

Drug Pricing Provisions of the *Inflation Reduction Act*

Where do we go from here?

Presented to Research!America by Clay Alspach (clay.alspach@leavittpartners.com)

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Drug Pricing Policy Landscape

Overview: *Inflation Reduction Act*

- Key Health Provisions
- Implementation Timeline

Negotiation Program

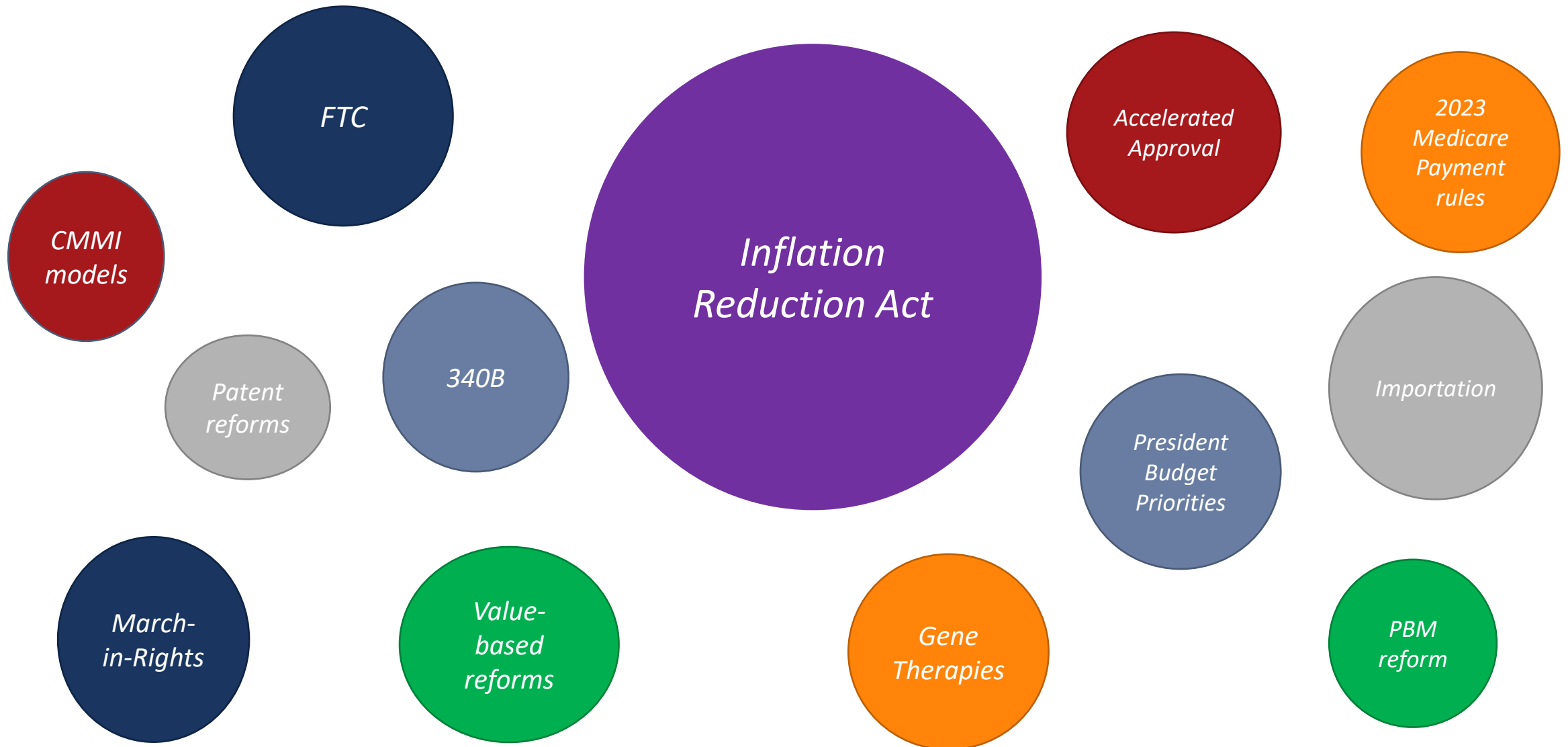
- Background
- Timeline
- Key Questions

Where Do We Go From Here?



Drug Pricing Policy Landscape





Overview: *Inflation Reduction Act*

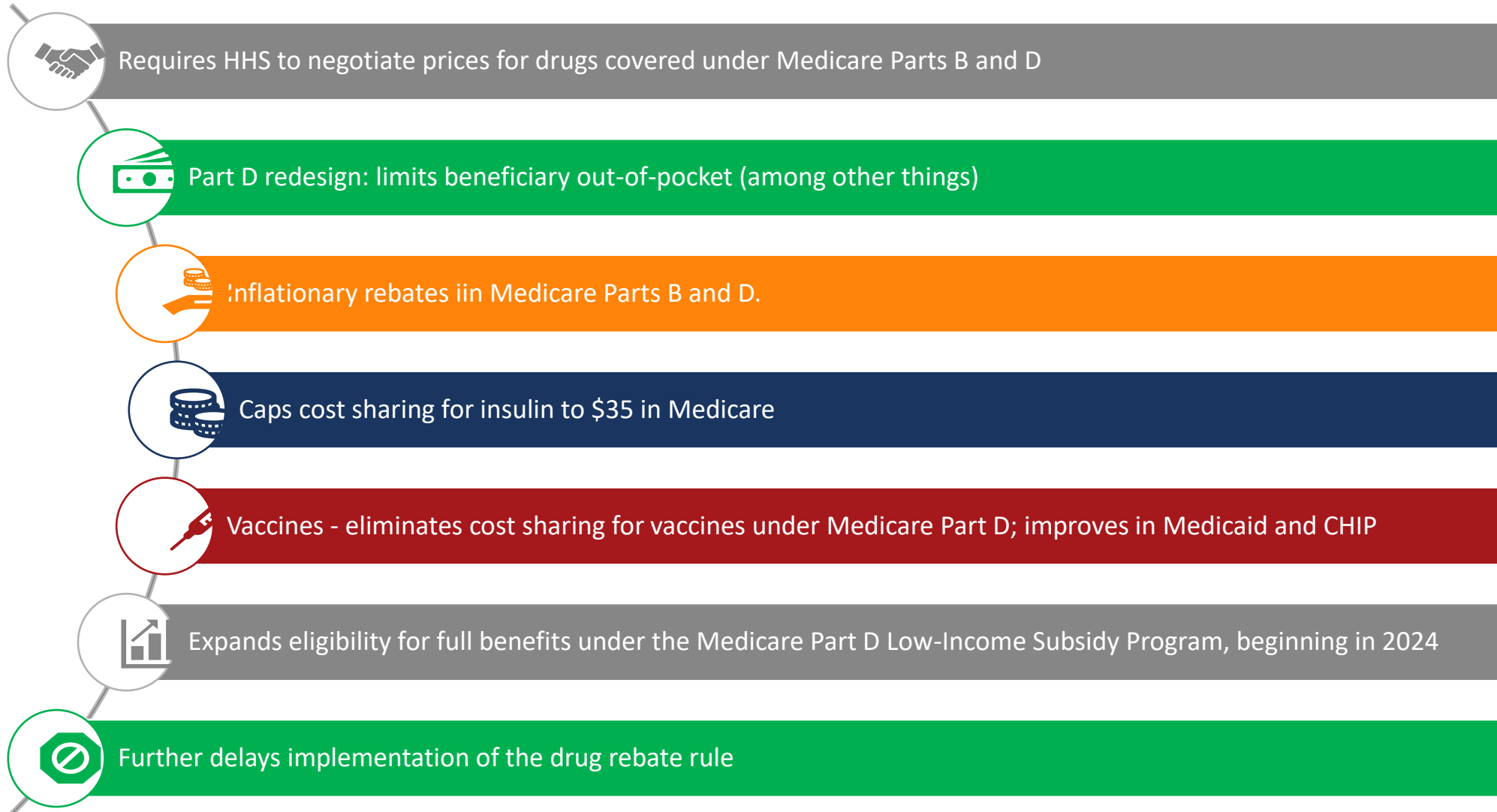


Inflation Reduction Act Signed Into Law

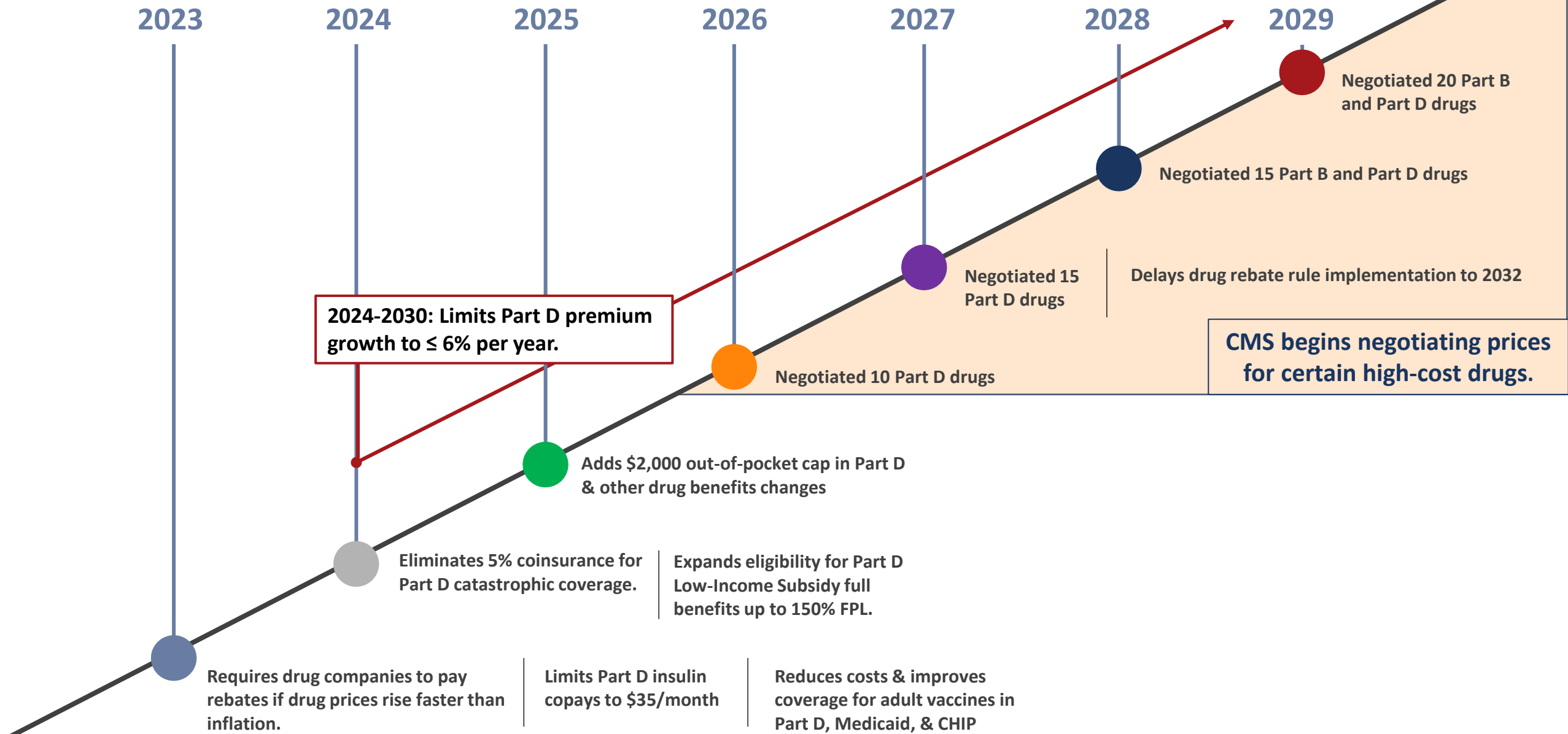
President Biden signed *Inflation Reduction Act* into law on August 16, 2022.



Drug Provisions of the IRA



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.



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.

