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# The Inflation Reduction Act Health Care Provisions: Implications for States

**National Council of Insurance Legislators Annual Meeting, November 19, 2022**

Speaker: Alex Dworkowitz

# Agenda



- Overview of the Inflation Reduction Act Prescription Drug Provisions
- Drug Price Negotiation
- Inflation Rebates
- Medicare Part D Redesign
- Other Health Care Provisions
- The State Perspective



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# Inflation Reduction Act (IRA) of 2022



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# IRA at a Glance



**IRA is a sweeping overhaul of prescription drug pricing regulation. For the first time, the federal government will directly regulate the price of prescription drugs in Medicare and, indirectly, limit the ability of drug manufacturers to increase wholesale prices. At the same time, the legislation makes major changes to the Medicare Part D prescription drug benefit.**

**Significant changes to U.S. prescription drug price law include:**

- Allowing the government to regulate the price of certain drugs under Medicare for the first time under the Drug Price Negotiation Program, through which the government must establish a “maximum fair price” for certain drugs
- Requiring pharmaceutical manufacturers to pay rebates to Medicare if they increase list prices faster than the rate of inflation
- Overhauling the Medicare Part D benefit including by creating an annual $2,000 out-of-pocket cap on beneficiary Part D prescription drug spending
- Capping insulin costs for Medicare enrollees at $35 per month



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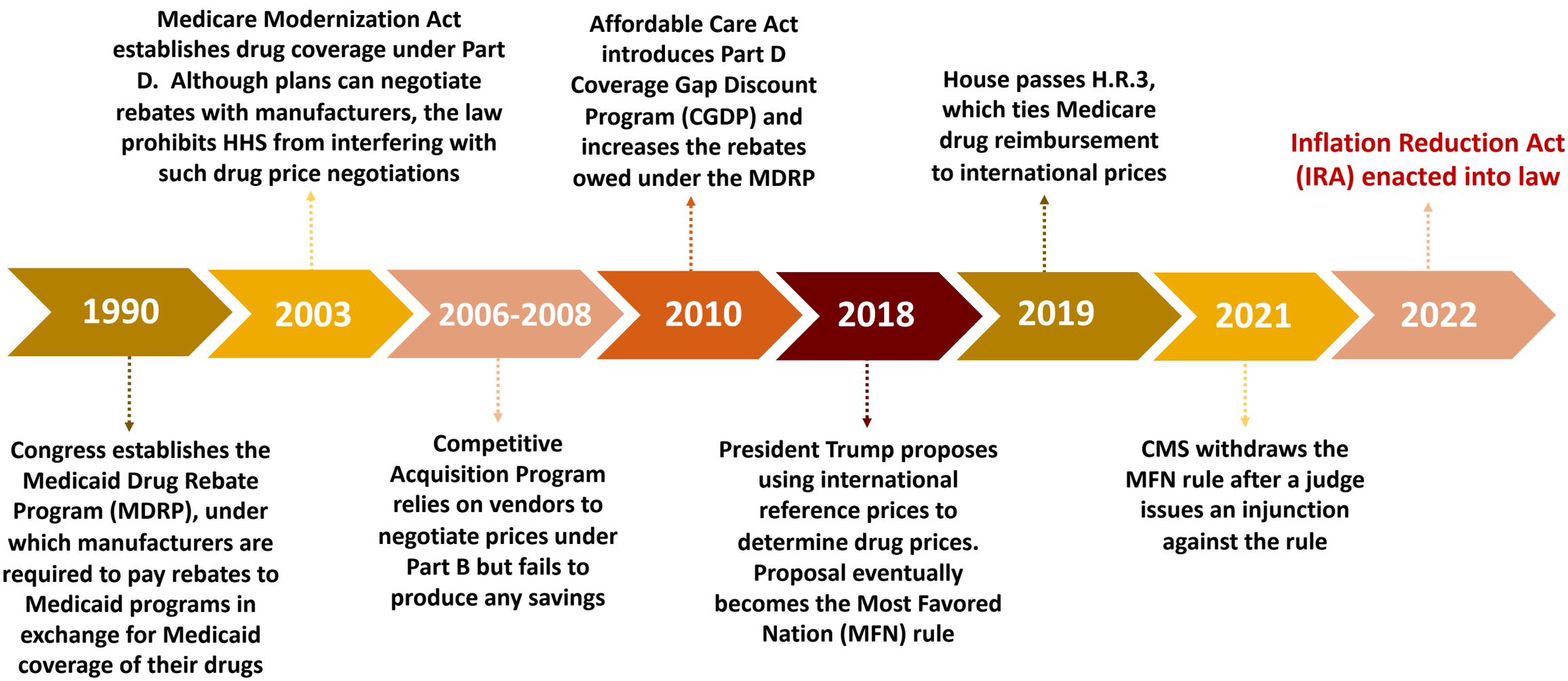
# History of Drug Price Regulation Under Medicare and Medicaid





