AMERICAN COLLEGE of RHEUMATOLOGY
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September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare and Medicaid Services
Department of Health and Human Services

Submitted electronically via regulations.gov

RE: [CMS-1807-P] Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

The American College of Rheumatology (ACR), representing over 9,600 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to provide feedback on the CY 2025 Physician Fee Schedule and Quality Payment Program proposed rule, as published in the Federal Register on July 31, 2024. 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 play a crucial role in the ongoing care of Medicare beneficiaries who suffer from complex chronic and acute conditions. These conditions require specialized expertise, often involving the management of severe diseases that are challenging to diagnose and treat. Rheumatologists primarily provide non-procedural, cognitive care to patients with severe conditions such as rheumatoid arthritis, other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and other debilitating rheumatic diseases that require continuous and highly specialized management.

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 cognitive care specialists in treating their patients. We appreciate the policies set forth by CMS to help alleviate these challenges amid complex environs for providing high quality healthcare. The ACR offers the following comments on policies regarding the decreased conversion factor, telemedicine flexibilities, G2211, complex drug administration coding, and the Quality Payment Program (QPP).

Proposed Provisions in the CY25 Physician Fee Schedule

Conversion Factor

The proposed rule reflects a conversion factor of $32.36 for 2025, which is a decrease of $0.93 (2.8%) from the current rate. This marks the fifth consecutive year of decreases, while inflation

continues to increase costs. The proposed rate reflects a 7.8% decrease from the 2020 conversion factor. According to the American Medical Association (AMA), Medicare physician payments have declined 29% from 2001 to 2024 when adjusted for inflation in practice costs.

The U.S. inflation rate rose by 7.0% in 2021, 6.5% in 2022, 3.4% in 2023, and currently sits at 3% for 2024, representing a cumulative inflation rate of about 20% since 2021. This has had grave effects on consumer prices, healthcare labor costs, prescription drug costs and supply procurement and other healthcare practice expenses. In particular, the cost of practicing medicine has risen dramatically over the past two decades with CMS estimating that the Medicare Economic Index (MEI) increased by 4.6% in 2024.[1] Despite this steep increase, physician payment rates were reduced by 3.4% percent in early 2024; Congress only mitigated a portion of this cut for the remainder of the year.

CMS is proposing this latest cut despite confirming that the MEI will rise to 3.6% in 2025, thus confirming that inflationary costs associated with running a practice continue to rise. This series of five annual payment reductions and the lack of an inflationary update threatens the viability of physician practices, adds considerable burden to the practice of medicine, and stifles innovation. When the cost of running a practice exceeds the revenue generated by that practice, this poses a significant barrier to practices staying open to caring for Medicare patients.

Rheumatology in particular faces unprecedented challenges due to these cuts. Cuts to reimbursements have already impacted rheumatologists with burnout, early retirements or departures, and staffing shortages. Additionally, the number of Medicare beneficiaries is expected to increase to over 80 million by 2030, with corresponding increases in rheumatic disease, leaving many beneficiaries without care. **The ACR strongly urges CMS not to proceed with this damaging adjustment that will further harm already strained practices and exacerbate the ongoing workforce shortages.**

Non-chemotherapy Administration

In response to the proposed CY 2024 PFS, the ACR called out the down-coding of complex chemotherapy services that has resulted mainly from flawed billing and coding articles created by the Medicare Administrative Contractors (MAC) that restricted which complex therapies will be reimbursed using the "chemotherapy" administration codes, forcing rheumatologists and other specialists (except for hematology and oncology) to bill these services with the therapeutic drug administration code. We called for the Current Procedural Terminology panel (CPT) to work with the key stakeholders to change the terminology in the CPT manual from "chemotherapy" to "immunomodulatory" therapies, which aligns with drug indications and risks. Also, to address Medicare Administrative Contractors (MACs) utilizing unsubstantiated criteria to determine which drugs should be defined as complex and warrant the use of complex administration codes, we called for CMS to convene stakeholder roundtables or workgroups to explore regulatory and legislative solutions to avoid unintended consequences with deleterious impacts on access and coverage for beneficiaries and their healthcare team.

