

ISPOR EDUCATIONAL SYMPOSIUM. 9<sup>TH</sup> MAY 2023

# Explaining the Inflation Reduction Act



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# moderator



**PROF GRAHAM COOKSON**

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The background of the slide is a grayscale photograph of various medical supplies. In the foreground, there are several blister packs containing white and dark pills. To the right, there are several capsules and a white pill bottle. On the left, there is a syringe with a needle and a small black object. The overall scene is a collection of pharmaceutical and medical equipment.

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# Welcome and Introduction

Prof Graham Cookson, Chief Executive, OHE

# Agenda

## AGENDA

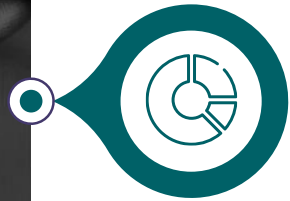
Welcome	Prof Graham Cookson
<b>Overview</b> of the three key provisions of the IRA relating to prescription drug pricing and access	Dr Amanda Cole
<b>How did we get here?</b> A look at the policy context and changing landscape for drug pricing in the US	Kirsten Axelsen
Audience Q & A	All
Closing Remarks	Prof Graham Cookson



# The US has a predominantly private, market-based health care system.



Largely a market-based system through private plans



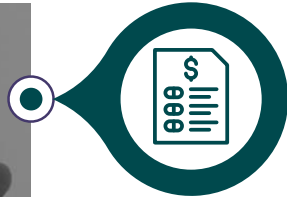
Complex mix of public and private, for-profit, and non-profit *insurers* and health care *providers*



Out of pocket expenses a common and controversial feature of US health care.



# The Inflation Reduction Act (IRA) introduces drug price setting into Medicare for the first time



Companies generally are free to set list prices, and negotiate net prices with plans, which can vary.



In Part D, Pharmacy Benefit Managers control formularies and negotiate discounts/rebates.



Before the IRA, Medicare didn't directly set prices for medicines covered by Part B or Part D.

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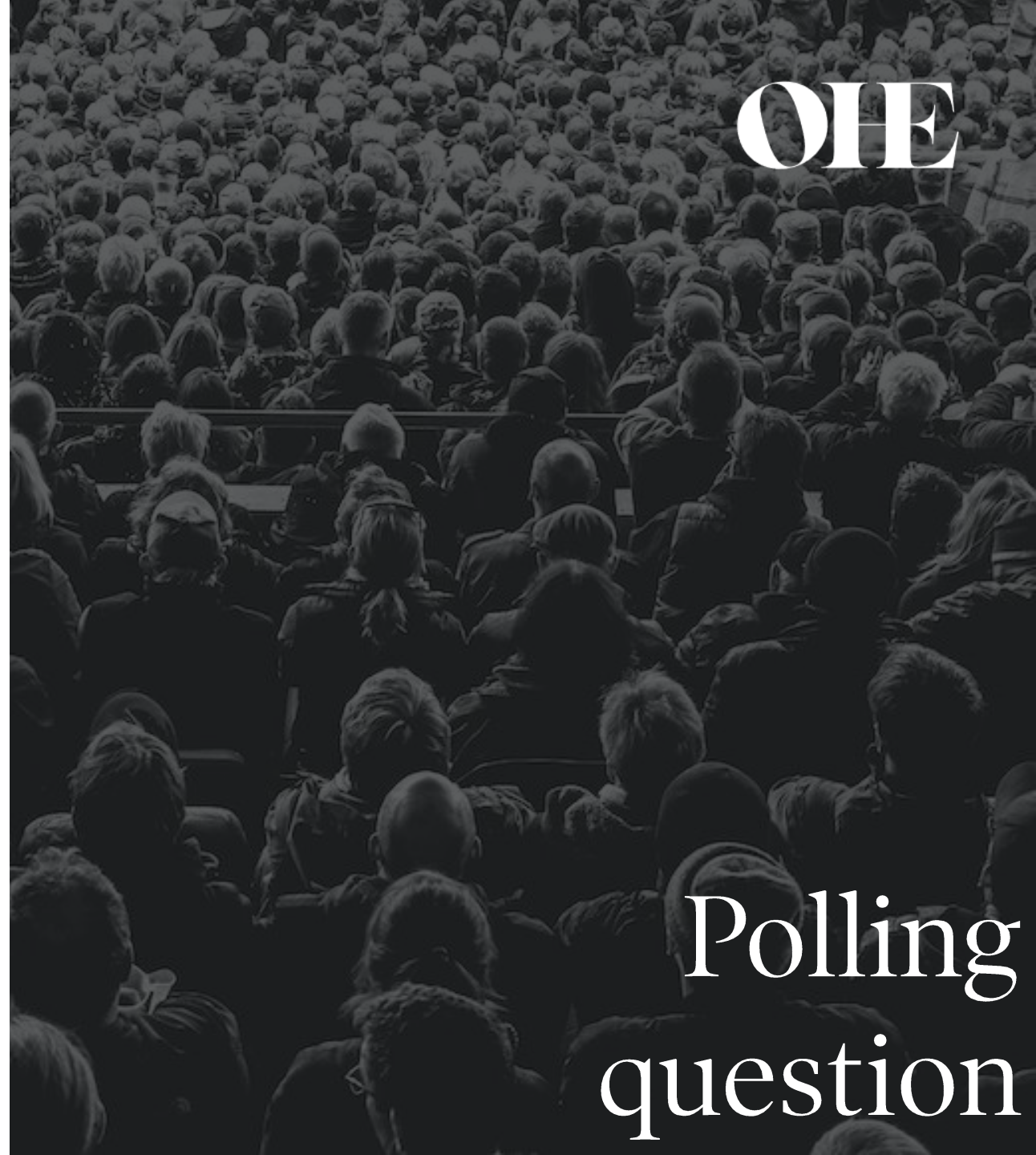
First, some questions for you...



Who's in the room?

OHE

Polling  
question





# Current understanding of the IRA and its provisions

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Polling  
question







# Overview of drug pricing provisions in the Inflation Reduction Act

## ***Price setting***

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Beginning in 2026, HHS will set Medicare prices for eligible prescription medicines in Part D. In 2028, this will be expanded to include medicines in Part B.



## ***Inflation Rebates***

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IRA introduces an inflation rebate to quarterly (Part B) and annual (Part D) price increases above inflation.



## ***Part D Redesign***

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Changes stakeholder liability for drug costs, caps out-of-pocket spending, smooths cost sharing, and other changes to benefits.



## ***Insulin policies***

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Beginning in 2023, requires pre-deductible coverage and limits cost sharing to \$35 for covered insulin.



# What are the aims of this Symposium?



To provide an accessible explanation of the technical detail of the IRA



To consider the background, how we got here, and what the changing landscape for drug pricing in the U.S. means



To equip attendees with the information needed to support informed conversation and debate on its potential impacts

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MODULE 0

## Introduction to the US Healthcare System

**PRMA**

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MODULE 1

## Drug selection and price setting process

**PRMA**

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MODULE 2

## Inflation Rebate Provisions

**PRMA**

**OHE**

MODULE 3

## Medicare Part D Benefit Redesign and Other Provisions

**PRMA**



You can find out more on OHE's dedicated platform

<https://www.ohecourseinflationreductionact.com/>





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# Key provisions in the IRA

Dr Amanda Cole, Associate Director, OHE

# What we'll be covering

**1** *Drug selection and price setting*

**2** *Inflation rebate provision*

**3** *Medicare Part D benefit redesign and other provisions*





# 1 *Drug selection and price setting*

# *Under the IRA, federal government will set prices for selected drugs covered under Medicare*



## *Before the Inflation Reduction Act (IRA)*

- Part D was a market-based system with drug prices privately negotiated
- Direct government involvement in pricing prohibited by the **non-interference clause** in Medicare Part D.
- Payment for physician-administered drugs covered by Medicare Part B generally based on Average Sales Price (ASP) + 6%

## *Now*

- IRA introduces provisions for the Secretary of the Department of Health and Human Services (HHS) to set Medicare prices for certain eligible medicines
- The Centers for Medicare & Medicaid Services (CMS) is an operating division of HHS and will implement the Medicare Drug Price Negotiation Program.





