September 16, 2019

The Honorable Seema Verma Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Submitted electronically via http://www.regulations.gov

Re: (CMS-1715-P) Medicare Program; CY 2020 Revisions to 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

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 2020 Physician Fee Schedule and Quality Payment Program proposed rule. We welcome the chance to share our concerns about the impact of these proposals on our ability to provide quality care to the 50 million Americans living with rheumatic diseases.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. Rheumatologists, and rheumatology physician assistants and nurse practitioners, provide face-to-face, primarily non-procedure-based care, and serve patients with serious conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other inflammatory arthritides, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases. 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 downstream procedures and care compared to care provided solely by primary care providers.
**Evaluation & Management (E/M) Visits and Add-On Codes**

CMS is proposing to adopt the American Medical Association (AMA), RVS Update Committee (RUC) recommended values for the office and outpatient evaluation and management (E/M) visit codes for CY 2021. We applaud CMS for giving the physician community time to develop a better solution for E/M code reimbursement. After sustained advocacy by the ACR and our specialty partners along with the American Medical Association, the agency’s new proposal aligns with recommendations set forth by the AMA in collaboration with physician societies, including the ACR.

The original proposal would have reduced reimbursements for physicians, such as rheumatologists, who provide complex E/M services to patients with complex chronic diseases. Had this policy been implemented as proposed, the severe economic impact of these cuts to physician practices would have adversely affected patient access to specialized services and further exacerbated the rheumatology workforce shortage. If finalized, the current CMS proposal would more appropriately value time-intensive healthcare services provided by cognitive specialists such as rheumatologists. These services include examinations, disease diagnosis, risk assessments, and care coordination. The result would be an increase in Medicare reimbursement across the board for rheumatology beginning in CY 2021. Further, we appreciate CMS for keeping the documentation reduction and flexibility for physicians and NPPs to use either 1995 or 1997 documentation guidelines. We strongly support CMS moving forward with finalizing this proposal.

**Add-on code consolidation**

We are also supportive of CMS proposing to simplify coding by consolidating the two proposed add-on codes into a single add-on code (GPC1X). The ACR agrees with the CMS revised single code descriptor, which better describes the work associated with visits that are part of ongoing, comprehensive complex care. The recommended RVU for this code was 0.75 and CMS has proposed an RVU of 0.61, only applicable to 99205 and 99215. We encourage CMS to accept the RUC recommended RVU of 0.75 to better reflect the intensity of care for complex patients. We do appreciate the proposal to keep add-on code GCG0X to allow reporting with all E/M levels and not only levels 2-4, and we encourage CMS to finalize as proposed.
CPT Codes 99358-9 Prolonged E/M without Direct Patient Contact

CMS proposes changing the scope of utilization regarding CPT codes 99358 and 99359, stating it will no longer accept billing with an office/outpatient E/M visit if time is the deciding factor for a visit. We feel it is important to keep the option of using both 99358 and 99359 as the AMA CPT Editorial Panel approved these codes to provide additional time and reimbursement when a prolonged service is provided that is neither face-to-face time in the office or outpatient setting, nor additional unit/floor time in the hospital or nursing facility setting during the same session of an evaluation and management service and is “beyond the usual physician or other qualified health care professional service time.” Additionally, the definition in the CPT manual, face-to-face time with a patient during an evaluation and management service is not counted towards the prolonged service codes without direct patient contact, no matter how much time is spent with the patient. Also, it is generally negative to lose coding options, which forces changes in workflow. We believe the utilization of these add-on codes should be reviewed on a case by case basis.

Principal Care Management Codes

CMS is proposing to add an additional two HCPCS codes for principal care management (PCM), which would be billed by a primary care physician as well as by other specialists. We thank CMS for the continuous work in responding to the gap in coding and reimbursement for patients with a single chronic condition as there are significant resources involved in the care and management for a single high-risk disease or complex chronic condition as seen in patients with rheumatic disease. We are pleased to see that the CMS is not proposing restrictions on specialties to bill PCM and expects that this code would be billed by specialists, when there is a single condition of such complexity that cannot be managed in a primary care setting.

Time-based billing

The revised definitions of these services will allow physicians to select the appropriate visit level based on the time a physician spends on the calendar date of service. The proposed rule explains that time spent 3-days prior and 7-days post-visit are already captured by these services, and will not be counted toward code selection. CMS is asking for comment on this interpretation. The ACR, along with other specialty colleagues, would like to see CMS revise the requirement for visit level selection, allowing it to be based on time spent during the 24-hour period that includes the face-to-face visit, not the calendar date of services, in recognition of those physicians who see patients during evening clinics. We also encourage CMS to consider allowing physicians the ability to add anticipated time under those circumstances where MDM cannot be concluded on the calendar date of services. In many circumstances, physicians’ MDM
is not complete until certain test information has returned. We echo the recommendations of
the Cognitive Care Alliance (CCA) and would propose that physicians be allowed to add time
spent beyond the first 24-hour interval, up to 5 days after the visit, when testing results
essential to the MDM are delayed.

