December 31, 2018

Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-ANPRM
P.O. Box 8013
Baltimore, MD 21244-8013
Submitted online via regulations.gov

Re: Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)

Dear Administrator Verma:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country 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 in charge of patient care for these illnesses.

The products we prescribe are often expensive biologic agents. As such, we are keenly aware of the rising out-of-pocket burdens on our patients. All too often, these burdens are prohibitive and result in patients rationing their medications or abandoning treatment altogether. We thank the Administration for its attention to this critical issue and its various proposals to help lower the cost of drugs for patients.

This letter contains our feedback related to the Administration's recent Advance Notice of Proposed Rulemaking (ANPRM), which described an International Pricing Index Model (IPI) for Part B drugs. **We are very encouraged by our ongoing conversations with the Administration and reiterate some of the ideas discussed during those interactions.** As explained during those meetings and in further detail below, **CSRO initially had deep concerns about the proposed changes to Part B drug payment as described in the IPI and was set to urge the Administration not to move forward with this demonstration project**. Again, we are encouraged to be working with the Administration to develop a plan that achieves the agency's stated goals within acceptable parameters. We hope to continue our productive dialogue.

First, practicing rheumatologists are extremely hesitant to introduce third party vendors in Part B. We are familiar with the concept of such middlemen in Part D, which covers several of the medicines used in rheumatology. In Part D, pharmacy benefit managers (PBMs) establish formularies based on price concessions they receive from manufacturers. To overcome formulary and utilization management

requirements is such a time-consuming, inconsistent, and unpredictable battle that many practices have at least one full-time person dedicated to that role. The physician's discretion and the patient's history matter little in this rebate-driven system.

This encroachment on clinical judgment might be more tolerable if our patients were seeing significant financial benefits from PBMs. However, even CMS itself has expressed concerns that price concessions are not being passed down to patients at the point-of-sale. Indeed, patients' coinsurance is often based on the list price. In the current system, the list price is a mere starting point for negotiations and is thus often artificially high. The patient is left holding the bag at every turn in this system.

We highlight these experiences to explain our concern about importing anything resembling that system into Part B. It is not unreasonable to believe that creating middlemen in Part B would, ten years from now, land us in the same predicament we are in with Part D: trying to regain some control over these entities. When the Part D benefit was created, no transparency or pass-through requirements were created for PBMs. The hope was that market forces would result in PBMs passing price concessions through to patients. No one could have foreseen the consolidation of the PBM industry, which, coupled with the opacity of its business practices, has resulted in a poor deal for patients. With the benefit of hindsight, we urge CMS not to make the same mistake again.

For these reasons, **CSRO opposes the creation of middlemen in Part B and prefers an alternative in which physicians could remain in a buy-and-bill system.** Rheumatologists who administer pharmaceuticals in their practices are familiar with this mechanism, and keeping it in place would ensure disruptions in patient care are minimized, should other aspects of this model concept be implemented. If the Administration must move forward with the vendor concept, we urge you to create strict limitations on their permissible functions. The proposed prohibition on volume-driven rebates by vendors is positive, but additional limitations must include a prohibition on utilization management, coupled with a fast and transparent enforcement mechanism for those who violate the prohibition. The Administration has indicated that it does not foresee vendors engaging in utilization management and we request that you state such an express prohibition in the regulation. Our concern is heightened by the fact that the Administration is proposing step therapy for Part B drugs in Medicare Advantage.

Second, the model would place significantly more financial and administrative burdens on physicians than the current system does. On the financial side, the ANPRM states that physicians would pay the vendor a fee to cover certain distribution costs. Under the current system, rheumatologists do not bear such costs. **CSRO opposes requiring physicians to pay for distribution of Part B drugs**.

On the administrative side, the ANPRM states that physicians would be responsible for collection of cost-sharing, but we urge the Administration to make the third party vendors responsible for collection of cost-sharing. The ANPRM describes an "administrative approach that deducts the cost-sharing amounts from Medicare payments made for other services to the model participants." We understand this to mean that Medicare would cut a physician's reimbursement for unrelated services to account for any cost-sharing he or she would be responsible for collecting. This is concerning. The fee schedule exists to compensate physicians for services rendered, not to be leveraged for beneficiary cost-sharing collection. Offering

physicians retroactive bad debt collection does not alleviate this concern, as bad debt payments are only a percentage of what was owed – yet the physician's reimbursement would likely be cut for the entire amount of the cost-sharing to be collected. **CSRO opposes making physicians responsible for cost-sharing collection**.

