

Key Implementation Dates

Policy/Action	Deadline/Effective Date
Drug Price Negotiation	
HHS selects 10 Part D negotiation-eligible drugs	September 1, 2023
2026 negotiation period begins	October 1, 2023
Manufacturers must submit required information to HHS Secretary	October 2, 2023
HHS Secretary to provide written initial offer including proposal for maximum fair price (MFP)	February 1, 2024
Manufacturers must accept offer or propose written counteroffer	March 2, 2024, or within 30 days of receiving written offer
2026 negotiation period ends	August 1, 2024
HHS publishes negotiated maximum fair prices for 2026 price applicability year	September 1, 2024
HHS selects 15 additional Part D negotiation-eligible drugs	February 1, 2025
2027 negotiation period begins	February 28, 2025
Manufacturers must submit required information to HHS Secretary	March 1, 2025
HHS Secretary to provide written initial offer including proposal for MFP	June 1, 2025
Manufacturers must accept offer or propose written counteroffer	July 1, 2025, or within 30 days of receiving written offer
2027 negotiation period ends	November 1, 2025
HHS publishes negotiated maximum fair prices for 2027 price applicability year	November 30, 2025
HHS selects additional 15 Part D or Part B negotiation-eligible drugs	February 1, 2026
2028 negotiation period begins	February 28, 2026
Manufacturers must submit required information to HHS Secretary	March 1, 2026
HHS Secretary to provide written initial offer including proposal for MFP	June 1, 2026
Manufacturers must accept offer or propose written counteroffer	July 1, 2026, or within 30 days of receiving written offer
Negotiation period ends	November 1, 2026
HHS publishes negotiated maximum fair prices for 2028 price applicability year	November 30, 2026
HHS selects 20 additional Part D or Part B negotiation-eligible drugs	February 1, 2027

Policy/Action	Deadline/Effective Date
2029 negotiation period begins	February 28, 2027
Manufacturers must submit required information to HHS Secretary	March 1, 2027
HHS Secretary to provide written initial offer including proposal for MFP	June 1, 2027
Manufacturers must accept offer or propose written counteroffer	July 1, 2027, or within 30 days of receiving written offer
2029 negotiation period ends	November 1, 2027
HHS publishes negotiated maximum fair prices for 2029 price applicability year	November 30, 2027
Inflation Rebates	
First annual applicability period begins (Part D)	October 1, 2022
First quarterly applicability period begins (Part B)	January 1, 2023
Coinsurance reduction for Part B rebatable drugs	Effective April 1, 2023
HHS reports applicable Part B rebate amounts to manufacturers	October 1, 2023 (within six months after the end of each applicable quarter)*
First Part B rebate payments due	October 31, 2023 (or 30 days after rebate amount reported to manufacturer)
HHS reports applicable Part D rebate amounts to manufacturers	July 1, 2024 (within nine months after the end of each applicable 12-month period)**
First Part D rebate payments due	July 31, 2024 (or 30 days after rebate amount reported to manufacturer)
<p>* The Secretary may delay the timeframe for reporting the Part B rebate information for calendar quarters beginning in 2023 and 2024 until not later than September 30, 2025.</p> <p>** The Secretary may delay the timeframe for reporting the Part D rebate information for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.</p>	
Insulin Cost Sharing	
Part D copayments for insulin capped at \$35/month with no deductible	Effective January 1, 2023
Part B coinsurance for insulin capped at \$35/month with no deductible	Effective July 1, 2023
Part D Benefit Redesign	
Out-of-pocket costs capped at the catastrophic coverage threshold	January 1, 2024
Annual increases in Part D base premium limited to 6 percent through 2029	Effective January 1, 2024
Deadline for manufacturers to enter into Manufacturer Discount Program for period beginning January 1, 2025	March 1, 2024
Out-of-pocket costs capped at \$2,000/year (subject to annual inflation indexing in future years), payable in monthly installments	January 1, 2025
Coverage Gap Discount Program replaced by Manufacturer Discount Program	January 1, 2025
Medicare reinsurance subsidy decreases from 80 percent to 20 percent for brand-name biologic and biosimilar drugs and to 40 percent for generic drugs	January 1, 2025

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Miscellaneous	
Biosimilar add-on payment increased from 6 percent of the reference product average sales price (ASP) to 8 percent	October 1, 2022
Part D coverage of Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines without cost-sharing	January 1, 2023
Medicaid/CHIP coverage of ACIP-recommended adult vaccines without cost-sharing	October 1, 2023
Part D low-income subsidy (LIS) eligibility expansion for individuals with incomes less than 150 percent of the federal poverty line	January 1, 2024
Part B payment capped for new biosimilars when ASP data unavailable	July 1, 2024
Expiration of ACA enhanced premium tax credits	December 31, 2025