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September 30, 2020

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21224

Submitted via regulations.gov

RE: [CMS-1734-P]; Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

The American College of Rheumatology (ACR), representing over 7,700 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the CY 2021 Physician Fee Schedule and Quality Payment Program proposed rule as published in the *Federal Register* on August 17, 2020. 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 recognizing the value of rheumatology and other cognitive care specialties by affirming last year's finalized Evaluation and Management (E/M) code revaluation to reflect better the work and expertise needed to treat our complex patient population. Our nation's healthcare system is experiencing unprecedented times that have strained resources and providers. We appreciate the policies and flexibilities set forth by CMS to help alleviate these challenges while we all work to continue to provide quality care for our patients. In light of the ongoing volatility and unknowns in the healthcare system, ACR offers the following comments on the policies for a permanent expansion of specific telehealth provisions, the importance of the GPC1X complexity code, care management services, and provisions to the Quality Payment Program (QPP).

Provisions of the Proposed Rule for PFS

Telehealth and Other Services Involving Communications Technology

The ACR appreciates the significant expansion of telehealth due to the SARS-CoV-2 Public Health Emergency (PHE) that includes substantial modifications to the existing telehealth reimbursement and regulatory policies. While we recognize these changes do not supersede the regulatory flexibilities that are in place for the duration of the PHE, CMS must continue to educate providers on the new services along with coding and billing guidelines that will be added to the Medicare telehealth list permanently versus the proposed additional services that will be added to the telehealth list temporarily through the end of the PHE.

During this time of uncertainty with the PHE and the impact on Medicare beneficiaries, the ACR is concerned that the proposal will not continue the current coding, coverage, and payment rates for audio-only telephone E/M services after the PHE is rescinded. Providers remain concerned that a significant subset of Medicare beneficiaries continues to grapple with access to technology. Considerable work and intensity are required to ensure these patients continue to get the care they need via audio-only services. Policy and reimbursement variances make it necessary for CMS to maintain payment parity for audio-only E/M services at least for another year or beyond as the landscape of patient care has drastically changed due to COVID-19. We expect that some vulnerable patients will remain uncomfortable to return to the office for evaluation even after the PHE has been rescinded. Many of these patients are not able to access remote video platforms and will only have access to audio evaluations. In the absence of audio-only payment parity for some time past the PHE, a proportion of vulnerable Medicare beneficiaries will lose access to care.

Rheumatologists continue to adapt to this new normal and work within the parameters of telehealth, but the complexity of the patient's diagnosis and treatment plan does not change. **Therefore, we urge CMS to work with the entire House of Medicine to improve coding and billing guidelines to properly reflect the administrative complexity and necessary option of delivering care through this medium. The ACR encourages the agency to allow direct supervision to be provided to members of the care team using real-time, interactive audio/video and audio-only technology to maximize time focused on delivering patient care.**

We note the importance of physical and occupational therapy as part of the treatment of many rheumatic diseases. Without these services, patients will not be able to experience the quality of life they deserve. Therefore, **the ACR supports the extension of telehealth reimbursement for physical and occupational therapy**. We welcome the opportunity to work with CMS to make the best modifications to telehealth policy by sharing our member experiences on how telehealth services have been in use in various rheumatology communities during the response to COVID-19, and how it can be effectively used in the future to continue providing the quality of care necessary for the patient population living with musculoskeletal and rheumatic diseases.

Determination of Practice Expense RVUs

To accurately price the E/M services, the AMA RVS Update Committee (RUC) proposed using a direct crosswalk to the work and direct practice expense inputs for E/M codes. The methodology may work systematically in a typical healthcare landscape. However, during the current PHE, where providers are seeing cuts in all aspects of their practice, it is prudent for CMS to offset any additional cuts to the physician fee schedule. A phase-in approach is the most appropriate method to allow providers to be reimbursed appropriately under the prospective payment system. The ACR welcomes the opportunity to work with the agency on the most appropriate methodology in the current healthcare landscape.

