January 27, 2025

Submitted via Regulations.gov

The Honorable Doctor Dorothy Fink
Acting Secretary
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: *Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-P)*

Dear Acting Secretary Fink and Acting Administrator Wu:

We appreciate the opportunity to comment on the *Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly*.[1]

On behalf of the patients we represent, we applaud CMS' commitment to lowering out-of-pocket costs for prescription drugs via broad access to generic and biosimilar treatment options. We believe that CMS was correct in its previous suggestion that Part D sponsors may fail to comply with the requirement to maintain cost-effective utilization management programs by excluding generic alternatives from formularies.[2] These practices constitute a significant source of unnecessary costs borne by both Medicare patients and the Part D program. We urge CMS to exercise its existing statutory authority as codified at 42 CFR § 423.153(b) to reign in the discriminatory formulary practices that limit access to low-cost generic and biosimilar treatments for patients.[3]

This issue, as identified by CMS, is substantiated by a growing pool of independent research and opinions from federal agencies. A widely cited report by Avalere Health compiled time-series data investigating trends in the formulary tier placement of generic drugs within Medicare Part D. This study revealed a notable and continuing decline in the percentage of generic prescription drugs placed on the appropriate lower cost sharing generic tiers. Today, only roughly 43% of generics in the Part D program appear on generic tiers— a figure representing a 22-point decline since 2016.[4] This practice is limiting access to affordable generics and biosimilars for Medicare beneficiaries, and unnecessarily raising out-of-pocket costs for patients covered under Part D.

Generics and biosimilars offer immense value to patients and the health care system. Over the last decade, they have saved America's patients and our system more than $3 trillion, including more than $137 billion in savings for Medicare in 2024.[5] However, these future savings to both patients and Medicare are at risk due to misaligned incentives within Part D that incentivize prescription drug plans to cover higher-cost brand drugs, despite the availability of lower-cost generic and biosimilar medicines.

[1] 89 FR 99340.
[2] Ibid., p. 140.
[3] 42 CFR 423.153(b).
[4] Avalere Health LLC. (2024). *57 Percent of Covered Generic Drugs Not on Part D Generic Tiers in 2025*. https://avalere.com/insights/57-of-covered-generic-drugs-not-on-part-d-generic-tiers-in-2025.
[5] Association for Accessible Medicines. (2024). *2024 U.S. Generic & Biosimilar Medicines Savings Report*. https://accessiblemeds.org/resources/blog/2024-savings-report.

The current trend works against the forces of price competition identified by CMS as being critical to "ensuring patient access to therapy while constraining costs."[6] As a result, patients face otherwise avoidable challenges to drug affordability, therapeutic adherence, and health outcomes.

Accordingly, we support CMS taking the following actions within its existing statutory authority to ensure patient access to lower cost generics and biosimilars:

- Finalize the clarification that Part D plans must provide "broad access" to generics and biosimilars as related to formulary inclusion, tier placement, and utilization management.
- Finalize the proposal to include an additional step to the formulary review process to ensure "broad access" to generics and biosimilars.
- Revisit the "alternative" tier composition policy prohibiting Part D plans from placing generics on brand tiers.
- Revisit the "preferred" specialty tier policy for generics.
- Publish formulary designs and utilization management practices that fail to meet the Part D program's "broad access" requirements.
- Increase transparency of utilization management and coverage limitations of generics on Medicare Plan Finder (MPF).

We appreciate CMS' attention to this pressing issue and stand ready to serve as partners in advancing access to treatment for the patients we serve.

Sincerely,

Allergy & Asthma Network
Asthma and Allergy Foundation of America
Autoimmune Association
Bonnell Foundation
Boomer Esiason Foundation
BreatheStrong CF
Children with Diabetes
Cystic Fibrosis Research Institute
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Emily's Entourage
HealthyWomen
Lupus Foundation of America
MS Foundation
National Multiple Sclerosis Society
Patients Rising
Rock CF Foundation
The Diabetes Link

[6] Centers for Medicare & Medicaid Services. (2019). *Advance Notice of Methodological Changes for Calendar Year 2020 for Medicare Advantage Capitation Rates, Part C and Part D Repayment Policies and 2020 Draft Call Letter*. https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2020.pdf, p. 210.