# What drugs are eligible for selection?



## Eligible for selection

Drugs with the highest total Medicare Part B & D expenditures\*

Top 50 eligible drugs in **Part B**, ranked by program expenditures



Top 50 eligible drugs in **Part D**, ranked by program expenditures

- ✓ Single-source drugs\*\*, 7 or more years after FDA approval
- ✓ Single-source biologics\*\*, 11 or more years after FDA approval

\* For years 2026 and 2027, only the top 50 Part D list is used

## Ineligible for selection

- ⊗ Drugs with a single orphan designation that are only approved for that indication(s)\*
- ⊗ Plasma-derived products
- ⊗ “Low spend Medicare drugs” (total Part B & Part D expend <\$200 mill annually)
- ⊗ Certain “small biotech drugs” up until 2028

\*Under CMS' guidance, risk that as soon as the sponsor has an additional designation or any additional indication (whether under a subsequent orphan designation or not) they are no longer ineligible

## Initial CMS guidance

\*\*A “Qualifying single source drug” includes all dosage forms and strengths with the same active moiety (for small molecule drugs) or active ingredient (for biologics). Note: If any dosage form/strength of a single source drug or biologic is on the market for 7 or 11 years, respectively, then all dosage forms/strength of the drug will be considered for “negotiation.”

# Manufacturer is subject to penalties for refusing to participate or not accepting MFP.

## Other penalties could apply



Excise tax is nominally between 65% and 95% of manufacturer's total sales for the drug, over the term in which manufacturer fails to accept MFP.



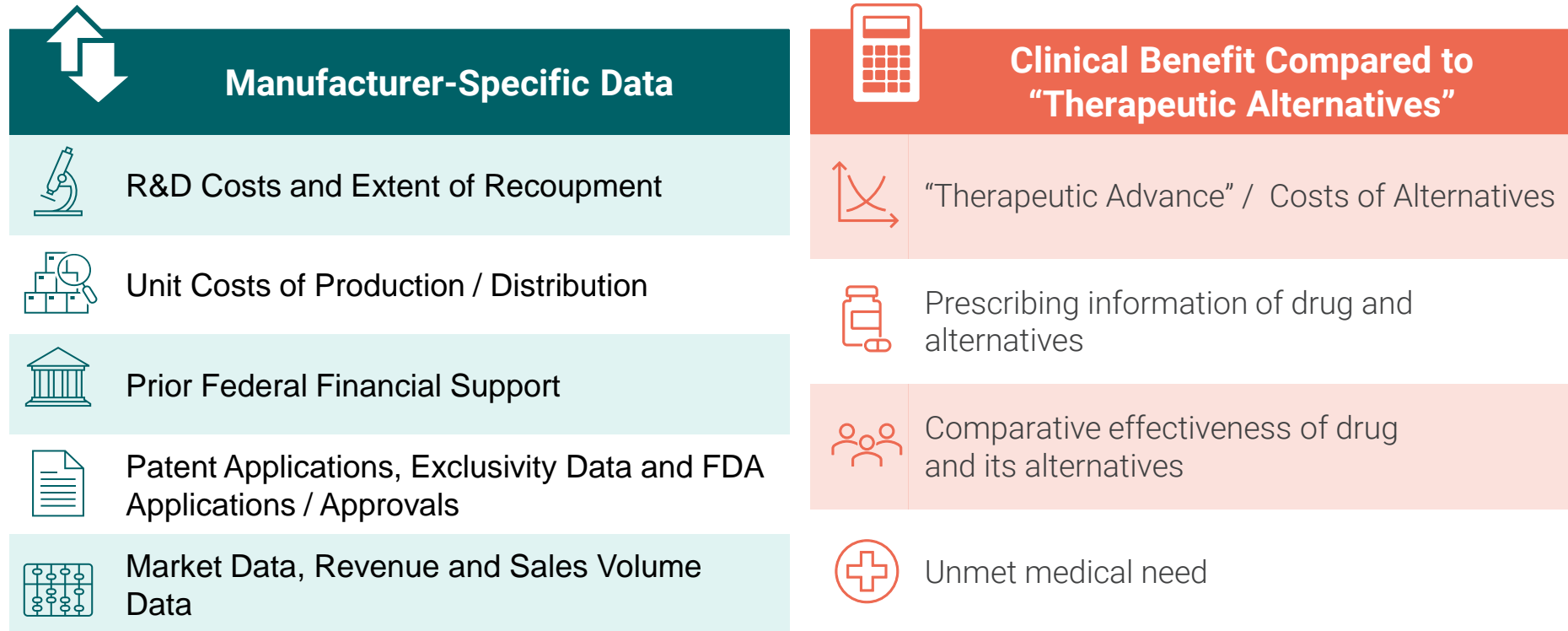
Alternatively, manufacturer can exit program but must remove all of its drugs from Medicare and Medicaid.



Significant civil monetary penalties for failing to comply with certain requirements or knowingly submitting false information

# Process for determining the maximum fair price

IRA specifies 2 sets of factors that HHS should consider in determining the *maximum fair price*.



