burdensome than those measures currently in place. The revision of PQRS criteria and the development of new requirements should be informed by experience reports and avoid the problems that physicians face in fulfilling current requirements. For example, the current PQRS requirement of reporting on nine measures across three domains is overly burdensome and forces practices to waste valuable resources reporting for the sake of reporting on measures of little or no relevance to their practice. Importantly, the transition to any new system should be flexible and forgiving so as to minimize disruptions to ongoing patient care.

Maintaining the nine measure reporting requirement in current PQRS methodology would also fail to recognize that the MIPS increases the total reporting burden of physicians with the addition of the new category of CPI activities. The current domain assignment is arbitrary and measures are moved from one domain to another from year to year. We ask that CMS remove the requirement of meeting multiple domains from the program.

We also believe that by adding the new category of Clinical Practice Improvement, CMS will inherently target a wider array of quality interventions that satisfy the goals of multiple domains. **We recommend that CMS consider doing away with the domain requirement and instead use domains to simply guide measuring national quality goals.** Alternatively, if this is not possible, CMS should at least allow measures to be assigned and counted towards meeting multiple domains.

- What is the appropriate number of measures on which an EP's performance should be based?

The current arbitrary requirement to report on nine measures should not be included. There is no reason for nine measures and this threshold makes it difficult for rheumatologists to meet the requirement because of insufficient numbers of relevant measures. **CMS should reduce the number of measures and should not propose increases every year as in PQRS.** Physicians need more stability under MIPS than in the current scheme. A two or even three-year interval between changes is necessary to allow EMR vendors to test the new code they must write.

We also request that measures be specialty specific and relevant, and there should be a transparent process and timeline for removal of measures. We request that the proposed rule not be the first time that specialties see their measures removed. Finally, while CMS needs a way to ensure measures are sound, the current process with NQF is tedious and inconsistent. CMS should review the approval processes, making them transparent and incorporating the needs of multiple specialty and subspecialty groups.

- How should CMS apply quality performance standards to physicians in specialties with insufficient numbers of measures?

For EPs practicing in specialties with insufficient quality measures, CMS should reduce the required number of measures to the number pertaining to the specialty or fewer. CMS should encourage these specialties to develop more meaningful measures, but not through punitive means and with the recognition that the development of high quality and meaningful measures takes time. Financial support for measure development should be directed to those specialties with insufficient measures, not to areas with abundant measures.

- Should CMS require that certain types of measures be reported? Should a minimum number of measures be outcomes-based? Should more weight be assigned to outcomes-based measures?

In reality, many specialties including rheumatology do not currently have outcome measures and their physicians should not be penalized for that fact. It would not be fair to impose a quality outcome measure when one does not yet exist. The American College of Rheumatology has initiated its work to attempt to develop a reliable and clinically meaningful outcome measure, but it may be years before such a measure is available for use. The ACR is concerned about risks of physician-level outcome measurement: high risk patient avoidance; peer competition as opposed to incentivizing multi-disciplinary cooperative care; and issues with sample size at the physician level. There are a number of methodological issues that must be addressed by CMS before assigning more weight to outcome measures, including risk adjustment and attribution. **Therefore we are strongly opposed to requiring that a minimum number of measures be outcomes-based and we oppose weighting outcome measures more heavily.** CMS should not assume that individual physicians can wield sufficient influence on which measures are developed and available to meet the needs of their patient population. The agency should not hold physicians accountable for something that is not necessarily within their direct control.

Valid and reliable outcome measures could potentially lead to more direct measures of quality and their development by medical specialties should be encouraged and funded. However, we also recognize that certain types of measures might be more appropriate for certain specialties and practice settings than for others. Furthermore, process measures that are evidence-based can be integral to improved outcomes and in some specialties, this foundational step must first be addressed before moving on to outcome measures.

In addition to outcome measures, there is also value in process measures. The ACR has developed quality measures that are meaningful for rheumatologists. A flexible approach is critical to ensuring relevant measures are available to as many physicians as possible.

- How should CMS apply the quality performance category to MIPS EPs that are in specialties that may not have enough measures to meet our defined criteria?

We recommend a focus on QCDRs, which help with these issues. The flexibility of QCDRs to implement non-PQRS measures provides significant flexibility for specialties and will help spur the development of measures going forward.

- What are the potential barriers to successfully meeting the MIPS quality performance category?

EPs are limited by how efficiently their EHR can capture performance, if it can do so at all.

b. Data Accuracy

According to the RFI, CMS' experience under the PQRS has shown that data quality is related to the mechanism selected for reporting. Because accuracy of the data is critical to the accurate calculation of a MIPS composite score, CMS is seeking comment on what additional data integrity requirements should be in place for reporting mechanisms.