Third, we understood from the ANPRM that the "pool" on which the ASP add-on percentage would be calculated for demo participants would be based on the most recent year of claims data available. Since ASPs would presumably go down significantly as a result of the IPI, the add-on payment intended to cover the cost of administration would go down in tandem. However, based on subsequent conversations with the Administration, we now understand the "pool" will be based on the most recent year of claims data available at the time the IPI starts, and will be held at that amount, excepting an annual update for inflation. **We support that approach and urge the agency to update the "pool" annually at the rate of medical inflation**.

In addition, with respect to distribution of the add-on pool to physicians practices, we appreciate that CMS is contemplating a variety of arrangements (e.g., capitated payment, monthly payment or per administration payment, among others) and based on various factors (e.g., class of drug, mechanism of action, indication, generic vs. brand, or by medical specialty, among others). We remind CMS that patients with rheumatologic disease depend on relatively expensive biologic pharmaceuticals to slow disease progression, and the price of most of these pharmaceuticals do not vary considerably in terms of their list price. Further, many of these drugs have multiple indications and are used by other specialties. We ask that CMS propose a menu of payment arrangements from which physician practices can choose based on their practice size, type, and specialty. This flexibility will be particularly important for those practices that wish to opt in to the demonstration.

Fourth, the ANPRM mentions the creation of a bonus pool that would reward physicians who prescribe lower-cost drugs or practice evidence-based utilization. We do not believe the agency should create a financial incentive for prescribing decisions that are solely cost-based. However, the agency could create an incentive for physicians to prescribe biosimilars, where available and clinically appropriate. This may help with some of the lower than expected uptake of this new, cheaper alternatives. **Bonus payments must be based on evidence-based, clinically supported utilization guidelines developed by the relevant medical societies**. **Additionally, the Administration should consider tying bonus payments to biosimilar prescribing rates**.

Fifth, the demo as described in the ANPRM would be mandatory and cover half of all Part B drug expenditures. We have in the past stated our strong objection to mandatory participation in demos that are so large-scale they almost amount to nationwide program changes. This Administration has previously stated their intent to refocus the Innovation Center on voluntary, smaller models, but this demo does not have either of those characteristics. **CSRO opposes mandatory participation and urges the Administration to test any payment reform experiment on a smaller scale to avoid disruptions in care for Medicare beneficiaries**. To avoid disruptions in patient care, particularly for smaller practices and in rural areas, we urge CMS to automatically exempt physician practices of four or fewer Medicare physicians and practices in rural areas. **At a minimum, we urge the Administration to provide an opt-out**

mechanism (i.e., hardship waiver or hardship exemption) for practices that are financially underwater as a result of their participation in the IPI.

Last, we urge CMS to provide additional clarity regarding the operational and administrative aspects of the demonstration (e.g., coding and billing of administration and pharmaceuticals to Medicare contractors) under the demonstration, as well as how CMS anticipates it would set benchmarks for new physician practices entering the demonstration if there were an option for receiving their add-on payment as a monthly or capitated payment.

In sum, **we urge the Administration to take into account the above concerns in any new iteration of the IPI**. We thank CMS for its willingness to engage with practicing physicians and look forward to continuing to work with the agency as it considers these and other Part B reforms.

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Thank you for your consideration of these comments. Should you have any questions, please contact Emily L. Graham, RHIA, CCS-P at egraham@hhs.com or Judith Gorsuch, JD at jgorsuch@hhs.com.

Sincerely,

Coalition of State Rheumatology Organizations
Alabama Society for the Rheumatic Diseases
Arizona United Rheumatology Association
Arkansas Rheumatology Association
California Rheumatology Alliance
Colorado Rheumatology Alliance
Florida Society of Rheumatology
Georgia Society of Rheumatology
Massachusetts, Maine, & New Hampshire Rheumatology Association
Metropolitan Atlanta Rheumatology Society
Michigan Rheumatism Society
MidWest Rheumatology Association
Mississippi Arthritis and Rheumatism Society
Nebraska Rheumatology Society
North Carolina Rheumatology Association
Ohio Rheumatology Association
Oregon Rheumatology Alliance
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Tennessee Rheumatology Society
Virginia Society of Rheumatologists
Washington Rheumatology Alliance
Wisconsin Rheumatology Association