ATAP
ALLIANCE *for* TRANSPARENT & AFFORDABLE PRESCRIPTIONS

March 2, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Re: CMS-9916-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted online via regulations.gov

RE: CMS-9916-P ("Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans")

Administrator Verma:

The Alliance for Transparent and Affordable Prescriptions (ATAP) consists of twenty-seven patient and provider groups who are concerned about the role pharmacy benefit managers (PBMs) play in our drug supply chain. We are writing to express our concern about a provision related to the use of copay accumulator programs in the above-reference proposed regulation.

In the 2021 Notice of Benefit and Payment Parameters (NBPP), CMS proposes to reverse its previous policy related to how PBMs and insurers may determine whether patients have met their annual cost-sharing limits. Specifically, CMS states that plans may disregard any copay assistance used by a patient for purposes of calculating whether that patient's annual limitation on cost-sharing is met. CMS proposes exclude this type of assistance from the definition of cost-sharing.

This is a reversal from CMS's previous position: in the 2020 NBPP, the agency finalized a change that "would allow issuers and plans to exclude drug manufacturer coupons from counting toward the annual limitation on cost sharing **when a medically appropriate generic drug is available**."[1]

[1] "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020" (CMS-9926-F)

(Emphasis added.) This approach was sensible, as the concern related to manufacturer coupons is that they drive brand adherence in situations where a less expensive, interchangeable generic is available. However, this concern does not exist for brands that do not yet have a generic. In those cases, the copay assistance has nothing to do with whether the patient chooses a brand over a generic. Rather, in those cases, the copay assistance may make the difference between the patient being able to afford treatment or not being treated at all.

However, in August 2019, the Department of Health and Human Services released a Frequently Asked Questions (FAQ) document in conjunction with the Department of Labor and the Department of the Treasury.[2] In the FAQ, the Departments note that the existing CMS policy on copay accumulators conflicts with existing policy from the Internal Revenue Service (IRS) related to high deductible health plans (HDHPs). Specifically, the IRS "requires an HDHP to disregard drug discounts and other manufacturers' and providers' discounts in determining if the minimum deductible for an HDHP has been satisfied and only allows amounts actually paid by the individual to be taken into account for that purpose." The FAQ points out that these conflicting requirements may make it impossible for a health insurer to comply with both rules. CMS stated that it planned to address this issue in the 2021 NBPP.

As mentioned above, the way CMS proposes to address this issue in the 2021 NBPP is to allow the use of copay accumulator programs across the board, even in situations where a medically appropriate generic drug is not available. While we appreciate the challenge of reconciling conflicting regulations, we must strongly object to this change in policy because it fails to put patients first. Instead of changing existing CMS policy on exchange plans that protects patients to conform to IRS policy on HDHPs that is harmful to patients, we urge the Administration to take the opposite approach in this case: change the IRS regulation to conform to CMS' existing policy. ***No federal agency should empower PBMs to create any barriers to the use of copay assistance in cases where there is no therapeutically equivalent, cheaper treatment available.***

The proposed policy is simply a cost shift from PBMs to patients. Barriers to the use of copay coupons in situations where a cheaper alternative does not exist saves money not through increased generic utilization, but through denial of treatment, since patients will not be able to afford their medications. Short-term cost savings realized through the denial of treatment are not only unethical, but are ultimately outweighed by the cost of long-term adverse health consequences, including poor disease management, reduced quality of life, secondary impact on caregivers, and more. The lack of management of chronic disease most severely impacts our nation's sickest and most vulnerable patients, whom cost-sharing assistance programs are intended to support.

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[2] "FAQs about Affordable Care Act Implementation Part 40," (August 26, 2019). Available: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf.

At a time when unprecedented numbers of Americans are struggling to afford their prescription drugs, we urge CMS to leave intact its existing policy, which allows the use of copay accumulator programs only in situations where a medically appropriate generic drug is available. Please do not hesitate to contact any of the undersigned organizations, 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 and Autoinflammatory Arthritis
Lupus and Allied Diseases Association, Inc.
MidWest Rheumatology Association
National Infusion Center Association
National Organization of Rheumatology Managers
North Carolina Rheumatology Association
New York State Rheumatology Society
Ohio Association of Rheumatology
Rheumatology Alliance of Louisiana
Rheumatology Nurses Society
South Carolina Rheumatism Society
Virginia Society of Rheumatologists