November 20, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Submitted electronically via CMMI_NewDirection@cms.hhs.gov

RE: Innovation Center New Direction – Request for Information

Dear Ms. Verma,

The Coalition of State Rheumatology Organizations, or CSRO, is a group of state and regional professional rheumatology societies formed 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.

We are pleased to respond to your request for information (RFI) on the agency's planned new direction for the Innovation Center, focusing on specific issues that uniquely impact practicing rheumatologists and the patients they serve. Through the Alliance of Specialty Medicine, CSRO has provided feedback on additional issues that broadly impact specialists, including rheumatologists.

Guiding Principles

Following CMS' withdrawal of the Part B Drug Payment Model and cancellation of two other episode payment models, CSRO agrees with the chorus of other health care stakeholders that "guardrails" are essential as the Innovation Center redirects is efforts. In addition to the Guiding Principles outlined in the RFI, we urge the agency to include the following:

- ***Preserve beneficiary access to care.*** Under the now-withdrawn Part B Drug Payment Model, beneficiary access to life-saving and life-changing medications, and the providers delivering them, would have been significantly hindered. In fact, the model did not include metrics that considered beneficiary experience or quality of care. Models advanced by the agency should put beneficiaries first, aiming to improve access to the right provider for the most appropriate diagnosis, treatment, and disease management. The Innovation Center should focus on preserving beneficiary access to care, halting any models that seek only to reduce Medicare spending to the detriment of beneficiary health and well-being.
- ***Engage stakeholders in model development.*** Despite the major impact on rheumatologists and their patients, rheumatologists were not engaged in a dialogue prior to the release of the Part B Drug Payment Model. The model was first released through notice-and-comment rulemaking, which left little opportunity for the Coalition and other stakeholders to meaningfully revise the model given the "logical outgrowth" hurdle that could not have been met. Moreover, CSRO, an organization that seeks to address challenges with beneficiary access to Part B and Part D drugs, would have welcomed a dialogue with agency officials at the outset to provide feedback that would have instructed a model that may have addressed issues facing the specialty and its patients with access to needed pharmaceuticals. As the agency proceeds, we urge early engagement of stakeholders through transparent, subregulatory processes, such as requests for comment and information. Models should never be released for the first time through rulemaking, where major revisions will be limited.

- ***Incentivize provider participation, not mandate.*** Providers should be appropriately incentivized to engage in alternative models of care and delivery, never forced. This is particularly true for those who lack the necessary infrastructure, data and analytical capabilities, staffing, and capital to assume downside-risk. This is likely to be the case for rheumatology practices, which are typically small. Furthermore, beneficiaries should not be forced to participate in demonstration projects that they do not feel comfortable participating in. Whether through an active opt-in or opt-out, a clear mechanism for beneficiaries to choose their engagement should be made available.

As members of the Healthcare Leaders for Accountable Innovation in Medicare and Medicaid, we also urge you to consider the addition of those principles as part of the Innovation Center's Guiding Principles.

Proposed Models

Expanded Opportunities for Participation in Advanced APMs

We appreciate that CMS seeks to expand opportunities for physicians to participate in existing Advanced APMs (A-APMs). Rheumatologists, like many other specialty physicians, face challenges with engagement in existing A-APMs. In fact, a report issued by Leavitt Partners explains that not every provider has a path forward under the APM track of the QPP.[1] As a result, most rheumatologists (80 percent) will be subject to the Merit-based Incentive Payment System (MIPS) with a miniscule amount (1.4 percent) who will be considered "qualifying participants" under the APM track in year 1 of the Quality Payment Program (QPP).

CSRO, independently, and as part of the Alliance of Specialty Medicine, have explained in multiple letters to the agency that participation in federally-sponsored APMs, such as the Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), presents challenges. Specifically, we have noted that Medicare ACOs use "narrow networks" to limit the participation of specialists as a mechanism to control costs, which limits beneficiary access to specialists. While CMS monitors beneficiary access to specialists through an "Access to Specialists" module as part of the CAHPS Survey measures set that ACOs are required to report, we remain concerned that this measure will not be enough to demonstrate whether beneficiaries are being referred for rheumatologic care at the most clinically appropriate point in their disease progression. As noted above, early intervention and referral to a rheumatologist will limit the development or progression of certain rheumatic illnesses, ultimately resulting in financial savings for the ACO and the Medicare program. Also, it remains unclear whether results from the "Access to Specialists" module will be reliable, as respondents may be unaware that rheumatologic care is necessary in order to properly manage their condition.

In addition, the quality metrics CMS has adopted for use by these entities are not consistent with the rheumatologic conditions we treat or have control over, making it even more challenging to "prove our value" to the A-APMs. Until such metrics are included, the chances of A-APMs including our specialty on their panels, are slim.

From a disease burden perspective, it is clear that rheumatologists should be working with A-APMs to improve quality and resource use, particularly for high-cost, chronic conditions, such as rheumatoid arthritis. However, the metrics on which to demonstrate our value must be present. We would be pleased to meet with CMMI to discuss ways to better incorporate rheumatologists, and the quality and resource use measures to which we are held, into existing A-APMs.

[1] https://leavittpartners.com/wp-content/uploads/2017/09/CMS-Initiatives-White-Paper-9.7.2017-1.pdf

Physician-Specialty Models

CSRO is eager to collaborate with the Innovation Center on models that will improve beneficiary access to rheumatologists and the expertise we bring in accurate and appropriate diagnosis, treatment, and long-term management of serious, complex health conditions, including rheumatoid arthritis, systemic lupus erythematosus, and other debilitating inflammatory diseases. When primary care physicians misdiagnose these conditions, or refer these patients for intervention by a rheumatologist too late, disease progression is heightened and more difficult to control; costs to the Medicare program and beneficiaries are increased; and, beneficiary outcomes and quality of life are diminished until control is regained, if at all.

As noted below, we are currently working to develop models that would improve access to pharmaceutical therapy for rheumatoid arthritis, which has been hindered by a number of factors, including inappropriate and perverse incentives by pharmacy benefit managers (PBMs).

Prescription Drug Models

As discussed in the RFI, CMS notes that it will look to test new models for prescription drug payment, in ***both*** Medicare Part B and Part D. CSRO recently met with Innovation Center leadership and staff to discuss model concepts that would address rheumatoid arthritis, a chronic condition that relies on pharmaceuticals and biologics paid under both Parts B and D. Our understanding was that limitations on the Secretary's authority prevented most of the novel arrangements we discussed. If a new interpretation of relevant statute has resulted in an expansion of the Innovation Center's ability to test models that would address drug spending across the medical and pharmacy benefit, we would like to discuss ways to address the challenges our patients continue to face in accessing medicines for rheumatologic conditions.

We are in the process of developing a white paper that would outline a more specific concept for a model, which would combine aspects of CMS' Oncology Care Model (OCM) and the Medicare Payment Advisory Commission's (MedPAC's) Drug Value Program (DVP). As a small organization, we would benefit from technical assistance that the Innovation Center may be able to provide. We do not have the resources to develop a model for submission to the Physician-Focused Payment Model Technical Advisory Committee (PTAC), nor do we believe that is the most appropriate pathway for such a model given the anticipated limitations on reviewer knowledge of the Secretary's authority related to Part D or expertise in medications, including biosimilars, that cross these Parts.

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Thank you for considering our comments, and we look forward to working with you as the Innovation Center continues to evolve. 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