July 16, 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 Association of Women in Rheumatology (AWIR) respectfully submits these comments to the Department of Health and Human Services (HHS) on "American Patients First," the Administration's blueprint to lower drug prices and reduce out-of-pocket costs.

AWIR is dedicated to promoting the science and practice of Rheumatology, fostering the advancement and education of women in Rheumatology, and advocating access to the highest quality health care, and management of patients with Rheumatic diseases. As frequent prescribers of expensive Biologic agents, we are quite familiar with the rising out-of-pocket burdens that these products have on our patients. All too often, these burdens are prohibitive and result in patients rationing their medications or abandoning treatment altogether, and we thank the Administration for its attention to this critical issue.

Proposed Changes to Medicare Part B

The RFI makes clear that the HHS is actively considering potential changes to Medicare Part B, specifically in the form of reinstating a Competitive Acquisition Program (CAP) for Part B drugs and moving drugs from Part B to Part D. For reasons outlined below, AWIR strongly opposes both reinstating a CAP and moving drugs to Part D.

With respect to a CAP, history in this case is quite telling: HHS previously suspended that effort in 2008, citing various implementation challenges. Among the challenges noted was a lack in vendor, and as a result physician, participation. This is disconcerting to AWIR, but perhaps even more so is the fact that under the 2008 CAP, third parties administering the program could conduct medical reviews. AWIR is strongly against allowing medical review procedures by a middleman in Part B, which would amount to aggressive utilization management beneficiaries and providers currently experienced in Part D.

With respect to moving Part B drugs to Part D, the fundamental problem with this proposal lies within the role of pharmacy benefit managers (PBMs). In short, as echoed by multiple colleagues and allies in their comments on the RFI as well, unless the practices of middlemen in Part D can be controlled, moving additional drugs into Part D will shift more costs onto beneficiaries and create more access issues for patients. Part D has historically done very little to control a rise in out-of-pocket costs for beneficiaries, so moving Part B

drugs to Part D would very likely have the same effect, due in part to the fact that beneficiaries participate in cost-sharing based on "list prices" rather than "negotiated prices" in Part D.

Pharmacy Benefit Managers

As practicing rheumatologists, we understand the real-life impact that rebates have in determining formulary placement on a day to day basis. 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, which is completely inappropriate and detrimental to the medical field in and of itself.

As many of our colleagues have pointed out, there are several potential solutions. From AWIR's perspective, however, the most effective solution, whatever it may be, will hinge on implementing the most appropriate and comprehensive definition of "rebate." Specifically, the concern here is that any sort of blanket ban on "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. As such, there 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.

There are two more specific issues with respect to PBMs in the RFI that we wish to address: fiduciary duty and gag clauses. With respect to the first, 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. The answer, in short, is yes, imposing a fiduciary duty on PBMs in paramount to bringing a proper level of oversight to the PBM industry. AWIR, as part of the Alliance of Transparent and Affordable Prescriptions (a coalition of patient and provider groups aimed at addressing the role of PBMs in rising drug costs and reduced patient access to treatment), has spoken out regarding the critical importance of imposing a fiduciary duty on PBMs on numerous occasions, and urges HHS to considering doing so in an effort to hold PBMs accountable to the people most affected by their business practices: patients.

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. Briefly put, gag clauses, to our knowledge, have no other purpose than to serve as mechanism 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. As such, AWIR strongly urges HHS to ban these clauses in all of their forms, across all federal health programs.

Biosimilars

AWIR is pleased that the RFI acknowledged the importance and potential benefit of biosimilars, outlining several questions particularly about these products and how to make them more accessible to patients and providers. As physicians who prescribe complex biologic medications on a near daily basis, we are encouraged that the Administration is actively working to streamline the approval process and ultimately make more of these products accessible to patients.

It is important to note, however, that whether biosimilars are ultimately successful in their aim of lowering biologic drug costs hinges on properly reforming the rebate system. More specifically, we believe that the rebate system is ultimately preventing bigger drops in list prices on biosimilars as manufacturers vie for position on formularies governed by the PBMs. In short, the rebates manufacturers provide to PBMs are based on a percentage of the list price; the higher the list price, the greater the rebate back to the PBM, and thus the greater the rebate to the PBM, the more assured the manufacturer's position on the formulary.

It is also important to note with respect to biosimilars that any related educational efforts must emphasize the statutory differentiation between "biosimilar" and "interchangeable" products. We are concerned that if this distinction is not properly understood, or worse purposefully disregarded, the realities of current

utilization management policies will inevitably lead to large-scale switching to biosimilar—not interchangeable—formulations based on economic reasons. No biosimilar products in rheumatology have been deemed interchangeable to date, but as many of our fellow rheumatology organizations have also noted, it is quite possible that payers may try to skirt this issue by switching to non-interchangeable alternative therapies for our patients if not closely monitored. As such, we urge HHS and the FDA to educate payers about the difference between the two approval thresholds and prevent mandated switching to products that are not interchangeable.

Thank you again for your thoughtful questions on topics that directly affect patients and prescribers. We appreciate your consideration of our viewpoints. Should you have any questions, please direct them to Ally Lopshire, JD at ally@wjweiser.com.

Sincerely,

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