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

The ACR applauds CMS for moving forward with its implementation of the finalized coding and payment structure for office/outpatient E/M services to align with the coding and documentation changes laid out by the CPT Editorial Panel. This major update to the E/M office/outpatient code will reduce administrative burdens and make code selection more intuitive to providers and staff. The finalized coding valuations are a significant step in the agency's Patients Over Paperwork initiative to decrease the unnecessary burden on Medicare and Medicaid providers. **The ACR strongly supports the new coding and payment structure as finalized in the CY2020 Physician Fee Schedule final rule. We urge the agency to move forward with implementation without delay or significant modification to the guidelines.**

Although E/M services will receive a significant increase for rheumatologists and other cognitive care specialists beginning in 2021, the ACR recognizes that the increase in payment for E/M services results in a decrease to other services due to the budget neutrality required by statute. During this PHE, physicians in all specialties and employment arrangements have faced financial uncertainty. The ACR supports efforts to waive budget neutrality to ensure that all specialties are financially supported during this time. However, **the process of waiving budget neutrality or otherwise mitigating payment decreases must not delay the implementation of the previously finalized E/M valuations.**

Additionally, the ACR recognizes the need for CMS to revalue certain services that are parallel with E/M service, including the transitional care management codes. We remain concerned with

the time modifications and discontinuing the current CPT prolonged codes 99358 and 99359 (prolonged E/M visit without direct patient contact). **Therefore, we urge CMS to implement a transitional period to continue utilizing these codes until providers are fully acclimated to using the revised E/M codes with the new add-on codes.** Furthermore, the new prolonged code 99XXX and GPC1X are not yet wholly defined without specific guidance on how and when specialists can use these codes with an E/M service.

Time Definition Discrepancies for E/M Office Visits

The ACR notes the time inconsistency between the recommended time allocations for the E/M codes from the AMA RUC in the CY2020 final rule versus the CY2021 proposed rule, as outlined in Table 1. The ACR agrees with the definition of total time; however, if CMS does not accept the survey respondent's median total time, the relativity of CPT codes 99202, 99203, 99205, 99212, and 99214 will be affected by causing unintended consequences to the work of providers. **The ACR urges CMS to collaborate with the AMA RUC to preserve the median pre, intra, and post-service times recommended from the survey to capture physician time for office visits in CY2021 appropriately.**

Table 1: AMA RUC Recommended Total Time versus CMS Proposed Total Time

CPT Code	Pre-Time	Intra-Time	Post-Time	RUC Recommended Total Time (survey median total)	CMS Proposed Total Time (based on the sum of components)
99202	2	15	3	22	20
99203	5	25	5	40	35
99204	10	40	10	60	60
99205	14	59	15	85	88
99211	0	5	2	7	7
99212	2	11	3	18	16
99213	5	20	5	30	30
99214	7	30	10	49	47
99215	10	45	15	70	70

GPC1X

The ACR strongly supports the adoption of the single complexity add-on code, GPCX1, which will be available to all specialties for visits that are part of ongoing care related to a

patient's single, serious, or complex chronic condition. Additionally, the ACR agrees with CMS that the revised office visit E/M codes still do not adequately describe or reflect the resources associated with the care and evaluation of rheumatology visits, and support the decision to implement the GPC1X add-on code to account for the lost resources. In response to feedback on this new code we recognize that the GPC1X code descriptor, as defined in the CY2021 proposed rule, will need refinement to ensure the descriptor meets its intended purpose.

The ACR disagrees with CMS' 50% utilization assumption and, instead, believes that around 23% utilization would be a more reasonable estimate. We note that while the code will be widely applicable, adoption will be slow at first, and rheumatologists will need time to be educated on appropriate use. **If the agency moves forward with the implementation of GPC1X, the ACR urges that CMS lower the 2021 utilization assumption. Additionally, the ACR recommends the following as it pertains to the proposed GPC1X code:**

- Revise the GPC1X code descriptor to read:
  "Visit complexity inherent to office-based evaluation and management services that serve as the first contact and continuing focal point for all needed health care services and/or with medical services that are part of ongoing care related to a patient's single serious, or complex chronic condition."

- Revise the estimated utilization assumptions to around ***23% of claims;***
- Ensure the add-on code is available to both ***new and established patients***; and
- Ensure the appropriate resource costs are accounted for in the code valuation.

Additionally, the following resources should be accounted for to ensure an accurate valuation of GPC1X:

- Pharmacy benefit manager use of certain medications;
- Documentation and other requests from health insurance companies;
- Actions at assisted living/nursing homes that require a physician response;
- Burden of population health requirements;
- Time spent by care/referral/medical record coordinators that help manage the ongoing flow of information;
- Physician time which remains unaccounted for to complete medication refills;
- Forms and review of consultant reports that fall outside the three days prior and seven days after the timeframe of an E/M visit, but do not necessitate a new visit;
- Electronic medical record systems to track preventive services; reminders to patients, scheduling, monitoring, tracking results of these services;
- Chronic disease management tracking - individual and populations;

- Physician and/or staff time spent coordinating care; and
- Additional mental effort and expertise are required to develop and implement treatment plans for chronic conditions.