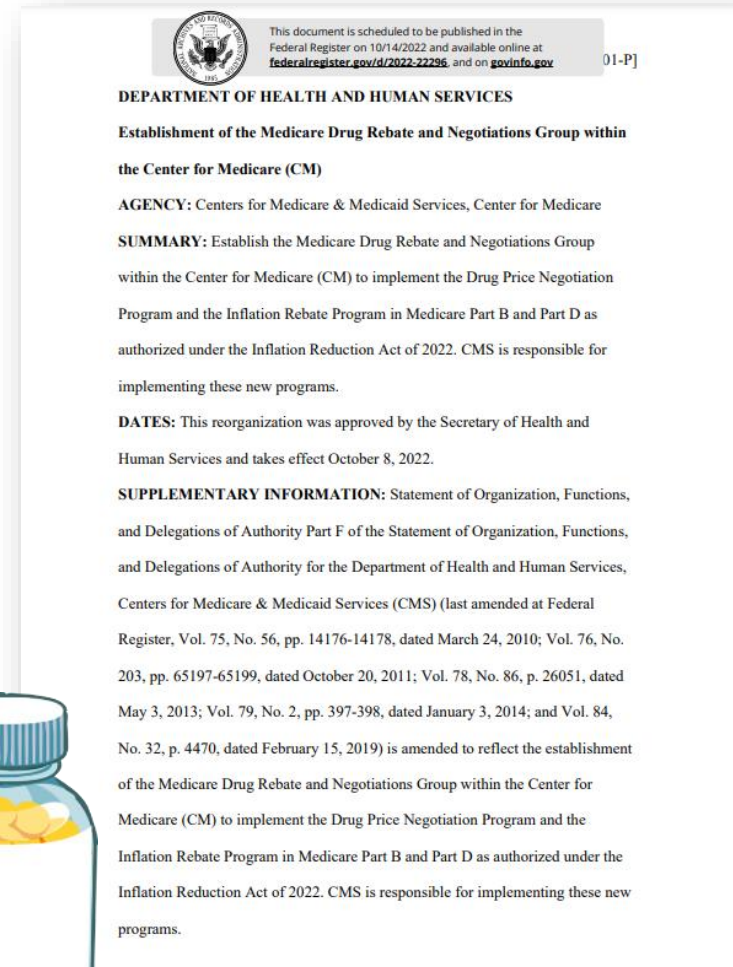
Purpose:

- 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.

[FedReg](#)



IRA Careers

Inflation Reduction Act



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 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*.

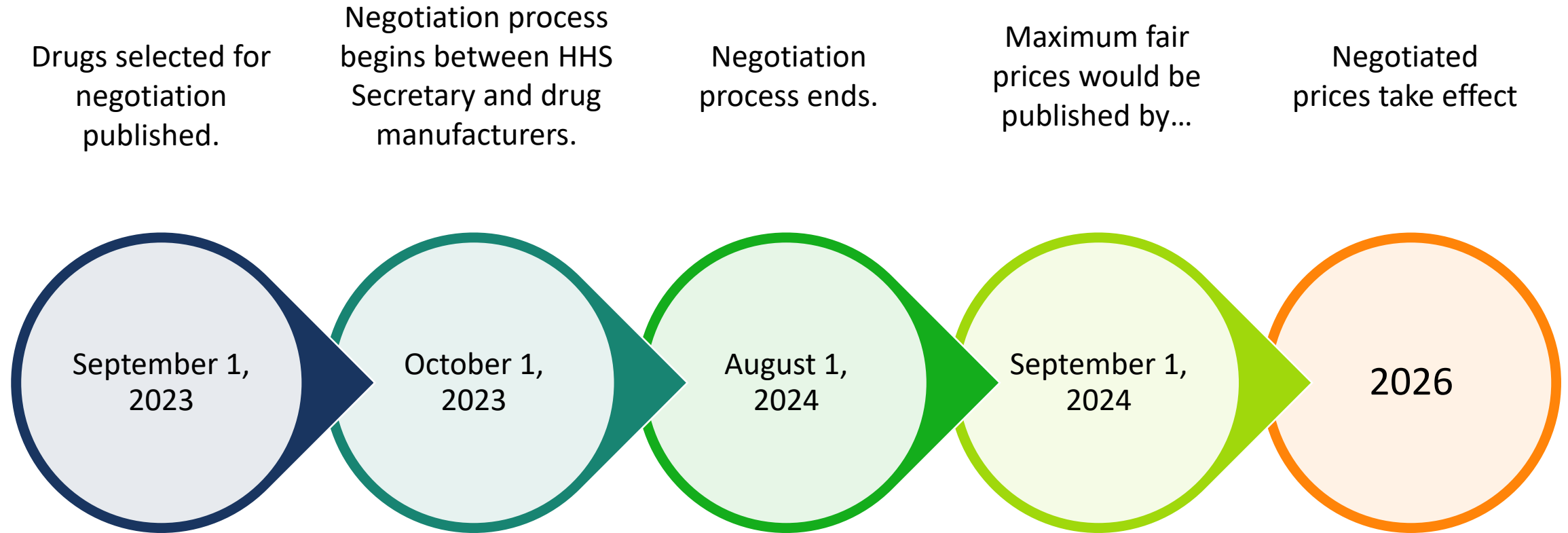
- The agency is hiring for positions that span the health care spectrum including:
 - Economists
 - Pharmacists
 - Directors and analysts.
- Desired expertise:
 - Drug pricing
 - Pharmacoeconomic research
 - Health policy
 - Information technology
 - Management.

