AMCP
Optimizing medicine.
Improving lives.

August 17, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via regulations.gov

Re: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program [CMS-4215-P]

Dear Administrator Oz:

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 Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program" [CMS-4215-P] (Proposed Rule).

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.

AMCP supports efforts to make prescription medications more affordable for Medicare beneficiaries. At the same time, implementation of the Medicare Drug Price Negotiation Program (Negotiation Program) should preserve the evidence-based formulary management, utilization management, market competition, and clinical decision-making processes fundamental to managed care pharmacy. The Inflation Reduction Act requires Part D sponsors to include selected drugs on their formularies, but it does not establish selected-drug status as a determination of clinical superiority or require preferential formulary placement. The Negotiation Program should therefore complement, but not displace, the ability of Part D sponsors and their Pharmacy and Therapeutics Committees (P&T Committees) to evaluate medications based on clinical evidence, effectiveness, safety, utilization, and net cost.[1]

[1] Hydery, T & Reddy, V. *A primer on formulary structures and strategies*, 30 Journal of Managed Care & Specialty Pharmacy 206 (2024), https://doi.org/10.18553/jmcp.2024.30.2.206.

AMCP's comments below focus on provisions of the Proposed Rule with direct implications for Medicare Part D sponsors, pharmacy benefit managers (PBMs), pharmacies, and beneficiaries.

Proposed Requirements for the Medicare Drug Price Negotiation Program

Implementation of the MFP (§§429.700-429.710)

CMS should resolve key operational questions regarding MFP eligibility and funds flow before implementation. The final rule should identify how pharmacies will determine whether a claim is MFP-eligible, which entity will transmit eligibility information, how payment adjustments will be reconciled, how errors will be corrected, and which entity is responsible for resolving disputes. These details are particularly important for pharmacies that dispense selected drugs but may not have direct manufacturer relationships or visibility into manufacturer payment processes.

CMS should establish standardized requirements for eligibility verification, transaction processing, reimbursement, reconciliation, error correction, and dispute resolution, including any required transaction or data elements. Clear and consistent processes are essential to avoiding claim-processing delays, pharmacy reimbursement uncertainty, and beneficiary access disruptions. Predictable operational requirements would reduce implementation burden and help ensure that administrative costs do not offset the affordability gains Congress intended.

Proposed Implementation of Inflation Reduction Act Provisions for the Medicare Prescription Drug Benefit Program

Part D Formulary Inclusion of Selected Drugs (§ 423.120)

AMCP supports CMS's proposal to codify the statutory requirement that Part D sponsors include each covered Part D drug that is a selected drug for which an MFP is in effect. This requirement appropriately implements section 1860D-4(b)(3)(I)(i) of the Social Security Act, as added by section 11001(b) of the Inflation Reduction Act (IRA), which provides that, beginning in 2026, a Part D sponsor must "include each covered part D drug that is a selected drug" for which an MFP is in effect.[2]

The statute does not prescribe a particular formulary tier, cost-sharing level, or utilization-management approach for selected drugs. The Proposed Rule appropriately recognizes that sections 1860D-2(b)(2)(B) and 1860D-4(c)(1)(A) continue to permit Part D sponsors to use formularies, tiered cost sharing, and cost-effective drug utilization management, subject to applicable statutory and regulatory requirements.

This distinction is important because selected-drug status is a pricing designation under the Negotiation Program, not a determination of clinical superiority. Part D sponsors and their P&T Committees must retain the ability to evaluate selected drugs alongside therapeutic alternatives based on clinical evidence, safety, effectiveness, utilization, and net cost. Maintaining this flexibility supports appropriate utilization and efficient stewardship of Medicare resources without compromising beneficiary access.[3]

---

[2] Pub. L. 117-169, https://uscode.house.gov/download/bills/117-2/117-169.pdf

[3] Yeung, K, Cruz, M, Tsiao,E, Watkins, JB & Sullivan, SD. *Drug use and spending under a formulary informed by cost-effectiveness*, 29 Journal of Managed Care & Specialty Pharmacy 1175 (2023), https://doi.org/10.18553/jmcp.2023.29.11.1175.

AMCP also encourages CMS to clarify that its proposed monitoring of formulary placement is intended to assess compliance with the statutory inclusion requirement and existing Part D requirements, rather than establish an implicit expectation regarding tier placement, cost sharing, or utilization-management design. CMS should avoid using formulary-placement trends, standing alone, as a basis for imposing additional requirements not established by statute or regulation. Part D sponsors must be able to respond to evolving clinical evidence, generic and biosimilar competition, utilization patterns, and changes in net costs. Preserving this flexibility promotes efficient stewardship of Medicare resources while allowing plans to maintain clinically appropriate access.

Successor Regulation Exception Permitting Formulary Substitutions of Selected Drugs (§ 423.120)

AMCP supports CMS's proposal to codify the successor-regulation exception permitting Part D sponsors to remove selected drugs when the applicable requirements for immediate substitution are satisfied. Section 1860D-4(b)(3)(I)(ii) of the Act expressly provides that the formulary-inclusion requirement does not prohibit removal of a selected drug when such removal is permitted under the specified regulation or its successor.

