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February 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via regulations.gov

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications [CMS-4201-P]

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the proposed rule titled "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications [CMS-4201-P]" published in the Federal Register on December 27, 2022.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Medication Therapy Management (MTM) Program (§ 423.153)

Because expanding access to affordable medications is central to AMCP's mission,[1] AMCP generally supports CMS' intention to increase access to MTM services for more Part D enrollees with complex

[1] https://www.amcp.org/about/about-amcp/amcp-strategic-priorities

drug regimens. However, AMCP urges caution about increasing the size of the program without first being certain that the program provides the necessary value to existing participants. CMS should consider the program holistically to ensure that outcomes are first optimized for the existing participants. CMS should also consider the costs of providing the services. Another concern voiced by AMCP's members is the difficulty in engagement with beneficiaries due to fewer people wanting in person interactions in a pharmacy setting and fewer people answering their phone, even when it is their local pharmacy calling. Once these challenges have been addressed, only then does it make sense to look at ways to expand access.

Strengthening Translation and Accessible Format Requirements for Medicare Advantage, Part D, and D-SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267)

AMCP's strategic priorities include a commitment to optimizing patients' health outcomes, addressing barriers to access to care, and addressing health disparities. Meaningful access to care requires addressing and removing language barriers for those with limited English proficiency and for those whose access to communication may be limited due to disability. AMCP applauds CMS' efforts to address barriers to communication by strengthening translation and accessible format requirements. AMCP encourages HHS to be mindful of the potential administrative burden of these requirements and offer covered entities additional flexibility to find innovative ways of addressing language barriers.

Health Equity in Medicare Advantage (MA) (§§ 422.111 and 422.112)

As a leading professional association dedicated to increasing patient access to affordable medicines,[2] improving health outcomes, and reducing health disparities, AMCP supports CMS' proposal to clarify that the requirement that services are provided in a culturally competent manner applies broadly to people (1) with limited English proficiency or reading skills; (2) of ethnic, cultural, racial, or religious minorities; (3) with disabilities; (4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (6) who live in rural areas and other areas with high levels of deprivation; and (7) otherwise adversely affected by persistent poverty or inequality. It is important to acknowledge the existence of systemic disparities in health care and to work toward health equity.

AMCP also supports CMS' proposal to require MA organizations to incorporate activities into their quality improvement (QI) programs that reduce disparities in health and health care among their enrollees. AMCP appreciates the flexibility for MA organizations to find innovative ways of incorporating effective health equity activities into their QI programs.

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[2] On June 9, 2022, AMCP brought experts together for a Health Disparities summit, https://www.amcp.org/education-meetings/events-meetings-webinars/amcp-summit-addressing-health-disparities, and prior to that, in 2021, AMCP held a Partnership Forum, "Racial Health Disparities: A Closer Look at Benefit Design," which brought together managed care experts to identify structural issues in prescription drug formulary and benefit design processes and propose concrete solutions to reduce racial health disparities, https://www.amcp.org/sites/default/files/2021-04/AMCP%20PF%20ExecSumm%200421_6.pdf.

Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

AMCP generally supports the proposal to codify definitions around negative formulary changes because this will serve to provide clarity and consistency in how plans approach formulary changes. AMCP supports CMS' proposal to broaden the scope of allowable immediate negative formulary changes to include authorized generics, interchangeable biologicals, and unbranded biologicals, but AMCP believes that this should be taken a step further.

AMCP supports expanding the use of biosimilars to reduce costs for the Part D program and its enrollees. There are currently 22 biosimilars available to patients in the United States. The prices of these biosimilars are, on average, at least 50% lower than the corresponding reference biologics.[3] HHS's Office of the Inspector General determined that spending on biologics could be reduced by 18% through greater use of biosimilars, resulting in beneficiaries saving 12% on out-of-pocket costs.[4]

AMCP encourages CMS to consider extending its proposal to allow immediate negative formulary changes to the substitution of biosimilars without the interchangeable designation. The interchangeability designation allows substitution at the pharmacy counter[5] but the lack of this designation should not affect the biosimilar's inclusion on a formulary. FDA has encouraged uptake of biosimilars as an alternative for reference biologics.[6] Biosimilars are as safe and effective as the original biologic.[7] A biosimilar and the reference product both go through a rigorous FDA approval process that must find the biosimilar highly similar to the original biologic with no clinically meaningful differences.

Alternatively, CMS could treat the substitution of new-to-market biosimilars as a maintenance change with appropriate protections for continuity of care. Notice to enrollees, as required for maintenance changes, would provide time for patients to consult with their prescribers about switching to a biosimilar and, if a prescriber does not believe the change appropriate, use of the formulary exception process.[8]

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[3] https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf

[4] https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf

[5] "An interchangeable biosimilar product may be substituted without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs. This is commonly called pharmacy-level substitution and is subject to state pharmacy laws." https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices

[6] "Health care providers do not need to wait for a biosimilar to be approved as an interchangeable biosimilar to prescribe it. FDA does not approve a product as interchangeable unless a manufacturer specifically seeks an interchangeability determination. Biosimilars are as safe and effective as the reference product they were compared to." https://www.fda.gov/media/154917/download.

[7] https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices

[8] "The purpose of providing a transition supply is to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated." Part D Manual, Chapter 6, 30-4.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer