ATAP
ALLIANCE *for* TRANSPARENT & AFFORDABLE PRESCRIPTIONS

January 24, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9915-P
Baltimore, Maryland 21244-8010

RE: ATAP Comments on "Transparency in Coverage" (CMS-9915-P)

Dear Administrator Verma:

The Alliance for Transparent and Affordable Prescriptions (ATAP) is a coalition of provider and patient groups who have joined together over our shared concern with the practices of pharmacy benefit managers (PBMs). As patient and healthcare provider advocates, we strongly favor increased transparency in PBM contracting. We hope that our comments will be helpful as the agency works towards our shared goal of a transparent and patient-centered pharmaceutical supply chain.

At the outset, it is important to note that the proposed rule provides a "floor," meaning that it preempts state law only to the extent that state law requires the provision of *less* information to the consumer. This will ensure that patients in all states have access to basic information about the financial picture related to their prescription drugs, but will not preclude states from further empowering patients. ATAP thanks CMS for ensuring that states are allowed to implement enhanced transparency requirements and we appreciate that CMS has acknowledged that it is important not to hamper these efforts.

The stated intent of the proposed rule is to provide consumers with out-of-pocket cost information upon request – including out-of-pocket cost information for pharmaceuticals. Patients often abandon prescriptions at the pharmacy counter due to out-of-pocket cost,[1] especially when such costs are unexpected. Insurers can do better by providing patients with accurate, up-to-date information *before* they arrive at the pharmacy. Empowering patients to

[1] IQVIA, "Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption" (May 2018). Available: https://www.iqvia.com/-/media/iqvia/pdfs/us-location-site/market-access/patient-affordability-part-two---implications-for-patient-behavior-and-therapy-consumption.pdf?_=1577997350630.

demand an exact out-of-pocket number from their insurance plan will enable them to plan better and hopefully lead to fewer abandoned prescriptions.

With regard to the proposed content elements, we will focus our comments on those most relevant to prescription drugs. CMS proposes to define "estimated cost-sharing liability" as the amount a beneficiary is responsible for paying for a covered item, including a drug, under the terms of the plan or coverage. This must take into account all forms of cost-sharing, including any applicable deductible but excludes premiums and the cost of non-covered items. We urge CMS to include a requirement for plans to provide the cost for the beneficiary to purchase a non-covered drug and to indicate whether and, if so, to what extent, that cost will be applied against the deductible. Knowing to what extent a non-covered drug expense will count towards meeting a deductible and an out-of-pocket limit, if at all, is critical because, especially with regard to specialty drugs, there are significant coverage gaps. Even in Part D, which is subject to more robust formulary requirements than individual and group health coverage, the Kaiser Family Foundation found that, "Sixteen of the 30 studied specialty drugs are covered by all plans in our analysis in 2019, 14 of which are for cancer, which is one of the six protected classes. In contrast, 12 of the studied specialty drugs are not covered by some plans and two drugs are not covered by any plan in our analysis[.]"[2]

With regard to the definition of "accumulated amounts," CMS proposes to define this as the amount of financial responsibility that a beneficiary has already incurred at the time (s)he makes the request for cost-sharing information. We thank CMS for clearly stating that this would be the financial responsibility incurred toward both an individual deductible and/or out-of-pocket limit and toward the "other-than-self-only coverage" deductible and/or out-of-pocket limit. Most beneficiaries are unaware of the distinction between embedded and aggregate deductibles, but this is critical information in a family's financial planning for the year.

The "negotiated rate" would be defined as the amount a plan or a third party on behalf of the plan has agreed to pay for a covered item, including a prescription drug. The rate must consist of an actual dollar amount instead of a formula. In the proposed rule, CMS asks whether "a rate other than the negotiated rate, such as the undiscounted price, should be required to be disclosed for prescription drugs, and whether and how to account for any and all rebates, discounts, and dispensing fees to ensure individuals have access to meaningful cost-sharing liability estimates for prescription drugs." Transparency must be meaningful to consumers. A list of every fee, discount, and other price concession on a drug, all separately itemized, would likely

[2] Kaiser Family Foundation, "The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019" (Feb. 2019). Available: https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-findings/.

overwhelm the beneficiary and thus not provide them with meaningful information. Rather, providing a drug's negotiated rate, the undiscounted price, and the total, cumulative price concession might be most helpful. The final, cumulative price concession number should reflect all discounts, fees, rebates, and any other price concession received by the PBM from the manufacturer of the drug. The undiscounted price should be the sum of the negotiated rate and the final price concession number.

As the proposed rule notes, plans "often base cost-sharing liability for prescription drugs on the undiscounted list price[.]" In those cases, providing the beneficiary with a negotiated rate from which they will not benefit is misleading. However, as the agency states, requiring only piecemeal data "would perpetuate the lack of transparency around drug pricing." To accomplish more robust transparency while avoiding inadvertently misleading the beneficiary, we urge CMS to require a plan to clearly state whether the beneficiary's coinsurance, if any, is based on the negotiated rate or the undiscounted price.

CMS asks whether there are situations in which drug pricing should not be included in cost-sharing liability statements. Given the high list prices for drugs, we strongly urge CMS to include cost-sharing for pharmaceuticals in any cost-sharing liability estimate, even for episodic, limited duration prescriptions such as antibiotics.

CMS proposes that disclosure of the negotiated rate would not be required "if it is not relevant for calculating an individual's cost-sharing liability for a particular item or service[.]" Meaning, if a beneficiary's cost-sharing liability consists of a flat copay rather than a percentage-based coinsurance, the plan would not be required to disclose the negotiated rate. We urge CMS to require disclosure of the negotiated rate for drugs in all situations, even where the beneficiary owes a flat copay. There have been reports of cases where, for inexpensive generics, the beneficiary's flat copay actually exceeded the negotiated rate, with the PBM pocketing the difference.[3] Requiring disclosure of the negotiated rate, the price concession total, and the undiscounted rate in all cases, regardless of cost-sharing design, may help put a stop to this behavior.

CMS also proposes to require disclosure of prerequisites to coverage, including prior authorization, step therapy, and fail-first protocols. This is especially relevant in the world of high-cost biologics, which are almost always subject to at least one type of utilization control. Often, these utilization controls are based on the negotiated prices between the PBM and the

[3] Reuters, "Drug copays sometimes exceed costs" by Lisa Rapaport (March 13, 2018). Available: https://www.reuters.com/article/us-health-medicines-copays/drug-copays-sometimes-exceed-costs-idUSKCN1GP2P4.

manufacturers, rather than on clinical information about the product. Utilization management requirements can be opaque and difficult for the patient to ascertain with accuracy. Sometimes, patients give up on treatment not for any financial reason but simply due to the impossibility of navigating insurer delays, conflicting requirements, and other administrative barriers. Requiring the plan to disclose these requirements in an easily understandable format may help patients complete the protocols and thus improve adherence. As such, ATAP strongly supports this proposed requirement.

Thank you for your consideration of our viewpoints. Please do not hesitate to contact us, should you require additional information.

Sincerely,

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
International Foundation for Autoimmune & Autoinflammatory Arthritis
Lupus and Allied Diseases Association, Inc.
MidWest Rheumatology Association
National Infusion Center Association
National Organization of Rheumatology Managers
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Rheumatology Alliance of Louisiana
Rheumatology Nurses Society
South Carolina Rheumatism Society
Tennessee Rheumatology Society
Virginia Society of Rheumatologists