ATAP
ALLIANCE *for* TRANSPARENT & AFFORDABLE PRESCRIPTIONS

July 23, 2021

RE: CMS-9905-NC

Submitted electronically via regulations.gov

The Alliance for Transparent and Affordable Prescriptions (ATAP) consists of twenty-five patient and provider groups who are concerned about the role pharmacy benefit managers (PBMs) play in our drug supply chain. ATAP thanks the Office of Personnel Management (OPM) and the Departments of Treasury, Labor, and Health and Human Services ("Departments") for their request for information (RFI) on key implementation questions related to section 204 of the *Consolidated Appropriations Act, 2021* ("CAA section 204"), which creates new disclosure requirements for group health plans and issuers offering group or individual coverage. We limit our feedback to the RFI questions replicated herein.

RFI question: What considerations should the Departments and OPM take into account in defining "rebates, fees, and any other remuneration"? Should bona fide service fees—for example, administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives—be included in this definition? Are there additional fees that the Departments and OPM should include in this definition? How should manufacturer copay assistance programs and coupon cards be accounted for? How should copay accumulator programs be accounted for?

CAA section 204 uses broad language to describe the types of remuneration that must be disclosed. In the past, when Congress has intended to exempt certain categories of remuneration from disclosure by payers or PBMs, it expressly said so. For example, in 2010, the *Affordable Care Act* created the "PBM Transparency for Qualified Health Plans" disclosure requirements in section 6005 and explicitly excluded certain types of remuneration (including bona fide service fees) from disclosure. In CAA section 204, Congress created no such exemption. Instead, the final legislation uses the broad phrase "and *any other* remuneration." (Emphasis added.) Given this unambiguous language by Congress, particularly when they've in the past explicitly stated definitional exceptions when they felt so inclined, **ATAP strongly urges OPM and the Departments to adhere to the statutory language and require full disclosure of all remuneration received by the insurers and their PBMs from manufacturers**. Full disclosure was not only

the clear goal of Congress, it also provides the only way to ensure that insurers and PBMs will not stretch the definitions of any exempted category of remuneration so as to render disclosure meaningless.

With regard to copay assistance, coupons, and copay accumulators, it would be useful to understand how much of the value of copay assistance and coupons is captured directly by the patient in the form of reduced out-of-pocket costs. One way to do this might be to have insurers disclose the total annual dollar amount of copay assistance and coupons used by patients per therapeutic class and the total annual dollar amount captured by copay accumulators per therapeutic class. In the case of accumulator programs that prohibit the application of the value of copay assistance to a patient's deductible, insurers should disclose where that value is applied, if anywhere. Furthermore, the annual report called for by CAA section 204 should quantify the relationship between the rise in list prices and the amount of copay assistance and coupons. That information should be as granular as possible, but at a minimum should be broken down by therapeutic class.

RFI question: What considerations should the Departments and OPM take into account in defining the term "therapeutic class"? How do plans and issuers currently classify prescription drugs by therapeutic class? Does the classification method rely on proprietary software, and how would the choice of therapeutic classification method influence plan and issuer operational costs?

One of the key challenges across the insurance and PBM industries is that there are no consistent definitions of contractual terms, including the term "therapeutic class." Even for purposes of Medicare Part D, the Centers for Medicare and Medicaid Services (CMS) allows insurers to use existing classification systems, such as the U.S. Pharmacopeia and the American Hospital Formulary Service, or simply create their own, in which case there is an additional "check" by CMS of the insurer's proposed classification system. This lack of standardization even in the largest federal drug benefit creates predictable problems: it allows insurers to vary their classification systems year to year or even among the varying insurance products they offer. This makes it almost impossible for even highly proactive and informed healthcare consumers to find accurate and consistent information about whether the drugs they require are covered in any given plan year – and if they are, whether they will remain covered or whether some change in classification will change their status.

While each classification system has its flaws, **we urge OPM and the Departments to commit to a single, publicly accessible classification system such as the U.S. Pharmacopeia for purposes of the CAA section 204 disclosure requirements**. This does not create any substantive changes for the patients covered by the insurers subject to the CAA section 204 requirements, but merely standardizes the data for disclosure purposes. Otherwise, if the disclosure requirement allows each insurer to create its own definition of "therapeutic class," the dataset will be mostly useless because the Departments and OPM will be left with data that is not comparable across insurers. It is a modest first step towards creating some consistency and transparency in prescription drug benefits.

