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Inflation Reduction Act: 2023 Marching Into the Darkness

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Introduction

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Insights

Core healthcare components of the Inflation Reduction Act (IRA)

- OOP cap in 2024
- Larger redesign to begin 2025
- Expands LIS eligibility
- $0 OOP for Part D vaccines
- $35 insulin OOP cap

- Medicare Part B and Part D price increases that outpace inflation owe rebates

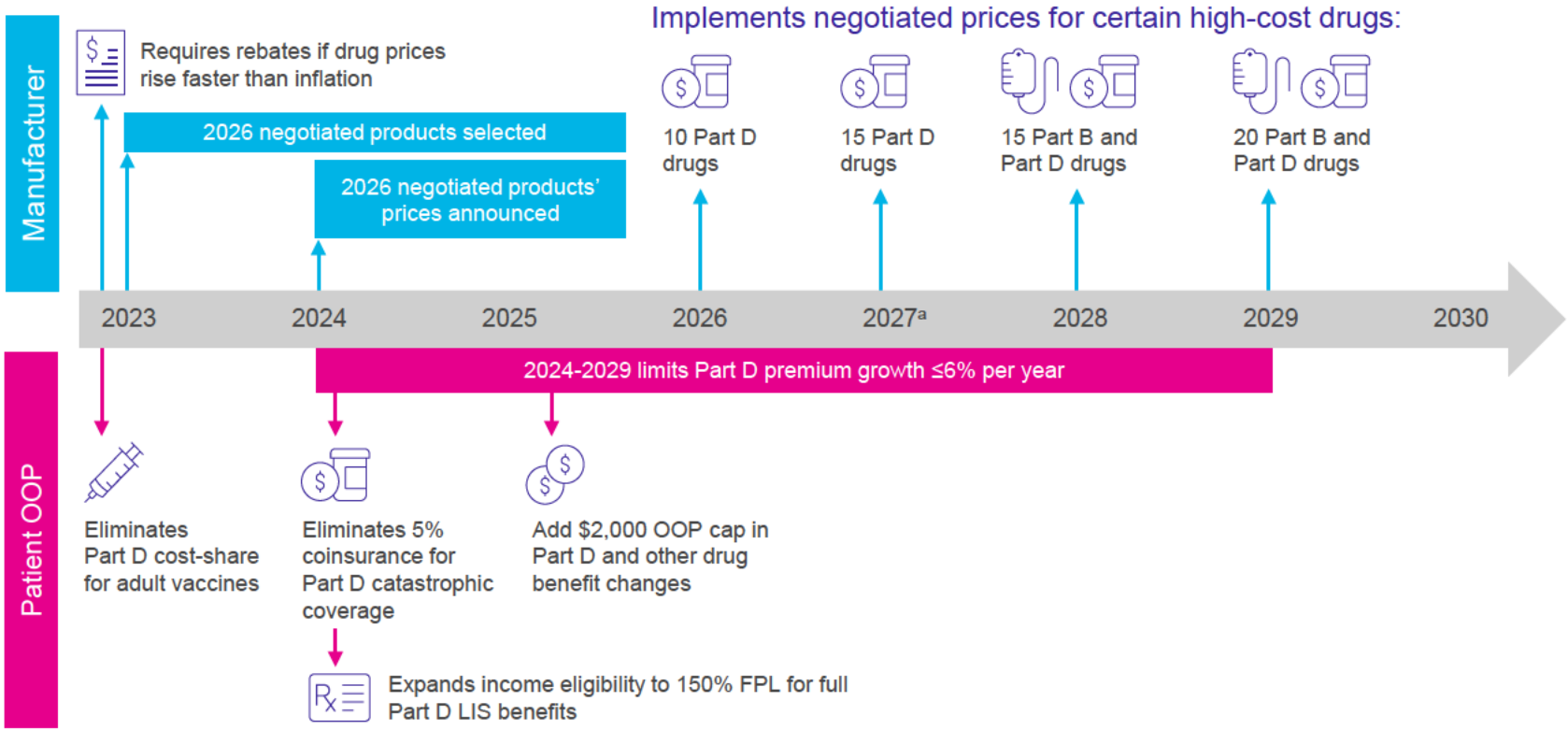
- Negotiation starts earlier (2023), implementation in 2026

- Starting October, ASP + 8% of reference biologics ASP
- Starting July 2024, when no ASP, lesser of 103% of WAC or ASP + 6% of reference

- Extends temporary subsidies through 2025 for <400% FPL

ASP – average sales price; FPL – Federal Poverty Level; LIS – low-income subsidy; OOP – out of pocket; WAC – wholesale acquisition cost.
Source: Inflation Reduction Act of 2022. https://www.congress.gov/117/bills/hr5376/BILLS-117hr5376enr.pdf

IRA implementation timeline for prescription drug provisions



Note: Repeals Trump Administration's drug rebate rule until 2031.