**Documentation Reduction**

We fully support CMS’ work to remove redundancy in documentation by making modifications
to the documentation policy so that physicians, physician assistants, nurse practitioners, clinical
nurse specialists, and certified nurse-midwives could review and verify (sign and date), rather
than re-documenting, notes made in the medical record by other physicians, residents, nurses,
students, or other members of the medical team. In the case of established patients, providers
and healthcare professionals should not be required to document information in the provider's
note that is already present in the medical record, particularly regarding history and exam. This
policy change will alleviate provider burden. We would ask that CMS clarify in the final rule that
this policy change would begin in CY2020.

**Supervision of Physician Assistant (PA) services**

CMS is proposing to modify the regulation on physician supervision to give PAs greater
flexibility to practice more broadly in the current health care system in accordance with state
law and state scope of practice. While this may work in the favor of practices and physicians to
not have to re-review or document for shared visits, we do ask that CMS clarify if this policy will
in any way impact reimbursement.

**Valuation of Specific Codes**

We believe it is necessary to have revaluation of specific services to reflect changing trends in
the practice of medicine as well as practice expenses. There is a need for consistency in
valuation of the 76881 diagnostic ultrasound family of codes. In the FY 2018 final Physician Fee
Schedule rule, CMS included a proposal to re-price the direct practice expense (PE) inputs for
musculoskeletal ultrasound (MSUS) codes 76881 and 76882. The AMA-RUC's recommended
direct PE inputs for CPT code 76881 from the CY 2018 rule cycle used data that misrepresented
the current practice landscape for MSUS. The PE recommendations were based on what was
typical for the dominant specialty, which at the time was podiatry.

According to the current RUC database, rheumatology is now the dominant provider of 76881.
Rheumatologists use 76881 (complete MSUS) for point of care testing to assist in diagnosis and
management, as well as show changes over time. Generally, patients are moved to dedicated
ultrasound rooms for proper positioning and draping, and to remove the procedure from other clinic workflow. The picture archiving and communication system (PACS) station is extremely important due to the need to store numerous images (ultrasound produces far more images than a standard radiograph) and to compare to previous scans for longitudinal chronic disease management. This procedure is essential for making appropriate diagnosis and managing patients with various rheumatologic conditions and musculoskeletal disorders. Cutting the reimbursement for the code would not only detract from patient care, but also disincentivize ultrasound training for future rheumatologists, as well as increase total costs through the use of more expensive magnetic resonance imaging (MRI) procedures.

The technical component of CPT code 76881 (Ultrasound, complete joint (i.e., joint space and peri-articular soft tissue structures) real-time with image documentation) has been significantly decreased. A PACS system was not typical a part of the PE in podiatry at the time of the revaluation and was therefore removed from 76881. Further, podiatrists were not the primary users of the complete ultrasound (76881), and therefore reimbursement changes were also recommended. In the final FY 2018 rule, CMS removed direct medical supply inputs of the practice expense (PE) for the ultrasound room, PACS workstation Proxy and the professional PACS workstation, leaving only the table and the portable ultrasound unit for 76881 (complete). For 76882 (limited) where podiatry and radiology are still the top billers, the equipment and post service time for practice expense is there for a PAC workstation, along with the ultrasound unit, and the technologist workstation. All of the technical components are included in the limited MSUS code, but not in the complete MSUS code.

Currently, CPT code 76881 (complete), for which rheumatology is the dominant provider, has had a 13% decrease in reimbursement, directly related to cutting reimbursement for practice expense and not physician work, while CPT 76882 (limited) had a slight increase. Please see the charts below for current code values and a prediction of these cuts in future years 2020 and 2021 (highlighted in blue) with the assumption that the CMS 4-year phased cut for MSUS will more than likely be the same percentage each year.