[1] https://www.ama-assn.org/system/files/medicare-basics-medicare-economic-index.pdf

These issues remain significant challenges for rheumatologists, therefore the ACR continues to encourage CMS to comprehensively review biological and non-chemotherapy administration as it relates to the claims processing instructions. CMS plays a critical role in working with the American Medical Association CPT Editorial Panel to make the necessary updates to the CPT manual's language. It is critical that CMS create a permanent solution to the down-coding issue related to complex chemotherapy administration of biologics by giving the MACs definitive guidance regarding the drugs that can be billed with the complex chemotherapy administration codes.

Based on the evolution of biologics and monoclonal antibody treatments on the market for auto-immune diseases in key specialties such as rheumatology and others, the ACR requests that CMS remove the "chemotherapy" terminology from the claims processing manual and replace it with "immunomodulatory therapies." This would align the processing manual with current drug indications and new therapies such as CAR-T. Immunomodulating agents, such as monoclonal antibodies, require the same level of supervision as oncology medications given the complexity associated with the design, manufacturing, storage, and level of risk in administration for autoimmune diseases. According to the 2003 Medicare Modernization Act (MMA), these treatments cost the same to administer (including the clinical labor costs) and thus should be reimbursed consistently among all specialties.

This will also require a complete update to the current Healthcare Common Procedure Coding System (HCPCS) drug classification system, which automatically assigns certain J-codes to oncology drugs versus monoclonal antibody and biologic therapies and reimburses at different rates. **We continue to ask CMS to not categorize biologic agents based solely on indications, but to also consider the innate properties of the drugs in addition to their side effects and complexity.** The ACR is concerned with the criteria currently used in this process and would observe that MACs continue to utilize unsubstantiated standards to determine which drugs should be defined as complex and warrant the use of the complex administration codes**.** The ACR appreciates previous CMS action, including providing technical direction to the Medicare Administrative Contractors (MACs) to reimburse the chemotherapy administration codes for all monoclonal, complex biological and rheumatological therapies as long as the appropriate billing criteria for complex administration are met. **Moving forward, the ACR reiterates our recommendation that CMS work with the key stakeholders and convene the necessary workgroups in creating the appropriate language and guidance in the claims processing manual so that providers can bill the complex drug administration codes and avoid deleterious impacts on access and coverage for beneficiaries.**

Inflation-Adjusted Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs with Price Increases Faster than Inflation

CMS proposes to use the payment amount in the quarterly pricing files to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance, the calculation to determine the adjusted Medicare payment (if applicable) will not be adjusted for sequestration, and drugs excluded from the identification of Part B rebatable drugs will not be subject to the inflation-adjusted beneficiary coinsurance.

The proposal includes changes to the calculation for whether a Part B rebatable drug should have an adjusted beneficiary coinsurance equal to 20 percent of the inflation-adjusted payment amount. CMS states that the intent with this change is to, "hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount." For rheumatology patients, this could be particularly important in situations where the Average Sales Price (ASP) data is very low or negative and other data is used to calculate the payment amount, resulting in an amount that exceeds the inflation-adjusted payment amount.

Changes to Calculating Payment Limits When Negative or Zero ASP Data are Reported

CMS discusses the calculation of payment limits for drugs payable under Medicare Part B on a quarterly basis using the manufacturer-reported ASP. Manufacturers are required to report ASP, and, in most cases, this is a positive dollar value. In some instances, however, the manufacturer's reported ASP may have a negative or zero-dollar value. CMS cites possible causes including lagged discounts, units returned to the manufacturer, drug shortages, discontinuation of drug, or other unknown reasons. CMS notes that using negative or zero manufacturer's ASP data to calculate payment limits could result in an unreasonable scenario where CMS would be required to collect payment from providers for a drug, rather than furnishing payment.