The ACR strongly recommends that, in order to incentivize providers to participate in QCDRs, participation in such registries should count toward credit for all categories of MIPS, including the quality portion. The QCDR approach is the most painless way for physicians to report data. QCDR participation also generates data that can ultimately be used to develop true and meaningful outcomes measures. Data integrity is an important issue and will require continuous efforts for improvement. Because QCDRs are relatively new and the quality of the data is also important to the specialties who develop the registries, we believe that data quality and integrity will improve over time.

- What should CMS require for testing of the qualified registry, QCDR, or direct EHR product, or EHR data submission vendor product? How can testing be enhanced to improve data integrity?

Current testing requirements are sufficient. We strongly recommend that true and meaningful interoperability be implemented by all qualified EHRs to ensure meaningful communication between software can occur. QCDRs are often collecting data from EHRs as the source, so the data quality and integrity of EHR data should be a primary focus.

- Should registries and qualified clinical data registries be required to submit data to CMS using certain standards?

Data standards are required for interoperability and efficient electronic communication. Data standards already required for QR and QCDR should continue.

- Should CMS require that qualified registries, QCDRs, and health IT systems undergo review and qualification by CMS to ensure that CMS' form and manner are met? What should be involved in the testing to ensure CMS' form and manner requirements are met?

Mechanisms to ensure CMS' form and manner requirements are met are already in place through the self-nomination process, data validation plan and data validation execution report. It will require substantial effort by each QCDR to ensure its file transmissions meet the form and manner of CMS specifications. 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. It would be beneficial for a QCDR to know at the start that its file format is accurate.

- What feedback from CMS during testing would be beneficial to these stakeholders? What thresholds for data integrity should CMS have in place for accuracy, completeness, and reliability of the data? What threshold of errors in submitted data should be acceptable?

We request that CMS provide detailed feedback reports that drill down to the specific issues encountered by CMS. CMS should calculate all of the rates, but must demonstrate capability. The ACR asks that, if data elements are missing, CMS should provide a timeframe for QCDRs to correct data submission.

- If CMS determines that the MIPS EP (participating as an individual EP or as part of a group practice or virtual group) has used a data reporting mechanism that does not meet data integrity standards, how should CMS assess the MIPS EP when calculating their quality performance category score? Should there be any consequences for the qualified registry, QCDR or EHR vendor in order to correct future practices? Should the qualified registry or EHR vendor be disqualified or unable to participate in future performance periods?

These data integrity standards should be established prior to submission such that each mechanism cannot submit substandard data sets (i.e. Data sets rejected during submission with the opportunity for the submission mechanism to submit corrections). **EPs should not be subjected to consequences as they are not directly involved in the submission process and should not be held responsible for mistakes made by a vendor.**

There should also be added flexibility in the process, rather than a one-time data submission that results in either a pass or fail. **It is important that there be adequate warning before any penalty or disqualification.** The warning should allow at least one year to correct problems, as it would take registries a significant amount of time to find a new way of reporting.

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

- How should CMS define hardship exemptions for MU?

Hardship exemptions are defined in the current system and they should be treated as true exemptions from the program. **If there is a true hardship, then the provider should be exempt from this standard and given 100 percent credit.**

Additionally, physicians should not be penalized if they have a true hardship. There is a possibility that receiving an average score for MU, because of a hardship exemption, could result in a lower overall score if they have lower scores in other areas. Having a hardship should not negatively affect a physician's score.

- Are there alternative methodologies that CMS should consider for this performance category?

The Stage 3 MU rule should not be included in MIPS as currently designed. The MU program should be changed entirely for purposes of MIPS. Among many potential

modifications, measures should be harmonized with other components and a sliding scale of achievement should be adopted. It is currently possible to fail attainment of MU because the EP misses by one patient one of the thresholds for a measure and this is unfair overly stringent. MU should be a separate and independent measure from quality. There must also be true interoperability and communications between proprietary software for MU to be successful.

- 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?

Using the EHR to capture and/or calculate the quality data should be sufficient. We support the current policy of allowing physicians to report quality measures through certified EHR systems to fulfill the clinical quality measure component of Meaningful Use. We also recommend that QCDR reporting count towards satisfying MU quality.

Because data capture and transmission will differ by mechanism and vendor, there should be a minimal set of standards that will broadly apply across all mechanisms and vendors. The vendor should demonstrate they are able to capture data in a structured format and transmit in the file format specified by CMS. Physicians need flexibility wherever possible.

4. Resource Use Performance Category

CMS seeks comments on the resource use measures (in addition to those that now apply under the Value Based Modifier) that should be considered for the MIPS, and what data sources would be required to calculate such measures. CMS notes in the RFI that the agency's experience under the VM will help shape the Resource Use category.