# Methodology for developing an initial offer: initial CMS guidance



CMS will in general determine an initial offer based on:

- **Therapeutic reference to determine the “starting point” for price**, adjusted up or down to reflect its assessment of:
  - **Clinical benefit**, including consideration of:
    - Unmet medical need
      - Defined as “treating a disease or condition in cases where very limited or no other treatment options exist”
    - Impact on specific populations
  - **Manufacturer-specific factors**, including, for example, the extent to which R&D costs have been recouped and remaining time on patents and exclusivities

# Methodology for developing an initial offer: initial CMS guidance (continued)



- To assess clinical benefit, CMS will consider submitted data from manufacturers and interested third parties as well as review of existing literature and internal analytics. Clinical trial evidence, real world evidence, and expert opinion will be considered.
- CMS intends to consider study rigor, relevance to selected drug, risk of bias, and other factors in assessing data but does not specify methodological standards it may apply.
- QALYs will not be relied on in developing price offers, but studies that use QALYs may be considered in assessment of clinical benefit if clearly separated from other evidence submitted.

*There is a 30-day window for manufacturers and interested parties to submit data to CMS.*



# The ceiling for the MFP will be the lower of the following:



1

## **Medicare net price**

- Part D: net price weighted by enrollment across all plans
- Part B: Average Sales Price +6%

2

## **A sliding scale percent of the non-federal AMP (“non-FAMP”) linked to time from the indication-specific FDA approval date\***

\*75% for small molecules between 9 and <12 years from FDA approval and for all vaccines; 65% for all drugs between 12 and 16 years from FDA approval; and 40% for all drugs 16 years or more from FDA approval

*Law establishes a ceiling for the MFP, but not a floor.*

# Maximum fair price: initial CMS guidance



- For each selected drug, CMS will set a MFP calculated for forms, strengths, and package sizes.
- By September 1st, 2024, CMS will publish the MFPs for IPAY 2026.
- CMS is not required to publish an explanation of how it determined the MFPs for IPAY 2026 until March 1, 2025.
- Following the determination of the MFP, manufacturers must provide access to the MFP to Medicare beneficiaries, pharmacies, providers, etc, either upfront or retrospectively, and submit their planned approach in writing to CMS 30 days prior to the MFP taking effect.

# Explanation of how CMS determined MFP: initial CMS guidance



Selected Drug



Contributing negotiation factors



Factors or circumstances unique to the selected drug



Focus on the factors that had the greatest influence



High-level comments on the data submitted to CMS,  
***without sharing any proprietary data***

Explanation for IPAY 2026 must be published by March 1, 2025, the same day that manufacturers must submit data for drugs selected for IPAY 2027

# The law creates a special rule for biosimilar products in the pipeline



A biologic qualifies for selection if there is no marketed biosimilar. However, biologics are eligible for selection at 11 years, whereas biosimilars are not eligible for approval until 12 years after the first licensure of a biologic. Therefore a biosimilar sponsor can apply for a "pause" in the price-setting process for the selected biologic, if certain criteria are met.

**The "pause" may be granted if...**



The reference biologic has been approved for more than 12 years, but fewer than 16 before the initial price applicability year.

There is a high likelihood of a biosimilar being FDA approved and marketed within two years (this is determined by HHS)

**The "pause" may not be granted if...**



A biosimilar sponsor has entered into an agreement with the biologic manufacturer that

- Incentivizes the biosimilar sponsor to request the pause
- Restricts the quantity of the biosimilar product to be sold in the US

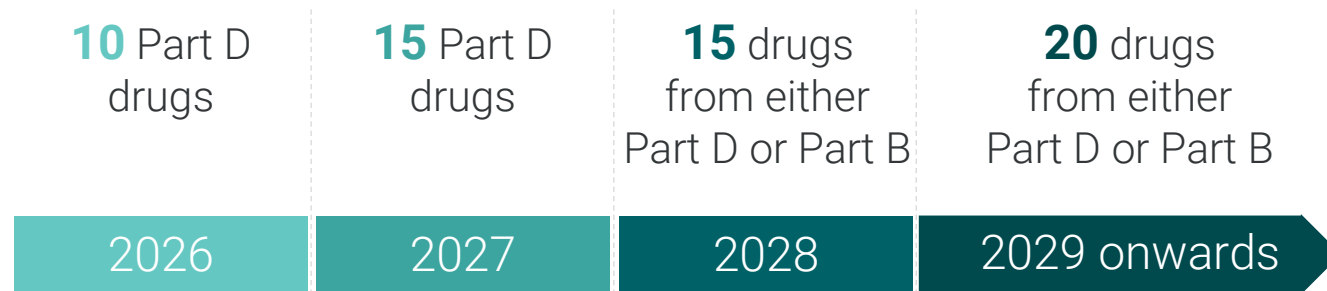
Biosimilars in patent litigation with the reference product manufacturer\*

