January 30, 2023

VIA REGULATIONS.GOV

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-9899-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024 (CMS-9899-P)

Dar Administrator Brooks-LaSure:

Viatris is pleased to provide comments in response to the proposed rule on *Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024* (hereinafter "proposed rule").[1]

Viatris Inc. is a global healthcare company, empowering people worldwide to live healthier at every stage of life. Formed in November 2020, Viatris brings together scientific, manufacturing and distribution expertise with proven regulatory, medical, and commercial capabilities to deliver high-quality medicines to patients in more than 165 countries and territories. Viatris' portfolio comprises more than 1,400 approved molecules across a wide range of therapeutic areas, spanning both non-communicable and infectious diseases, including globally recognized brands, generics, complex generic and branded medicines. We see access to medicines as fundamental to our mission—a powerful concept in challenging times.

I. Overview of Comments

Viatris shares CMS' concerns outlined in the proposed rule that issuers of standardized plan options may not be including generic drugs on appropriate cost-sharing tiers for the standardized plan options. As CMS points out, some issuers may be including brand name drugs in the generic drug cost-sharing tier, and some issuers may include generic drugs in the preferred or non-preferred brand drug cost-sharing tiers.

We appreciate CMS' continued attention to this issue, and support finalization of the proposal to specify that issuers of standardized plan options must:

(1) place all covered generic drugs in the standardized plan options' generic drug cost-sharing tier, or the specialty drug tier if there is an appropriate and non-discriminatory basis for doing so; and

[1] 87 Fed. Reg. 7826 (Dec. 21, 2022).

(2) place brand name drugs in either the standardized plan options' preferred brand or non-preferred brand tiers, or specialty drug tier if there is an appropriate and non-discriminatory basis for doing so.

We also appreciate that CMS indicates that the Agency will consider in future rulemaking proposing additional drug cost-sharing tiers in the standardized plan options. To this end, CMS may consider proposing in next year's rulemaking for plan year (PY) 2025 adding a second specialty tier in the standardized plan options dedicated to generic drugs with cost-sharing obligations that are meaningfully lower than that of the existing specialty tier that will be dedicated to brand drugs.

II. Detailed Comments

(a) Viatris Supports CMS Efforts to Address Tiering Composition

Viatris appreciates that CMS has consistently supported increasing access to generic drugs across the health care system, including in qualified health plans (QHPs) through Federally facilitated Exchanges and State-based Exchanges on the Federal platform. We appreciate that in the proposed rule, CMS acknowledges concerns that issuers of QHPs may not be including generic drugs on appropriate cost-sharing tiers for the standardized plan options. Ending such practices are important to ensure lower out-of-pocket costs for patients and savings for the health care system.

As such, we support CMS's finalization of the proposal by specifying that issuers of standardized plan options must place generic drugs on the appropriate cost-sharing tier, whether that be generic drug cost-sharing tiers (or specialty tiers if appropriate under the relevant statute and regulations), and place brand drugs on either a preferred brand or non-preferred brand tier (or specialty tiers if appropriate).

(1) Current Mix Tiering Practices May Impede Access to Generics

The U.S. health care system has saved more than $2.6 trillion in the last 10 years due to the availability of affordable generics and biosimilars.[2] Generics demonstrate a high value proposition for U.S. patients – they represent 91 percent of all prescriptions in the U.S., but only 18.2 percent of spending.[3] Savings offered by generics are in large part due to their structural favoring throughout the healthcare system, including in plan benefit design to help encourage utilization of generics that will, in turn, enhance patient access and lower costs. This foundational cost-saving, element of health care is important across all aspects of the U.S. system, including in QHPs.

Nevertheless, this success is being challenged due to evolving changes in formulary practices. As Viatris has noted in several of our submissions to CMS over the past few years, generics – particularly newer, more complex generics – are experiencing significant challenges

[2] Association for Accessible Medicines, 2022 Generic Drug Access & Savings in the U.S., Sept. 2022, available online at: https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[3] Id.

in gaining and sustaining market share, despite their value as cost-effective alternatives.[4] Historically, once FDA-approved generics launched, these products would go on formulary on a generic tier soon after launch and patients would immediately garner the benefits of generic competition through lower out-of-pocket costs.

Unfortunately, this is no longer the case in a growing number of instances. Increasingly, lower cost generic drugs are being placed onto brand drug tiers with much higher patient cost sharing, and in some cases, generics are not being added to formularies at all. The result of such practices is higher out-of-pocket costs at the pharmacy counter for patients who have historically directly accessed and benefited from lower-cost generics. Such tiering practices can also translate to minimal utilization of certain generics, which could have a chilling effect on decisions to invest in development of new generic medicines, particularly for complex medicines.

