August 21, 2017

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-5522-P, Medicare Program, CY 2018 Updates to the Quality Payment Program, 42 CFR Part 414

Submitted electronically via Regulations.gov

Dear Ms. Verma,

The Coalition of State Rheumatology Organizations, or CSRO, is a group of state or regional professional rheumatology societies formed in order to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist.

On behalf of CSRO and the undersigned state rheumatology societies, we are pleased to provide input that will inform the implementation of the Quality Payment Program (QPP) in Year 2.

Proposed Implementation of the Medicare Quality Payment Program – Year 2

In its 2018 updates to the QPP, CMS is proposing significant flexibility and incentives for small practices, which will benefit the vast majority of practicing rheumatologists across the country. We are particularly supportive of CMS' proposals that would increase the low-volume threshold, excluding more practices from the Merit-Based Incentive Payment System (MIPS) in Year 2. For those that remain included in MIPS, we support CMS' proposals that continue aspects of "pick your pace," provide new bonuses for small practices and for those treating complex patients, as well as new exceptions for practices that are struggling with the adoption and implementation of certified electronic health record technology (CEHRT).

Nonetheless, we continue to believe there are several issues that must be addressed as the program continues, particularly with respect to the MIPS cost performance category and the MIPS payment adjustment. We expand on these issues in the paragraphs below.

MIPS Program

MIPS Eligible Clinicians

CSRO opposes CMS' policy to include Part B drugs in the calculation of MIPS payment adjustments and eligibility determinations. First, CSRO does not believe this was Congress' intent when drafting the legislation. Second, we believe that finalizing this policy would be a violation of the Administrative Procedures Act (APA).

First, CSRO disagrees with CMS' interpretation of the statute, which led it to believe that Part B drugs are subject to the MIPS payment adjustment. The MIPS payment adjustment provisions are included in Section 1848 of the Social Security Act (the Act), which is entitled "payment for physician services" and pertains to payment under the Physician Fee Schedule (PFS). It is our contention that, if Congress meant for the MIPS adjustments to apply to "items and services" outside the PFS, it would have stated that *explicitly*, or placed the MIPS adjustment provisions in a different section of the Act to make clear that they apply to items and services going beyond those paid under the PFS. Under CMS predecessor quality improvement programs (i.e., the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VM) and the Electronic Health Record (EHR) Incentive Program), Part B drugs were *excluded* from payment adjustments. Given MIPS was expressly designed to consolidate and streamline those adjustments, we do not believe Congress intended for CMS to expand them. Further, under the Advanced APM track of the QPP, Part B drugs are not included in the incentive payment. We do not believe that Congress intended for the MIPS adjustment to apply to more services than the Advanced APM incentive.

Second, we firmly believe CMS would violate the APA should it finalize the confusing "proposal" described in the preamble. In the 2017 QPP final rule, CMS delayed responding to commenter questions as to whether Part B drugs would be included in MIPS program payment adjustments, stating it would "consider this issue and provide clarification" in the future. In this proposed rule, CMS has not offered a clear proposal; instead, the agency appears to be "clarifying" what it believes to be existing policy without the clarity necessary to make meaningful comments. Under the Administrative Procedures Act (APA), a final rule must be a logical outgrowth of a proposed rule. Again, what has been outlined in this rule is not a clear proposal; rather CMS provides a confusing "clarification" of what it suggests is existing policy. Without a clear proposal for stakeholders to consider and provide comment, the logical outgrowth test cannot be met.

Small rheumatology practices are already facing significant challenges purchasing Part B medications for their Medicare patients at Average Sales Price (ASP) +6%, not counting the reductions due to sequestration, which reduce that rate closer to ASP +4.3%. It is unconscionable to think that further reductions would be imposed on these practices if they fail to properly "test" the MIPS program in 2017 or meet the performance threshold set in 2018 and beyond. It is even more surprising that, during a time when high drug prices are at the forefront of the healthcare debate, and in the very program that aims to reward physicians for the quality and value of services they deliver, CMS would provide incentives, substantial in some cases, to physicians based on the volume of drugs they prescribe to Medicare beneficiaries. This proposal conflicts with the very core of the Medicare Access and CHIP Reauthorization Act (MACRA), as we understand it.

MIPS payment adjustments should only apply to covered PFS services; therefore, CMS must reconsider its proposal and **exclude Part B drugs from MIPS eligibility determinations and payment adjustments.**

MIPS Performance Category Measures/Activities

Quality Performance Category

CMS has proposed revisions the Rheumatology specialty measure set, eliminating important quality measures, while adding others. We oppose the removal of Measure 337: *Tuberculosis (TB) Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier.* **We urge CMS to retain this measure in the rheumatology specialty measure set.**

Cost Performance Category

CSRO appreciates and supports CMS' proposal to modify the weight of the cost performance category from 10% to 0% for the 2020 MIPS payment year. In future years, however, the cost performance category will consume a greater proportion of the final score relative to other performance categories (i.e., 30% in the 2021 MIPS payment year). This is of particular concern for rheumatologists, given episode-based measures for our specialty remain in development, leaving CMS to continue its reliance on the Total Per Capita Cost and Medicare Spending Per Beneficiary (MSPB) measures, which were carried over from the VM program.

CSRO does not believe these measures appropriately or adequately capture the cost and resource use of rheumatologists for the conditions and diseases they treat, nor do the data provided from their use yield information that is meaningful and actionable to help them change behavior in a direction that would drive down costs relative to their peers.

Rheumatologists continue working with CMS on the development of episode-based measures that are applicable to the rheumatologic conditions, such as rheumatoid arthritis (RA) and lupus. **Until episode-based measures are fully developed and available for use, CMS should reweight the cost performance category of MIPS to 0% for rheumatologists, beginning with the 2021 MIPS payment year.**

In addition, we want to ensure that CMS' efforts to develop cost and resource use measures for rheumatologic conditions take into consideration *all* pharmaceutical costs incurred during an episode of care. Under MACRA, the Secretary is authorized to, "as appropriate, and, as feasible and applicable" account for "the cost of drugs under part D." CMS has stated in prior rulemaking that it would consider how best to incorporate Part D into the cost performance category, and has continuously sought public comments on how it should incorporate these costs under MIPS for future years.

In our comments on the development of an RA episode of care, we noted that this condition is prime for "sub-group" episodes, parsed by disease progression and whether the pharmaceutical therapy chosen is covered under Part D or Part B. For example, we stated that depending on how drugs are incorporated into the RA episode group, it will be important to differentiate between whether Part D or Part B drugs are chosen (see below).

Again, when cost and resource use measures exclude Part D costs, it puts physicians who administer Part B drugs in their office at a significant disadvantage compared to those who order/prescribe drugs

covered under Part D, since the former would appear to have higher Medicare expenditures than the latter. It may also disadvantage beneficiaries, as treatment options could become more limited when providers are inappropriately held accountable for costs beyond their control. CMS has previously noted that use of the Hierarchical Condition Categories (HCC) model in its VM measures may account for some conditions that require Part B drugs, however, it does not distinguish between the *appropriateness* of Part D drugs v. Part B drugs and unduly punishes physicians who ultimately determine that Part B drugs are most appropriate for their patient. This must be addressed as CMS develops episode-based cost measures for use in the MIPS cost performance category.

Whether the solution is to remove Part B drug costs from resource use calculations or to incorporate Part D drug costs into these calculations, the most important thing is that cost-of-care measures not have an adverse impact on practice patterns and do not discourage treatments that best meet the needs of the patient.

Improvement Activities Performance Category

CSRO submitted a request for an improvement activity – *Use of clinical assessment modalities and diagnostic screening tools in specialty medicine (e.g., WHO Fracture Risk Assessment (FRAX) Tool)* – in February 2017 during CMS' call for activities, for inclusion in the 2018 MIPS. We were recently notified that our improvement activity request was "*proposed for inclusion in the MIPS improvement activities inventory as a new improvement activity or incorporated into an existing improvement activity*," however, it is unclear where this IA was incorporated into a new or existing IA based on our review of the rule. In 2017, the QPP HelpDesk and CMS medical officers provided conflicting advice as to whether rheumatologists should use IA_PSPA_8, Use of patient safety tools, or IA_PSPA_21, Implementation of fall screening and assessment programs, for the FRAX tool. **We urge CMS to finalize this new IA as a stand-alone IA; however, if that is not possible, we urge CMS to incorporate the FRAX tool into IA_PSPA_8, and to specifically list the tool as one of the examples.**

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Thank you for considering our comments, and we look forward to working with you as you implement the Medicare QPP in 2018 and future years. Should you have any questions, please contact Emily L. Graham, RHIA, CCS-P at 703-975-6395 or egraham@hhs.com.

Sincerely,

Coalition of State Rheumatology Organizations
Arkansas Rheumatology Association
Kentuckiana Rheumatology Alliance
Rheumatology Association of Nevada
Tennessee Rheumatology Society
Rheumatology Alliance of Louisiana
Michigan Rheumatism Society
New York State Society of Rheumatology

Rheumatology Association of Minnesota and the Dakotas
Georgia Society of Rheumatology
Ohio Association of Rheumatology
Rheumatology Association of Iowa
Midwest Rheumatology Association
California Rheumatology Alliance