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



Medicare Drug Price Negotiation Timeline: 2027

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





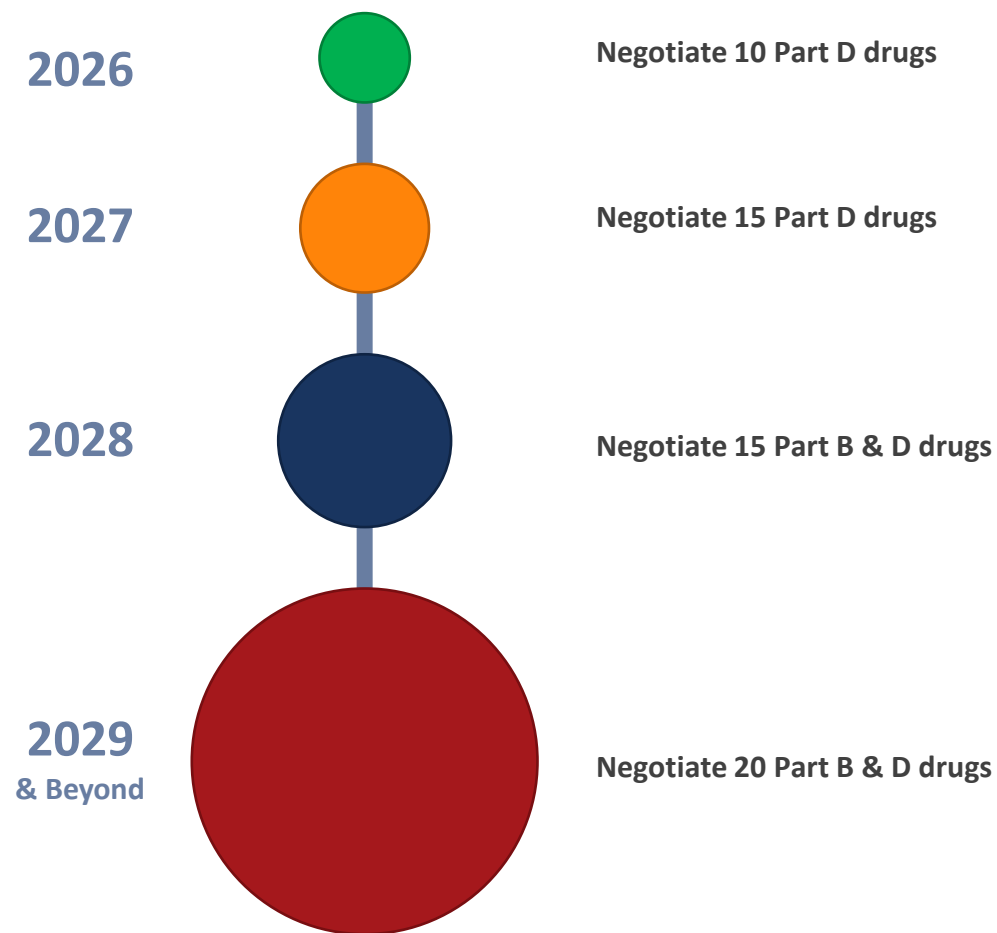
Background

- 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.