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# Drug Price Negotiation



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# Drug Price Negotiation



**The Inflation Reduction Act requires HHS to regulate the price of certain drugs under Medicare under a "Drug Price Negotiation Program"**

- HHS establishes a "maximum fair price" (MFP) for selected drugs.
- Each drug has a ceiling price that is tied to the drug's historical pricing and other factors.
- But MFP may be lower than the ceiling price; no limit on how low MFP may be.
- The MFP will first apply in 2026 in Medicare Part D and, starting in 2028, in both Parts B and D.
- MFP applies to Medicaid and the 340B program as well, since MFP impacts Medicaid best price and therefore the 340B price.



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# Selection Process for the Drug Price Negotiation Program



## Step 1

**Establish List of "Qualifying Single Source Drugs"**

1. **On the selected drug publication date, identify all drugs with Medicare sales exceeding $200 million/year in the reference period that:**
   - For small molecule drugs with no marketed generic, were FDA-approved more than 7 years ago
   - For biologics with no marketed biosimilar, were FDA- licensed more than 11 years ago
2. **Exclude drugs and biologics that are exempted (orphans, plasma-derived)**

## Step 2

**Establish List of "Negotiation-Eligible Drugs"**

1. **Order from highest to lowest spending the 50 Part D "Qualifying Single Source Drugs" with the highest spending for the applicable year**
   - Excluding drugs and biologics previously selected
   - Excluding any Small Biotech Drugs (for 2026, 2027, 2028)
2. **Order from highest to lowest spending the 50 Part B "Qualifying Single Source Drugs" with the highest spending for the Medicare spending reference period**
   - Excluding drugs and biologics previously selected
   - Excluding any Small Biotech Drugs (for 2026, 2027, 2028)
3. **Combine lists (except only use Part D list for 2026 and 2027), and rank again from highest to lowest spending**
4. **Select starting from the drug with the highest spending up to the number of drugs required for particular year (i.e., 10 for 2026, 15 for 2027, 15 for 2028, and 20 in subsequent years) or, if there is not a sufficient number, all ranked drugs**



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# Drug Selection Timeline



## Number of Drugs Selected by Year

**Price Applicability Year 2026**

**Drugs Selected**

10 qualifying Part D drugs with highest Medicare spending in reference period

**Medicare Spending Reference Period**

Jun 1, 2022 – May 31, 2023

**Selected Drug Publication Date**

Sep 2023

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**Price Applicability Year 2027**

**Drugs Selected**

15 additional qualifying Part D drugs with highest Medicare spending in reference period

**Medicare Spending Reference Period**

Nov 1, 2023 – Oct 31, 2024

**Selected Drug Publication Date**

Feb 2025

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**Price Applicability Year 2028**

**Drugs Selected**

15 additional qualifying Part B or D drugs with highest Medicare spending in reference period

**Medicare Spending Reference Period**

Nov 1, 2024 – Oct 31, 2025

**Selected Drug Publication Date**

Feb 2026

## Number of Drugs Selected by Year

**Price Applicability Year 2029**

**Drugs Selected**

20 additional qualifying Part B or D drugs with highest Medicare spending in reference period

**Medicare Spending Reference Period**

Nov 1, 2025 – Oct 31, 2026

**Selected Drug Publication Date**

Feb 2027

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**Price Applicability Year 2030 and Beyond**

**Drugs Selected**

20 additional qualifying Part B or D drugs with highest Medicare spending in reference period

**Medicare Spending Reference Period**

(period in year prior to selected drug publication date)

Nov 1 – Oct 31

**Selected Drug Publication Date**

Feb, two years prior to applicability

Note: For each year, the number of selected drugs may be less than the number specified if there is not a sufficient number of qualifying drugs.



