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Coalition of State Rheumatology Organizations

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September 24, 2018

Department of Health and Human Services
Office of the Secretary
200 Independence Avenue, SW
Room 600E
Washington, D.C. 20201

RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; RIN 0938-AT30

*Submitted electronically via www.regulations.gov*

To Whom It May Concern:

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 proposals to help lower the cost of drugs for patients. Our comments will focus solely on the Competitive Acquisition Program Request for Information (RFI) contained in the OPPS proposed rule. We hope you will find our feedback useful.

## Part B Competitive Acquisition Program

### Background

As the RFI outlines, the Department of Health and Human Services (HHS) is considering reinstating a Competitive Acquisition Program (CAP) for Part B drugs. The CAP was established as an alternative to the average sales price (ASP) methodology. Instead of physicians buying drugs for their offices, the CAP would allow them to voluntarily choose to participate in the program and place patient-specific drug orders with

an approved CAP vendor; the CAP vendor would acquire and distribute the drugs to the physician's office and then bill Medicare and collect cost-sharing amounts from the beneficiary.

As CMS notes, in June 2017, the Medicare Payment Advisory Commission (MedPAC) recommended a program similar to a CAP, calling it the Part B Drug Value Program (DVP). The DVP would be designed differently from the CAP to address several issues encountered with the CAP program and to allow hospitals to obtain drugs through the DVP.

We have organized our feedback into the categories CMS outlined in the RFI:

Included Providers and Suppliers

As CMS suggests, the model must be voluntary, so CMS asks what protections or incentives would be necessary for providers to participate. The 2008 CAP is instructive in this regard. As explained in more detail below, physicians need multiple vendors to ensure competition. Additionally, practices need the ability to buy medicine on a non-patient-specific basis. Currently, for traditional Medicare patients, a practice will put in an order for some time ahead – usually for the following week. In other words, there is a time lag between the time the order is placed and the time the medicine is administered to the patient. Sometimes, medication is ordered but a patient does not show up to receive it the following week. There may be a variety of reasons for this: the patient may have an infection, scheduled surgery, be hospitalized, or may have simply changed their mind. Currently, we can repurpose that medication and use it for a different patient. For Medicare Advantage patients, this is not the case. When Medicare Advantage patients do not show up, the medication we ordered for them must be disposed of. It cannot be used for anyone else, nor can it be returned to the specialty pharmacy from which it was ordered. This is hugely wasteful, especially when one considers the cost of these medications. **We urge CMS to ensure that any CAP-like program operate like traditional Medicare in terms of ordering logistics, in that it should allow physicians to repurpose medication that might otherwise be wasted.**

Included Drugs and Biologicals

CMS asks which specific drugs, drug classes, groups of drugs, or indications would be appropriate candidates for inclusion in a potential CAP-like model or in specific types of value-based pricing strategies. Throughout, CMS seems focused on incorporating value-based pricing into any new CAP-like program. While we appreciate CMS' attempts to introduce value-based pricing into Medicare, this will not work for rheumatologic products with the current state of science. While diagnostics are getting more sophisticated, we still cannot predict which product will work for which patient. We have no agreed-upon definition of " value" within rheumatology. Further, we start naïve patients on what we consider the best product based on their health history, lifestyle, and a variety of other factors, but we often have to try several products before we find one that is effective. The patient may respond clinically but continue to have radiographic damage that is not discovered for another year or may initially respond and then lose efficacy because of neutralizing antibodies. This does not mean the initially prescribed products were of no value; it only means that particular patient's disease pathway did not respond adequately within the arbitrarily

determined time frame to that particular drug's mechanism of action. As such, **it is difficult to envision how value-based payment could be applied meaningfully to rheumatology drugs at this point**.

Beneficiary Cost-Sharing, Protections, and Fiscal Considerations

CMS asks a series of questions related to access for beneficiaries. Most disconcerting from the perspective of practicing rheumatologists, CMS has noted that third parties administering the program could conduct medical reviews. Currently, Part B is an open formulary program. The concept of instituting medical review procedures in Part B is reminiscent of the so-called "utilization management" tactics employed by payers and pharmacy benefit managers (PBMs) in Part D. There are access issues in Part D that are a direct result of this utilization management. Formularies are created with little actual medical consideration and prior authorization requirements are opaque and unpredictable. Providing third party entities with the ability to conduct medical reviews in Part B would be the first step towards a system that is more similar to Part D, i.e., delays in patient access to medical therapy, at best, and authorization denials based on financial rather than medical reasons. **We oppose any CAP program that allows third party entities to conduct so-called medical reviews or any other utilization management**.

Model Vendors

CMS states that a potential model would include competitively selected private-sector vendors that would establish payment arrangements with manufacturers of drugs included in the model. In December 2008, HHS suspended the first CAP program due to various implementation challenges, including a lack of participating vendors. There was only one approved CAP vendor and physician participation rates were low. The lack of vendors is concerning because it leaves participating physicians and patients with no recourse in the event of substandard vendor performance. If CMS moves forward with another CAP-like program, **we urge the agency to ensure there are multiple vendors for physicians to work with**.

Thank you for so thoughtfully exploring a program that could greatly affect many of our Medicare patients. We hope our viewpoints were helpful. Should you have questions or require additional information, please contact Judith Gorsuch, jgorsuch@hhs.com.

Sincerely,

Madelaine Feldman, M.D.
President, Coalition of State Rheumatology Organizations