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July 13, 2018

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

RE: Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; RIN: 0991-ZA49

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. We hope you will find our feedback useful.

Part B Competitive Acquisition Program

The RFI makes clear that the Department of Health and Human Services (HHS) is considering reinstating a Competitive Acquisition Program (CAP) for Part B drugs. In December 2008, HHS suspended the 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.[1] The lack of vendors is concerning because it leaves participating physicians with no recourse in the event of substandard vendor performance.

Most disconcerting from the perspective of practicing rheumatologists, CMS noted that third parties administering the program could conduct medical reviews.[1] 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 unpredictability.

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 that in reality are misapplied utilization management tools***.

Moving drugs from Part B to Part D

The RFI asks several questions related to moving drugs from Part B to Part D. The answers are complicated, as the source for many of the issues related to moving drugs from Part B to Part D hinge fundamentally on the role of PBMs in the management of Part D drugs. PBMs have played the role of middlemen in this management for years, without governance, review, transparency or accountability. The concept of bringing more products within their purview should not be under consideration until their role in the supply chain can be better controlled. If not, we create additional access issues for Medicare beneficiaries. ***For the reasons outlined below, we oppose moving Part B products into Part D***.

First and foremost, we are troubled about a potential rise in out-of-pocket costs for beneficiaries. In 2011, CMS contracted with Acumen to simulate a move from Part B to D for six categories of products. Cumulatively across all categories, the simulation found that an increase of $200 for beneficiaries partially offset decreases of $230 for Medicare and $100 for Medicaid. This means that the savings for federal programs largely result from an increase in cost burden for beneficiaries. We urge the Administration to find real savings through reductions in prices rather than simple cost shifts onto patients.

Secondly, the perverse incentives inherent in Part D are best illustrated by the steep rise in list prices in that program, when compared to Part B products. The CMS Drug Spending Dashboard indicates that 11 of the 15 drugs with the highest total spending in Part D had annual growth rates over ten percent. One had an annual spending growth rate over 20 percent. Of the 15 drugs with the highest total spending in Medicare Part B, however, only one product had an annual spending growth rate in excess of 10 percent. Only the top three products saw growth rates over eight percent. There are other variables at play, but at a minimum these data suggest that the Part D system, with its middlemen intended to control cost, is not doing very well at controlling spending at all. Part B, by contrast, is actually shown to be better at controlling spending. We urge the agency to reexamine these data on list prices before moving any products from Part B into Part D.

A third concern is data indicating that beneficiaries participate in cost-sharing based on "list prices" rather than "negotiated prices" in Part D. The Administration previously expressed interest in a mandatory pass-through of price concessions or a ban on rebates. We urge the Administration to further explore these policies prior to moving any additional products into Part D. This is particularly critical given the lack of wraparound coverage for beneficiaries in Part D.

Reducing the impact of manufacturer rebates to Pharmacy Benefit Managers

As practicing rheumatologists, we see every day the impact that rebates have in determining formulary placement. The insurance plan formularies are the menus that determine what products patients can access. Some of the formulary-driven utilization management practices are so aggressive as to amount to the practice of medicine. This must stop.

There are several potential solutions. First, HHS could ban the use of rebates in federal programs outright – a question raised by the RFI. Second, HHS could mandate pass-through of rebates and all other price concessions so that beneficiaries at least see the benefit of these negotiations in their out-of-pocket obligations.

Whatever solution HHS explores further will hinge on the definition of "rebate." We are concerned that HHS banning "rebates" will only result in streams of retroactive price concessions being labeled something other than "rebate." The same may occur with a mandatory pass-through policy. To avoid this game of whack-a-mole, ***the first step must be to require full transparency of the money streams flowing into PBMs. After that, HHS must define common nomenclature for contracts in federal programs***.

Copay discount cards

The RFI asks several questions related to copay discount cards. These are banned in federal healthcare programs but HHS asks whether there would be circumstances when allowing use of these cards would advance public health benefits such as medication adherence. When it comes to medications for which there is no cheaper alternative, we believe that allowing beneficiaries to use these cards will advance medication compliance.

The main criticism related to copay cards is that they promote brand adherence and reduce generic use. There is data supporting this premise. However, in situations where there is only a branded treatment available, these cards are the difference between a patient being able to access their medicine or foregoing treatment altogether. In rheumatology, many of our therapies are expensive branded biologics. The limited number of biosimilars coming to market are not as discounted as hoped for, nor are they much less in cost than the original biologics from which they are derived. Unfortunately, we have no traditional generics among this group of medications in rheumatology. As a result, copay cards are the difference between our patients accessing treatment, or not. In commercial plans, we are already starting to see PBMs and payers prohibiting use of copay cards. This too is financially driven on their behalf and, predictably, it has caused access issues for our patients. Patients who have successfully halted progression of their disease, in some cases for years, suddenly can't afford their medications. With this loss of treatment, the indirect cost to the healthcare system over time rises as a result of lost productivity in the work place and subsequent job loss. There are other negative ramifications to society as a whole that have been well validated in previous studies of this subject. Our ask for our patients is simple: ***we urge HHS to allow use of these cards when a branded treatment is the only option***.

