Drug Pricing Provisions of the Inflation Reduction Act

Where do we go from here?

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Agenda

Drug Pricing Policy Landscape

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- 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

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- Patent reforms
- CMMI models
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- March-in-Rights
- Value-based reforms
- Accelerated Approval
- President Budget Priorities
- 2023 Medicare Payment rules
- Importation
- PBM reform
- Patent reforms
- March-in-Rights
- Value-based reforms

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Overview: Inflation Reduction Act
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)
- Caps cost sharing for insulin to $35 in Medicare
- Inflationary rebates in Medicare Parts B and D
- 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

- **2023**: Requires drug companies to pay rebates if drug prices rise faster than inflation.
- **2024**: Limits Part D premium growth to ≤ 6% per year.
- **2025**: Eliminates 5% coinsurance for Part D catastrophic coverage.
- **2026**: Adds $2,000 out-of-pocket cap in Part D & other drug benefits changes.
- **2027**: Expands eligibility for Part D Low-Income Subsidy full benefits up to 150% FPL.
- **2028**: Negotiated 15 Part D drugs.
- **2029**: Negotiated 20 Part B and Part D drugs.
- **2029**: Delays drug rebate rule implementation to 2032.
- **2024-2030**: Negotiated 10 Part D drugs.
- **2024-2030**: Negotiated 15 Part D drugs.
- **2024-2030**: Negotiated 15 Part B and Part D drugs.
- **2024-2030**: Negotiated 20 Part B and Part D drugs.

CMS begins negotiating prices for certain high-cost drugs.
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.
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.
CMS Implementation of IRA

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.

President Biden’s Inflation Reduction Act 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 January 11, CMS released a memo highlighting important dates and milestones for the Drug Negotiation Program created under the Inflation Reduction Act.

**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: 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
Medicare Drug Price Negotiation Timeline: 2027

- **February 1, 2025**: Drugs selected for negotiation published.
- **February 28, 2025**: Negotiation process begins between HHS Secretary and drug manufacturers.
- **November 1, 2025**: Negotiation process ends. Maximum fair prices would be published by...
- **November 30, 2025**: Negotiated prices take effect

2027
Negotiation Program: Key Questions

- How Many Drugs?
- Which Drugs are Eligible?
- What Factors Must CMS Consider During Negotiations?
- What’s Included in the Initial Agreements?
- What is the Maximum Fair Price?
- How Will It Be Enforced?
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?

- 2026: Negotiate 15 Part D drugs
- 2027: Negotiate 15 Part D drugs
- 2028: Negotiate 15 Part B & D drugs
- 2029 & Beyond: Negotiate 20 Part B & D drugs

The number of drugs included in the Program will accumulate over time.
### Negotiation: Which Drugs are Eligible?

<table>
<thead>
<tr>
<th>Eligible Drug Products</th>
<th>Eligible Biological Products</th>
<th>Excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>A covered Part D or Part B drug that is FDA approved.</td>
<td>A covered Part D or Part B biological product that is licensed.</td>
<td>Drugs that have a generic or biosimilar available.</td>
</tr>
<tr>
<td>Continues to be marketed pursuant to FDA approval.</td>
<td>Continues to be marketed pursuant to the license.</td>
<td>Certain small biotech drugs (only from 2026 to 2028).</td>
</tr>
<tr>
<td>Has had at least seven years elapse since FDA approval, and</td>
<td>Has had at least 11 years elapse since the date of licensure, and</td>
<td>Low-spend Medicare drugs.</td>
</tr>
<tr>
<td>Is not the listed drug for any approved and marketed generic drug.</td>
<td>Is not the reference product for any approved and marketed biosimilar.</td>
<td>Orphan drugs with only one rare disease indication (and it is the only FDA-approved indication).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plasma-derived products.</td>
</tr>
</tbody>
</table>
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
- Ongoing compliance with requirements of the Program
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.
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.
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.
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.

Where Do We Go From Here?