The ACR strongly recommends that, in order to incentivize providers to participate in Qualified Clinical Data Registries (QCDRs), participation in such registries should count toward credit for all categories of MIPS, including the resource use portion. **If QCDRs are collecting at least one resource use measure, which is a requirement for QCDR, that should be translatable and reportable to CMS for the resource use measure.**

The current cost measures under the Value Based Modifier are so flawed that they lead to physicians being accountable for costs of care components that have nothing to do with the care they provide, or the measures inappropriately disadvantage certain providers based on the treatments they prescribe. **In particular, we are very concerned that the current cost component of the Value Based Modifier does not accurately portray quality and cost for rheumatologists.** Because Part B drugs are included in the cost measure while Part D drugs are excluded, the cost measure is not accurate for rheumatologists and for many other specialties who prescribe biologic therapy.

The ACR has raised the issue of non-inclusion of Part D drug costs with CMS several times. Inclusion of Part D drug costs in the VM cost measure is necessary to ensure the cost calculation does not unfairly disadvantage certain providers based on the treatments they prescribe. Under current VBM policy, payments to groups that administer biologics under Part B may be reduced, and there is no adjustment taking into account costs incurred by prescriptions from providers who prescribe biologic therapies primarily through Part D. **This flaw in the VBM inappropriately**

penalizes physicians based on the way they prescribe medications, which causes concern for potential skewing of practice costs and impacts on treatment decisions.

The current VBM policy may force providers to choose between prescribing Part B drugs and increasing their cost measure – potentially resulting in a VBM penalty – or prescribing medication under Part D which their patients cannot afford, causing patients to go without crucial treatment. Due to the way Medicare covers biologics, patients often pay considerably more for Part D medications than Part B, and many patients who have a medical need to access biologics cannot afford access to Part D medications. Both physicians and patients will be negatively impacted by this policy. While we understand that CMS is prohibited from considering out-of-pocket costs to patients, it is important that it recognize that physicians are not so encumbered. It is the position of the ACR that a patient unable to afford medication is an untreated patient and therefore will not have favorable outcomes. **Therefore, CMS should modify the VBM cost attribution to ensure the cost calculation does not unfairly disadvantage providers and their patients by ignoring part D costs. Conversely, elimination of the drug cost portion of Part B and counting only the costs of providing the services would also more accurately reflect the true incremental cost difference between parts B and D services.**

Additionally, 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. It is unclear with regard to value or cost effectiveness of treatment of rheumatic diseases whether value is indicated by low disease activity, preventing disability, lowest cost of drug, lowest aggregate cost per patient, patient satisfaction or other factors.

Finally, the current measures have little clinical relevance for many physicians. Some physicians have no costs attributed to them, while others are tagged with costs for services they had no opportunity to control. As can be seen in the Quality and Resource Use Reports and VM experience reports, the current cost and outcome measures also discriminate against physicians with high numbers of chronically ill and high risk patients. **CMS should devote significant data analysis and resources to this effort in order to replace, not expand, the current VM cost measures.**

- Apart from the cost measures noted above, are there additional cost or resource use measures (such as measures associated with services that are potentially harmful or over-used, including those identified by the Choosing Wisely initiative) that should be considered?

It would be premature to judge physicians' resource use based on AUC or Choosing Wisely guidelines. Additionally, not all of the ACR's Choosing Wisely items can be easily made into measures. Instead, physicians who use these recommendations should be given credit under the Clinical Practice Improvement category.

- What role should episode-based costs play in calculating resource use and/or providing feedback reports to MIPS EPs under section 1848(q)(12) of the Act?

It will be difficult to compare short-term episodes of care when treating long-term disease. The CMS calculations are based on "acute care" models of disease, even when dealing with chronic diseases. Rheumatologists and many other providers deal with a different category of chronic, generally non-life threatening diseases. We will need a different model involving long-term measures and outcomes that are not suited for simple calculations based on whether something was done or not done.

We need appropriately risk adjusted cost assessments and/or actual value assessments. For rheumatology and many subspecialties with majority of patients with complex chronic diseases, episode of care cost measures need to account for disease severity and thus total unadjusted cost measures cannot account for known variation in patient severity across providers, even within the same practice. CMS should either adjust for case mix or reflect a measure of value: outcomes achieved per dollar spent. **Providing physicians with raw data about costs and resource use is helpful to make providers aware, but payments based upon such data run the very real risk of marginalizing high risk patients by incentivizing providers to exclude high risk patients from their practice.**

- How should CMS consider aligning measures used under the MIPS resource use performance category with resource use based measures used in other parts of the Medicare program?

The best incentive programs reward collaborative care and shared information. Providers should not be put into double jeopardy with regard to receiving penalties in multiple areas based on shared components. For smaller practices, investment in resources that support or develop multispecialty communication and collaboration could be rewarded. Quality measurement should be removed from MU.

- How should CMS incorporate Part D drug costs into MIPS?

The ACR would be happy to work with CMS to address this problem, but currently does not have a detailed enough understanding about the barriers to incorporating Part D costs into the calculation to provide specific ways to remedy this problem. As we have discussed, without including Part D costs all calculations are flawed. For example, if a rheumatologist were to prescribe a subcutaneous Part D treatment for every patient, despite obvious increases in costs they would appear to cost far less than a rheumatologist who uses an infusion drug covered under Part B. While counting the incremental cost of infusion over self-administered drugs (Part B vs. Part D) may be appropriate, not counting the part D costs creates a false cost differential.