The above modifications to the GPC1X code descriptor will provide greater clarity to the add-on code descriptor. The ACR urges CMS to work closely with the provider community to safeguard the appropriate implementation of the code.

Physical and Occupational Therapists as Part of the Rheumatology Care Team

The ACR is concerned with the finalized policy that will decrease reimbursement rates for physical therapy services. The projected 8% to 9% cuts to our colleagues' reimbursement is detrimental to our patients, as these therapy services are an integral part of treating rheumatic diseases by helping to regain, maintain and improve the musculoskeletal condition and physical function in adults and children. Without adequate reimbursement for their services, we fear that access to occupational and physical therapists will decrease, putting our patients in jeopardy. We urge CMS to reconsider this policy and more appropriately value the role of occupational and physical therapists as part of the care team to maximize the ability of patients to achieve and maintain independence and functional abilities outside of health care settings.

Care Management Services

CMS finalized its proposed policy to separate coding and payment for Principal Care Management (PCM) services. These services describe care management services for one chronic severe condition and are typically expected to last between three months to one year, or until the death of a patient, the cause of recent hospitalization, and/or a significant risk of death, acute exacerbation, or functional decline. CMS expects that these services will be billed by specialists focused on managing patients with a single chronic condition who require substantial care management. **ACR appreciates efforts to increase the utilization of care management services by adopting these new care management codes. We urge CMS to implement these codes for CY2021.**

The ACR notes that rheumatologists have not widely adopted these services because of the various billing requirements imposed on their use. **ACR recommends that CMS implement its proposal to create two G-codes for Principal Care Management (PCM) services.** Several rheumatic conditions will meet the requirements of the service expected to last between three months and a year, or until the death of the patient, acute exacerbation/decompensation, or functional decline. We welcome the opportunity to work with CMS and other cognitive specialties to define the utilization and documentation requirements for the new PCM G-code.

Review and Verification of Medical Record Documentation

The ACR reiterates our support for the finalized policy outlined in the CY2020 PFS that allows a physician, resident, or nurse to document that the teaching physician was present at the time the service was delivered. We appreciate that this policy eliminates the requirement for a teaching physician to document the extent of his/her participation in the review and direction of the services furnished to each beneficiary and instead allows the resident or nurse to document the scope of the teaching physician's involvement. **Accordingly, ACR supports the CMS policy to provide added flexibility for non-physician practitioners authorized to deliver Part B services, including Nurse Practitioners, Clinical Nurse Specialists, and Physician Assistants, to document teaching physician involvement.**

Quality Payment Program (QPP)

The proposed rule outlines several proposals that will implement programmatic changes to the Quality Payment Program to reduce burden among providers and allow patients to compare provider quality and value of care in a more streamlined manner. While the ACR supports the overall goal of these proposals to improve the QPP, we are concerned that continual programmatic changes have confused the provider community and put added administrative burden on specialty associations trying to help providers navigate the program effectively. We offer the following comments on the MIPS Value Pathway (MVP) development, MIPS scoring, and performance threshold. We urge CMS to consider the administrative burden on specialty societies and our members as the QPP continues to evolve.

MIPS Value Pathway

The ACR strongly supports the introduction of the MIPS Value Pathway (MVP) model to streamline the program, provide a model for providers to understand alternative payment models better, and ensure that qualified clinical data registry (QCDR) measures are meaningful. While we support the principles of the MVP model, we reiterate the administrative burden placed on QCDRs in the development of this new program with limited guidance from CMS. Since MVPs were first proposed, the American Medical Association and other specialty societies have developed appropriate episodes for the program. Unfortunately, progress has been slow as there remain essential questions and specifics that have not been addressed in subsequent communications with CMS. Without a more concrete understanding of the program goals, specific requirements, and a more collaborative development model, we fear the MVP program will not meet the stated purpose of a more streamlined approach to quality measurement.

