Drug Pricing Provisions of the Inflation Reduction Act

Where do we go from here?

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Agenda



Drug Pricing Policy Landscape

Overview: Inflation Reduction Act

- Key Health Provisions
- Implementation Timeline

Negotiation Program

- Background
- Timeline
- Key Questions

Where Do We Go From Here?



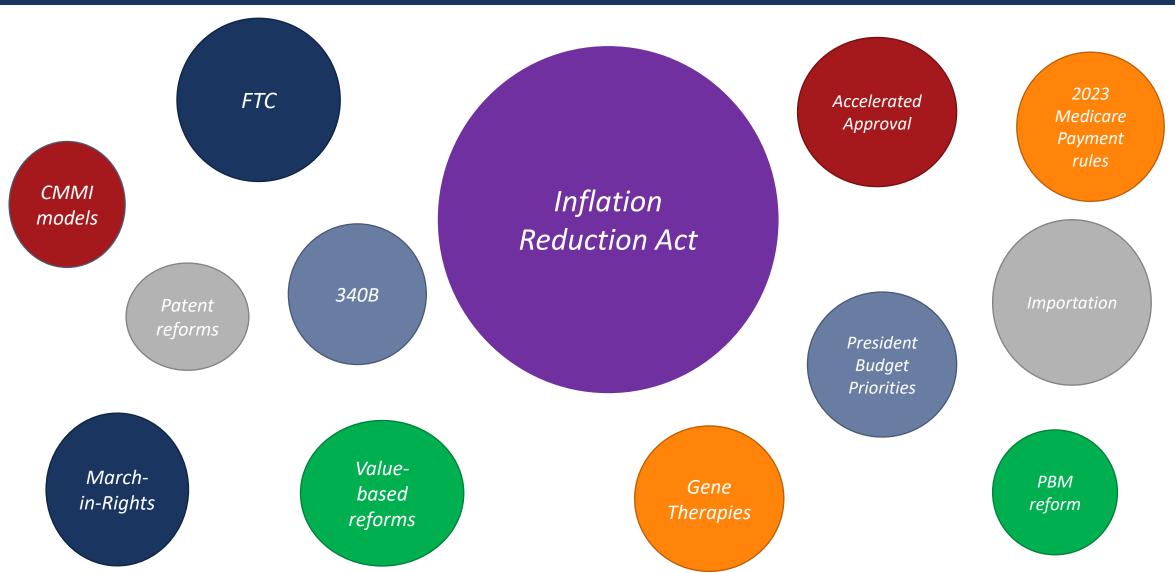
Drug Pricing Policy Landscape





Drug Pricing Policy Landscape





Overview: Inflation Reduction Act





Inflation Reduction Act Signed Into Law



President Biden signed Inflation Reduction Act into law on August 16, 2022.



Drug Provisions of the IRA





Requires HHS to negotiate prices for drugs covered under Medicare Parts B and D



Part D redesign: limits beneficiary out-of-pocket (among other things)



Inflationary rebates iin Medicare Parts B and D.



Caps cost sharing for insulin to \$35 in Medicare



Vaccines - eliminates cost sharing for vaccines under Medicare Part D; improves in Medicaid and CHIP