Ultimately, we are concerned about the potential for tension between appropriate treatment of rheumatic disease, which involves high costs due to the expense of biologics, and efforts to control costs as part of value-based care. Rheumatology, as with many subspecialties, has many patients and diseases where short-term, less expensive treatments may not offer the best long-term outcomes. This makes this a very complicated area to measure well and to not have unintended consequences of measurement.

- What peer groups or benchmarks should be used when assessing performance under the resource use performance category?

Ideal peer groups are those serving populations with both similar disease severity and similar access to resources. The comparison would be difficult to do well at the physician level, but small practices could be compared to each other and then also benchmarked against the national average. Risk adjustment will also be key. Overall, resource use is very difficult to measure in rheumatic diseases. The components that would make the most sense are difficult to measure in the short-term, i.e. death, hospitalizations, infections, joint replacement surgery.

- CMS has received stakeholder feedback encouraging us to align resource use measures with clinical quality measures. How could the MIPS methodology, which includes domains for clinical quality and resource use, be designed to achieve such alignment?

Alignment of resource use measures with clinical quality measures is imperative. The only reasonable way to achieve this alignment would be to measure resource use for the same patient, to get the same outcome over a long-term. Instead of focusing on cost in isolation or total cost, we ask that CMS focus on actual value: risk-adjusted outcomes per dollar spent, although such measures do not yet exist. Ideally, reporting should show either cost and outcome side by side or combined into a holistic measure of value. Overall, the agency should keep in mind that there are adverse cost outcomes with over-utilization, but adverse patient outcomes with under-utilization.

5. Clinical Practice Improvement Activities Performance Category

The MACRA specifies that the measures and activities for clinical practice improvement activities must include at least the following subcategories of activities: expanded practice access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, and participation in an APM. The Secretary has discretion under this provision to add other subcategories of activities as well. The term “clinical practice improvement activity” is defined as an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that HHS determines, when effectively executed, is likely to result in improved outcomes.

The ACR recommends that CMS should allow for the broadest interpretation of CPI activities possible. The selection of activities should be optional, and no category should be mandatory. **CMS should minimize burden on physicians to attest to completion of CPI activities.** Additionally, physicians 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. **We would strongly oppose any efforts to use the CPI portion of MIPS to force physicians to participate in various federal health programs, or to require any single program as a mandatory CPI activity.**

- Should physicians be required to attest to CPI activities directly to CMS or should qualified registries, QCDRs, EHRs, and other health IT systems be able to transmit results of these activities to CMS?

Overall, it appears that the proposal may be overcomplicating this category, with the considerations of subcategories and weighting various subcategories. The ACR asks that CPI activities should be wide-ranging and not overly prescriptive. **The ACR recommends that CMS make CPI simpler by providing a broad list of eligible activities and allowing the physician to go into the system to attest to which one they completed.**

Physicians should be able to demonstrate their completion 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, and transmission of CPI activity results should also be permitted but not required through EHRs and QCDRs, when and where the capabilities exist. If the payer or organization hosting the CPI activity

can provide a certificate or other paper trail to keep on hand for records in case of any future auditing that would be helpful.

CPI activities should include participation in a QCDR as well as activities such as participation in APMs outside of the Medicare program. Additionally, programs offered by national and state specialty societies should count in the CPI category. Many physicians participate in a risk management CME programs for their malpractice coverage and that should count as practice improvement. CME lectures on CPI should also be included.

- What information should be reported and what quality checks and/or data validation should occur to ensure successful completion of these activities?

Most programs provide certificates. Physicians could attest to completing the CPI activity, and then maintain the certificate in case of audit by CMS.

- How often providers should report or attest that they have met the required activities?

We recommend that providers be required to attest no more frequently than annually. Some states require CME certification every two years for licensure, and a two-year frequency would also be appropriate.

- How should clinical practice improvement activities be applied to physicians in small practices (15 or fewer professionals) or practices in rural areas?

For smaller or rural practices, because of the burden of completing practice improvement activity, the relative weight in EP performance could be reduced. **Participation in QCDR or a certain number of CME hours on quality improvement could be a viable solution.** Additionally, funding directed for support of small and rural practices could be used to support QCDR adoption, and the QCDR use subsequently could satisfy the CPI requirement for these groups.

- What should be classified as “clinical practice improvement activity?” Can participation in a QCDR count?

Participation in a QCDR should count as a clinical practice improvement activity. At a minimum, providers would show they are collecting and reviewing meaningful data.

- What threshold or quantity of activities should be established under the clinical practice improvement activities performance category? Should performance in this category be based on completion of a specific number of clinical practice improvement activities, or a specific number of hours? If so, what is the minimum number of activities or hours that should be completed? Should the threshold or quantity of activities increase over time?

