AMERICAN COLLEGE of RHEUMATOLOGY
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September 10, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically via regulations.gov

RE: [CMS-1751-P] Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure,

The American College of Rheumatology (ACR), representing over 7,700 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the CY 2022 Physician Fee Schedule and Quality Payment Program proposed rule as published in the *Federal Register* on July 13, 2021. We welcome the opportunity to share our comments regarding the impact of these policies on our ability to provide quality care to the 50 million Americans living with rheumatic diseases.

Rheumatologists and rheumatology healthcare professionals provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. They provide primarily non-procedure-based care to patients with severe conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases. Rheumatologists and rheumatology professionals also work closely with physical and occupational therapists to maximize the ability of patients to achieve and maintain independence outside of healthcare settings. Early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly surgical or interventional procedures. The improved outcome enables our patients to continue to be more productive than they would have been without timely treatment.

The ACR thanks the Centers for Medicare and Medicaid Services (CMS) for its continued recognition of the value of complex medical decision making provided by rheumatologists and other cognitive care specialists in treating their patients by continuing to operationalize and fine-tune the Evaluation and Management (E/M) code revaluation and documentation requirements. Our nation's healthcare system continues to navigate the challenges of a global pandemic that has strained resources and providers. We appreciate the policies and flexibilities set forth by CMS to help alleviate these challenges while we all work to provide quality care for our patients. In light of the ongoing volatility and unknowns in the healthcare system, the ACR offers the following comments on the policies regarding the decreased conversion factor, practice expenses, E/M split visits, telehealth flexibilities, Part B calculations, and the Quality Payment Program (QPP).

Proposed Provisions in the CY22 Physician Fee Schedule

Conversion Factor
For the PFS in CY 2022, the proposed conversion factor (CF) is $33.5848, representing a 3.75% decrease from the 2021 CF of $34.8931. The Consolidated Appropriations Act (CAA) of 2021 funded a 3.75% positive payment adjustment, which helped mitigate some of the scheduled reductions to the CY 2021 CF. This update was only funded for CY 2021, and Congress will need to extend it through CY 2022 and beyond. **The ACR strongly urges CMS not to move forward with this damaging impact to an already strained system. We urge CMS to maintain the CF of $34.8931 at least through CY23. The reduction in the CF comes when physician practices and hospitals face the uncertainty of the future and their pandemic recovery.**

Physician Work and Practice Expense (PE) Relative Value Changes
CY 2022 is the final year of the four-year transition to update pricing data for supplies and equipment, meaning PE input pricing for the affected items in 2022 will be based on 100% of the new pricing. The effect of this policy has varied across codes in the Medicare PFS. Rheumatology practices have closely monitored its impact on practice expense (PE) RVU and have had to make significant changes to their practices. In conjunction with this final year of the equipment pricing update, CMS proposes an update to the CY 2022 clinical labor pricing, using data from the US Bureau of Labor Statistics and a methodology outlined in statute (66 FR 55257). Stakeholders recognize there will be potential distortion in the allocation of direct PE that would result from updating the supply and equipment pricing without updating the clinical labor pricing. All changes are disruptive to the business model of medical practices, but changes that adequately reflect actual expenses are necessary to prevent skewed reimbursements from being exaggerated over time. **Therefore, the ACR recommends CMS using a similar four-year transition to implement the clinical labor pricing update to minimize the financial impact on physician practices and other providers such as physical and occupational therapists.**

Evaluation and Management (E/M) Services
The ACR appreciates that CMS recognizes the value of cognitive care specialties by continuing to operationalize the revalued evaluation and management (E/M). Unfortunately, many rheumatologists across the country have yet to benefit from these revalued codes as their employers have decided to postpone operationalizing these codes and subsequent reimbursement to the specialists in their healthcare system while benefitting from the increased CMS reimbursement. We can appreciate the logistical and financial challenges presented to institutions to appropriately implement these new revalued codes for providers that they employ. However, after years of under-valuation of cognitive specialties' work and medical decision-making requirements, **we urge CMS to continue to monitor how the updated E/M codes are operationalized.**

