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Jeff Wu
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
7500 Security Boulevard
Baltimore, MD 21244–1850

*Submitted electronically to PartDRedesignPI@cms.hhs.gov*

Re: Draft CY 2026 Part D Redesign Program Instructions

Dear Administrator Wu:

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 Draft CY 2026 Part D Redesign Program Instructions.

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.

**Creditable Coverage**

AMCP supports the revised simplified methodology for non-Retiree Drug Subsidy group health plans to calculate whether their drug coverage is considered "creditable coverage" for purposes of avoiding late enrollment penalties.

AMCP is concerned that impacted employees may suffer unintended consequences due to a loss of creditable coverage. An impacted employee may have had insufficient time to enroll in Part D, especially given that they must first have enrolled in Part A to receive a Medicare identification number to get access to Part D. This process can take significant time to complete. Although such an employee would have a special enrollment period to enroll in Medicare Part D based on the plan's loss of creditable status, their Part D enrollment wouldn't be effective until the following month, creating a short creditable coverage gap. If the employee is moving to Part D from a HDHP plan option, enrollment in Part A is retroactive up to six months. This would cause a loss of HSA eligibility for that retroactive period and could potentially create issues for the employee where they need to work with the HSA custodian to process a corrective distribution. AMCP urges CMS to minimize potential issues for these employees.

**Successor Regulation Exception to the Formulary Inclusion Requirement for Selected Drugs**

AMCP would like to emphasize the importance of encouraging greater uptake of biosimilars as these products are safe, effective, and often more cost-effective than the reference product. In 2015, AMCP launched the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), an unbiased, policy-neutral repository of educational resources and information on biosimilars. BBCIC is a non-profit research consortium that monitors the safety and effectiveness of biosimilars and novel biologics and provides the assurance needed to determine which medications deliver the best health outcomes.[1]

AMCP supports the selection of current § 423.120(e)(2)(i) as part of the successor regulation, to include continued ability to remove a selected brand drug from the formulary and replace it with a generic as an immediate substitution, and the expanded ability to remove reference biologics and replace with newly available interchangeable biosimilars. AMCP's members appreciate the expanded flexibility to immediately remove selected drugs from the formulary if a biosimilar or generic would be more cost effective. AMCP recommends an interpretation of the statute and its regulations to permit a sponsor to make such a generic substitution for a selected drug even if the generic product came to market before the sponsor's initial formulary submission for the year. AMCP also encourages CMS to include provisions allowing for maintenance changes of generic drugs and interchangeable biological products and maintenance changes of biosimilar biological products other than interchangeable biological products. AMCP's members need flexibility in formulary management to ensure that patients have access to safe and effective drugs at an affordable price.

**Conclusion**

AMCP appreciates your consideration of the above concerns and looks forward to continuing work on these issues with CMS to maximize the benefit for all stakeholders. If you have any questions regarding AMCP's comments or would like further information, please contact Vicky Jucelin, AMCP's Manager of Regulatory Affairs, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

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

[1] https://www.bbcic.org/about/about-bbcic