For most Part B drugs with negative or zero manufacturer's ASP data, CMS proposes calculating the payment limit from the most recent calendar quarter for which positive manufacturer ASP data is available. In this case, CMS believes that using the most recently available manufacturer data will likely be more reflective of providers 'actual acquisition cost and is less likely to result in access challenges for providers or patients. For biosimilar drugs however, CMS proposes using a different formula to calculate the payment limit when there is negative or zero manufacturer's ASP data. For this group of drugs only, CMS proposes using the volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product plus either 6 or 8 percent, as appropriate, of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter. CMS believes this formula will help ensure payment limit stability and avoid potential access issues resulting from payment limits that are below the provider's cost for acquiring these drugs.

This proposal is a step in the right direction toward ensuring payment limits for biosimilars are not set below providers' acquisition costs. While the ACR is generally supportive of the proposed changes, we remain concerned that this does not go far enough. Specifically, the ACR would like to see Section 1847a of the Social Security Act [42 U.S.C. 1395w–3a] amended to include an 8% add-on to the actual acquisition cost and/or removal of manufacturer rebates to pharmacy benefit managers (PBMs) from the ASP equation. Rebates paid by manufacturers, which are not passed along to the providers purchasing the drug for patients, reduce the ASP to a level at or below the acquisition cost of the medication. The proposed methodology for calculating payment limits only applies in the case of negative or zero manufacturer's ASP data. For a biosimilar whose ASP has dropped significantly due to rebates – yet remains positive—it is still possible for the payment limit to fall below the provider's acquisition cost. This scenario plays out with multiple biosimilar drugs used to treat patients with rheumatic diseases, stifling the adoption of

biosimilars by our members, which in turn prevents realizing the savings we all hoped biosimilars would bring the system.

The proposed rule also seeks public comment on two alternative approaches CMS has considered for establishing payment limits for biosimilar drugs with negative or zero manufacturer's ASP data. The first scenario is a blended calculation including the volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product and the reference product itself plus either 6 or 8 percent. **The ACR supports this variant of the proposal to include the reference product in the calculation as it would go further to helping ensure that the payment limit is not lower than provider's acquisition cost.**

In the second alternative approach, CMS seeks feedback on a scenario where payment limits for all biosimilars with only negative or zero manufacturer's ASP data would be calculated using the volume-weighted average of its own most recent available positive manufacturer's ASP data from a previous quarter and either 6 or 8 percent. This scenario would not include data from other biosimilars with the same reference product or the reference product itself. **The ACR is not in support of this second alternative as it provides less stability than the other proposals and is more likely to result in payment limits that are below providers 'acquisition costs.**

Telemedicine

The ACR commends CMS for its continuous endeavor to expand healthcare accessibility through telemedicine. The benefits of telemedicine in rheumatology are clear. Rheumatic disease has served as a proving ground for this technology as these patients often reside in areas where the availability of rheumatologists is severely limited. It has also enabled rheumatologists to extend care and provide better healthcare outcomes to aging patients and to those with mobility and/or transportation barriers.

However, we are concerned that many patients with rheumatic disease will be without access to high-quality care if the flexibilities put in place during the COVID-19 pandemic expire at the end of CY 2024. Over the past three years, our members have had remarkable experiences with telemedicine adoption across diverse populations. We have seen firsthand how telemedicine enables working individuals to receive necessary care without jeopardizing their jobs or health and how it improves access to rheumatologists for those in hard-to-reach communities.[2] The loss of geographic flexibilities, such as a patient's home being a reimbursable originating site, would drastically reduce access to care for many patients, except for those already enrolled in established telemedicine programs.[3] **The ACR encourages CMS to work with Congress to permanently extend all regulatory flexibilities on telemedicine reimbursement. We also call for CMS to remove all restrictions on payment parity and remove any barriers to interstate licensure that bar providers from treating beneficiaries across state lines.**

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[2] Jackson LE, Edgil TA, Hill B, Owensby JK, Smith CH, Singh JA, Danila MI. Telemedicine in rheumatology care: A systematic review. Semin Arthritis Rheum. 2022 Oct;56:152045.