With the 2021 implementation of the office and outpatient E/M visits recommended by the CPT Editorial Panel and the Relative Value Update Committee (RUC), CMS proposes revisions to the policy on split (or shared) visits and teaching physician visits. CMS recommends defining a split (or shared) E/M visit in the facility setting (i.e., an institutional setting in which payment for services are furnished "incident-to" a physician or practitioners professional services) and performed in part by both physician and non-physician practitioners (NPPs) practicing in the same group. This proposal also includes a policy modification to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients. CMS proposes that a modifier be created to describe these split (or shared) visits in claims data.

Additionally, CMS proposes that when total time is used to determine the office or outpatient E/M visit level for teaching physician services, only the time that the teaching physician was present can be included. Under the current Medicare telehealth exceptions, this includes virtual supervision.

The ACR appreciates CMS' revisions to its long-standing policy on billing for split (or shared) visits as the changes provide new opportunities for billing these services but may also restrict the reimbursement opportunity of providers overall. **While we recognize the need to fine-tune the rules for E/M visits, we want to ensure that providers can successfully implement the revised policy for split (or shared) visits. We encourage CMS to work with specialties to ensure that these revisions will not be burdensome, especially as it relates to time tracking for the "substantive performance" of the provider to allow for accurate billing.** Additionally, we ask CMS to ensure that "Same Group" is defined as a situation where the NPP and physician are employed by the same employer or are in the same clinical specialty practice.

Telehealth / Audio Only

Extension of Coverage for Category 3 Services Through the End of 2023
In the CY 2021 MPFS, CMS extended several telehealth flexibilities to allow continued care during the pandemic by establishing a list of Category 3 telehealth services that would have limited coverage after the end of the PHE. CMS is proposing to continue to cover these Category 3 services through December 31, 2023. The extension allows CMS to evaluate these services for permanent inclusion in Categories 1 and 2 covered Medicare telehealth services. **The ACR appreciates this proposal and looks forward to working with CMS in their evaluation and analysis of the PHE data. We anticipate the data will show the appropriateness of these flexibilities and the specific benefit of increased access in rural areas and other areas where beneficiaries have difficulty getting to their providers.**

Direct Supervision Requirements
The CMS 2021 Medicare Physician Fee Schedule temporarily changed direct supervision rules to allow a supervising physician to be remote and use real-time, interactive audio-video technology during the public health emergency (PHE). The direct supervision waiver is scheduled to expire on December 31, 2021, or at the end of the PHE (whichever is later). CMS is seeking comments on whether this policy should be extended beyond the PHE to permanently allow direct supervision via telehealth.

The ACR appreciates the flexibility of CMS to allow for direct supervision via audio-video communication during the PHE and recommends permanently allowing this service as it would immediately provide timely access to cognitive services for Medicare beneficiaries and relieve undue burden to an aging population.

Permanent Adoption of Virtual Check-In (Code G2252)
In the CY 2021 MPFS Final Rule, CMS established, on an interim basis, code G2252 for an extended virtual check-in (11-20 minutes), which allows healthcare providers to briefly check in with an established patient using any form of synchronous communication technology, including audio-only. **The ACR strongly supports CMS in permanently adopting coding and payment for code G2252 as this is an added benefit for the Medicare population, especially in rural areas.**

Determination of ASP for Certain Self-Administered Drug Products
The Consolidated Appropriations Act of 2021 includes a provision that calls on the Office of the Inspector General to identify drugs for which there is a self-administered code and physician office-administered code and recommend adjustments in the payment method. The Secretary will use these reports to base payment on the lesser of either the current payment methodology or a calculation that does not include the self-administered formulation. For the CY22 Physician Fee Schedule, CMS has determined that drug products, Cimzia and Orencia, should be calculated using the lesser payment model. **The ACR strongly opposes these recommended payment adjustments as they may negatively impact patient's access to the most appropriate treatment for their disease.**

Biologic drugs are critical therapeutic options for patients with rheumatic diseases. Choosing one drug over another requires careful clinical evaluation and consideration by a physician specializing in diagnosing and treating rheumatic diseases. An individual patient's age, gender, diagnosis, medications, specific organ manifestations, antibody status, disease severity, comorbid conditions, functional status, social support, and ability to tolerate the route of administration strongly influence the specific biologic choice.

Biologics with separate formulations, such as those administered by subcutaneous versus intravenous routes, are distinct with sufficiently unique indications, risks, and target patient populations. Several factors influence a rheumatologist's choice of biologic therapy. Among these are previous allergic or infusion reactions, painful injections or infusions, an individual's infection risk, other safety concerns, as well as the different methods of delivery. In addition, the clinical response and adverse effects of any biologic will vary by the individual patient. Thus, a patient relies on the specialized training and experience of the treating rheumatologist to determine the most reasonable, medically necessary treatment. To make an appropriate medical decision, the rheumatologist follows the standards of medical practice and incorporates the patient's unique medical history.

The OIG report erroneously asserted that providers are monetarily incentivized to administer Orencia or Cimzia over other therapies. We strongly refute this assertion. Rheumatologists select the most appropriate treatment for their patients without any consideration of financial incentives. We must note that most Medicare patients are unable to afford biologic therapies unless offered through Part B. While the OIG report references patient's high copays on Medicare, our experience is that patients with part B coverage can access treatment if they have a supplemental plan but have fewer options if they do not.

Excluding self-administered formulations of Orencia and Cimzia from the Part B calculations will jeopardize the provider's ability to provide the most appropriate care and treatment for their patient. **Therefore, we urge CMS not to implement OIG's recommendation of excluding self-administered formulations of Orencia and Cimzia from the Part B calculations.**

Proposed Provisions in the Quality Payment Program (QPP)

The ACR appreciates the effort CMS has invested in this proposed rule. We support many of the steps that CMS is taking to reduce burdens and move stakeholders forward to greater data standardization and interoperability.

While the ACR strongly supports and looks forward to participating in data standardization and interoperability efforts, we encourage CMS to conduct an environmental landscape assessment of EHR software capabilities with a particular focus on EHRs used primarily by small and/or rural practices. The ACR hopes that CMS will conduct this assessment both now and following the ONC's deadline to update technology to meet the new certification criteria. However, we do not share the same level of optimism as CMS that EHR vendors will successfully meet all requirements in the allotted timeline, which would help facilitate many of CMS' proposals in this rule. Therefore, **we remain concerned with recommendations in this rule (e.g., digital quality measures, PI measure Provide Patients Electronic Access to Their Health Information) that require providers to meet interoperability standards that their EHR may or may not fully support.**

CMS should consider a practice's reasonable ability to meet the requirements outlined. For example, while efforts are underway on the side of EHRs to provide data to patients, registries, CMS, and various other interested parties and provide it in a standardized format, those efforts are far from complete. As a result, most clinicians, particularly those in small or rural practices, cannot meet interoperability technology requirements without direct and often expensive work from the EHR vendor.

We agree standardizing data and making it available to patients is an important and worthwhile effort. Our concern is that CMS holds practices and clinicians accountable, which they often do not control. The environmental scan should consider costs to the practice for access, specialty-specific templates and reports, registry participation, patient portal access, and more for the EHR implementation. It may be particularly worthwhile to consider the cost of all necessary features to perform well in the evolving MIPS/MVP program concerning practice income. In addition, we encourage CMS to consider the practice resources and staff time needed to implement CMS's vision of EHR functionality within a practice. We understand CMS requiring practices to use the technology available to them through the EHR, but it can be a burden to implement. We hope CMS will consider which elements of interoperability are genuinely and solely under the purview of the clinician and will not make requirements beyond those limits or will update the appropriate exemption policies to allow clinicians and practices to advocate for themselves on a case-by-case basis.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs- Request for Information

The ACR also strongly supports CMS's efforts to include quality measurement to push data standardization and interoperability forward. We see these efforts as a significant step forward in reducing data collection and reporting burden for health care providers. We are encouraged to see the shift toward digital quality measures and believe building digital quality measures (dQMs) that interface with FHIR-based APIs is very promising.