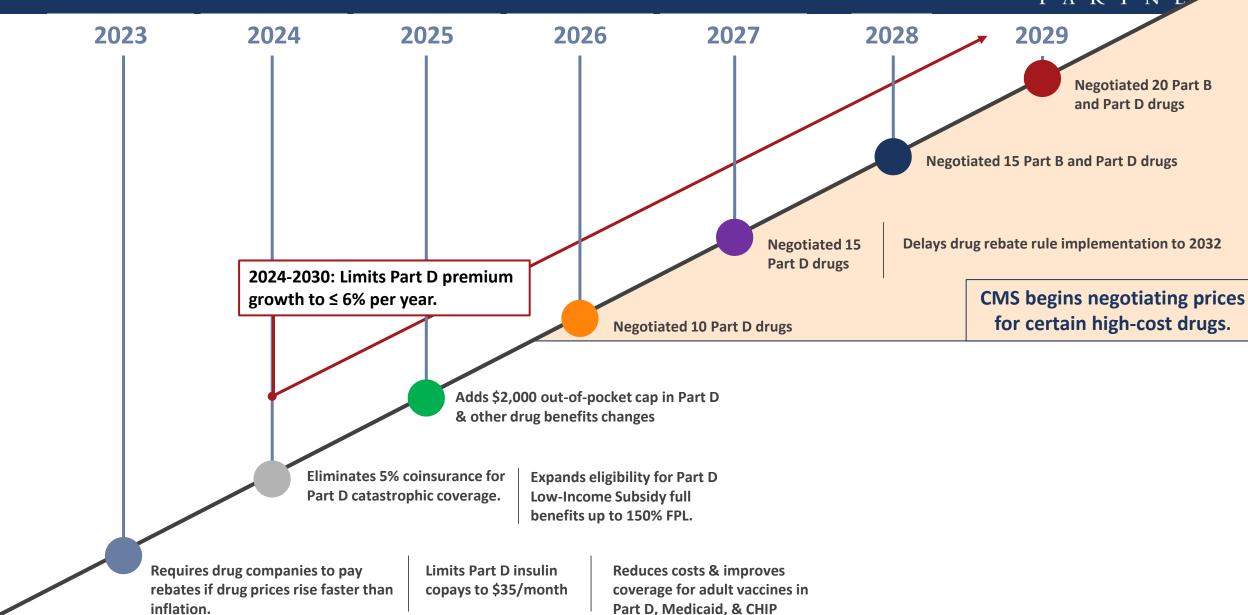
Expands eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program, beginning in 2024



Further delays implementation of the drug rebate rule

IRA Drug Provisions Implementation Timeline





Negotiation Program





Noninterference Clause Amended



 "Noninterference" clause prevented HHS Secretary from directly negotiating drug prices in Medicare Part D.

- IRA amended that restriction to enable the Negotiation program to move forward.
- Also allows negotiation in Medicare Part B.



CMS Implementation of IRA



On October 14, HHS announced the approval of charter amendments, renewals and terminations, and the establishment of the Medicare Drug Rebate and Negotiations Group

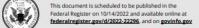
within CMS's Center for Medicare.

Purpose:

- Implement the *Inflation Reduction Act's* Drug Price Negotiation Program and the Inflation Rebate Program in Medicare Part B and D.
- Each year, the new group will negotiate drug prices with pharmaceutical manufacturers for certain Part B and Part D drugs.

Tasks:

- Developing policy, including identifying and vetting policy options and preparing policy memoranda, rulemaking, and technical guidance.
- Briefing policy officials in CMS, HHS, and Executive Office of the President.
- Establishing operational processes to collect data from manufacturers and other sources.
- Conducting pharmacoeconomic analyses and assessments of selected drugs.
- Establishing operational processes to negotiate and re-negotiate drug prices and conducting those negotiations with manufacturers.
- Establishing operational processes to calculate and invoice rebates.



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EPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Medicare Drug Rebate and Negotiations Group within the Center for Medicare (CM)

AGENCY: Centers for Medicare & Medicaid Services, Center for Medicare SUMMARY: Establish the Medicare Drug Rebate and Negotiations Group within the Center for Medicare (CM) to implement the Drug Price Negotiation Program and the Inflation Rebate Program in Medicare Part B and Part D as authorized under the Inflation Reduction Act of 2022. CMS is responsible for implementing these new programs.

DATES: This reorganization was approved by the Secretary of Health and Human Services and takes effect October 8, 2022.

SUPPLEMENTARY INFORMATION: Statement of Organization, Functions, and Delegations of Authority Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) (last amended at Federal Register, Vol. 75, No. 56, pp. 14176-14178, dated March 24, 2010; Vol. 76, No. 203, pp. 65197-65199, dated October 20, 2011; Vol. 78, No. 86, p. 26051, dated May 3, 2013; Vol. 79, No. 2, pp. 397-398, dated January 3, 2014; and Vol. 84, No. 32, p. 4470, dated February 15, 2019) is amended to reflect the establishment of the Medicare Drug Rebate and Negotiations Group within the Center for Medicare (CM) to implement the Drug Price Negotiation Program and the Inflation Rebate Program in Medicare Part B and Part D as authorized under the Inflation Reduction Act of 2022. CMS is responsible for implementing these new programs.