Capturing the Patient Voice

The proposed rule outlines that stakeholders should incorporate patients or patient representatives during the development of an MVP before submission. While ACR supports the inclusion of patient representatives in the MVP development, we note that patient groups may not be as entrenched in quality measurement as medical specialty societies. Therefore, **the ACR urges CMS to accept patient-reported data or outcomes within the measures whenever reasonable to include the patient voice in the MVP development process. If patient-reported outcomes cannot be used, we urge CMS to remove this provision as a pre-**

requisite for a candidate MVP. There may be legitimate barriers that organizations face when trying to include the patient voice in MVP development. Organizations should be allowed to enumerate these barriers to allow proposed measures for inclusion in the MVP. To ensure the patient perspective is included in the MVP development, we welcome assistance from CMS to 1) develop patient-friendly materials outlining the components of the MVP and 2) serve as the primary educator to patient groups on quality measurement and the goals of the MVP. These initiatives will allow consistent education among the patients involved in the process.

Candidate MVP Co-Development, Solicitation Process, and Evaluation

The proposed rule outlines the process by which CMS will evaluate MVP submissions, including internal review criteria and stakeholder meetings for candidate MVPs applicable in the upcoming performance period. We note that most organizations developing candidate MVPs are necessarily focused on other CMS reporting requirements from January to March. These include MIPS reporting through the end of March and data validation execution reports due on May 31. Therefore, **we urge CMS to establish the submission deadline for candidate MVPs after May 31 to consider inclusion in the following performance year.**

The proposed rule provides greater clarity on the evaluation criteria of candidate MVPs. The ACR appreciates that CMS has provided greater detail on the program following stakeholder feedback. However, we remain concerned that the proposed standards will require developers to defend the integrity of the proposed measures to be included in the candidate MVP. In most instances, CMS has either developed or already vetted the proposed measures included in the candidate MVP. **We encourage CMS to ensure a streamlined submission and review process to eliminate redundancy in vetting the proposed measures within a candidate MVP.**

Incorporating QCDR Measures into MVPs

CMS is proposing to include QCDR measures in MVPs. However, these measures must first be included in the MIPS program for a year before being included in an MVP. We assume that the reasoning behind this proposal is to ensure measures are thoroughly vetted before inclusion in an MVP. **Instead of this one-year vetting period within the MIPS program, we encourage CMS to require QCDR measures to be tested entirely before inclusion an MVP.** Like other QCDRs, ACR is developing measures specifically for the MVP/APM programs. While these measures will be available for MIPS, our focus in creating these measures is on the future of the QPP. We fear that if CMS limits QCDR measures to MIPS for the first year, it will result in a delay of meaningful measures for providers to use in an MVP or APM.

Establishing the Performance Threshold

CMS proposes to decrease the performance threshold to 50 points. The SARS-CoV-2 pandemic has created volatility and disruption for all providers with significant uncertainty or understanding of the long-term effects of the pandemic. Despite this uncertainty, the requirements for MIPS are clearly outlined in the Medicare Access and Reauthorization Act (MACRA), which requires the performance threshold to be set by the mean scores by 2022.

Should CMS finalize the proposed performance threshold at 50 points, there would be an approximate 25-point increase from 2021 to 2022. This drastic increase will put undue stress on providers to continue to participate in the MIPS program successfully. Therefore, **the ACR urges CMS to maintain the performance threshold to 60 points, but not less than 50 points**. **Additionally, we encourage CMS to continue the option for providers to request a hardship exemption if they are detrimentally impacted by the COVID-19 pandemic to relieve the reporting burden.**

Cost Performance Category

The ACR recognizes that MACRA clearly outlines the weight for the cost performance category to be 30% of a provider's overall score by the 2022 performance year. While we appreciate the need to consider the cost to deliver efficient, quality care, we do not believe that a fair cost measure has been identified for rheumatologists. The Total Per Capita Cost and Medicare Spending Per Beneficiary are the only two cost measures that may apply to rheumatologists; however, these measures ***cannot*** give an accurate snapshot of the cost of care from our providers.

