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January 5, 2024

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 2025 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; Health Information Technology Standards and Implementation Specifications [CMS-4205-P]

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the proposed rule titled "Medicare Program; Contract Year 2025 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; Health Information Technology Standards and Implementation Specifications," published in the Federal Register on November 15, 2023.

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.

Annual Health Equity Analysis of Utilization Management Policies and Procedures

AMCP believes that improving health equity requires integrating proactive strategies into all aspects of health care.[1] For this reason, AMCP supports CMS' proposal to require that a member of each Utilization Management (UM) committee have health equity expertise and to require these committees to perform an annual health equity analysis. AMCP applauds CMS' consistent demonstration of its commitment to advancing healthcare equity.

[1] https://www.amcp.org/policy-advocacy/policy-resource-center/where-we-stand-position-statements/addressing-racial-health-disparities

Incorporating health equity expertise into UM committees represents a tangible step towards advancing equitable healthcare access for all Medicare beneficiaries and would bring a crucial perspective to UM committees. This requirement would encourage UM strategies that address disparities and promote equitable access to healthcare services and could potentially aid in identifying and mitigating biases and discriminatory practices. Additionally, this type of expertise would lead to a more culturally competent and sensitive decision-making process and may help to proactively prevent unintended consequences from affecting vulnerable populations. A nuanced understanding of cultural factors is essential to tailor UM strategies that meet the unique needs of Medicare's diverse beneficiaries. By embracing this policy, CMS demonstrates its commitment to fostering a healthcare system that prioritizes the well-being of all beneficiaries while striving for improved health outcomes for all beneficiaries.

CMS' proposal to require that each Medicare Advantage (MA) plan's UM committee annually perform an analysis of the use of prior authorization (PA) on enrollees with certain social risk factors (receipt of low-income subsidy, dual eligibility, disability) is a crucial step in addressing health disparities. Analyzing PA approval rates among enrollees with social risk factors may reveal potential disparities in access to healthcare services, even when the PA criteria are facially neutral. For instance, a lower approval rate for specific populations may indicate barriers in the PA process that need attention.

CMS should also consider requiring UM committees to analyze health equity through an intersectional lens. Many individuals belong to multiple marginalized groups, experiencing intersecting forms of discrimination and disadvantage. Analyzing health equity across these various dimensions helps capture the intersectionality of health disparities and ensures a more comprehensive understanding of the challenges faced by individuals with overlapping identities. Including intersectionality in health equity analyses supports the development of policies and practices that promote inclusive and patient-centered healthcare.

AMCP cautions CMS that some of the information gathered as part of a health equity analysis may be proprietary to the MA plan and, thus, competitively sensitive. AMCP encourages CMS to permit the plan to withhold confidential and proprietary information included in these analyses from publication. AMCP believes that MA plans should also be given the flexibility to create solutions to address any issues identified in the committee's initial health equity analysis. AMCP suggests that plans be afforded an opportunity to voluntarily address any inequities discovered in the initial health equity analysis and to implement needed changes identified in the first year, before being required to publish the annual health equity analysis in subsequent years. AMCP agrees that CMS should require that the UM Committee submit the link to the analysis report to CMS to post in one centralized location to improve accessibility and transparency.

Substituting Biosimilar Biological Products for their Reference Products as Maintenance Changes

AMCP generally supports CMS' proposal to permit substitution of biosimilar biological products other than interchangeable biological products as maintenance changes because this approach would facilitate greater adoption of biosimilars within the Medicare program. Biosimilars offer a more affordable alternative to originator biologics, potentially resulting in substantial cost savings for both Medicare beneficiaries and the Medicare program. Biosimilars undergo rigorous regulatory scrutiny to demonstrate similarity and efficacy compared to their reference biologics and provide comparable therapeutic benefits. Expanding access to biosimilars

promotes patient-centered care by providing Medicare beneficiaries with a wider range of treatment options, fosters healthy competition and innovation in the biopharmaceutical industry, and incentivizes manufacturers to invest in research and development, ultimately leading to a more dynamic and innovative healthcare landscape.

AMCP encourages CMS to consider extending its proposal to allow immediate negative formulary changes to the substitution of biosimilars without the interchangeable designation. Adopting this approach would further CMS' stated policy goal of encouraging greater use of biosimilar biological products.[2] The interchangeability designation is meaningful only insofar as it allows substitution at the pharmacy counter,[3] but the lack of this designation should not affect formulary design as it does not signify any difference in safety or efficacy. Biosimilars, with or without the interchangeable designation, have undergone a rigorous FDA approval process that must find the biosimilar highly similar to the original biologic with no clinically meaningful differences and are as safe and effective as the original biologic.[4] FDA has encouraged uptake of biosimilars as an alternative for reference biologics.[5]

In the Proposed Rule, CMS outlines a hypothetical situation where an enrollee is unable to obtain a refill of a reference product that has been substituted with a biosimilar biological product. However, Part D plans are already required to follow a coverage determination and appeals process and must provide notice of the determination to the enrollee "as expeditiously as the enrollee's health condition requires."[6] Substituting a biosimilar without the interchangeable designation would not alter this existing process. Because patients are able to obtain coverage through the formulary exceptions process, AMCP sees no reason to treat biosimilar biological products without the interchangeable designation differently.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing to 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

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[2] See Proposed Rule at p. 119.
[3] "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-treatmentchoices
[4] https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-moretreatment-choices
[5] "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.
[6] 42 C.F.R. §§ 423.568(b), 423.572(a).