

CMS Issues MA and Part D Policy and Technical Rule

- On April 4, 2024, the Centers for Medicare and Medicaid Services (CMS) issued a final rule (Final Rule) on policy and technical changes to Medicare Advantage (MA), Part D, Medicare Cost Plan, and Programs of All-Inclusive Care for the Elderly (PACE).
 - Major policies finalized for Calendar Year 2025 include:
 - Changes to the midyear substitution policy for biosimilars:
 - CMS will treat substitution of biosimilars other than interchangeable biological products as maintenance changes, allowing such substitutions to apply to enrollees taking a reference product when the change occurs.
 - When a reference product is substituted for a biosimilar other than an interchangeable biological product, the biosimilar must be added to the same or lower cost-sharing tier, with the same or less restrictive utilization management (UM) requirements.
 - Part D sponsors must make any negative formulary changes within 30 days (immediate substitution) or 90 days (maintenance change) of adding a corresponding drug to their formulary.
 - An annual health equity analysis of UM policies by CMS and requirement that a member of the UM committee must have expertise in health equity;
 - Modifications to special enrollment periods (SEPs) for dually eligible individuals (for example, creation of a new integrated care SEP to allow dual-eligibles enroll in an integrated D-SNP on a monthly basis). Enrollment in certain D-SNPs will be limited to those individuals also enrolled in an affiliated Medicaid MCO.
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More on This Topic:

- [Final Rule](#)
- [Fact Sheet](#)

For questions, please reach out to [Vicky Jucelin](#).

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