Rheumatologists often prescribe biologics for their patients. These protein-based medications are costly due to the complexity of development and manufacturing and do not have generic equivalents. Unfortunately, the two applicable cost measures split biologics between Part B and Part D. Providers cannot control the cost of the most appropriate medication for the patient. Therefore, we urge CMS to exclude Part B medication costs from the cost performance category or at least include both Part D and Part B costs for a fair comparison. The proposed provisions within the cost category will incentivize physicians to prescribe Part D medications instead of Part B medications. They may cause the unintended consequence of increased patient cost-sharing because they cannot afford high cost-sharing for a biologic and may worsen healthcare disparities. Therefore, t**he ACR advises that all costs incurred outside the provider's control must not be attributed to them in the cost category.**

Without adequate adjustment for social risk factors, the overall cost of care will not be appropriately measured. The Assistant Secretary for Planning and Evaluation's second report to Congress on social risk factors and performance in Medicare value-based purchasing programs recommends that resource use and patient experiences be adjusted for social risk factors in value-based models.[1] ACR urges CMS to reconsider the impact of social risk on these measures and their use. **Until new cost measures are developed that more accurately account for the actual cost of care provided and adequately adjust for social risk factors, the ACR urges CMS to reassign the cost category points to the quality category.**

Access to Medicare Claims Data

[1] *Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs*. (2020, July 17). ASPE. https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress

The ACR has taken steps to evaluate the work of rheumatology providers to identify ways to measure cost more accurately. Unfortunately, there are significant barriers to completing this work. The Quasi-Qualified Entity Program and the Research Data Assistance Center (ResDAC) have failed to provide clinician-led clinical data registries (registries) with meaningful access to claims data. Without these data, registries cannot accurately assess the actual cost of care. CMS has repeatedly claimed that the Quasi-QE program is an appropriate avenue for registries to gain access to claims data. However, this program limits the number of years this data can be used and restricts the data. Clinical data registries must access Medicare claims data without the restrictions of the Quasi-QE program to successfully measure and research quality, cost, and outcomes. Section 105(b) of MACRA provides clinical data registries access to Medicare claims data. To date, CMS has not implemented this provision to the intent of the statute. Therefore, **we urge CMS to implement this provision to allow registries with real-time, broad, and continuous access to claims data for purposes of both research *and* quality improvement.** In doing so, registries will develop cost measures specific to the providers they support and accurately measure care, cost, and outcomes.

Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)
The proposed rule continues to expand on the agency's efforts to promote the use of health information technology (HIT) in a more effective and meaningful way. CMS outlines the importance of health information exchanges (HIE) in the advancement of HIT. To incentivize the use of HIE in the Promoting Interoperability category, CMS is proposing to include a new measure that will allow providers to attest that they are participating in an HIE. The ACR supports this new measure; however, we are concerned with the expectations of QCDRs to audit the integrity of the attestation. Auditing the PI category is new for CY2020, and QCDRs have yet to complete the process. While the proposed measure only requires an attestation, we urge CMS to clearly define the necessary documentation to prove a "yes" attestation. This is crucial for QCDRs as they complete these audits.

Scoring the Quality Performance Category

The ACR appreciates the agency's concern regarding accurate benchmarking given the changed reporting patterns for the performance year 2019 due to the SARS-CoV-2 pandemic. The proposed rule outlines two options regarding quality benchmarking in light of the data submission flexibilities during the PHE. **The ACR strongly supports the alternative option outlined to allow historical benchmarks from the 2020 performance year/2018 calendar year for the 2021 performance year.** Using the historical benchmarks may offer relief to providers managing their performance towards the increased performance thresholds. Providers must have an accurate estimate of their scores before submission as QCDRs will not provide those estimates without established benchmarks. Providers will be uncertain of 20% of their score in 2021 as the cost category score, or even an estimated score, is not released before submission. Therefore, it is essential to give providers the most accurate assessment of their performance before submission. This assessment will allow ample time to adjust their practice, see the improvement, and report their success to CMS, earning their positive payment adjustment for providing quality care to their patients.

Measure Testing Requirements

The ACR appreciates that CMS has incorporated feedback from QCDR measure developers into the proposed measure testing requirements. **We support the measure testing requirements as proposed.**

While we support the proposed requirements, we offer the following recommendations to reduce the administrative burden on both QCDR measure developers and measure submission reviewers:

- When assessing face validity, CMS should allow for a clear and direct association with a clinical guideline to be sufficient to fulfill face validity for a measure, especially when the guidelines are released by organizations with a strong record of high-quality clinical guideline development.
- If a QCDR measure has been endorsed by the NQF and is submitted to CMS, the requirement to document measure testing information for CMS should be waived, as long as the NQF measure ID is provided.
- Once a thoroughly tested QCDR measure has been approved by CMS, the testing requirement should be waived for subsequent years unless CMS identifies a significant substantive change to the measure that would necessitate new testing.

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,

Ellen M. Gravallese, MD
President, American College of Rheumatology