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# Process is Based on Drugs Without Competition



- Drugs with marketed generics or biosimilars are excluded
- Biologics also may be excluded that face “imminent” biosimilar competition
  - Application made by potential biosimilar
  - HHS must determine if there is “clear and convincing evidence”
  - One year deferral extendable to two years
  - If biosimilar doesn’t come to market, reference product subject to retrospective rebate
- Competitors coming to market can terminate the negotiation and price regulation process

# Inflation Rebates



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# Overview of Inflation Rebates



**IRA mandates that manufacturers pay rebates to the Supplemental Medical Insurance trust fund if they increase the price of their Medicare Part B and Part D drugs faster than inflation**

- Rebates are modeled under the Medicaid Drug Rebate Program, which has required inflationary rebates since its inception in 1990.
- Due to a ruling of the Senate parliamentarian, the bill was modified so that rebates are only owed for units paid for under Medicare Part B or Part D. Earlier versions of the legislation required the payment of rebates to Medicare for units reimbursed by commercial payers.
- Rebates are excluded from calculations of best price and AMP, which are used to determine the amount of rebates owed under Medicaid.
- Manufacturers are subject to civil monetary penalties for failure to pay rebates.
- There is no administrative or judicial review of the determination of the number of units subject to such rebates, the determination of whether a drug is subject to rebates, and the calculation of the rebate amount.

# Medicare Rebates Compared to Medicaid Rebates



| | Medicare Part B | Medicare Part D | Medicaid |
|---|---|---|---|
| Rebates owed for generics/ biosimilars? | Typically no | Typically no | Yes |
| Units included if subject to bundled payments? | No | N/A | No |
| 340B units included? | No | Yes until 2026 | No |
| Managed care units included? | Not specified | Yes (Part D all managed care) | Yes |
| Rebates owed if no price increase? | No | No | Yes (minimum of 23.1% of AMP) |
| Manufacturer reporting requirements? | None | None | Yes (AMP, best price, WAC) |
| Dispute resolution process? | None | None | Yes |
| Reduces beneficiary cost sharing? | Yes | No | No |

# Part D Redesign



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# Overview of Part D Redesign



**IRA makes the most significant changes to the Part D benefit since the program's creation and the Affordable Care Act's (ACA) provisions to close the so-called "donut hole."**

## Beneficiaries

- New OOP cap (2025)
- Transitional OOP cap (2024)
- Insulin and vaccine cost sharing limits
- Premium increases limited

## Plans

- More responsibility in former coverage gap
- More risk in catastrophic phase

## Manufacturers

- Coverage Gap Discount Program sunset
- New manufacturer discounts:
  - 10% in coverage phase
  - 20% after OOP cap
  - Applies to LIS beneficiaries (with phase in)



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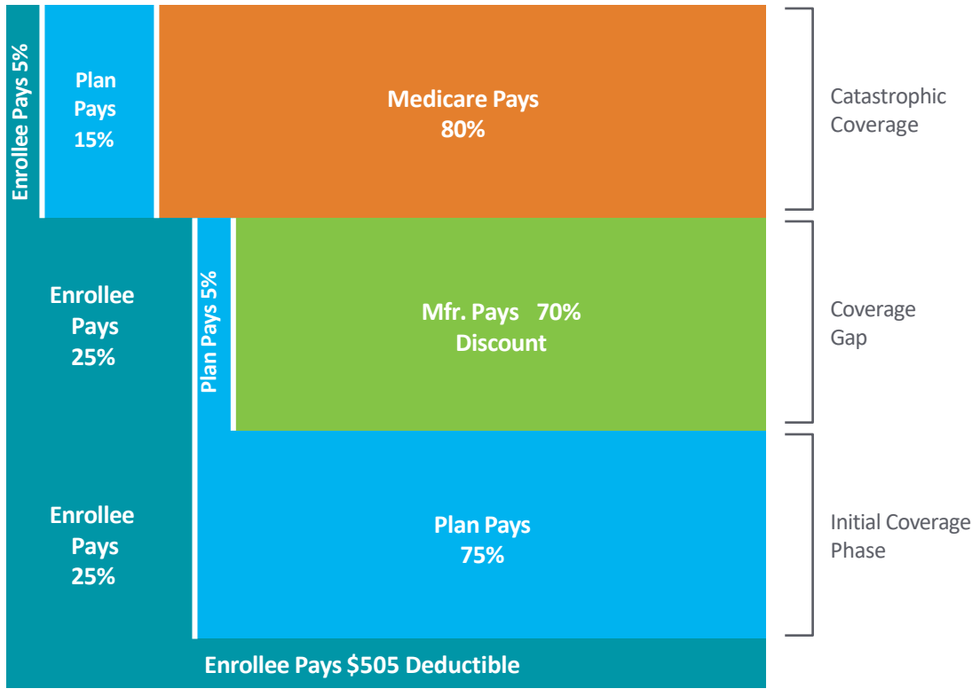
# Changes in Part D benefit for Brand Drugs