Although we understand that Medicare Part D is outside the scope of the current proposed rule, it is noteworthy that a recent Avalere study showed that Part D beneficiary spending on generic drugs increased by more than $11 billion (more than 135%) from 2011 to 2019 – with the increase largely driven by plan and PBM decisions to place generics on non-generic formulary tiers, even as the prices for those generics declined.[5] Further, a July 2022 analysis published by Avalere showed that as Part D plans continue to place generics on brand formulary tiers, more patients are liable for the full cost of their medication, though they were previously paying a generic tier co-payment. Avalere found that in 2020, 63% of beneficiaries (an 18% increase from 2017) across all Part D plans paid the full cost of a generic at least once.[6] Many QHPs have similarly employed such formulary practices, resulting in higher out-of-pocket costs at the pharmacy counter for their enrollees.

Moreover, the inclusion of generic drugs on tiers alongside brands leads to patient confusion. We agree with CMS that consumers understand the difference between generic and brand name drugs, and that it is reasonable to assume that consumers expect that only generic drugs are covered at the cost-sharing amount in the generic drug cost-sharing tier, and that only brand name drugs are covered at the cost-sharing amount in the preferred or non-preferred brand drug cost-sharing tiers. Unfortunately, tier compositions that mix generics with brands on the same tier and thus have the same copayment obligations regardless of the generic's lower cost, confuses patients who may not have accounted for the higher out-of-pocket costs for their existing generic medications when they signed up for their plans.

(2) Viatris Urges CMS to Finalize the Tiering Composition Proposal

[4] Viatris comments to "Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (CMS-2022-0021)," as submitted on March 4, 2022; and Viatris comments to "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" as submitted on March 7, 2022.
[5] Avalere, "New Analysis of Trends in Part D Generic Tiering, Pricing, and Patient Spending," Sept. 14, 2022, available online at: https://avalere.com/insights/new-analysis-of-trends-in-part-d-generic-tiering-pricing-and-patient-spending.
[6] Avalere, July 12, 2022 "Some Medicare Part D Beneficiaries Pay Full Price for Generic Drugs". available online at https://avalere.com/insights/some-medicare-part-d-beneficiaries-pay-full-price-for-generic-drugs

Viatris applauds CMS for recognizing these concerning practices in QHPs and for proposing changes to address them. As such, we support CMS's finalization of the proposal to specify that issuers of standardized plan options must: (1) place all covered generic drugs in the standardized plan options' generic drug cost-sharing tier, or the specialty drug tier if there is an appropriate and non-discriminatory basis for doing so; and (2) place brand name drugs in either the standardized plan options' preferred brand or non- preferred brand tiers, or specialty drug tier if there is an appropriate and non-discriminatory basis for doing so.

Under such a policy, drug tiers would no longer mix generics with brand products. Generics would be part of generic formulary tiers and brands would be part of brand formulary tiers. The policy, if finalized, will encourage utilization of more affordable generics, lower patient out-of-pocket costs, and avoid patient confusion.

(b) Viatris Urges CMS to Propose a Second Specialty Tier Dedicated to Generic Drugs for PY 2025

We understand that for plan year (PY) 2024, CMS is proposing to continue the use of the following four tiers in the standardized plan options: generic drugs, preferred brand drugs, non-preferred brand drugs, and specialty drugs. Nevertheless, we appreciate that CMS indicates in the rule that the Agency may consider in the future proposing additional drug cost-sharing tiers in the standardized plan options and will at such time solicit comment on the appropriate number of drug tiers.

To this end, Viatris encourages CMS to consider proposing in next year's rulemaking for PY 2025 adding a second specialty tier in the standardized plan options dedicated to generic drugs with cost-sharing obligations that are meaningfully lower than that of the existing specialty tier that will be dedicated to brand drugs. The creation of a second specialty tier for generics will further enable beneficiary access to and lower patient cost-sharing for specialty generics, which may be above the specialty tier cost threshold but substantially lower-priced than equivalent specialty brands.

III. Conclusion

Thank you for the opportunity to provide comments on the proposed rule. We would be happy to provide further information regarding these comments at your convenience. Should you have any questions, please contact me at erika.satterwhite@viatris.com.

Sincerely,

Erika Satterwhite
Head of Global Policy