While we want to see this work move forward, the timeline put forth by CMS to accomplish its goal of moving entirely to digital measures is concerning. CMS writes, "We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data." Efforts to meet this standard by 2025 have the potential to disproportionately impact specialists. Unfortunately, many key data elements required to evaluate the care of rheumatology patients, such as assessment of disease activity and results of patient-reported outcome tools, are currently not incorporated into the FHIR standard. The time and work required to build FHIR resources for these elements are extensive. They include updating specifications and value sets, implementing the updated measures in reporting systems, such as the ACR's qualified clinical data registry (QCDR), and ensuring that the providers' EHR systems have incorporated the new standards are likely to strain CMS' goal of 2025. These elements will also strain measure stewards' resources such as staff, volunteers, and financial considerations.

As the steward of several measures in the MIPS program, the **ACR requests that CMS consider and provide more information on what will be expected of measure stewards to assist in modernizing the quality measurement enterprise.** With this information, the ACR can provide more detailed feedback on logistical concerns and our ability to assist in meeting CMS' timeline or setting a new one.

As previously noted, an essential requirement to successfully modernize the quality measurement enterprise is ensuring EHR systems have incorporated the new FHIR standards required to facilitate the calculation and reporting of dQMs. We hear from our providers regularly about their struggles in finding an EHR system that accommodates the specific needs of rheumatology providers for a reasonable price. Often, practices must make additional investments – beyond obtaining an EHR system – to access specialty-specific templates or develop custom forms to facilitate the collection of specialty-specific data. **We urge CMS to consider taking the following steps in evaluating the readiness of CMS, its measure stewards, EHR systems, and the medical community to move to dQMs by 2025:**

- **Evaluate the success of a wide variety of EHR systems in adopting and incorporating FHIR and interoperability standards as laid out by ONC and CMS and the cost to providers to access all relevant functionality**
- **Review the data elements required to support each of CMS' measures against available FHIR resources and identify elements where no FHIR resources currently exist to support the calculation of dQMs**
- **Define the role that CMS will play in the development of new FHIR resources to support the transition to and development of new dQMs**
- **Determine the role that measure stewards and measure developers, including organizations with QCDR measures, will play in supporting the transition to dQMs**

The ACR also has concerns with CMS' interest in developing dQM software as an end-to-end measure solution. CMS refers to its vision of "an end state where technology will allow for the submission of discrete data elements several times. As a result, CMS will be able to calculate measure performance for clinicians, subgroups, and groups, rather than having measure performance aggregated and calculated at a group or subgroup level before reporting." **We strongly encourage CMS to leverage the already available resources through the network of experienced QCDRs to support this vision.**

As an organization that operates a QCDR that has assisted rheumatology providers in completing their federal reporting under both PQRS and QPP since 2014, we are experienced in measure development and implementation. While data standardization and improvements in interoperability will undoubtedly lead to significant improvements in the ability of all stakeholders to implement measures consistently, we are concerned that developing dQM software as an end-to-end measure solution can limit the overall usefulness of the dQMs.

The ACR QCDR staff members interact directly with providers to better understand their specific processes, data collection, and mapping implications. These efforts continue the shared goal of ACR and CMS to reduce the burden of reporting for health care providers by allowing them to continue with the most efficient data capture method. The ACR successfully extracts the necessary data to complete measure calculations showing actual, accurate, and complete performance results with direct input. Moving to end-to-end software would risk limiting innovation and flexibility in providers capturing the information required for measures. This flexibility is crucial as FHIR does not currently provide the necessary standards for rheumatology data. FHIR standards still contain glaring gaps, and the ACR does not anticipate that they will change quickly given the ever-evolving data needs of the health care community. Furthermore, while the existence of more comprehensive and interoperable standards would be a significant step toward dQMs, the success of those efforts remains heavily dependent on whether the documentation patterns happening daily during the normal course of patient care align with data and interoperability standards.

