Understanding the Health Care Provisions in the Inflation Reduction Act

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Submit Questions for Q&A

**Attendee audio and video is turned off**, so if you would like to submit a question for the panelists, please click on the Q&A button at the bottom of your screen:

You can submit questions for the Q&A session at any time during the web briefing; we will answer as many as we can after the presentation.
Americans Are Concerned About the Cost of Prescription Drugs

83% of adults think the cost of prescription drugs is unreasonable

29% say in the last year, they have not taken prescription medicines as directed because of costs

26% of adults say it is very difficult for them to afford to pay for their prescription drugs

SOURCE: KFF, “Public Opinion on Prescription Drugs and Their Prices,” April 2022.
For the first time, requires the federal government to negotiate prices for some of the highest-spending drugs covered under Medicare.

Requires drug companies to pay rebates if prices rise faster than inflation for drugs used by Medicare beneficiaries.

Eliminates 5% coinsurance for catastrophic coverage in Medicare Part D in 2024, adds a $2,000 cap on Part D out-of-pocket spending in 2025, and limits annual increases in Part D premiums for 2024-2030.

Limits monthly cost sharing for insulin products to $35 for people with Medicare.

Expands eligibility for Medicare Part D Low-Income Subsidy full benefits.

Eliminates cost sharing for adult vaccines covered under Medicare Part D and improves access to adult vaccines under Medicaid and CHIP.

Further delays implementation of the Trump Administration’s drug rebate rule.

NOTE: *Based on the Senate-passed legislation.
Implementation Timeline of the Prescription Drug Provisions in the Inflation Reduction Act

- **2023**: Requires drug companies to pay rebates if drug prices rise faster than inflation.
- **2023**: Limits insulin copays to $35/month in Part D.
- **2023**: Reduces costs and improves coverage for adult vaccines in Medicare Part D, Medicaid & CHIP.

- **2024**: Eliminates 5% coinsurance for Part D catastrophic coverage.

- **2025**: Adds $2,000 out-of-pocket cap in Part D and other drug benefit changes.

- **2026**: Implements negotiated prices for certain high-cost drugs:
  - 10 Medicare Part D drugs

- **2027**: Implements negotiated prices for certain high-cost drugs:
  - 15 Medicare Part D drugs

- **2028**: Implements negotiated prices for certain high-cost drugs:
  - 15 Medicare Part B and Part D drugs

- **2029**: Implements negotiated prices for certain high-cost drugs:
  - 20 Medicare Part B and Part D drugs

- **2024-2030**: Limits Medicare Part D premium growth to no more than 6% per year.

- **2023-2029**: Further delays implementation of the Trump Administration’s drug rebate rule to 2032.
Requiring the Federal Government to Negotiate Prices for Some High-Cost Drugs Covered by Medicare

Which drugs qualify?
High-spending brands and biologics without generic or biosimilar equivalents and 9+ years (small-molecule drugs) or 13+ years (biologicals) from FDA approval (with some exceptions)

How many drugs qualify?
- 10 Part D drugs in 2026; 15 Part D drugs in 2027; 15 Part D and Part B drugs in 2028; 20 Part D and Part B drugs in 2029 & later years

What is the “maximum fair price”?
The lowest of the Part D enrollment-weighted negotiated price, the Part B average sales price, or a % of the drug’s non-federal average manufacturer price:
- 75%: 9 years but <12 years beyond approval
- 65%: 12 years but <16 years beyond approval
- 40%: 16+ years beyond approval

What are the penalties for non-compliance?
- Excise tax for not negotiating, starting at 65% of a drug’s prior year sales, increasing by 10% every quarter up to 95%; tax suspended if manufacturers choose to have their drugs no longer covered by Medicare or Medicaid
- Civil monetary penalty for not offering negotiated price of up to 10x difference between price charged and negotiated price
Medicare Drug Price Negotiation Timeline for 2026 & 2027

- **Drugs selected for negotiation published**: September 1, 2023
- **Negotiation process begins between HHS Secretary and drug manufacturers**: October 1, 2023
- **Negotiation process ends**: August 1, 2024
- **Maximum fair prices would be published by**: September 1, 2024
- **Negotiated prices take effect**: 2026

- **Drugs selected for negotiation published**: February 1, 2025
- **Negotiation process begins between HHS Secretary and drug manufacturers**: February 28, 2025
- **Negotiation process ends**: November 1, 2025
- **Maximum fair prices would be published by**: November 30, 2025
- **Negotiated prices take effect**: 2027
Requires Drug Manufacturers to Pay Rebates For Drug Price Increases Above Inflation