## Old Standard Medicare Part D Benefit

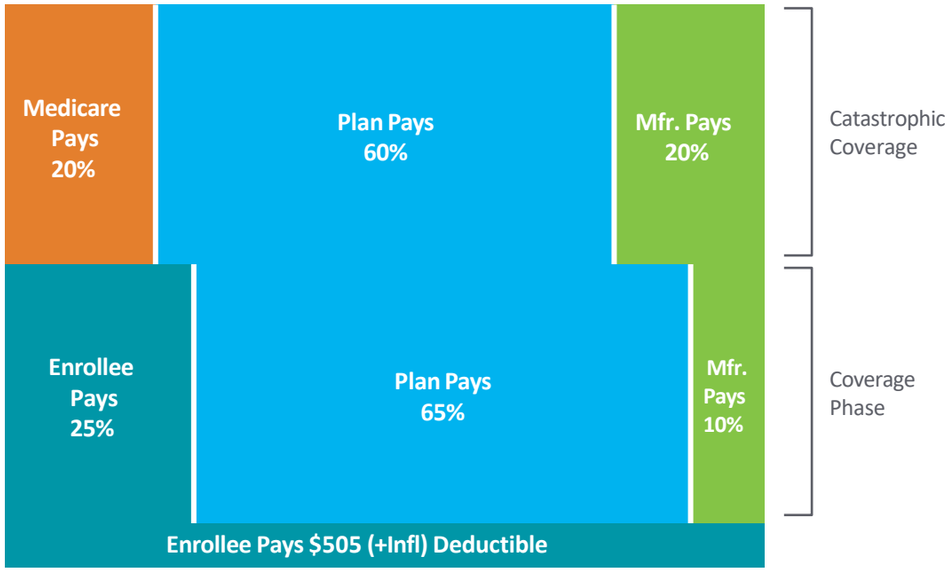
2023 True Out- of-Pocket (OOP) Spending Threshold: $7,400

2023 Initial Coverage Limit: $4,660 in total drug costs




## New Standard Medicare Part D Benefit

2025 OOP Max: $2,000



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# Additional Part D Enhancements



- **Capped copays: $35 insulin and $0 vaccines**
  - CMS will subsidize costs for PDP sponsors in 2023 that haven't been priced into premium
- **Optional monthly smoothing of enrollee OOP costs**
  - Plans pay pharmacy immediately and collect **optional monthly payment** from members
  - $2000 per year = **$166.66 per** month
- **Enrollee premium increases capped**
  - Base beneficiary premium increases capped **at 6% per year**
  - For 2030 CMS makes one-time adjustment to premium percentage
- Low-Income Subsidy eligibility **increased to 150% of the federal poverty level** (FPL)

# Marketplace Changes



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# Marketplace Subsidies



- Extends the American Rescue Plan Act (2021) expansion of Marketplace health insurance premium tax credits through 2025, which reduce the cost of purchasing a health plan through the health insurance marketplaces.
- The extended changes include
  - Increasing subsidy amounts for those with household incomes below the federal poverty level (FPL)
  - Allowing those with incomes above 400% FPL to quality for credits.

| Household Income (% of FPL) | Original Contribution% (pre-American Rescue Plan Act) | Updated Percentage, 2021-2025 |
|---|---|---|
| Up to 150% | 2.07-4.14% | 0% |
| 150-200% | 4.14-6.52% | 0-2% |
| 200-250% | 6.52-8.33% | 2-4% |
| 250-300% | 8.33-9.83% | 4-6% |
| 300-400% | 9.83% | 6-8.5% |
| Over 400% | No subsidies | 8.5% |

# The State Perspective



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# Key Implications for State Insurance Legislators and Regulators



- Potential for commercial health insurance plans to incur higher drug costs
  - With lower expected Medicare revenues, manufacturers might seek higher margins from commercial enrollees
  - May occur with higher launch prices for drugs
  - May be fewer new generics, given reduced incentives to launch generics
- Certain provisions could serve as a model for state regulation
  - Insulin copay caps
  - Maximum fair price could become benchmark for state drug price affordability boards
  - Mandatory inflationary rebates
- Higher enrollment in insurance marketplaces

