

Health Policy and Legislation Alert

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HHS is Moving ‘Full Steam Ahead’ with the Implementation of the Inflation Reduction Act: Here are the Key Health Care Reform Effective Dates

October 7, 2022

The Inflation Reduction Act (IRA), P.L. 117-169, which became law on August 16th, included some of the most consequential prescription drug pricing reforms ever passed by Congress. This week marked a pivotal milestone in the Department of Health and Human Services’ (HHS) implementation of the IRA, with changes to Medicare reimbursement for biosimilars going into effect as of October 1, 2022. On October 3rd, HHS and the Centers for Medicare & Medicaid Services (CMS) announced the implementation of the temporary increase in biosimilar add-on payments under Medicare Part B. Qualifying biosimilars will be paid the average sales price (ASP) plus 8 percent of the reference product’s ASP (rather than plus 6 percent) for a five-year period. For existing qualifying biosimilars as of September 30, 2022, the five-year period begins October 1, 2022. For new qualifying biosimilars, the five-year period begins on the first day of the calendar quarter during which payment is first made using ASP.

While the biosimilar payment changes announced this week constitute one of the first IRA health care reforms to go into effect, they will not be the last. In marking the implementation of these biosimilar payment reforms, Secretary Xavier Becerra stated that HHS is “moving full-speed ahead on Inflation Reduction Act implementation.” Notably, the law provides approximately \$3.5 billion to HHS to implement its health care provisions, and the use of these funds is likely to be closely watched as part of the overall implementation by the Department.

While HHS recently released materials intended to provide a beneficiary-focused audience an overview of the IRA, significant stakeholder uncertainty remains regarding how and when HHS will implement these various reforms. It is reasonable to expect that the Department will provide further details regarding how the agency intends to approach implementation of the IRA given the breadth of these provisions and related resources. That said, the law does outline effective dates for various provisions. The implementation timeline chart below provides insight into when specific reforms will go into effect as well as when to anticipate that HHS may provide additional details regarding various provisions as corresponding effective dates draw near.

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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
Manufacturer 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
Manufacturer 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
Manufacturer must submit required information to HHS Secretary	March 1, 2025
HHS Secretary to provide written initial offer including proposal for MFP	June 1, 2025
Manufacturer 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
Manufacturer must submit required information to HHS Secretary to provide written initial offer including proposal for MFP	March 1, 2026
Manufacturer must accept offer or propose written counteroffer	June 1, 2026
Negotiation period ends	July 1, 2026, or within 30 days of receiving written offer
HHS publishes negotiated maximum fair prices for 2028 price applicability year	November 1, 2026
HHS selects 20 additional Part D or Part B negotiation-eligible drugs	November 30, 2026
2029 negotiation period begins	February 28, 2027
Manufacturer must submit required information to HHS Secretary	March 1, 2027

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Policy Action	Deadline/Effective Date
HHS Secretary to provide written initial offer including proposal for MFP	June 1, 2027
Manufacturer 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

Policy Action	Deadline/Effective Date
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
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

Stakeholders should continue to watch for additional announcements from HHS regarding the implementation of the IRA as each of the above dates draws near.

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