Implementation starts now

ICR:
- Biotech exception published on January 24

- **Revised guidance:** Medicare Drug Pricing Negotiation Program initial price applicability in 2026
- **ICR:**
  - Negotiation data elements published
  - Negotiation offer and counteroffer published
- **Deadline:** Submission to qualify for small biotech exception

- **February - August 2024:** Negotiation period
- **September 1, 2024:** Negotiated prices for the first 10 drugs announced
- **November 2024:** Presidential election
- **September 2025:** Part B inflation rebate invoices
- **December 31, 2025:** Part D inflation rebate invoices
- **January 1, 2026:** Negotiated prices go into effect

Winter 2023 | **Spring 2023** | **Summer 2023** | **Fall 2023** | **Looking Ahead**

- **Initial guidance:** Medicare Drug Pricing Negotiation Program initial price applicability in 2026
- **Comments Due:** Comment period on implementation of the Medicare Prescription Drug Inflation Rebate Program due March 11
- **ICR:**
  - Biotech exception comments due **March 27**
  - Negotiation data elements published
  - Negotiation offer and counteroffer exchange published

- **September 1:** CMS publishes list of first set of drugs selected for negotiation
- **October 1:** Deadline to sign manufacturer agreements
- **October 2:** Deadline to submit manufacturer-specific data for negotiation of maximum fair price
- **Revised guidance:** Medicare Prescription Drug Inflation Rebate Program expected in Q4

CMS – Centers for Medicare & Medicaid Services
ICR – Information Collection Request

Small Biotech Exception Information Collection Request (ICR)

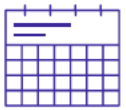
Background

In accordance with the IRA, CMS will exclude small biotech drugs for 2026 – 2028 that would otherwise qualify for negotiation

Key information

CMS seeks to identify whether a given drug meets the criteria for the Small Biotech Exception

Manufacturers seeking the exception must submit information to CMS about the company and its products to be considered for the exception



Key dates

Published in the Federal Register January 24, 2023

Comments due March 27, 2023

Initial guidance on inflation penalties released

Part B:
Medicare sales x (ASP inflation − CPI)

Initial guidance deemed to be final:
- Determination of Part B rebatable drugs
- Computation of beneficiary coinsurance
- Calculation of the Medicare Part B inflation rebate amount

CMS seeks comments to determine:
- Total number of drug units for calculating rebates, including but not limited to the removal of 340B units
- Units that are packaged into the payment amount for an item or service and are not separately payable
- Units that become multiple-source drugs
- Dual-eligible units (ie, when a Medicaid drug rebate was paid for a covered outpatient drug)

Part D:
Medicare sales x (AMP inflation − CPI)

CMS seeks comment on the following provisions:
- Part D rebatable drug
- Calculation of the Part D drug inflation rebate amount

CMS also seeks feedback on various procedures outlined in the guidance

ASP – average sales price; AMP – average manufacturer price; CPI – Consumer Price Index.
Source: Inflation rebates in Medicare. https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare

Brand manufacturers facing tough decisions

Prices

- Likely will pursue higher launch prices
- Prices for brand drugs and biosimilars *may* increase only at rate of inflation because of penalties
- May consider product-specific pricing changes
- Will be asked for rebates from payers for formulary placement or to compete with negotiated products
- Could be asked for rebates to help providers on commercial side

R&D

- Innovation could be focused on non-Medicare and/or biologics
- Pipelines could be reduced
- Could reconsider pursuing other indications
- Biosimilar launches (eventually) could be curtailed due to uncertainty of the originator brand price post-negotiation

R&D – research and development.

Many unanswered questions on Part D redesign

Part D plan reactions?

- How have Part D plans initially reacted to the increased financial liability?
- Will Part D formularies be narrower, starting in 2025?
- How will utilization management shift, especially in the protected classes?
- Will Part D plan availability become a challenge?
- How will CMS maintain its rigorous review process?

Manufacturer liability?

- What type of agreement will manufacturers need to sign with CMS?
- Will there be a third-party entity managing this new process?

Smoothing mechanism?

- What are the specifics related to the smoothing mechanism calculation?
- What will the enrollment process look like?
- What beneficiary protections will be built into CMS' guidance on the smoothing mechanism?
- How will these changes be communicated to Part D beneficiaries?

Part D plan initial reactions to IRA

Narrower formularies, especially outside of the protected classes

Increase in utilization management for specialty medications

Looking to industry for greater rebates and price concessions

Part D plan availability may be a concern for smaller Part D sponsors

Spillover effect from drug negotiations into the commercial sector

Need for greater regulatory clarity from CMS to gauge the full impact on Part D plans

The roadmap forward for planning for IRA


thank
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