We believe that organizations with established QCDRs are uniquely positioned to partner with CMS in helping guide the transition to and management of dQMs. Organizations like the ACR have been integral to the success of MIPS thus far. QCDRs spend significant time and resources to help providers understand and successfully navigate the world of quality measurement and federal reporting. As a result, we are familiar with measure development and implementation processes and common pitfalls when translating quality measures into computer software and accurately feeding back performance information to providers.

Through such a partnership, organizations with QCDRs could not only serve as a source of valuable information while transitioning to dQMS, but they could also serve as a direct line to providers to help ensure that the entire medical community is moving forward together. We believe that QCDRs,

particularly those maintained by specialty organizations, have much to offer CMS to move toward data standards, interoperability, and dQMs. CMS would be remiss if it failed to leverage the resources already available to support its efforts.

Closing the Health Equity Gap RFI
CMS' efforts towards addressing the health equity gap should be applauded. However, it is a complex issue plagued with a core shortfall seen across many healthcare issues – the data required to understand the problems and develop solutions entirely are fraught with disparities and inaccuracies. As CMS works to continue improvements in data collection relevant to health equity, the **ACR recommends ongoing collaboration with organizations that manage QRs and QCDRs to identify and collect health equity data.** Many of these organizations are uniquely positioned to conduct targeted provider outreach about educational opportunities and further encourage data collection by incorporating the data elements into actionable feedback providers can access via the registry.

MIPS Value Pathway (MVP)
The ACR is pleased that CMS has included more details for the MVP pathway than previous rules and plans to approve a rheumatology-specific MVP. However, we continue to be concerned that the MVP pathway is simply MIPS with fewer measure options per category, which we do not believe is the aim, nor is it ideal for the clinicians attempting to report using this pathway. We hope our comments will help CMS to create a more meaningful and genuinely unique MVP pathway.

Implementation Timeline
The ACR appreciates the reasons for delaying the timeline for implementing MVPs to the 2023 performance year. Therefore, we support this proposed provision. Additionally, we understand the proposed timeline for the inclusion of fully tested QCDR measures in MVPs. This timeline creates an efficient pathway for the inclusion of QCDR measures in both MIPS and an MVP.

Sunset Traditional MIPS
CMS has outlined the plan to evolve the QPP by moving away from traditional MIPS towards MVPs and APMs. **The ACR encourages CMS to delay setting a deadline for sunsetting traditional MIPS until the success of implementing MVPs is evaluated.** Many details of the MVP program are still being addressed through the rulemaking process, and it simply seems too early to assess the timeline for sunsetting MIPS accurately. We believe it should be no earlier than after the 2027 performance year.

Requiring MVP Support by QCDRs & QRs
We understand the intent behind the plan to require QCDRs, Qualified Registries (QRs), and Health IT Vendors to support MVPs relevant to their users. Still, we have significant concerns about the same groups' abilities to meet the requirement. Some logistics must be addressed before MVPs are operationalized (e.g., measure licensing). The ACR has invested significant time and resources in developing high-quality QCDR measures and developing and submitting MVP proposals to CMS. We are pleased to be among the first MVPs offered in the program but need more time to understand whether and how the MVP we developed might be shared with another organization. We are also concerned that the burden will be significant to organizations tasked with implementing an MVP that they did not propose to CMS. It is unrealistic for providers to learn of a new MVP that applies to a specific patient population in July and is expected to support the MVP the following January. **We recommend CMS suspend the plan to require MVP support until at least 2025 to allow all involved time to complete one complete cycle of MVP reporting.**

Subgroup Timeline & Registration
The ACR supports the delay in requiring multispecialty groups to form subgroups for reporting in the initial years of the MVP. However, CMS should consider when to require registration as a subgroup after

the first round of MVP reporting. It is appropriate to state intentions to require subgroup reporting by 2025. Still, we encourage CMS to remain open to revising timelines after all involved have experience implementing the MVP performance and reporting processes.