The ACR asks that CMS avoid mandating specific pathways such as a required number of hours. The requirements should also not increase over time. Measurement for the sake of measurement is meaningless. As an alternative, CMS should define meaningful steps towards ultimate goal of continuous quality improvement, and then reward physicians for taking those steps.

- Should performance in this category be based on demonstrated availability of specific functions and capabilities?

The requirements for this category should be flexible and not overly prescriptive.

- How should the various subcategories be weighted? Should each subcategory have equal weight, or should certain subcategories be weighted more than others?

Physicians should be allowed to attest to CPI activities out of a flexible portfolio of activities. Subcategories are not necessary. Physicians should be able to pick and choose activities, and therefore the categories should be weighted equally.

- How should CMS define the subcategory of participation in an APM?

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

6. Meaningful Use of Certified EHR Technology Performance Category

Under MACRA, MU of certified EHR technology will determine 25 percent of the composite MIPS score, though CMS is given leverage to reduce this to 15 percent in any year which they estimate the proportion of eligible professionals who are meaningful users is 75 percent or greater.

The ACR strongly recommends that, in order to incentivize providers to participate in QCDRs, participation in such registries should count toward credit for all four categories of MIPS, including the Meaningful Use portion. **If a physician is linked to a QCDR that is pulling quality data for CPI and using the provider's EHR, that is a meaningful use of EHR technology.**

- Should the performance score for this category be based solely on full achievement of meaningful use? For example, an EP might receive full credit under this performance category for meeting or exceeding the thresholds of all meaningful use objectives and measures; however, failing to meet or exceed all objectives and measures would result in the EP receiving no credit for this performance category.

Full achievement of MU should not be the basis of the score for this category. **Partial credit should apply, as an all or nothing approach is unrealistic and not fair to providers putting forth the effort and attempting to achieve meaningful use. The MU program should be modified in MIPS in order to focus specifically on use of EHRs and not quality measures, which are adequately covered in other categories.**

Therefore MU objectives should score in an accumulative fashion toward the 25 percent of the MU category. In other words, if an EP fails to satisfy an individual measure, and does not meet the prerequisites of any available exclusion from the failed measure, that EP should only lose a smaller, proportional percentage. Additionally, incorporating Stage 3, as finalized by CMS, into the MIPS program would prohibit physicians from being successful, and therefore jeopardize their ultimate MIPS composite score.

Further, many of the MU measures have no impact on clinical care or on patient outcomes. MU measures should be redesigned to focus on outcomes and use cases rather than processes and data entry. Rather than emphasizing counting and thresholds, measures should focus on whether data is accessible and usable. Finally, unless all of the EMRs are open sourced, the central issue of interconnectivity is not being addressed.

We also request that CMS reopen Stage 3 Meaningful Use to realign the program and take time to evaluate whether providers are successful under the Stage 2 Modifications rule. We urge CMS to return to the statutory intent for the program and to focus Stage 3 on electronic prescribing, information exchange, interoperability and quality reporting.

- Should CMS 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 meaningful use objectives and measures? Should scoring in this category be based on an EP's under- or over-performance relative to the required thresholds of the objectives and measures, or should the scoring methodology of this category be based on an EP's performance relative to the performance of his or her peers?

The methodology should be specialty-specific and should be developed through a consensus-based process with experts in this area. However, overall we strongly believe that the MU program is inherently flawed and needs to be revisited. We also caution that a tiered methodology could disadvantage small practices for which it is more expensive to make changes and for whom sample sizes will mean harder to see significant improvement.

We again strongly urge CMS to eliminate the pass or fail approach to MU. If providers are attesting for MU and meet a certain percentage of the measures, there should be an option to receive credit for the percentage that were completed. Finally, given that there are significant interoperability issues in the current MU program, CMS must ensure that EHR systems address these challenges and resolve basic cornerstones necessary for data exchange, such as patient matching, provider directories, standards, privacy and security.

- What alternate methodologies should CMS consider for this performance category?

CMS should identify ways to incentivize EMRs with certain market share to provide standardized data flow and extraction as part of their certification. CMS should also consider stratification by meaningful peer group. This could be based on considerations including size, regional resource availability, or proportion of disadvantaged patients. The agency should avoid creating significantly different performance standards, but this stratification may help move smaller practices by recognizing they have a greater challenge than larger practices.

- How should hardship exemptions be treated?

Hardship exemptions should be treated as true exemptions from the program. If there is a true hardship the physician should be exempt from this standard and given full credit for the category. Additionally, having a hardship should not negatively affect a physician's score. If a physician experiencing a hardship is given an average score, rather than 100 percent credit for MU, this could result in a lower overall score for the physician if they have

lower scores in other areas. Finally, hardship exceptions should not be capped at five years, as many practices simply cannot participate due to their specialty or patient population.

