ATAP

ALLIANCE *for* TRANSPARENT & AFFORDABLE PRESCRIPTIONS

April 6, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4190-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-4190-P, "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly"

Dear 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. Given ATAP's focus, we will limit our comments to the agency's proposal to allow creation of a second specialty tier in Medicare Part D, which is contained in the above-referenced regulation.

Under current program rules, insurance companies and PBMs are permitted to include only one specialty tier in their Part D plan designs. CMS allows Part D plans to exempt drugs placed on the specialty tier from the tiering exceptions process. Although CMS guidance has limited the maximum allowable cost sharing for drugs on the specialty tier to a maximum of 25 or 33 percent coinsurance (depending on the deductible), this is a very high out-of-pocket financial burden for beneficiaries to bear.

CMS proposes to allow PBMs and insurers to establish up to two specialty tiers. The maximum cost-sharing would still apply to a single specialty tier or, if two exist, to the higher cost-sharing specialty tier. Plans would be allowed to design their exceptions process so that drugs on these tiers are exempted from exceptions to non-specialty tiers. CMS would require Part D sponsors to permit tiering exception requests for drugs on the higher cost-sharing specialty tier to the lower cost-sharing specialty tier. The PBMs and plans would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to an ingredient cost threshold established by CMS and the requirements of the CMS formulary review and approval process.

ATAP opposes the creation of a second specialty tier in Part D. The access issues created by tiering are well-documented, and would be exacerbated for Part D beneficiaries with the creation of another specialty tier. The proposed policy would simply provide PBMs with yet another way to deny or delay necessary treatments.

Furthermore, tier placement is inextricably tied to rebates and other price concessions paid by pharmaceutical manufacturers to PBMs. In addition to this system's implications on patient care, CMS itself has documented the financial impact of these price concessions on the program, as well as the competitive distortions they create for beneficiaries during plan selection.

Specifically, CMS has in past rulemaking[1] indicated that in recent years, its analysis found that the direct and indirect remuneration (DIR) amounts that Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts. This matters because DIR received above the bid-projected amount contributes primarily to plan profits, not to lower premiums. There is even evidence that plans may sometimes choose higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative.

Currently, some sponsors include price concessions in negotiated prices while others include them in DIR. This leaves beneficiaries with no consistent meaning for negotiated prices and little consistent reference point for comparing plans. They may select one plan over another based on lower monthly premiums – but the premium may be lower in large part because the other plan applies price concessions at the point of sale rather than factor them into premiums. While the beneficiary may be attracted by the lower premium cost in plan selection, they may ultimately be faced with higher out-of-pocket costs for prescriptions.

Until these underlying issues with price concessions are addressed, it seems imprudent to provide PBMs with more tiering authority, as the practice of tiering is directly tied to price concessions. As such, ***ATAP must oppose CMS' proposal to allow a second specialty tier in Medicare Part D***.

Thank you for your consideration. Please do not hesitate to contact any of the undersigned organizations, should you require more 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
Kentuckiana Rheumatology Alliance

[1] Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program.

Looms for Lupus, Inc.
Lupus and Allied Diseases Association, Inc.
MidWest Rheumatology Association
National Infusion Center Association
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Rheumatology Alliance of Louisiana
Rheumatology Nurses Society
South Carolina Rheumatism Society
Virginia Society of Rheumatologists