[3] https://digital.ahrq.gov/ahrq-funded-projects/past-initiatives/transforming-healthcare-quality-through-health-it/project-echo-bringing

Additionally, the ACR supports the proposals by CMS to permanently reimburse for the use audio-only technologies in healthcare delivery and to continue defining "direct supervision" to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through the end of 2025.

G2211

The ACR applauds CMS for maintaining the current reimbursement for the G2211 add-on code for visit complexity. We believe it provides a more accurate representation of the resource costs associated with treating complex rheumatic diseases inherent to evaluation and management (E/M) services. However, the ACR is disappointed in the continued limitations on reporting modifier -25 when reporting the G2211 with an E/M service. While we understand CMS is "testing the water" by proposing to allow the use of G2211 when the base E/M code is reported on the same day as the annual wellness visit, vaccine administration, or Medicare Part B preventive services, we believe that the continued limitations on modifier -25 are unwarranted and antithetical to the intent of the code to foster longitudinal care in an outpatient environment. **The rationale behind the ongoing limitations should be provided and the ACR encourages CMS to continue working on comprehensive clinical guidelines and allow for billing modifier -25 with services such as infusions and injections.**

Enhanced Care Management

CMS is proposing to establish coding and payment under the PFS for a new set of advanced primary care services described by three new HCPCS G-codes (GPCM1, GPCM2, and GPCM3). **To avoid adding duplicative codes to the system, the ACR proposes collapsing these new codes with the current complex chronic care management (CCCM), chronic care management (CCM) and principal care management (PCM) codes to simplify CMS's coding and billing guidelines.**

<u>Proposed Policies for the Quality Payment Program (QPP)</u>

The proposed rule outlines several proposals to implement programmatic changes to the Quality Payment Program to reduce the burden among care teams and allow patients to compare health professional quality and value of care in more streamlined ways. While the ACR supports the overall goal of these proposals to improve the QPP, we are concerned that continual programmatic changes have confused participants and put the added administrative burden on specialty associations trying to help care teams navigate the program effectively. We offer comments on the Advancing Rheumatology Patient Care Merit-based Incentive Payment System (MIPS) Value Pathway (MVP), MVPs for Ambulatory Specialty Care, the transition to MVPs, and various other proposed changes to MIPS. **We urge CMS to consider the administrative burden on specialty societies and our members as the QPP evolves.**

Advancing Rheumatology Patient Care MVP

CMS proposed several changes to the Advancing Rheumatology Patient Care MVP. We offer the following feedback on these proposals:

The ACR supports the following additions to measures and proposals:

- Adding Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age.
- Adding UREQA2: Ankylosing Spondylitis: Appropriate Pharmacologic Therapy.
- Adding UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older.
- Requiring MVP participants to report only one Improvement Activities (IA).

The ACR proposes to modify the following:

- Removing IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record.
  The ACR encourages CMS to retain IA_EPA_1 in both MIPS and MVP for at least one additional year given its wide use across multiple specialties. By providing a year's notice in the final rule, practices have a greater duration of time to review all IAs and identify and plan for more meaningful activities for the 2026 performance year.

- 1) Automatically calculating highest performance measure and no longer requiring identification for the measure, 2) Automatically calculating highest population health measure based on administrative claims data, and no longer requiring identification of MVP population health measures during registration, and 3) Excluding measures from MVP total achievement points if they don't have a benchmark or meet the case minimum.
  The ACR strongly encourages CMS to move to population health measures that provide eligible clinicians with real-time data to drive meaningful quality improvement. It is noted that no longer requiring identification of population health measure at time of MVP registration will address the lack of minimum case requirements, however, there remains a concern that use of administrative-claims data is not conducive to a quality payment program as changes and improvements cannot be made in real-time to drive meaningful outcome improvement.

- Adding Rheumatoid Arthritis to the list of Cost Measures.
  The ACR strongly encourages CMS to review and address the ACR's comments made during the Pre-rulemaking Measure Review public comment period, and points included in this letter, before adopting this measure in payment programs.

Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care

The ACR supports CMS re-evaluating the larger framework of driving improved outcomes through payment incentives. The ACR is aware of collaborative efforts to propose alternative frameworks supporting improved outcomes tied to compensation, which includes direct

engagement with specialty societies. Therefore, it is more appropriate to hold any framework advancement until CMS has had an opportunity to review and analyze all possible frameworks to meet the Quality Payment Program intent while reducing reporting burdens on clinicians.

If CMS decides to move forward with a payment model where adjustments are determined by performance, as compared to a clinician's peers in the same specialty reporting the same measures, the ACR strongly encourages CMS to allow the specialty societies that are interested to build the proposed models with CMS' guidance and approval. Medical specialty societies, especially ones who manage Qualified Registries (QRs) and Qualified Clinical Data Registries (QCDRs), are in the unique position of having experience and access to the required expertise specific to their clinicians and patients.

Furthermore, many of these specialty societies, including the ACR, have been supporting CMS' payment programs and their clinicians' participation for years. They have unparalleled experience with developing and maintaining quality measures that are relevant to their specialties, understanding the real-world implications of federal payment programs on their clinicians, and creating the resources to close the gap between program requirements and how their clinicians work every day. While building such a program will take a significant amount of time and effort, the ACR believes that specialists would much prefer to have such a program designed by their own specialty society wherever possible.

Furthermore, each specialty has its unique complexity with which its respective specialty society is intimately familiar. For example, in rheumatology, the ACR is aware and supportive of the desire to move quality measurement towards patient outcomes. However, there are few rheumatic diseases where the ideal outcome is clearly defined. When it is defined, it takes time for clinicians to build collection outcome data into their workflow in a way that will make outcome measurement feasible. In addition, the struggle to develop an MVP-based model would only get more complicated in non-patient facing specialties such as pathology**.** Further challenges to adopting more complex outcome measures include the diversity of electronic medical records (EMRs) used by outpatient providers, including rheumatologists, and the fact that these EMRs are less likely to be ONC-certified, making complex measurement difficult. This lack of standardization is complicated by the frequent need for risk adjustment to account for clinical differences in patient disease severity across providers, which often requires national data to inform and implement risk models (which also supports engaging professional societies with registries in strategic planning for MVPs).

Request for Information: Sunsetting Traditional MIPS and Completing the Transition to MVPs for the 2029 Reporting Year/2031 Performance Period

The ACR quite successfully encouraged rheumatologists to report the Advancing Rheumatology Patient Care MVP through our QCDR – the ACR's Rheumatology Informatics System for Effectiveness (RISE) registry – but has only experienced one reporting period. Following that, the ACR surveyed our RISE users who reported the MVP, and one of the most common requests was for more specialty-specific measures in the MVP.

As CMS notes, measure development is a time and resource intensive activity. The above ambulatory specialty MVP section further highlights the complexity of outcome measure development and implementation. While the ACR is working hard to address this gap, more time is needed to evaluate the future direction of the rheumatology-specific MVP. This includes review of CMS' final decisions on the Rheumatoid Arthritis cost measure and removing topped out measures. **ACR believes CMS must also plan for how to incorporate new QCDR measures into MVPs without requiring a MIPS trial period.**

MIPS Performance Category Weighting

The ACR supports CMS' proposal to maintain the same performance category weights as they were in 2024. The ACR also supports CMS' proposal to narrow the minimum criteria for what qualifies as a data submission and appreciates CMS' efforts to reduce the negative effects of this error on eligible clinicians.

Performance Threshold

The ACR supports CMS' proposal to maintain the performance threshold at 75 points.

Data Completeness Threshold

The ACR supports CMS' proposal to maintain the 75% data completeness threshold through the 2028 performance period.