<table>
<thead>
<tr>
<th>Table I</th>
<th>2018 Medicare National Fee Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>Descriptor</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>76881</td>
<td>Us xtr non-vasc complete</td>
</tr>
<tr>
<td>76881-26</td>
<td>Us xtr non-vasc complete</td>
</tr>
<tr>
<td>76881-TC</td>
<td>Us xtr non-vasc complete</td>
</tr>
<tr>
<td>76882</td>
<td>Us xtr non-vasc ltd</td>
</tr>
<tr>
<td>76882-26</td>
<td>Us xtr non-vasc ltd</td>
</tr>
<tr>
<td>76882-TC</td>
<td>Us xtr non-vasc ltd</td>
</tr>
</tbody>
</table>
As an immediate solution, CMS could include PACS station in the complete ultrasound code (76881). This should include the post service staff labor time to scan exam documents into PACs and technologist quality control (QCs) of images in PACs which includes, checking for images, reformat and dose. This solution would alleviate some of the stress of these significant cuts to reimbursement and more accurately reflect inputs to allow for consistency in practice expense in the family of codes

GPCI Review/Update

For CY 2020, there is a 0.5 GPCI work phase in. The current proposal does not include the 1.0 work GPCI floor, as the Balanced Budget Act of 2018 (BBA) only extended the floor through December 31, 2019. This is a major component of the payment structure and since this is the
Global Packages

We appreciate CMS’ commitment to review global packages, especially considering the new E/M values for CY2021. We are concerned about comments related to procedures that are closely tied to E/M codes. It appears CMS is looking at procedures performed on the same day as an E/M visit and may be exploring ways to adjust the RVUs or cut back on reimbursement in a way which would not adequately pay for both procedures. This is reminiscent of the CY 2019 multiple procedure reduction proposal. The medical community and CMS have worked for several years to remove any overlap in the clinical labor time and practice expense for procedures commonly performed during the same encounter as an office visit. Therefore, we oppose any future proposal that would result in an excessive, unjustified reduction in reimbursement because the overlap between clinical labor time and practice expense has already been accounted for in the valuation of these services. A proposal such as this could result in patients being asked to return on a different day for minor procedures (e.g., injections, joint aspirations, treatment of actinic keratosis), a situation that could also reduce the quality of care and increase copayments for patients.

CY 2020 Quality Payment Program

MIPS Value Pathways (MVPs)

We appreciate CMS’ efforts to make the MIPS program more successful by reducing the complexity of the program and physician reporting burden. However, the proposed MIPS Value Pathway is not ready to be implemented or even phased in without more robust vetting and stakeholder input. We agree that the goal of any new proposal such as the CMS MVPs should focus on optimizing and streamlining the MIPS program. We understand this proposal would move MIPS from its current state to a different reporting system, which would be a significant departure from the current processes. We understand this is a first step and we would like to partner with CMS in making the MIPS program more successful for physicians. To this end we have several discussion points and areas of concern relating to this proposal.

The ACR strongly believes that if the MVP program moves forward, it must be voluntary and focus on measures that are meaningful to clinical care versus administrative claims or population health measures. CMS proposes to assign clinicians to MVPs stating that this will reduce the physician administrative burdens. Again, MVPs must be voluntary, and CMS should
not mandate how physicians participate in MIPS with several options on the table for participation.

We urge CMS to view the first few years of MVP implementation as, at minimum, a pilot period, and we recommend against implementation without vetting and stakeholder input. The physician community has just gone through a significant change implementing MIPS. Overhauling and reworking systems in order to implement MVPs would be extraordinarily resource-intensive with uncertain gains.

If CMS envisions specialty societies creating MVPs, it will take substantial time and resources to develop, refine, and educate physicians on this new QPP track. We further advocate for an opt-in policy, which would allow physicians to opt-in to CMS’ suggested MVP, or to choose an alternative MVP, or to continue to report measures through the traditional MIPS pathway. We are concerned about physician burden during this transitional period and CMS should ensure that providers do not have to participate in an MVP for one disease but report in traditional MIPS for other patients that do not fit in the CMS MVP.

CMS states that the MVP pathway will help move providers into alternative payment models (APMs) by enabling providers to learn the pros of data utilization and become comfortable with building the skill set needed to succeed in an APM. We appreciate that the intent of MVPs is to help physicians to acquire the tools to succeed in an APM; however, there is no clear direction on how MVPs will increase APM utilization, and there are few options for providers to currently participate in APMs.

The ACR along with the AMA opposes CMS’ proposal to layer population health or administrative claims-based measures into MVPs. Many of the existing administrative claims measures have not been tested at the physician level and are based on retrospective analysis of claims that does not provide a granular enough level of information for physicians to make improvements in practice. To our knowledge, CMS also prohibits specialty societies from developing and proposing administrative claims measures.