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

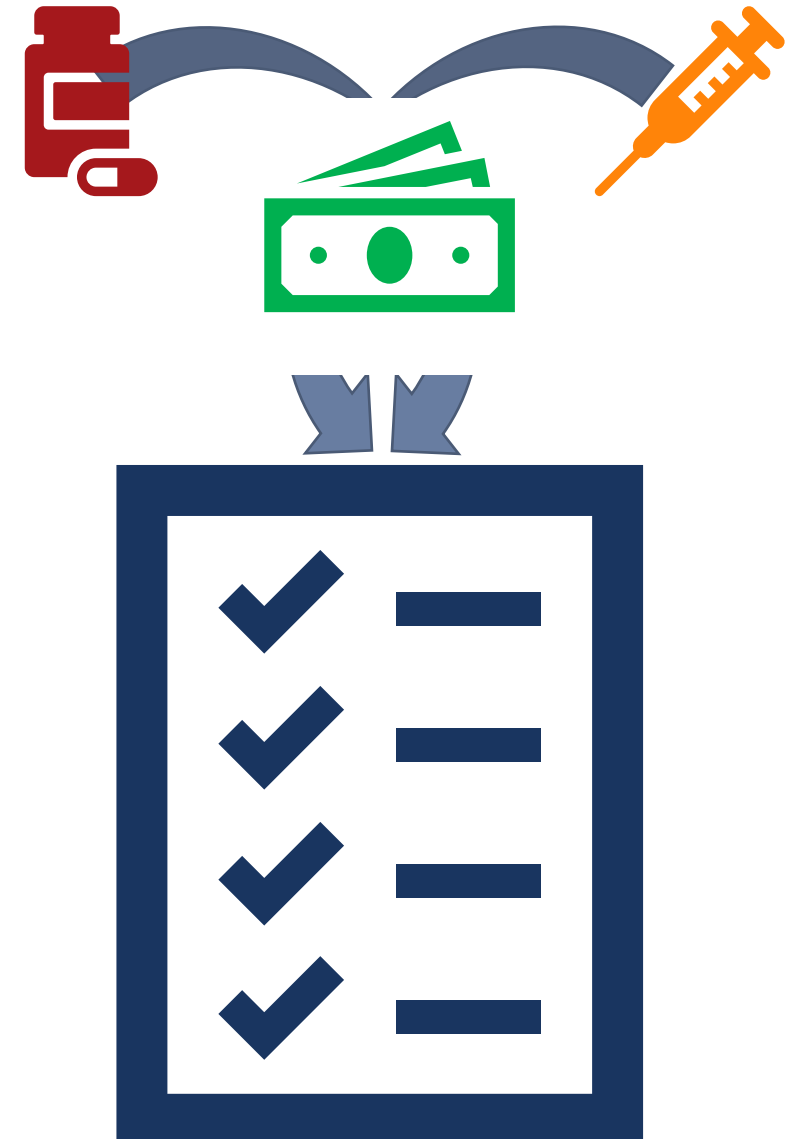
- A covered Part D or Part B biological product that is licensed
- Continues to be marketed pursuant to the license.
- Has had at least 11 years elapse since the date of licensure, and
- Is not the reference product for any approved and marketed biosimilar

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

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



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.

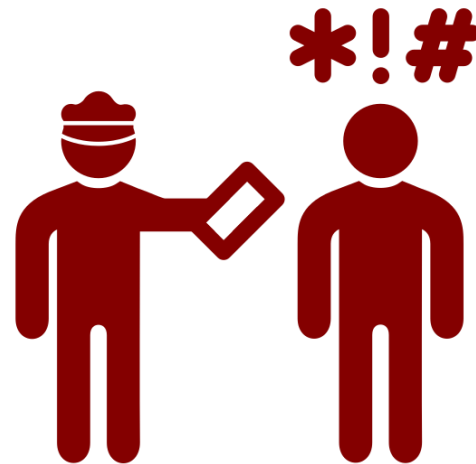
Simply Put:

- 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.



What's Next?



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.