RFI question: What considerations are important for plans and issuers in determining the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year? Should rebates and other remuneration be measured by total dollar amount? Should rebates and

other remuneration be measured in comparison to another measure, such as total spending on a drug or a unit price? If a price measure is used, which price measure should be used and why?

The twenty-five drugs that yield the highest amount of rebates and other remuneration could be measured by total dollar amounts, but a more pressing issue to look at is the twenty-five drugs that yield the highest "spread" between the list price before all price concessions and the net price after all price concessions. That difference, often referred to as the "gross-to-net bubble," has been identified as one of the major distortions in pharmaceutical pricing. Indeed, research has found that for every dollar a drug's rebates increase, its list price increase by $1.17.[1] When proponents of the rebating system claim it holds down drug prices, they refer to net prices, but patients do not experience the benefit of net prices. Indeed, their cost-sharing is often calculated based on the list prices – those same list prices that are driven *up* by rebates and price concessions. The bubble between list and net prices provides a very robust revenue stream for the PBMs, but there is no transparency into how that money is spent. As such, **we urge OPM and the Departments to measure rebates and other remuneration in comparison to list prices**, because a critical first step towards fixing any problem is quantifying exactly how big of a problem it is.

RFI question: What role, if any, will Pharmacy Benefits Managers (PBMs) play in furnishing necessary information to plans and issuers, or to the Departments or OPM? If permitted, would plans and issuers rely on PBMs to help satisfy their reporting obligations, such as by retaining PBMs to conduct some or all of the reporting? Could PBMs obtain all the information required to be reported, including general information on the plan or coverage, such as the number of participants, beneficiaries, and enrollees; each state in which the plan or coverage is offered; monthly premiums paid by employers and by participants, beneficiaries, and enrollees; total spending on health care services broken down by type; and the impact on premiums of prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers? If not, would allowing separate reporting forms, modules, or data collection systems for PBMs and issuers and plan administrators to report such information be administratively and operationally feasible? How would separate reporting forms change the costs or burdens associated with compliance?

It is likely that some of the insurers subject to CAA section 204 will not be able to comply with the new disclosure requirements without their PBMs. One of the key features of the PBM industry is disproportionate information access. A PBM sits at the center of a web involving, at a minimum, pharmacies, manufacturers, payers, and patients. None of these parties have visibility into the others' contractual arrangements. Only the PBM knows all of the information, which puts it in a position of enormous power. Additionally, in recent years, several of the country's largest insurers have merged with or purchased some of the largest PBMs, a vertical consolidation that has resulted in highly consolidated market power. Several of these entities own their own pharmacy networks as well. **We urge OPM and the Departments to allow the reporting entities to rely on PBMs (or any other entity needed) to ensure that OPM and the Departments receive the data they are statutorily entitled to receive**. In addition to the PBMs themselves, this includes any and all insurer and PBM subsidiaries in the U.S. or abroad that may hold the data to which the Departments and OPM are entitled pursuant to CAA section 204.

---

[1] "The Association Between Drug Rebates and List Prices" by Neeraj Sood, PhD, Rocio Ribero, PhD, Martha Ryan, and Karen Van Nuys, PhD, University of Southern California, Leonard D. Schaeffer Center for Health Policy & Economic (Feb. 11, 2020). Available: https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.

****

We hope these comments are helpful as you decide how best to implement CAA section 204. If you require additional information or have any follow-up questions, please don't hesitate to contact Judith Gorsuch, jgorsuch@hhs.com.

Sincerely,

American Academy of Dermatology Association
American Association of Clinical Urologists
American College of Rheumatology
Association of Women in Rheumatology
California Rheumatology Alliance
Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Georgia Society of Rheumatology
Global Healthy Living Foundation
Kentuckiana Rheumatology Alliance
Lupus and Allied Diseases Association, Inc.
MidWest Rheumatology Association
National Infusion Center Association
National Organization of Rheumatology Management
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Rheumatology Nurses Society
Virginia Society of Rheumatology