7. Other Measures

We recommend that CMS include measures in MIPS that are focused on chronic conditions, preventive services, and care coordination. When selecting measures, CMS should consider a measure's likelihood to contribute to progress, interoperability, and utility in multiple settings.

8. Development of Performance Standards

CMS seeks comments on what performance standard should be used to evaluate physicians under the MIPS. CMS also requests comments on how it should measure and incorporate continual improvement by physicians in calculating the MIPS performance score.

The ACR notes that for any given measure, continual improvement becomes asymptotic. Each Standard Deviation of improvement captures progressively smaller percentages of improvement, therefore physicians should not be penalized for failure to achieve improvement year over year. A physician who is already highly compliant with measures is unlikely to show much improvement from year to year, while one who was markedly deficient will have greater opportunity to improve.

Additionally, the ACR strongly urges CMS to make every effort to reduce the gap between the performance period and the payment year. Payment adjustments based upon a performance period that occurred two years earlier force the agency to truncate development of policies and hinders timely modifications in the program. It also translates into physicians having little or no understanding of the components on which they are being judged at any given time.

- Which specific historical performance standards should be used? Should CMS use providers' historical quality and cost performance benchmarks and/or thresholds from the most recent year feasible prior to the commencement of MIPS? Should performance standards be stratified by group size or other criteria?

Physicians should be compared to peers based on specialty and regional variations. The benchmark should be stabilized for two years and should take into account risk. CMS should collect and validate a baseline first before looking to 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 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. Because a 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.

- For the CPI performance category, what, if any, historical data sources should be leveraged?

Historical comparisons should be avoided. If improvement is the goal, there could be an incentive to be as non-compliant as possible in the first year, and to then make slow improvement over the ensuing years. This does not make sense from a patient outcomes perspective. **We strongly recommend that CMS incentivize participation in QCDRs, and ultimately EHRs, and focus on promoting real time data feedback to providers in the form of dashboards and reports.**

- How should CMS define improvement and the opportunity for continued improvement?

Measuring improvement is difficult. **We would encourage a focus on the baseline score over a longer period of time rather than recalculating every year or every quarter.** There will be much random movement, and as the goal is to identify trends there will need to be more than two data points.

- What should be the threshold(s) for measuring improvement?

If a physician does well under MIPS, that success should not lead to penalizing the physician in later years because their beginning baseline reflects higher performance expectations. CMS should be measure meaningful improvement, not year to year variation.

- How would different approaches to defining the baseline period for measuring improvement affect EPs' incentives to increase quality performance? Would periodically updating the baseline period penalize EPs who increase performance by holding them to a higher standard in future performance periods, thereby undermining the incentive to improve?

A fixed baseline comparator would be best. It will be difficult for EP-level measures to show statistically significant improvement due to small sample sizes, smaller practices most of all. Therefore the reasonable option is to focus on relative performance first, and then to transition to improvement or allow providers to be rewarded for either.

- Should CMS use the same approach for assessing improvement as is used for the Hospital Value-Based Purchasing Program?

The advantage of this approach is that it rewards either relative performance or improvement. The disadvantage is it does not acknowledge there is likely a performance floor. We encourage CMS to evaluate this annually for signs that providers are approaching a floor, e.g., variation has narrowed and there is no longer a consistent trend toward narrowing of distribution and provider performance is showing only random movement.

- Should improvements in health equity and the reductions of health disparities be considered in the definition of improvement? If so, how should CMS incorporate health equity in the formula?

The ACR encourages CMS to invest in additional bonuses to reduce disparities, which would then give providers serving vulnerable patients more resources, rather than making them compete for a share of limited resources.

9. Flexibility in Weighting Performance Categories

CMS also seeks comments on how it should assess performance under each of the four MIPS performance categories and combine the performance to determine a single composite score. CMS requests feedback on technical questions related to determining the performance score.

- Generally, what methodologies should be used as CMS determines whether there are not sufficient measures and activities applicable and available to types of EPs such that the weight for a given performance category should be modified or should not apply to an EP?

The determination should be based on the EP's scope practice. Unfortunately, meaningful outcome measures at the specialty level are rare. As noted previously, a simple and fair way to inject flexibility and allow providers to participate in measures and activities relevant to their scope of practice is to create a points system. As an example, under such a system, if all available MIPS programs were worth a total of 150 points, then an individual provider or group might fulfill MIPS requirements by participating in activities most relevant to their scope of practice from a range of the performance categories while achieving the required 100 points. Minimum requirements for points from specific categories would preserve the goal that quality improvement activities span a range of domains. Exceptions must be allowed for subspecialties with too few measures in a given category. The basic principle we endorse is that there should be more points available than the required threshold, such that providers can leverage some flexibility.

- What safeguards should CMS have in place to ensure statistical significance when establishing performance thresholds? For example, under the VM one standard deviation is used. Should CMS apply a similar threshold under MIPS?