We understand that CMS needs to set a deadline for subgroup registration, but QCDR/QR registration deadlines must also be considered. For example, CMS established a deadline for subgroup registration by November 30. However, the QCDR supporting the subgroup's selected MVP has its registration deadline (as approved in the self-nomination process) of September 30 to report for the performance year. Thus, even though the subgroup has until November 30 to register with CMS and declare the MVP they wish to participate in, the QCDR's deadline must override CMS's deadline for MVP participation for the performance year. The QCDR/QR set deadlines for enrollment to ensure the completeness and accuracy of reporting for all users. Registration with the QCDR/QR should occur before registration with CMS, or CMS must allow for changes to planned MVP reporting after the deadline if a practice cannot onboard to the QCDR/QR in time to report.

Changing Reporting Pathways
The ACR urges CMS to allow practices to move from a selected MVP back to traditional MIPS before submission for the 2023 and 2024 performance years. We understand CMS's desire to limit any shifting to a particular timeframe (e.g., April 1 to November 30 per the proposed rule). However, we feel strongly that practices will need flexibility in reporting as they embrace the new model, especially in the first years of MVP implementation. For example, a practice may select and register for an MVP but later discover their EHR does not support accessible collection and sharing of crucial data points for the measures within the MVP. Practices and clinicians should be given every opportunity to succeed in the QPP, including reporting traditional MIPS so long as it is an available pathway.

Subgroup Reporting PI at Group Level
We recognize the proposal that subgroups continue to report the Promoting Interoperability score at the group level. However, the ACR is concerned about practices' real-world ability to make this work. The organizations most likely to utilize the new subgroup designations are large and complex, with multiple sites and many staff. To allow them to split into smaller groups for reporting everything except this one category creates a coordination burden and raises the likelihood of an accidental double-reporting of the same category, which CMS currently handles as a score cancellation. Therefore, **we support subgroup scoring of PI at the group level but urge CMS to accept subgroup reporting at both the subgroup and group level.** The scores should match because the data is coming from the group, so there is no reason to have two submissions cancel each other.

Population Health Measures
The ACR appreciates the importance of including population health measures in the MVP. However, we continue to be concerned about the lack of measures applicable to specialty clinicians and the lack of transparency in the attribution for the population health measures currently in use. CMS consistently states the desire for the QPP to be a tool for transparency to patients selecting a clinician. **We strongly believe the QPP scoring process must also be transparent to clinicians.** It is appropriate to require oversight for federal funds, but it is unreasonable to arrive at a score without transparency in the calculation. Clinicians cannot address any issues in real-time to improve patient outcomes and their performance outcomes in the QPP.

One way to address this would be to expand population health measures to include CQMs and QCDR measures options. Many standard quality measures are broad enough to capture a significant population of patients who share a general characteristic. For example, QI 176: Tuberculosis Screening Prior to First Course Biologic Therapy is a measure that could cover multiple specialties. It is focused on patient safety by encouraging providers to screen patients for TB before starting the first course of biologic therapy.

Such measures would also help address the lack of real-time performance feedback as QRs and QCDRs can implement them.

The ACR is also concerned with including the population health measure score in the quality category score. Clinicians have the opportunity throughout the year to monitor and improve their performance on quality measures. As noted above, the same is not valid for the population health measures currently included in the QPP. **We encourage CMS to score the population health measures separately from the Quality category and limit the extent to which those measures can harm a practice or individual or remove them entirely.** If the opportunity for practices and clinicians to fully understand and track the existing population health measures throughout the year comes around or if the list of population health measures is extended to include trackable, transparent measures, it would be appropriate to have in the quality category again.

Scoring

Final Score Selection
The ACR appreciates CMS's intent to select the highest final score achieved for a TIN/NPI across the QPP pathways. This is appropriate given the effort practices and clinicians put into completing reporting each year.

