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Coalition of State Rheumatology Organizations

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RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs, CMS-9905-NC

To Whom It May Concern:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist. CSRO thanks the Departments of Health and Human Services, Labor, and Treasury and the Office of Personnel Management ("the Departments and OPM") for the opportunity to provide feedback on implementation of section 204 of the *Consolidated Appropriations Act, 2021* ("section 204").

Our drug supply chain is opaque and complex, two characteristics that those resistant to reform hide behind. Thus, we appreciate the Departments and OPM taking a thoughtful approach by soliciting input on a wide range of implementation questions in this request for information (RFI). As practicing rheumatologists, we experience firsthand the consequences that high out-of-pocket costs have on medication adherence and, thus, our patients' quality of life. The drugs available to treat rheumatoid arthritis and other autoimmune diseases are often heavily rebated, yet still prohibitively expensive for patients. This tells us that the current system is broken. Given our perspective as clinicians, we limit our feedback to four specific questions contained in the RFI.

First, the Departments and OPM ask feedback for how to define the terms "rebates, fees, and any other remuneration" as used in the statute, and whether "*bona fide* service fees" should be included in that definition. As noted above, our drug supply chain is needlessly complex, and this is an opportunity to introduce some much needed simplicity. To that end, we urge the Departments and OPM to include all fees and payments in the disclosure requirements.

Most importantly, the statute includes no limitation on what must be disclosed: in fact, it uses the phrase "and *any other* remuneration." The Congress is aware that *bona fide* service fees are a routine feature of contracts between insurers, pharmacy benefit managers (PBMs), and drug companies, but chose not to exclude these or any other fees from section 204's disclosure requirement. Indeed, the PBM Transparency for

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Qualified Health Plans data disclosure requirements – which the RFI references – were created in 2010 by Affordable Care Act section 6005, and that statutory language specifically excluded *bona fide* service fees from disclosure. **Yet no such exclusion appears in the language of section 204**. Thus, we urge the Departments and OPM not to create a regulatory exemption where Congress clearly did not want one. The plain language of the statute supports full disclosure of all remuneration, regardless of how it is contractually categorized.

In addition to the statutory text supporting full disclosure, it is also the only way to avoid gaming. If the Departments and OPM exempt "*bona fide* service fees" from the disclosure requirements this year, by the next contract year virtually every revenue stream into the insurers and PBMs will be characterized as a "*bona fide* service fee." Full disclosure of all remuneration will avoid gaming, set the same rules for every entity that must disclose, and introduce some much needed simplicity.

The RFI also asks whether insurers should be allowed to rely on PBMs to provide the required data. This should not only be allowed, but it will likely be necessary. To that end, we urge the Departments and OPM to require reporting entities to work with any of their contractual partners to obtain all necessary data, including from PBMs and any of their subsidiary entities, whether organized under United States law or the laws of any foreign jurisdiction. One of the newest challenges is that some PBMs have organized group purchasing organizations in Switzerland, which enables them to avoid any legislation or regulation that places prohibitions or limitations on PBMs charging administrative fees based on a percentage of list prices.

Second, the RFI asks for considerations to take into account when defining the term "therapeutic class." Specifically, the RFI asks how plans currently classify drugs by therapeutic class and whether these classifications rely on proprietary software. Here too, we urge the Departments and OPM to establish a single definition of "therapeutic class" for section 204 reporting purposes. Otherwise, each reporting entity will be using its own definition, resulting in a set of data that is not comparable across reporting entities. In light of that, we strongly urge the Departments and OPM not to let reporting entities use proprietary software or other tools into which we have no visibility. There should be nothing proprietary about how an insurer groups medications, all of which have extensive labels approved by the Food and Drug Administration to publicly disclose their indications, mechanisms of action, and potential side effects.

To provide an example of the variety in drug classification, etanercept – a commonly prescribed medication for rheumatoid arthritis – is classified in three different manners by three different PBMs in Part D formularies:

- PBM 1 classifies etanercept under: "Immunologic agents, drugs for immune system stimulation or suppression"
- PBM 2 under: "Other rheumatologicals"
- PBM 3 under: "Autoimmune agents, self-administered"

We hope that this helps illustrate the immense discretion PBMs and insurers have to categorize the very same product in totally different ways on their formularies. Again, to ensure a uniform data set, we ask that the Departments and OPM establish their own, uniform definition of therapeutic class for purposes of section 204 reporting.

Third, the RFI asks whether rebates and other remuneration should be measured by total amount or against another measure. At a minimum, the key metrics are list prices (not reflecting any price concessions), net prices (after applying all price concessions), and the difference between these two price points. In the industry, this is referred to as the gross-to-net bubble. This bubble is what allows net prices to hold steady or increase slightly, while list prices soar. The issue with this is that the list price is mostly fictional for everyone except the patient, whose cost-sharing percentages are based on the list prices. Additionally, the price concessions influence formulary placement, which means that the current system results in higher out-of-pocket costs for patients *and* potentially restricted access on the medications they're paying too much for. This system cannot continue. We urge the Departments and OPM to, at a minimum, require full disclosure of all data required to fully examine the gross-to-net bubble, the influence of price concessions on formulary construction, and the basis on which cost-sharing is calculated.

Fourth and finally, the RFI asks whether it should collect drug spending information separately based on the setting of care. We strongly support collecting drug spending information based on setting. Data indicates that medical benefit drug administration can be twice as expensive in a hospital outpatient department, as compared to a physician's office. This is likely because outpatient departments charge facility fees and have a higher cost basis on which to request reimbursement. Physician's offices are much leaner operations and do not charge facility fees. Drug spending differentiated by site of care would be useful information as Congress considers site neutrality for medical benefit drug administration. This data should be paired with relevant metrics to give it context, such as the number of patients served in each setting over the same time period.

In closing, thank you again for the opportunity to provide our feedback as you think about how to best implement section 204. We are always available as a resource to you, if you have follow-up questions, so please don't hesitate to contact us.

Sincerely,

Madelaine A. Feldman, MD
President
Coalition of State Rheumatology Organizations