CMS Implementation of IRA



IRA Careers

Inflation Reduction Act



President Biden's <u>Inflation Reduction Act</u> allows Medicare to negotiate drug prices, caps out-of-pocket spending for prescription drugs in Medicare, and gives more Americans access to affordable health insurance coverage at HealthCare.gov.

To support implementation of this new law, CMS is hiring talented professionals in the following areas:

- > Health Insurance Specialist (Policy)
- > Supervisory Health Insurance Specialist
- > Director, Medicare Drug Rebate and Negotiations Group

On November 1, CMS launched a website seeking to hire more than 200 health care positions that were created as part of the *Inflation Reduction Act*.

- The agency is hiring for positions that span the health care spectrum including:
 - Economists
 - Pharmacists
 - Directors and analysts.
- Desired expertise:
 - Drug pricing
 - Pharmacoeconomic research
 - Health policy
 - Information technology
 - Management.

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CMS Guidance: IRA Drug Price Negotiation



On January 11, CMS released a memo highlighting important dates and milestones for the Drug Negotiation Program created under the *Inflation Reduction Act*.





Date: January 11, 2023
On Interested Parties

rom: Centers for Medicare & Medicaid Services Administrator Chiquita Brooks-LaSure ubject: Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026

Introduction

In August 2022, President Biden signed the Inflation Reduction Act (IRA) of 2022 (Pt. 117-169) into law. Among many other provisions, this landmark legislation will lower the cost of health insurance for American families; give peace of mind to 50 million seniors and people with disabilities by placing an annual out-of-pocket cap on Medicare prescription drug costs; build a clean energy economy and reduce harmful pollution; and make the tax code fairer for low- and middle-income Americans.

Further, this historic legislation will permit Medicare to negotiate the price of prescription drugs for the first time. Through this memo, the Centers for Medicare & Medicaid Services (CMS) is taking its first steps toward implementing the Medicare Drug Price Negotiation Program (or "Negotiation Program"), setting the stage for multiple comment opportunities for members of the public, people with Medicare and their families, beneficiary and consumer advocates, pharmaceutical manufacturers, health care providers, and other interested parties. As the law is implemented, with this memo and through opportunities that follow, CMS intends to prioritize transparency and robust engagement among all interested parties.

Summary

The IRA authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare Part B or Part D drugs. For the first year of the Negotiation Program, the Secretary will select 10 Part D high expenditure, single source drugs for negotiation. The maximum fair prices that are negotiated for these drugs will apply beginning in initial price applicability year 2026. The Secretary will select an additional 15 Part D drugs for negotiation for initial price applicability year 2027, 15 Part B or Part D drugs for initial price applicability year 2029, and 20 Part B or Part D drugs for initial price applicability year 2029 and subsequent initial price and pulcability year 2029.

This memo outlines how CMS will approach implementation of the Negotiation Program of the IRA for initial price applicability year 2026, including the following:

- (1) Engagement with the public;
- (2) Program guidance;
- (3) Information Collection Requests (ICRs) through the Paperwork Reduction Act (PRA) clearance process: and
- (4) A timeline outlining key dates.

Public feedback is critical to the success of the Negotiation Program, and this memo is one tool, among many, CMS will use to ensure interested parties know when and how they can make their voices heard on IRA implementation for initial price applicability year 2026. Plans for implementation of the Negotiation Program in subsequent years are forthcoming.

Winter 2023	ICR for small biotech exception published with a 60-day notice and public comment period
Spring 2023	Initial guidance: initial price applicability year 2026 (30-day comment period); ICR for small biotech exception submitted to OMB (30-day notice/comment period); ICR on negotiation data elements (60-day notice/comment period); ICR for negotiation offer and counteroffer exchange (60-day notice/comment period)
Summer 2023	Publish revised guidance for initial price applicability year 2026; deadlines for manufacturer requests on exceptions; ICR on negotiation offer and counteroffer exchange submitted to OMB (30-day notice/comment period); ICR for negotiation data elements submitted to OMB and published with a 30-day notice/comment period
Sept 1, 2023	CMS publishes list of 10 Part D selected drugs for initial price applicability year 2026
Oct 1, 2023	Deadline for manufacturers of selected drugs to sign an agreement with the Secretary to conduct negotiations
Oct 2, 2023	Deadline for manufacturers of selected drugs to submit data elements
Feb 1 – Aug 1 2024	Negotiation period; CMS sends initial offers of fair price on Feb 1, manufacturers have 30 days to respond
Sept 1, 2024	CMS publishes maximum fair prices
January 1, 2026	Price applicability period begins for selected drugs



