

# MEDICARE DRUG PRICE NEGOTIATION PROGRAM

CENTERS FOR MEDICARE & MEDICAID SERVICES

In August 2022, President Biden signed the Inflation Reduction Act into law – one of the most consequential health care laws since the Affordable Care Act. The Biden-Harris Administration has made expanding access to high-quality, affordable health care a top priority, and with the Inflation Reduction Act, millions of Americans will see lower health care costs and finally see their prescription drug costs go down.

Key health care provisions of the Inflation Reduction Act include:



Continuing enhanced tax credits that helped 13 million people covered under the Affordable Care Act **save an average of \$800** on their Marketplace health insurance in 2022



Capping a month's supply of each **covered insulin at \$35** for people with Medicare



**Eliminating catastrophic cost sharing** and capping annual out-of-pocket drug costs for prescription drugs for people with Medicare Part D



Allowing Medicare to **negotiate** better prescription drug prices



Requiring drug companies to **pay a rebate to Medicare** if they raise their prices faster than inflation

## Drug Price Negotiation Timeline for 2026

### Initial actions for the Medicare Drug Price Negotiation Program:

#### January 11, 2023

The Centers for Medicare & Medicaid Services (CMS) will release information on how it will engage members of the public (including people with Medicare, consumer advocates, prescription drug companies, Medicare Advantage and Part D plans, health care providers and pharmacies, and other interested parties) on key policies, make requests for information, and inform the public on other implementation timelines and milestones.

#### Winter 2023

CMS will begin to propose its data collection processes essential to carrying out the first year of the Negotiation Program. These proposals will be available for public input. The first proposal will include a data collection process to gather information necessary to identify which drugs qualify for the small biotech manufacturer exemption in the early years, as provided for under the Inflation Reduction Act.

#### Spring 2023

CMS will issue guidance for the negotiation process for 2026 and invite public comment on key elements, such as the offer and counteroffer process between Medicare and prescription drug companies, and the methodology for applying maximum fair prices.

In addition, CMS will propose its data collection processes and invite public comments on proposals that will ask for input on data and information the federal government must collect for consideration when negotiating the maximum fair prices, as well as information to be included in the offer and counteroffer process.

#### June 1, 2022 - May 31, 2023

The time period for which data on total expenditures under Medicare Part D will be used to determine Medicare Part D negotiation-eligible drugs for 2026 (the first year of negotiation).

For decades, leaders have tried and failed to pass legislation allowing Medicare to negotiate prescription drug prices. The Biden-Harris Administration finally got it done by signing into law the Inflation Reduction Act. Starting this year, the Secretary of the Department of Health and Human Services will begin the process of negotiating the prices of prescription drugs in Medicare.

The law outlines multiple steps in the negotiation process, including:



**Identifying** Medicare drugs eligible for negotiation



**Selecting** Medicare drugs for which prices will be negotiated



**Collecting information** to use for negotiation



An **offer and counteroffer process** between Medicare and prescription drug companies

As required by the Inflation Reduction Act, the first 10 drugs selected will be Medicare Part D drugs and will be announced in 2023, allowing the negotiation process to proceed. The negotiated maximum fair prices for these drugs will apply beginning in 2026.

Find additional details in the [\*\*accompanying memo\*\*](#).



### Summer 2023

CMS will update its guidance as needed for the negotiation process for 2026 and data collection requests. CMS will seek additional comment on the proposals for data and information collection.

### September 1, 2023

CMS will publish a list of 10 Medicare Part D drugs selected for negotiation for 2026.

### October 1, 2023

Deadline for companies of drugs selected for the Negotiation Program to sign agreements to participate in the negotiation process for 2026.

### October 2, 2023

Deadline for companies of drugs selected for the Negotiation Program to submit manufacturer-specific data to CMS to consider in the negotiation of maximum fair price.

### February 1, 2024

CMS sends initial offers of a maximum fair price with a justification for a selected drug to each company participating in the Negotiation Program. The negotiation period begins.

### March 2, 2024

Companies have 30 days from receiving offers of a maximum fair price for a drug to accept the offer or propose a counteroffer, if desired.

### August 1, 2024

The negotiation period ends.

### September 1, 2024

CMS will publish maximum fair prices for drugs selected for negotiation for 2026.

### January 1, 2026

Maximum fair prices are effective for selected drugs.

### More information:

[cms.gov/inflation-reduction-act-and-medicare](https://www.cms.gov/inflation-reduction-act-and-medicare)