Cost Measures

CMS is proposing to add six new measures in the Cost category, including Rheumatoid Arthritis. The ACR previously raised three concerns during the pre-rulemaking measure review public comment period for the Rheumatoid Arthritis cost measure and suggests these issues be addressed before use in any CMS payment program. First, the measure developer states the measure is stratified by Part D coverage, which is appropriate given how critical medication access and coverage are for our patient population. However, the stratified results could not be located in the public comment specification materials. It appears this is embedded in the measure calculation, but it would be important to see national data stratified by Part D coverage since the ACR views this as a major concern for our patients.

Second, the measure developer reports construct validity based upon directional correlations with cost categories. While this is one approach to construct validity and some of the results are reassuring (that is, the directional correlations are consistent with clinical intuition and carry face validity), other findings are not, and the developer does not adequately explain these. The developer states "Outpatient E&M services and outpatient physical, occupational, or speech and language pathology therapy are associated with higher costs of adverse events, which may reflect higher clinical needs related to adverse events" but this does not seem like a sufficient explanation; the developer provides no additional evidence supporting this explanation. Overall, this approach to empirical validation feels inadequate, particularly when not all findings support the presumed a priori assumptions.

Finally, biosimilar medications appear to be missing or intentionally excluded from the Part D medication list. The ACR considers this a significant threat to measure validity, given the shift towards the use of biosimilar RA medications.

MIPS Measure Set

CMS proposes multiple changes to the rheumatology MIPS measure set. The ACR offers the following comments on the proposed changes to our specialty's measure set:

- Add Adult COVID-19 Vaccination Status.
  The ACR supports CMS' proposal to include Adult COVID-19 Vaccination Status in the Rheumatology Specialty Set.
- QPP176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy.
  The ACR supports the inclusion of new biosimilar medications as requested.
- QPP177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity.
  The ACR supports the denominator and numerator changes as requested.
- QPP178: Rheumatoid Arthritis (RA): Functional Status Assessment.
  The ACR supports the denominator changes as requested.
- QPP180: Rheumatoid Arthritis (RA): Glucocorticoid Management.
  The ACR supports the denominator changes as requested.

Improvement Activities

The ACR disagrees with CMS' proposal to remove IA_EPA_1. We encourage CMS to retain it in both MIPS and MVP for at least one additional year given its wide use across multiple specialties. By providing a year's notice in the final rule, practices have a greater duration of time to review all IAs and identify and plan for more meaningful activities for the 2026 performance year.

Regarding the removal of improvement activities that are identified as redundant with quality and QCDR measures, such as IA_CC_1, the ACR encourages CMS to reconsider using redundancy with quality measures as a reason for removal. The intent of improvement activities is to drive meaningful quality improvement projects. The QPP receives criticism for producing data that is not relevant or meaningful to clinicians and linking IAs to quality measures is one method to make the QPP more meaningful and relevant to clinicians. Rather than only collecting data to submit, there is an additional incentive to use the data as part of quality improvement work by linking or aligning with an IA. This allows clinicians to receive credit for completing an improvement activity, and then if the improvement has resulted in high performance, to receive appropriate credit for that performance as well. The ACR believes these incentives are needed to link improved outcomes in a payment program.

Request for Information: Principles for Patient Reported Outcome Measure (PROM) in Quality Reporting and Payment Programs

The ACR believes that the list of guiding principles provided (i.e., data infrastructure, measures testing, feasible clinical implementation, accessible, patient engagement, and equity) should be expanded to address condition-specificity/specialty care needs. The ACR strongly supports the use of PROMIS measures and has integrated their use in condition-specific PRO-PMs. However, the ACR also recognizes that global PROMs may not meet the needs of patients with varied condition-specific comorbidities and complications warranting tailored questioning with targeted PROMs. As a result, an additional guiding principle is warranted.

Regarding the accelerated development of PRO-PMs and advances in the field, there has been demonstrated examples of success using a process measure to outcome strategy (e.g., PHQ-9 and surgical outcomes). The ACR notes that this pathway of providing incentives for eligible clinicians to collect PROMs through process measures leads to wider adoption and buy-in for PRO collection versus a direct mandate to collect and report PRO-PM. Eligible clinicians often are hesitant to adopt PRO-PM without demonstration of the value of this data, which is achieved by gradually stepping up from a process to an outcome measure. Further, CMS should not underestimate the complexity of clinical workflows eligible clinicians have to put into place to routinely collect PROMs, and a stepped approach of measuring performance on the process of collecting these measures acknowledges this significant amount of work.