Incentives to lower or not increase list prices

The RFI asks questions related to novel ways to create incentives for manufacturers to lower or at least not increase list prices. One of these ideas relates to the six protected classes in Part D. Current policy assures patients access to "all or substantially all" medications in the six enumerated classes. The RFI asks whether access to the protected classes could serve as an incentive for a manufacturer who has not raised prices. Implicit in this concept is the fact that manufacturers who do raise prices over a certain threshold would *not* have their product qualify for the protected classes. This is concerning because the protected classes were never intended to be leveraged as an incentive or deterrent for the actions of manufacturers. They were intended to assure patients uninterrupted access to medications for certain serious conditions. As such, ***we would oppose leveraging the protected classes to control prices. A more direct way to control list prices is to meaningfully reform the rebate system***.

Fiduciary duty for Pharmacy Benefit Managers

The RFI asks whether PBMs should be obligated to act in the interest of anyone other than the entity for which they are managing pharmaceutical benefits. It is noteworthy that many of the issues we have been discussing stem from the fact that, with the exception of medical professionals, stakeholders in the drug supply chain are not accountable to the ultimate end user: the patient. Clinicians have a standard of care to which they are held accountable, yet this obligation does not extend to PBMs and payers. Their aggressive utilization management policies, at one time touted to be for the benefit of patient care but now admittedly used more for the benefit of shareholders, directly affect patient care. As a result, many clinicians feel as though the various utilization management tactics have become so heavy-handed that they amount to the practice of medicine. As such***, it is time to impose standards on PBMs that will hold them accountable to the people most affected by their business practices: patients.***

Federal Preemption of Pharmacy Gag Clause Laws

The RFI also raises the issue of so-called "gag clauses" in pharmacy-PBM contracts and asks whether there is a purpose to these clauses other than to require beneficiaries to pay higher out-of-pocket costs. We are not aware of *any* other purpose to these clauses. They are another tool by which PBMs ultimately end-up costing beneficiaries more money while augmenting their profit margins. These clauses are unconscionable and should be banned across federal programs. We have heard recently from pharmacists that some contracts no longer explicitly prohibit sharing information with patients. Instead, the contracts contain "non-disparagement" clauses that have the same ultimate effect. For example, a pharmacist informing a patient that the medicine would be cheaper for him or her paying directly without insurance is deemed "disparagement." This may lead the PBM to penalize the pharmacy or even expel them from their Pharmacy network altogether. ***We ask that HHS ban these clauses in all of their forms, across all federal health programs.***

Biosimilars

The RFI asks several questions related to provider education on biosimilars. Since enactment of the Biologics Price Competition and Innovation Act (BPCIA), CSRO has been actively involved in the implementation process, both at the Food and Drug Administration and in various State legislatures as biosimilar substitution legislation is being debated. Rheumatology has a few biosimilar options now-but we have not seen the large price drops that generics traditionally generate. We believe that, again, the rebate system may be preventing bigger drops in list prices on biosimilars as manufacturers vie for position on formularies governed by the PBMs. The rebate to the PBM is based on a percentage of the list price. The higher the list price, the greater the rebate back to the PBM. The greater the rebate to the PBM, the more assured the manufacturer's position on the formulary.

We would be remiss not to highlight that, though the BPCIA statute mandates two separate levels of "sameness," biosimilarity and interchangeability, there have already been indications that this statutory nuance is being discounted in the real world of utilization management policies. We are concerned there will inevitably be large-scale switching to biosimilar – not interchangeable – formulations based on economic reasons. To date, there *are* no biosimilars in rheumatology deemed interchangeable. However, we feel it would be naïve for us to assume payers will not try to skirt this issue by switching to non-interchangeable alternative therapies for our patients if not closely monitored. ***We urge FDA to educate payers about the difference between the two approval thresholds and prevent mandated switching to products that are not interchangeable especially when done for non-medical reasons***. As always, CSRO is eager to work with HHS on these efforts and any provider education activities.

Thank you for tackling these serious issues that directly affect our patients. We hope our viewpoints were helpful and we appreciate your consideration. Should you have questions or require additional information, please contact Judith Gorsuch, jgorsuch@hhs.com.

Sincerely,

Alabama Society for the Rheumatic Diseases
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association
California Rheumatology Alliance
Colorado Rheumatology Association
Florida Society of Rheumatology
Georgia Society of Rheumatology
Kentuckiana Rheumatology Alliance
Massachusetts, Maine, & New Hampshire Rheumatology Association
Michigan Rheumatism Society
Midwest Rheumatology Association
Mississippi Arthritis & Rheumatism Society
Nebraska Rheumatology Society
Ohio Association of Rheumatology

Oregon Rheumatology Alliance
Rheumatology Association of Iowa
Rheumatology Association of Minnesota & the Dakotas
Washington Rheumatology Alliance
West Virginia Rheumatology State Society
Wisconsin Rheumatology Association