AMCP particularly supports CMS's continued recognition of interchangeable biological products within the immediate-substitution framework. Preserving flexibility to adopt lower-cost generic and biosimilar alternatives remains important to maintaining formulary competition and reducing program costs.[4]

CMS should clarify that the successor-regulation framework can evolve as the generic and biosimilar markets mature. The Proposed Rule recognizes that CMS may identify additional provisions as successor regulations in the future, including as the biosimilar market develops. AMCP supports this flexibility and encourages CMS to use it when necessary to ensure that Part D sponsors can respond efficiently to newly available lower-cost alternatives without unnecessary delays or administrative barriers to substitution.

Exception Permitting Formulary Substitutions of Selected Drugs (§ 423.120)

AMCP supports CMS's proposal to apply immediate-substitution rules consistently to generic and interchangeable biological products and encourages CMS to provide clear operational guidance for circumstances in which such products become available during or after the formulary-development and bid-submission cycles. CMS should ensure that the timing requirements do not unnecessarily delay adoption of clinically appropriate lower-cost alternatives.

The Proposed Rule contemplates circumstances in which a generic or interchangeable biosimilar becomes available after initial formulary submission. CMS should specify when a sponsor may implement a substitution, what notice is required, and how the change should be reflected in the applicable formulary and beneficiary materials. The objective should be to minimize unnecessary periods during which beneficiaries and the Medicare program remain

---

[4] Beinfeld, MT, Ghule, P, LaMountain, F, Wong, W, Ko, S & Chambers, JD. *The unintended consequences of the inflation reduction act on biosimilar market incentives and Medicare savings*, 3 Health Affairs Scholar qxaf222 (2025), https://doi.org/10.1093/haschl/qxaf222.

exposed to a higher-cost reference product when an appropriate lower-cost alternative is available.

At the same time, beneficiary protections should remain central. Existing notice and formulary-exception processes provide an appropriate mechanism for beneficiaries who have a documented medical need to remain on a particular product. CMS should preserve these safeguards while avoiding unnecessary restrictions on plan ability to implement clinically appropriate substitution.

Negotiated Price for Selected Drugs (§ 423.100)

AMCP supports CMS's proposal to codify section 1860D-2(d)(1)(D) of the Act, which provides that, for a selected drug, the negotiated price "used for payment" may not exceed the MFP "plus any dispensing fees for such drug." The statutory language establishes a maximum, not a minimum, price.

CMS should expressly confirm that the MFP is a ceiling on the negotiated price used for payment and does not limit the ability of Part D sponsors or PBMs to negotiate lower prices when market conditions permit. This distinction is fundamental to managed care pharmacy. Plans and PBMs evaluate net cost, utilization, clinical value, market competition, and therapeutic alternatives when developing formularies and negotiating payment arrangements. Preserving the ability to negotiate below the MFP will allow market competition and formulary management to continue generating savings beyond the negotiated MFP.

CMS should also clarify that the MFP ceiling does not alter the ability of Part D sponsors or PBMs to negotiate permissible pharmacy reimbursement arrangements or other contractual terms, provided that the resulting negotiated price used for payment complies with the statutory ceiling. The final rule should avoid any implication that the MFP establishes a minimum reimbursement amount or otherwise limits competition below the MFP.

Downstream Impacts

CMS should monitor the downstream effects of the Negotiation Program on beneficiary access, formulary competition, utilization-management practices, generic and biosimilar uptake, medication utilization, and overall program spending.[5] Evaluation should distinguish changes that improve affordability and value from changes that create clinically inappropriate barriers to care.

AMCP also urges CMS to monitor whether the Negotiation Program affects incentives for generic and biosimilar development, pharmaceutical innovation, and the availability of therapeutic alternatives over time. CMS should use these findings to inform future implementation and, where appropriate, address unintended consequences that could undermine access, competition, or innovation.

Conclusion

AMCP supports CMS's effort to codify the Negotiation Program and encourages CMS to finalize the rule in a manner that faithfully implements the statutory formulary-inclusion and MFP

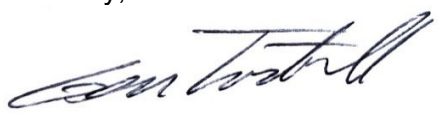
---

[5] Kyle, MA, Dusetzina, SB, & Keating, NL. *Utilization Management Trends in Medicare Part D Oncology Drugs*, 2010-2020, 330 JAMA 278 (2023), https://doi.org/10.1001/jama.2023.10753.

requirements while preserving evidence-based formulary management, clinically appropriate utilization management, and competition below the MFP. CMS should also provide clear operational requirements for MFP eligibility, payment, reconciliation, error correction, and dispute resolution and preserve flexibility to facilitate timely generic and biosimilar substitution. These policies will help achieve the IRA's affordability objectives while maintaining access to clinically appropriate therapies and the value-based practices fundamental to managed care pharmacy.

AMCP appreciates your consideration of AMCP's comments 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 me at etunstall@amcp.org or (703) 705-9358.

Sincerely,



Geni Tunstall, JD
Associate Vice President, Regulatory Affairs