Ideally this would be empirically determined for each measure, but one standard deviation is reasonable generally. However, if there are no statistics, at a national, practice level, that the measure has improvement in long-term outcomes, they should not be included.

10. MIPS Composite Performance Score and Performance Threshold

- How should we assess performance on each of the four performance categories and combine the assessments to determine a composite performance score?

First, the ACR recommends that the focus on improvement should be postponed until well accepted metrics are agreed upon. Second, we believe that MU should be eliminated until there is a push by CMS to hold vendors accountable for interoperability and true usability standards. Again, the availability of a greater number of menu items to achieve the necessary score is the key to allowing specialty and scope of practice flexibility in the program, and would be more efficient than making provider based rules and exemptions.

- How can we establish a base threshold for the clinical practice improvement activities? How should this be incorporated into the overall performance threshold?

CMS should not establish a base threshold for the clinical practice improvement activities. It would be premature to define this without knowing what the measures will be.

11. Public Reporting

MACRA requires CMS to provide physicians with confidential feedback reports on their performance under the MIPS. CMS seeks input on the content and format of these reports and the mechanisms that should be used to make them available. CMS also seeks comments on the minimum threshold for publicly reporting physicians' MIPS performance scores and activities on the Physician Compare website.

The ACR recommends that if physician performance is made public, reference to specialty-specific EPs and EPs in similar regions should be provided. Most importantly, data should not be presented in raw fashion but in context, with clear explanations as to what measures were used to judge performance, and what percentages each was weighed, and what variables were outside of the physician's control. Ideally, as few measures as possible would be out of a physician's control.

The ACR also points out that MIPS is an opportunity to learn from failures in current programs. We suggest that CMS first work on carefully designing the MIPS system, in a way that is as simple, transparent, and meaningful as possible. Then the agency could accrue a minimum foundation of data using the new system, e.g., at least two years of data; confidentially share that data with practicing physicians via clear, easy to understand feedback reports; and at the same time 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.

We 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 providers for internal analysis.

- What should be the minimum threshold used for publicly reporting MIPS measures and activities for all of the MIPS performance categories on the Physician Compare website?

Non-participation, or non-compliance should be the minimum reportable criteria.

The physician either complied or they did not. Comparative reporting can lead to false conclusions, because unless the standard errors are reported for each physician and this is properly explained and understood, comparing one practice to another will often be interpreted as one practice doing a better job, when in reality they are performing equally.

12. Feedback Reports

We request that CMS 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. CMS should clearly describe in feedback reports the methodologies used to comprise any benchmarks or attribute patients for a particular measure. This information must be clearly identified and easy to interpret. Current feedback reports lack key details to understanding the methodologies used to arrive at the benchmarks and other calculations made.

Additionally, the log-in process for accessing reports must be simple and user-friendly. There have been problems with accessing reports due to the complicated log-in process and password requirements which reset at short intervals, complicating the log-in process and ultimately limiting access to reports. CMS should make staff available to help physicians and administrators interpret the reports. Additionally, CMS should 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.

- What types of information should we provide to EPs about their practice's performance within the feedback report? What level of detail will be beneficial to practices?

It will be helpful to have as much data as possible reported back to EPs, with as much context as possible, including clear explanations of how the data was used to calculate performance, and comparison to similar specialists and local physicians. The data should be patient-level, identified to allow local quality improvement efforts.

- With what frequency is it beneficial for an EP to receive feedback? Currently, CMS provides Annual Quality and Resource Use Reports (QRUR), mid-year QRURs and supplemental QRURs. Should we continue to provide feedback to MIPS EPs on this cycle?

Currently, feedback is not being given to EPs in a timely fashion that allows adjustments. CMS should provide feedback on a quarterly basis so that performance can be improved prior to subsequent cycles. The feedback should be simplified.

B. Alternative Payment Models

The ACR notes that existing APMs that are eligible for credit under MACRA are too limited and few are natural fits for most rheumatologists. For example, within Accountable Care Organizations, rheumatologists are a very small community compared to large service lines such as orthopedic, cardiology, oncology, etc. Other specialties also have long histories of working in health care systems. Additionally, the high cost of the drugs used to treat patients with rheumatic disease may make rheumatologists less attractive to include in ACOs.

1. Information Regarding APMs

Payment Incentive for APM Participation

CMS requests comments on issues related to whether a physician meets the definition of a “qualifying APM participant.” For example, CMS requests input on how to determine whether the APM payment thresholds are met if payments are made to a group practice or ACO rather than directly to the physician. CMS also requests comments on how to account for payments to physicians on other than a fee-for-service basis (e.g., capitation).

The ACR recognizes that the problem of attribution is extremely complex. We encourage a low bar for reimbursement funds to be included in the threshold, to encourage providers to make shifts toward participating in APMs. If funds are parsed inaccurately, providers risk losing qualification status. In order to help CMS attribute non-FFS payments, providers should have the option of disclosing specific RVU or raw income totals, but should not be forced to do so.