# Discussion



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# Thank You



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# Appendix



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# Maximum Fair Price (MFP)



Law establishes an upper limit on what HHS may negotiate. The MFP can be no more than the lesser of either:

- Part B drug's Average Sales Price for the year prior to the selected drug publication date; or a Part D drug's price net of all price concessions, using the most recent year for which data is available (calculated on a plan-specific enrollment-weighted basis), or
- Percentage of the drug's past nonfederal Average Manufacturers Price (AMP).
  - For drugs first selected in 2026, the legislation uses 2021 prices (or the first full year following market entry), increased by inflation.
  - For drugs first selected in 2027 and subsequent years, the legislation uses the lesser of 2021's nonfederal AMP (or the first full year following market entry) increased by inflation, or the nonfederal AMP for the year prior to the selected drug publication date.
  - The percentage by which that number is multiplied is based on the type of drug at issue:
    - 75% for "short-monopoly drugs
    - 65% for "extended-monopoly drugs"
    - 40% for "long-monopoly drugs"

**This is an upper limit on MFP. There is no lower limit.**

# What's Most Important to Know About Negotiation Provisions



- HHS appears to have no discretion in choosing drugs for regulation
- While it's called negotiation, if it chooses to, HHS can get any price it wants *
- Starts with 10 drugs but will grow to many
- Will impact drugs that compete with selected drugs
- Law is more about Part D than Part B
  - Part B $40.7 billion (2020)
  - Part D $198.6 billion (2020)
- HHS does not need to issue regulations until for price regulation year 2029
- There will be no opportunity for judicial review of key actions

Spending numbers from MedPAC July 2022 Data Book

# Part B Inflation Rebates



- **Drugs Subject to Rebate**: Part B drugs with annual costs per individual ≥$100 (indexed for inflation), including biosimilars with prices greater than or equal to their referenced biologic. Flu, COVID-19, hepatitis B, and pneumococcal vaccines are excluded.
- **Units Subject to Rebate**: Part B units, excluding Medicaid units, 340B units, and those reimbursed under a bundled payment (e.g., packaging for outpatient hospitals).
- **Price Benchmark**: 106% of ASP (or, in the case of a biosimilar subject to rebates, the biosimilar's ASP plus 6% of the ASP of the reference product) during Q3 2021 (or shortly after initial marketing date, for new drugs).
- **Initial Rebate Period**: Q1 2023. For new drugs, 6 calendar quarters after first marketed.
- **Rebate Billing**: Quarterly beginning October 2023; however, HHS can delay billing for 2023 and 2024 until September 30, 2025.
- **Cost Sharing Impact**: Beneficiary coinsurance would be reduced to reflect any rebates owed.

| Timing of and Benchmarks for Rebate Obligation for Part B Drugs | | | | | |
|---|---|---|---|---|---|
| **Quarter** | **Price Benchmark** | **Benchmark Period CPI-U** | **Benchmark Period CPI-U** | **HHS Sends Mfrs. Bill** | **Mfrs. Pay Rebates** |
| Q1 2023 | Q3 2021 | Jan. 2021 | July 2022 | Oct. 1, 2023 | Oct. 31, 2023 |
| Q2 2023 | Q3 2021 | Jan. 2021 | Sept. 2022 | Jan. 1, 2024 | Jan. 31, 2024 |
| Q3 2023 | Q3 2021 | Jan. 2021 | Jan. 2023 | April 1, 2024 | May 1, 2024 |
| Q4 2023 | Q3 2021 | Jan. 2021 | April 2023 | July 1, 2024 | July 31, 2024 |
| Q1 2024 | Q3 2021 | Jan. 2021 | July 2023 | Oct. 1, 2024 | Oct. 31, 2024 |



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# Part D Inflation Rebates



- **Drugs subject to rebates**: Part D drugs with average annual costs per individual ≥$100 (indexed for inflation). A generic would be subject to rebates only in special circumstances.
- **Units Subject to Rebate:** Part D units, excluding 340B units as of 2026.
- **Price Benchmark:** Weighted-average AMP for the nine-month period from January 1, 2021, through September 30, 2021 (for new drugs, weighted-average AMP for the first calendar year beginning the day after the drug is first marketed).
- **Price Benchmark**: January 2021
- **Initial Rebate Period**: Oct. 2022 – Sept. 2023.
- **Rebate Billing**: Annually beginning July 2024; however, HHS can delay the billing for 2023 and 2024 until December 31, 2025.