- Requires drug manufacturers to pay a rebate if drug prices increase faster than the rate of inflation (CPI-U) for:
  - Single-source drugs and biologicals covered under Medicare Part B
  - All covered drugs under Medicare Part D except those where average annual cost is <$100

- 2021 is the base year for measuring cumulative price changes relative to inflation
- The rebate amount is based on units sold in Medicare multiplied by the amount that a drug’s price in a given year exceeds the inflation-adjusted price
- Price changes are measured based on the average sales price (for Part B drugs) or the average manufacturer price (for Part D); these measures include prices charged in the commercial market
- Rebates paid by manufacturers would be deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund
- Manufacturers that do not pay the required rebate would face a penalty of at least 125% of the original rebate amount
Capping Medicare Part D Out-of-Pocket Spending and Other Part D Benefit Changes

Changes would lower beneficiary spending, reduce Medicare’s liability for high drug costs, and increase Part D plan and manufacturer liability for high drug costs

<table>
<thead>
<tr>
<th>Beneficiaries</th>
<th>Medicare</th>
<th>Part D Plans</th>
<th>Drug Companies</th>
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<tbody>
<tr>
<td>• Eliminates 5% coinsurance for catastrophic coverage in 2024</td>
<td>• Lowers share of costs above the out-of-pocket spending cap (“reinsurance”)</td>
<td>• Increases share of costs above the out-of-pocket spending cap</td>
<td>• Requires a price discount on brand-name drugs above the out-of-pocket spending cap</td>
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<td>• Caps out-of-pocket drug spending at $2,000 beginning in 2025</td>
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<td>• Modifies share of costs below the out-of-pocket spending cap</td>
<td>• Modifies the price discount on brands below the out-of-pocket spending cap</td>
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<td>• Allows spreading out of out-of-pocket costs over the year</td>
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<td>• Limits premium growth to no more than 6% per year for 2024-2030</td>
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NOTE: OOP is out-of-pocket. The out-of-pocket spending threshold will be $7,400 in 2023 and is projected to be $7,750 in 2024 and $8,100 in 2025, including what beneficiaries pay directly out of pocket and the value of the manufacturer discount on brand-name drugs in the coverage gap phase. These amounts translate to out-of-pocket spending of approximately $3,100, $3,250, and $3,400 (based on brand-name drug use only).
Beginning in 2023, **limits copayments to $35 per month** per prescription for **covered insulin** products in **Medicare Part D** plans and for insulin furnished through durable medical equipment under **Medicare Part B**, **with no deductible**

For 2026 and beyond, limits monthly Part D copayments for insulin to the lesser of:

- $35
- 25% of the maximum fair price (in cases where the insulin product has been selected for negotiation)
- 25% of the negotiated price in Part D plans
Expands Eligibility for Part D Full Low-Income Subsidy Benefits and Improves Coverage of Adult Vaccines

Expands Eligibility for Full Benefits under the Part D Low-Income Subsidy (LIS) Program

- The LIS program helps Medicare beneficiaries with their Part D premiums, deductibles, and cost sharing. Beneficiaries qualify for full or partial benefits depending on their income and resources:
  - **Full benefits:** income up to 135% FPL & resources up to $9,900 individual, $15,600 couple in 2022*
  - **Partial benefits:** income between 135-150% FPL & resources up to $15,510 individual, $30,950 couple in 2022*
- The Inflation Reduction Act expands eligibility for full LIS benefits to individuals with incomes between 135-150% of FPL and resources at or below the limits for partial LIS benefits

Implements Coverage of Adult Vaccines

- Eliminates cost sharing for adult vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as for shingles
- Requires state Medicaid programs to cover all approved adult vaccines recommended by ACIP and vaccine administration, without cost sharing

NOTE: *Includes a $1,500 per person allowance for funeral/burial expenses.
Delays Implementation of the Trump Administration’s Rebate Rule

What is the Rebate Rule?
It would eliminate rebates negotiated between drug manufacturers and pharmacy benefit managers (PBMs) or health plan sponsors in Medicare Part D by removing the safe harbor protection currently extended to these rebate arrangements under the federal anti-kickback statute. The rule was estimated to result in higher Medicare spending and higher Part D premiums.