Ultimately, physicians treat patients at the individual level and not the population health level; therefore, measuring them on population health measures would hold them accountable for variables outside of their control. Measures included in MVPs should be meaningful to the clinical care of a physician’s particular practice and patients, and measure things that a physician can actually control. We also encourage CMS to consider providing incentives to providers for participating in MVPs and specialty societies for developing MVPs.
Small Practice Bonus

Last year, CMS finalized the policy to retain a small practice bonus under MIPS by moving it to the quality performance category. We still believe this reduces the small practice bonuses to a negligible amount that does not truly help small practices as they face challenges adapting to the Quality Payment Program. We request that CMS maintains the bonus at 5% of the final score further explores how small practices can be better supported in the future MIPS years.

Cost Category

The ACR urges CMS to not continue to increase the weights of categories that are outside of provider control at the expense of the Quality Category, which is the largest category that can be controlled by providers. 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 calculation of resource use (i.e., costs) as currently proposed includes medication costs from Part B, but not Part D, and so h would result in inaccurate MIPS scoring. The current proposal incentivizes physicians to prescribe Part D medications instead of Part B medications, with the unintended negative consequence of increasing patient cost sharing because of the relative lack of coinsurance in Part D compared to Part B. The ACR continues to advocate for addressing this inaccuracy. Additionally, the ACR suggests that costs incurred outside of specialists’ control should not be attributed to them, as happens when attributing patients to specialty providers when they do not have a primary care provider.

Performance Category

We also encourage CMS to continue its 2018 PI Performance Category policy to enable more EHRs and providers more time to upgrade to this standard. Maintaining the bonus for 2015 CERHT use would be less disruptive in the short-term and incentivize compliance in the long-term. Alternatively, CMS could also allow for an exemption for the 2015 CERHT requirement if a provider is utilizing a QCDR for submission or is a small practice.

Qualified Clinical Data Registries (QCDR) Measures and Scoring

We believe that, in order to further the development of meaningful specialty-specific measures, CMS should support the protection of these measures as intellectual property, given the extensive resources that go into measure development, especially for QCDR measures. To develop these measures, an organization must go through the rigorous process of development, collaboration with relevant external stakeholders, and endorsement. Allowing duplicative measure concepts to go forward in the MIPS program at a later time fosters
confusion among physicians and competition among QCDRs, rather than collaboration. The ACR feels strongly that organizations will not be able to continue to invest in advancing meaningful quality measures if their measure concepts are able to be appropriated with superficial changes and then supported by CMS.

Measure Development and Testing Requirements

The ACR supports CMS’ proposal to require that QCDR measures be developed and tested in accordance with established standards, such as the CMS Blueprint. Requirements for appropriate measure development and testing will ensure providers using QCDRs are not only focused on using the most relevant measures but also ones that are held to a high standard of validity and reliability. Nevertheless, we believe it is important to point out that the CMS Blueprint was developed for use by measure contractors who presumably have dedicated resources, both in staffing and funding, to do the sole work of measure development, testing and maintenance.

The CMS Blueprint is certainly a good framework for expectations of measure development and testing. However, strict use of the CMS Blueprint raises some concerns. For example, the measure development timeline and requirements as laid out in the Blueprint are aggressive, particularly for organizations dependent on limited funds and expert volunteers to complete the work. Given this, we request that if the proposal is finalized, CMS provide some leniency on following the Blueprint. The ACR and the Registry Coalition would be good resources for helping to set an acceptable standard that is both feasible and rigorous. We also request that CMS continue to work closely with measure developers to fully understand, accommodate and provide guidance on the developer’s measure development pathway and timeline.

Measure Removal

CMS is proposing to remove measure 179: RA Disease Prognosis from the program, and we agree with CMS that it is appropriate to remove this measure. We anticipated that this measure would soon be topped out. CMS also proposes to remove the ACR-stewarded measure 178: Rheumatoid Arthritis (RA): Functional Status Assessment and replace it with the non-rheumatology-specific measure 182: Functional Outcome Assessment. We believe the removal of 178 would have a negative effect on Rheumatology. This change would remove a specialty-specific measure from the program. This is especially troublesome given the concepts in measure 178 are important for and tailored to rheumatology providers and have the potential to be an important part of a rheumatology-specific MIPS Value Pathway. The ACR believes this measure should be kept in the program in order to facilitate movement towards evidence-based outcome measure implementation through CMS’ MVPs. Removing 178, a measure that
might fit into a new rheumatology MVP, prior to roll out of the actual MVP could create confusion among providers and result in greater provider burden. For example, providers would suddenly have to move to assessing some FSAM that may not be as reliable, responsive, or valid as those ACR supports, and then they would have to change again when an MVP is an option. We ask that CMS create a clear and efficient transition plan to help providers prepare for these substantial QPP changes.