| Timing of and Benchmarks for Rebate Obligation for Part D Drugs | | | | | |
|---|---|---|---|---|---|
| **Period** | **Price Benchmark** | **Benchmark Period CPI-U** | **Benchmark Period CPI-U** | **HHS Sends Mfrs. Bill** | **Mfrs. Pay Rebates** |
| Oct. 2022 – Sept. 2023 | Jan 2021 – Sept 2021 | Jan. 2021 | Oct. 2022 | July 1, 2024 | July 31, 2024 |
| Oct. 2023 – Sept. 2024 | Jan 2021 – Sept 2021 | Jan. 2021 | Oct. 2023 | July 1, 2025 | July 31, 2026 |
| Oct. 2024 – Sept. 2025 | Jan 2021 – Sept 2021 | Jan. 2021 | Oct. 2024 | July 1, 2026 | July 31, 2026 |



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# Part D Interaction With IRA



## Negotiated Prices

- PDP sponsors must place selected drugs on formulary
  - No detail on tiering or allowable UM for selected drugs
- No coverage of drugs from manufacturers that pay excise tax
- Negotiated price must be no more than MFP plus dispensing fee
- No manufacturer discount paid on selected drugs
  - CMS subsidizes 10% in coverage phase, but no subsidy after OOP cap



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# IRA Milestones Timeline



| Timeline of Key Milestones | | | |
|---|---|---|---|
| **2022** | **2023** | **2024** | **2025** |
| ▪ October 1: First year for which inflation rebates owed in Part D begins (through Sept. 2023) | ▪ Part D $35 insulin cost sharing and $0 vaccines take effect, with CMS retrospective subsidy<br>▪ HDHP Insulin coverage safe harbor effective<br>▪ Q1: First quarter for which inflation rebates owed in Part B<br>▪ April 1: Part B coinsurance is based on inflation adjusted payment amount<br>▪ September 13: CMS announces selected drugs for first year of drug price negotiation (AY 2026)<br>▪ October 1: Medicaid and CHIP vaccine coverage without cost sharing effective | ▪ First year of Part D premium stabilization<br>▪ Elimination of Part D cost sharing in the catastrophic phase | ▪ Part D Out-of-Pocket Cap<br>▪ New Part D manufacturer discount program<br>▪ Expanded Part D Low-Income Subsidy eligibility<br>▪ Last year of enhanced ACA premium subsidies<br>▪ September 30: Latest CMS may bill manufacturers for 2023 and 2024 Part B inflation rebates<br>▪ December 31: Latest CMS may bill manufacturers for 2023 and 2024 Part D inflation rebates |



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# IRA Milestones Timeline Continued



| Timeline of Key Milestones | | | | |
|---|---|---|---|---|
| **2026** | **2028** | **2029** | **2030** | **2032** |
| ▪ First price applicability year of selected drugs in Medicare at Maximum Fair Price (Part D only) | ▪ First price applicability year for which selected drugs subject to negotiation include Part B drugs | ▪ First price applicability year for which small biotech exempt drugs are eligible for price negotiation | ▪ Last year of Part D premium stabilization; CMS makes permanent adjustment to beneficiary premium percentage for this year | ▪ Moratorium on implementation of HHS OIG rebate rule expires |



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# Rules and Program Instruction



## IRA gives HHS authority to implement much of the law by program instruction

| Element of IRA | Authority to Implement by Program Instruction or Guidance |
|---|---|
| **Medicare Price Negotiation and 2-year delay for biologics with biosimilars** | For 2026, 2027 and 2028. |
| **Part D Inflation Rebates** | For 2022, 2023, and 2024. |
| **Part D Redesign and Manufacturer Discount Program** | For 2024, 2025 and 2026. |
| **Part D OOP Smoothing** | For 2025. |
| **Part D Vaccine Coverage & Insulin Copayments** | For 2023, 2024 and 2025. |
| **Part B Insulin** | For 2023. |

| Elements of IRA without Program Instruction Authority | |
|---|---|
| **Excise Tax** | **HDHP Insulin Safe Harbor** |
| **Part B Inflation Rebates** | **Part B Biosimilar Payment** |
| **Part D LIS Expansion** | **Medicaid & CHIP Vaccines** |



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