Medicare Drug Price Negotiation Timeline: 2026



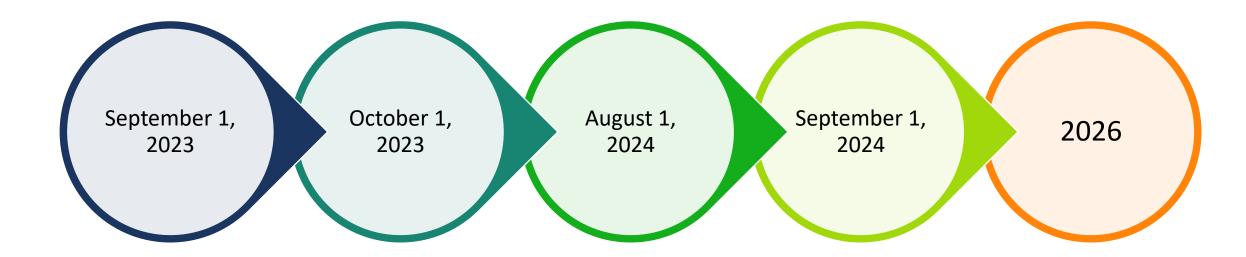
Drugs selected for negotiation published.

Negotiation process begins between HHS Secretary and drug manufacturers.

Negotiation process ends.

Maximum fair prices would be published by...

Negotiated prices take effect



Medicare Drug Price Negotiation Timeline: 2027



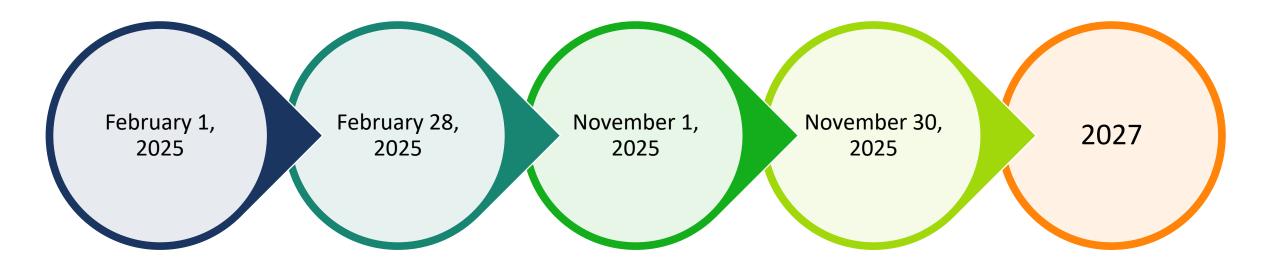
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Negotiation Program: Key Questions







Drugs?

Key

What's Included in the Initial Agreements?

Which Drugs are Eligible?

What is the Maximum Fair Price?

What Factors Must CMS **Consider During** Negotiations?



Negotiation: How Many Drugs?



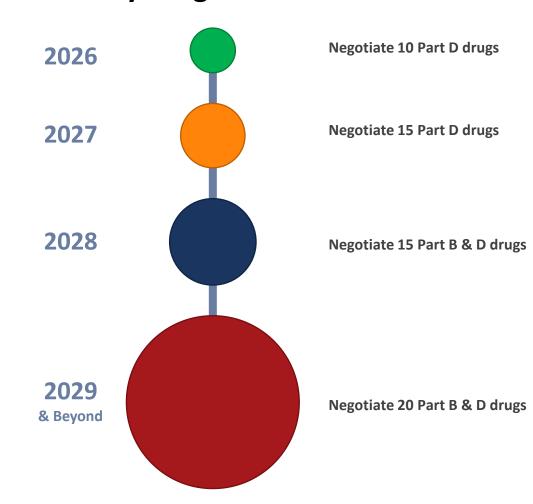
Background

- Annually, CMS will identify and publicize the list of selected drugs subject to negotiations
- A Maximum Fair Price (MFP), which is the result of the negotiation, applies until the drug is no longer a selected drug (which generally means it has market competition). More on this later.
- Renegotiation of the MFP is possible

Which drugs?