2019
- Jan: Trump Administration issued proposed rule to ban rebates in Part D
- July: Trump Administration withdrew proposed rebate rule

2020
- July: Trump Administration issued executive order to finalize rebate rule

2021
- Mar: Biden Administration delayed implementation of rebate rule to 2023

2022
- June: Bipartisan Safer Communities Act delays implementation from 2026 to 2027
- July: Infrastructure Investment and Jobs Act delays implementation from 2023 until 2026
- July: Inflation Reduction Act further delays rebate rule implementation to 2032

What is the Rebate Rule?
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Number of Medicare Beneficiaries Potentially Affected by Selected Provisions in the Inflation Reduction Act

- **Eliminating the 5% coinsurance requirement for Medicare Part D catastrophic coverage**: 1.3 million Medicare Part D enrollees without low-income subsidies had spending above the catastrophic coverage threshold in 2020.
- **Capping out-of-pocket drug costs in Medicare Part D at $2,000**: 1.4 million Medicare Part D enrollees without low-income subsidies had annual out-of-pocket drug spending of $2,000 or more in 2020.
- **Eliminating cost sharing for adult vaccines covered under Medicare Part D**: 4.1 million Medicare Part D enrollees received a vaccine covered under Part D in 2020.
- **Expanding eligibility for full benefits for Medicare Part D Low-Income Subsidies up to 150% FPL**: 0.4 million Medicare Part D enrollees received partial benefits under the Low-Income Subsidy program in 2020.

NOTE: Estimates of beneficiaries potentially affected by these provisions are likely to be conservative because they are based on 2020 data and do not reflect increases in drug spending from 2020 to the year of implementation, growth in the population, or any increase in drug use and spending attributable to reduced financial barriers.

A Tale in Three Acts

The Affordable Care Act (ACA), 2010:
- Created health insurance Marketplaces where people can get subsidies
- Subsidies originally only available to people with incomes between 1 and 4 times the poverty level (roughly $50k for an individual or $100k for a family of four)
- Many people making over 4 times poverty were priced out and subject to steep premium increases

The American Rescue Plan Act (ARPA), 2021:
- Removed the upper income limit on subsidies
- Increased the amount of financial assistance for people who were already eligible
- A record 14.5 million people signed up for coverage, including 13 million with subsidies

The Inflation Reduction Act (IRA), 2022:
- If passed, will continue the subsidies in the American Rescue Plan Act without interruption for additional 3 years (through 2025)
- Prevents hikes in premium payments millions of enrollees would have faced if ARPA expired
The Inflation Reduction Act would continue eligibility for premium assistance for middle-income enrollees

Number of People Eligible for Marketplace Subsidies Before and After American Rescue Plan Act

- Below 150% FPL
- 150%-250%
- 250%-400%
- 400%-600%
- More Than 600%

**NOTE:** Prior to the ARPA, California was the only state to offer financial assistance to people making over 400% of poverty.

**SOURCE:** KFF analysis of 2019 American Community Survey - PNG
The Inflation Reduction Act would continue to lower Marketplace premium payments across the board.

Average Premium Cost and Subsidy Among Current Individual Market Enrollees Under American Rescue Plan Act

NOTE: Premiums shown reflect the second-lowest cost silver plan. Average premiums in the chart rise with income because higher income enrollees tend to be older and thus have higher premiums on average. Prior to the ARPA, California was the only state to offer premium subsidies to people making over 400% of poverty.

SOURCE: KFF analysis of 2019 American Community Survey. • Get the data
If the Inflation Reduction Act did not pass…

- American Rescue Plan Act subsidies expire
- Nearly all 13 million subsidized enrollees experience a hike in premium payment
- Average premium payment 53% higher, over $700 increase annually
- The “subsidy cliff” would return
- Marketplace shoppers find out about these increased in late October/early November
- Premium payments effective January 1, 2023
- Some would be hit by “double whammy”
If the Inflation Reduction Act did not pass, premium increases would vary by state.
These enhanced subsidies come at a cost

- For permanently extending the American Rescue Plan Act subsidies, the Congressional Budget Office (CBO) estimated:
  - Cost of about $25 billion per year based on 10-year estimate¹
  - Includes both increased federal spending and changes in revenue
  - Includes assumptions on changes in enrollment, premiums, and risk pool

- How much it actually costs will depend on:
  - How many people will sign up?
    - CBO expects 4.8 million more Marketplace enrollees than baseline
    - In 2022, 14.5 million signed up for Marketplace coverage (net 2.5 million increase from 2021)
  - How much premium costs rise?
    - For 2023, rate increases in 13 states and DC about 10%, based on early analysis²

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