This pathway of process to PRO-PM collection has been closed to measure stewards who have proposed adoption of PROM process measures for use in QPP MIPS and MVP programs in recent years. The ACR would encourage CMS to re-evaluate this stance and to further incentivize eligible clinicians to collect data first before tying incentives to outcomes from PROMs data.

As noted above, the ACR would encourage condition-specific PROMs when there are clinical scenarios that warrant consideration (e.g., depression for patients with SLE given the health equity considerations and identified patient prioritization of long-term outcomes, disease-activity PROMs for patients diagnosed with SLE or RA to identify and track clinically meaningful outcomes for patients lost through global screening).

MIPS Scoring Methodology

The ACR appreciates the recognition that CMS is giving to an issue that has been one of our concerns for the past few years: the impact of topped-out measures and limited measure choices on MIPS/MVP reporting clinicians. **The ACR supports the proposal to modify benchmarks for topped-out measures in specialty sets with limited measure choice. In addition to the criteria specified, the ACR also recommends that CMS consider the number and percentage of specialty-specific measures in the specialty measure set that are topped out.** CMS is at risk of unfairly punishing specialties that have worked diligently to address gaps in care if the removal of topped out measures results in a lack of specialty-specific measures.

To illustrate these concerns, the ACR would like CMS to review the rheumatology-specific measures available. The ACR believes rheumatology is also at risk given that 100% of the four measures focused on treating patients with rheumatic diseases in the measure set are topped out, thus limiting the ability of rheumatology clinicians to report on measures that are relevant to

their specialty and perform well in the program. **Given this, the ACR encourages CMS to consider removing the 7-point cap on QPP176, QPP177, QPP178 and QPP180. The ACR also encourages CMS to consider how a specialty can guide choices when evaluating QCDR measures for inclusion in the MIPS program, assuming the measures are shown to be valid and reliable.**

The ACR notes that CMS emphasizes specialty-specific MVPs in some parts of the proposed rule while in other sections identifying a desire to focus on cross-cutting, disease-agnostic outcome measures that incorporate the patient experience. **The ACR encourages CMS to recognize that QCDR condition-specific measures expand meaningful choices to clinicians with limited measures related to their specialty**. Such measures would help CMS address these measure gaps and meet the overall program goals and thus should be adopted.

Cost Measure Scoring

The ACR supports CMS' efforts to modify cost measure scoring processes which include the new measure exclusion policy if CMS makes an error in calculation or significant changes to a cost measure which results in a negative impact. Likewise, that CMS address previously raised concerns on overall calculation which adversely impacted eligible clinicians performing near the median. The ACR remains concerned about the lack of meaningful, real-time cost measure data and calculation transparency, which includes the use of the proposed Rheumatoid Arthritis measure. Transparency is needed for improved participation in the cost category. Specifically, real-time data should be made available as well as measure stratification strategies. Eligible clinicians should have access to data to understand how this score is calculated, including the ability to dive into patient attribution concerns when identified.

Conclusion

The ACR is dedicated to working with CMS to ensure that rheumatologists and rheumatology interprofessional team members are fully equipped to deliver high-quality care to patients. As the public health emergency has ended, it is essential to recognize how the pandemic changed the healthcare system. We urge CMS to recognize the value of telemedicine in chronic care management, the need for appropriate reimbursement for our members and the services they provide, and the importance of streamlining programs aimed at advancing quality care. We look forward to serving as a resource to you and working with the agency to explore changes and improvements needed to ensure that patients with rheumatic diseases have access to quality care. Please contact Colby Tiner, MA, Manager of Regulatory Affairs, at ctiner@rheumatology.org if we can assist or have questions.

Sincerely,

Deborah Dyett Desir, MD
President, American College of Rheumatology