- HHS Secretary selects drugs to be negotiated from:
 - The 50 "negotiation-eligible" drugs with the highest total Medicare Part D spending and
 - The 50 "negotiation-eligible" drugs with the highest total Medicare Part B spending.

How many drugs?



The number of drugs included in the Program will accumulate over time.

Negotiation: Which Drugs are Eligible?



Eligible Drug Products

- A covered Part D or Part B drug that is FDA approved
- Continues to be marketed pursuant to FDA approval.
- Has had at least seven years elapse since FDA approval, and
- Is not the listed drug for any approved and marketed generic drug.

Eligible Biological Products

- A covered Part D or Part B biological product that is licensed
- Continues to be marketed pursuant to the license.
- Has had at least 11 years elapse since the date of licensure, and
- Is not the reference product for any approved and marketed biosimilar

Excluded

- Drugs that have a generic or biosimilar available
- Certain small biotech drugs (only from 2026 to 2028)
- Low-spend Medicare drugs
- Orphan drugs with only one rare disease indication (and it is the only FDA-approved indication)
- Plasma-derived products

Negotiation: What Must Be in the Initial Agreement?



After publication of the list of selected drugs, CMS and the drug manufacturers must enter into agreements detailing the negotiation process and consenting to Program requirements, including

- Providing the drug at the MFP
- Renegotiating the MFP under specific circumstances
- Providing drug pricing information (e.g. Average Manufacturing Price) for the negotiation manufacturer Drugs that have a generic or biosimilar available
- Ongoing compliance with requirements of the Program



Negotiation: What Must CMS Consider?



During price negotiations or renegotiations, the Secretary is required to consider the following specified factors.

Manufacturer-Specific Information

(including as submitted by the manufacturer)

- The manufacturer's research and development costs for the drug and the extent to which the manufacturer has recouped those costs
- Unit costs of production and distribution.
- Prior federal financial support for novel therapeutic discovery and development with respect to the drug
- Data on patents and on existing and pending exclusivity for the drug
- Market data and national sales volume data for the drug

Information on the Drug and Alternative Treatments

- The extent to which the drug represents a therapeutic advance, as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives
- Prescribing information approved by the FDA for such drug and therapeutic alternatives of such drug
- Comparative effectiveness for such products and therapeutic alternatives for such products....
- The extent to which such alternatives address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by an available therapy

The Secretary is **prohibited** from using evidence or findings from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill

Negotiation: What is the Maximum Fair Price?



Key Point:

• The negotiated MFPs face a price ceiling and floor.

Simply Put:

- This ceiling will be the lower of the drug's:
 - Enrollment-weighted negotiated price (net of all price concessions) for a Part D drug or Average Sales Price for a Part B drug; or
 - Percentage of the non-federal average manufacturer price.
- The Secretary will publish information on the MFP and the factors used to determine the MFP by the dates set forth in the statute.
- If a drug is not subject to renegotiation, the price will increase each year by the annual percentage increase in the CPI-U.



Negotiation: What if No Agreement?



Financial penalties will be imposed on drug manufacturers for non-compliance

- An excise tax will be imposed for not negotiating with CMS, starting at 65 percent and increasing to 95 percent.
- Also, there is a civil monetary penalty for failure to offer the agreed-upon maximum fair price.







What's Next?





Where Do We Go From Here?



CMS implementation

- Many issues of first impression which will have significant precedential impact.
- Massive undertaking to build the infrastructure, hire the employees, etc.

Congressional Oversight

- Congressional Republicans have raised concerns with Negotiation Program.
- Democratic efforts to ensure Inflationary Rebate policy goes forward as scheduled.

Possible Legislation

- Increase the years before drugs eligible for negotiation.
- Allow additional orphan designations.
- Other issues may be identified as the implementation and oversight continue.