Additionally, measure 178, especially with the ACR’s requested changes for 2020, is an important steppingstone for the ACR’s work toward developing and implementing rheumatology outcome measures. For example, the ACR is currently working with the NQF to develop a patient-reported functional status outcome measure that is reliant on the process of assessing functional status using the specific tools that are laid out in our requested changes to measure 178. Removing the measure would significantly set back the ACR’s efforts to lay the appropriate groundwork for that outcome measure.

Furthermore, the ACR has invested significant time and resources to conduct a comprehensive assessment of the appropriate tools to use when assessing functional status among RA patients and is incorporating the results of that assessment into measure 178. Replacing measure 178 with measure 182, in effect, removes restrictions around requiring specific tools to meet the measure, thereby lowering performance thresholds for rheumatology providers and providing opportunities for loopholes by using tools that are not appropriate for rheumatologic care. Additionally, measure 182 is more focused on functional status assessments and care plans within physical and occupational therapy. While that is an important aspect of care for people with rheumatic diseases, the role of functional status assessments and how they inform treatment in rheumatology is not quite the same and may not warrant the same actions as would be appropriate among PTs and OTs. For example, while documentation of a follow-up plan can be helpful in rheumatology care, it is not always necessary. Treating RA is typically about tracking disease progression over months and years to identify worsening and flares, not about providing acute treatment. We strongly believe measure 178 is an appropriate rheumatology-specific measure that complements both best practice rheumatologic care and measure 182 and should remain in the program.

Finally, the changes the ACR requested be made to measure 178 are incorrectly captured. It appears the language in the change request document was copied and pasted without regard to formatting, which provided a visualization of deletions and additions.

**The requested changes should appear as follows:**
New numerator statement: Patients for whom a functional status assessment using an ACR-preferred, patient-reported functional status assessment tool was performed at least once within 12 months

New numerator definition: This measure assesses if physicians are using a standardized tool to assess the impact of RA on patient activities of daily living. Functional status should be assessed using a measurement tool assigned preferred status by the ACR. The instruments listed are the ACR-preferred tools that fulfill the measure requirements:

- PROMIS Physical Function 10-item (PROMIS PF10a)
- Health Assessment Questionnaire-II (HAQ-II)
- Multi-Dimensional Health Assessment Questionnaire (MD-HAQ)

Promoting Interoperability

We encourage CMS to provide physicians with more credit for participating in specialty clinical data registries under MIPS. Participation in the ACR RISE® Registry (Rheumatology Informatics System for Effectiveness) signifies that rheumatologists are meaningfully using electronic health records to improve patient care, outcomes, and practice efficiency. ACR strongly urges CMS to increase incentives for physicians to participate in clinical data registries by providing full PI credit for participation.

Alternative Payment Models (APMs)

There are few existing Alternative Payment Models (APMs) that are feasible for rheumatologists. ACR has invested significant time and resources to produce a workable alternative in the form of an RA-specific APM. This APM is designed to facilitate participation of small and solo practices. We are concerned that none of the disease-specific APMs approved by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) have been piloted or approved by the Innovation Center (CMMI). We recommend that CMS work with CMMI to test and adopt additional APM options in order to encourage better physician engagement with alternative payment models.

Risk

The current nominal risk criterion makes it difficult for smaller practices to attempt the APM track. Smaller groups engaged in Physician Focused APMs should not be held to the same degree of nominal risk as large organizations such as ACOs. We also recommend that CMS lower the payment and patient count thresholds for Physician Focused APMs to allow "qualifying participant" status to be more achievable for smaller practices and those providers
who use disease-specific models. We feel this would encourage more small practices to pursue Physician Focused APMs. We also continue to urge CMS to allow the set-up cost of physician-focused APMs to serve as the financial risk, at least on an interim basis.

In conclusion, the ACR is dedicated to ensuring that rheumatologists and rheumatology interprofessional team members have the resources they need to work with CMS and provide patients with high-quality care. We believe that for CMS, clinicians, and patients to all achieve their objectives, payment programs must be designed to reflect the way practices treat patients. The American College of Rheumatology appreciates the work CMS does and the opportunity to respond to this proposed rule. We look forward to serving as a resource to you and to working with the agency. Please contact Adam Cooper, Sr. Director of Government Affairs, at acooper@rheumatology.org or (404) 633-3777 if you have questions or if we can be of assistance.

Sincerely,

Paula Marchetta, MD, MBA
President, American College of Rheumatology