- How should CMS define “services furnished under this part through an EAPM entity”?

The definition should be broad, and we recommend allowing variance in meeting thresholds. In order to ensure that the physicians participating in the APM are able to influence the governance policies of the APM Entity, CMS should require such entities to provide for meaningful participation in governance by physicians whether or not the APM Entity is a physician-owned organization. APM Entities could include physician practices, independent practice associations, physician-hospital organizations and other organizations. If the organization is a hospital or other entity that is not physician-owned, it should be required to provide a means for physicians to influence governing policies.

Additionally, it is important for CMS to allow flexibility for proposed APMs to outline different organizational structures to serve as APM Entities and different pathways by which revenues might flow through the APM Entity. CMS should not require all APM Entities to be organized the same way, nor should it require every physician participating in an APM to obtain a new APM identification number. Different APM designs will require different types of APM Entities.

a. Patient Approach

It is important to note that physicians in an APM could be contributing to the patient's care and the goals of the APM in other ways besides face-to-face visits and procedures for patients. In some cases rheumatologists, for example, could be consulting with primary care physicians on how to manage patients without seeing the patients themselves. Diagnosis, treatment, and management for many patients in the population served by an APM may involve multiple physicians, each of whom could potentially legitimately count the patient as their patient. We also contend that eligible physicians should not be required to use either the patient or payments approach. They should retain the option to use the patient approach to calculating the share of their Medicare business attributable to one or more APMs or to use the revenue approach.

b. Nominal Financial Risk

- CMS seeks input on the requirements for qualifying as an "eligible" APM for purposes of the incentive payment. For example, what should be the appropriate level of risk that an APM must bear to qualify, and what quality measures the APM must use to measure performance?

APM eligibility could be automatically granted by certification or endorsement from a variety of groups including not only NCQA but also state and local insurance commissioners or specialty societies. Lower risk thresholds will help speed adoption. **All quality measures published by specialty societies should be automatically eligible to be APM quality measures, but specialty society designation should not be a prerequisite.**

Additionally, one-sided risk should be considered more than nominal financial risk due to upfront investment. Non-billable costs should count as risk (i.e., startup, technology infrastructure, maintenance, etc.). Physicians will be much more willing to take accountability for costs that they can affect through their own performance, such as the costs of preventable complications.

2. Information Regarding Physician-Focused Payment Models

CMS seeks comments on establishing criteria for evaluating new physician-focused payment models, including whether different criteria should apply to payment models aimed at physician specialists. CMS also requests feedback on what information should be included in stakeholder proposals to the Technical Advisory Committee for new APMs.

The ACR notes that small practices, especially in lower visibility specialties, such as rheumatology, will likely do poorly under this system. **Therefore, special attention should be given to facilitating the participation of small and solo practices in APM entities.** There should be opportunities developed for physicians to transition into value-based payment and APMs. Without

special attention it will be difficult for small and solo practices in rural and under-served areas to participate in APMs.

It will be important for CMS to develop the APM program in a way that facilitates a broad spectrum of physician participation. **In many cases it will be essential for a single EAPM entity to be able to participate in multiple APMs.** With regard to financial risk of individual providers participating in APMs, we recommend that each APM entity can determine whether and how each participating provider bears financial risk, and CMS need only verify that the entity has a means for handling risk.

CMS should collaborate with specialty societies to provide feedback on drafts and upfront data to help in modeling impact. **New PFFM proposals should be developed by identifying opportunities to improve care for patients that will also reduce spending.** For example, if better management of a patient's chronic disease can prevent the patient from being hospitalized or from requiring expensive surgeries, the patient is getting better care that also reduces spending. There are many high-value physician services that would benefit patients and help reduce avoidable spending, but the current payment system generally does not provide payment for them. **APMs should also not necessarily be complex.** For example, models that simply pay physicians for specific high-value services in return for a commitment from the physicians to manage specific types of avoidable spending should qualify.

C. Technical Assistance to Small Practices and Practices in Health Professional Shortage Areas

MACRA provides for technical assistance to small practices and practices in Health Professional Shortage Areas. CMS is to enter into contracts with organizations to offer guidance and assistance to MIPS EPs in practices of 15 or fewer professionals, with priority given to small practices in rural areas, HPSAs, and medically underserved areas, and practices with low composite scores. **The ACR asks that determination of medically-underserved areas include consideration by specialty.** For example, the same area that has an abundance of cardiologists may have a severe shortage of rheumatologists serving the area. The agency should also allow for a multi-year provider technical assistance commitment.

The American College of Rheumatology appreciates the work that CMS does and the opportunity to respond to the Request for Information. We look forward to being a resource to you and to working with the agency as MACRA is implemented. Please contact Adam Cooper, Senior Director of Government Affairs, at acooper@rheumatology.org or (404) 633-3777 if you have questions or if we can be of assistance.

Sincerely,



Joan M. Von Feldt, MD, MEd
President, American College of Rheumatology