New Measures
The ACR supports CMS's proposal to establish a 5-point floor for the first two years that a new measure is included in the MIPS and MVP programs until a baseline benchmark can be created. We sincerely appreciate CMS listening to stakeholder concerns and proposing a potential solution.

Bonus Points
The ACR urges CMS to reevaluate its plan to remove the end-to-end electronic and, more importantly, the high-priority bonus points. In the case of end-to-end electronic reporting, these bonus points appropriately reward practices for participating in the program as CMS desires, capturing data electronically until it is required through rulemaking.

The high priority bonus encourages providers to track and improve on more measures that benefit patients. The high priority bonus is also key to QCDRs introducing new QCDR measures that align with CMS' measurement goals as providers are often willing to submit them in addition to – but not in place of – other benchmarked measures.

Additionally, maintaining the bonus points can help combat problems obtaining appropriate differentiation among practice performance due to clinical quality measure selection bias, a concern noted by CMS in this proposed rule. The bonus points encourage providers to report on a wider variety of measures, particularly measures that CMS has identified as important indicators of quality of care even if a measure is not a top-scoring measure for the clinician or practice. Furthermore, maintaining bonus points helps to incentivize a broader range of practices to take time to implement new measures. As a result, there is more willingness among providers to implement new measures. Providers recognize the importance of data elements where no current standard exists if these new measures provide an opportunity to impact their MIPS score positively.

Benchmarks for 2022
The ACR understands the concerns regarding using 2020 performance year data for benchmarking. **We support the proposed plan to apply the same process used for evaluating 2019 performance year data to 2020 performance year data to determine if data from that year are sufficient to establish benchmarks for the 2022 performance year.** Suppose it is determined that 2020 performance year data

would be inaccurate, or its use would negatively impact clinicians. In that case, we are in favor of using 2019 performance year data for benchmarking purposes. Suppose the 2019 benchmarks are used for the 2022 performance year. In that case, we encourage CMS to suspend categorizing topped-out measures as the benchmark would not appropriately acknowledge any measure changes made, which may lower the overall performance rate of the measure.

MIPS Cost Category

Cost Measure Development
The ACR recognizes that assessing the cost of care is an essential component of evaluating a provider's quality of care under the MACRA framework. While we understand the importance of considering cost, there is not yet an accurate cost measure for rheumatologists. The generally applicable measures of Total Per Capita Cost and Medicare Spending Per Beneficiary are the only two cost measures that might apply to our providers. **Unfortunately, these measures cannot give an accurate picture of the cost of care from our providers.** A cost measure that continues to split biologics between Part B and Part D artificially is significant for our providers. Medicare patients generally have a much lower out-of-pocket cost for Part B infusible biologics than for Part D biologics. Measures must be developed that align with the work of specialist providers, or the current measures are updated. **Until these measures capture the work of specialists and not the drugs used to treat the conditions, it is necessary to include both Part B and Part D medications. Therefore, the ACR urges CMS to reassign the Cost category points (or at least a significant portion of them) to the Quality category to reflect the work of specialty providers.**

CMS has requested comments on the factors that would limit the ability to calculate cost measures to adequately capture performance and may require reweighting of the category in the future. **ACR recommends that CMS contractors involve all specialty groups who benefit from the new measure in the development process.**

The process for creating cost measures should be transparent and open to others beyond CMS contractors. **The ACR appreciates CMS proposed pathway for other organizations to develop and submit cost measures for inclusion in MIPS.** The proposal would serve as an opportunity for interested stakeholders to help CMS move an essential aspect of QPP performance forward.

Section 105(b) of the Medicare Access and CHIP Reauthorization Act
The ACR has taken steps to conduct cost evaluations among rheumatology providers to identify ways to measure cost. However, there are significant barriers to completing this work. Even established programs for providing access to claims data have failed to provide clinician-led clinical data registries with meaningful access to claims data. **We urge CMS to completely implement Section 105(b) of the Medicare Access and CHIP Reauthorization Act as Congress intended. Implementation must include access to Medicare claims data for both quality improvement purposes *and* research efforts.** Access to claims data must be timely, broad, and continuous to link such data with clinical outcomes data, provide quality information to providers, and perform risk-adjusted, scientifically valid analyses and research. Once Section 105(b) is fully implemented, organizations can develop their own cost measures specific to the providers they support and submit those measures to CMS for approval and use across the QPP. Additionally, the implemented program will allow organizations to support necessary research within their fields and perhaps even offer a new avenue to bring in the resources required to continue to support CMS programs.

MIPS Promoting Interoperability (PI) Category

Automatic Reweighting for Small Practices

The ACR commends CMS for establishing the policy of automatically reweighting the PI category for small practices moving forward. This proposal reduces the burden for practices most likely to require assistance.

PI requirements
We support the goal of providing patients better access to their health data. However, some required measures (e.g., Support Electronic Referral Loops by Receiving and Reconciling Health Information) raise the concern that clinicians will bear the brunt of a lack of interoperability infrastructure. Much of a clinician's interoperability depends on their EHR and other technology vendors (e.g., web designers). While legislation such as the 21st Century Cures Act puts more pressure on EHRs to meet interoperability standards, there is much improvement to be made. Indeed, many of the requirements for EHRs will not be in place until 2022-2023, and those requirements may not resolve all current issues. A reasonable solution in the interim is to allow for hardship exemptions for either specific measures or the PI category generally for practices or clinicians who make the best, reasonable effort, given their EHR vendor and other technical capabilities, to meet the category requirements. If the EHR offers no solution, a partial solution (e.g., meets some required measures but not all), or only an expensive solution (particularly for small practices), clinicians should not be penalized.

Public Health & Clinical Data Exchange Objective
The ACR encourages CMS to delay implementing the requirement to report on the Immunization Registry Reporting and Electronic Case Reporting measures. We recognize and support CMS' goal to improve public health data. However, clinicians continue to practice under the uncertainty of a public health emergency while concurrently participating in MIPS. In addition, clinicians need at least a year to find, register, and implement reporting to a public health agency without penalty. Therefore, CMS should, at most, announce its intention of implementing this change but delay the implementation until the performance year 2023 to give clinicians adequate time to meet the new requirement.

MIPS Improvement Activities Category

Suspending Activities
The ACR understands the agency's goal to ensure that clinicians are completing meaningful Improvement Activities. **We appreciate that new information comes to light that must be addressed outside the rulemaking process. If information comes to light indicating possible patient safety concerns, we agree the improvement activity should be suspended immediately. Declaring an activity "obsolete" during the performance year seems inappropriate. There should be adequate review ahead of the start of the performance period to remove any improper activities.**

If CMS is determined to move forward with suspending activities during the performance year, for any reason, there should be constraints on CMS and transparent solutions for clinicians. For example, a condition may be that CMS may not suspend any activities on the grounds of obsolescence later than September 1 of the performance year. Practices must have ample time to receive the decision that the improvement activity they are planning to report and may actively be working on completing has been removed. Providers will then have to select a new activity and make plans for its implementation in their practice. Since completing improvement activities requires a 90-day implementation period, these activities must begin by October 1 of the performance year. Suppose CMS suspends an activity after September 1. In that case, practices and clinicians should be allowed to submit for a hardship exemption for the category as they may not meet the requirements through no fault of their own.

The ACR is dedicated to working with CMS to ensure that rheumatologists and rheumatology interprofessional team members are equipped to provide patients with quality care. During this PHE, providers must be supported via appropriate reimbursement, embracing telehealth, alleviating

administrative burden, and streamlining programs designed to advance quality care. We look forward to serving as a resource to you and working with the agency as we continue to navigate this unprecedented time. Please contact Amanda Grimm Wiegrefe, MScHSRA, Director of Regulatory Affairs, at awiegrefe@rheumatology.org or (202) 991-1127 if we can be of assistance or if you have questions.

Sincerely,

David Karp, MD, PhD
President, American College of Rheumatology