\*This point comes from the most recent CMS guidance

# There will be a gradual rollout, in which more drugs will be selected for price setting each and every year



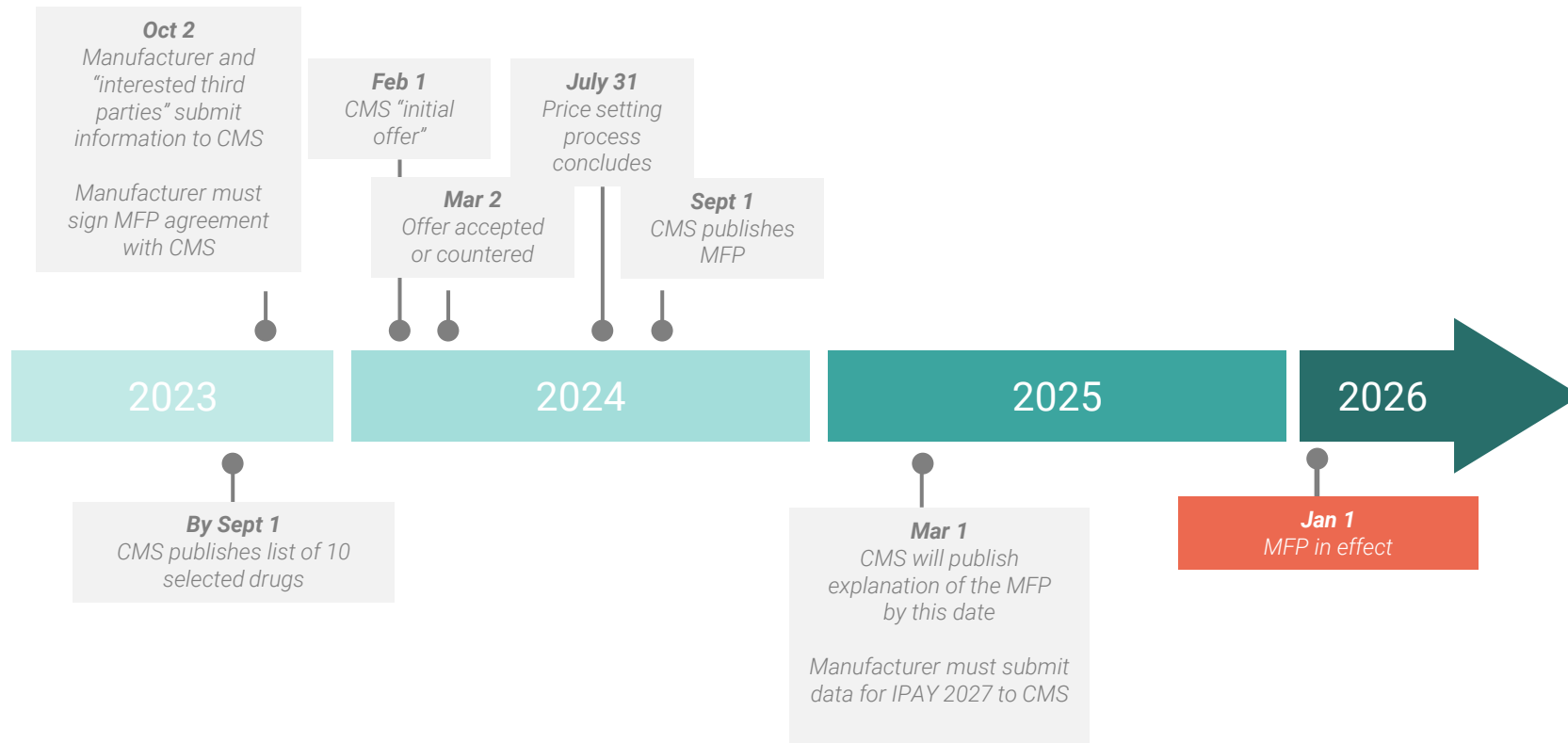
- Beginning in 2026, CMS will set Medicare prices for eligible prescription drugs



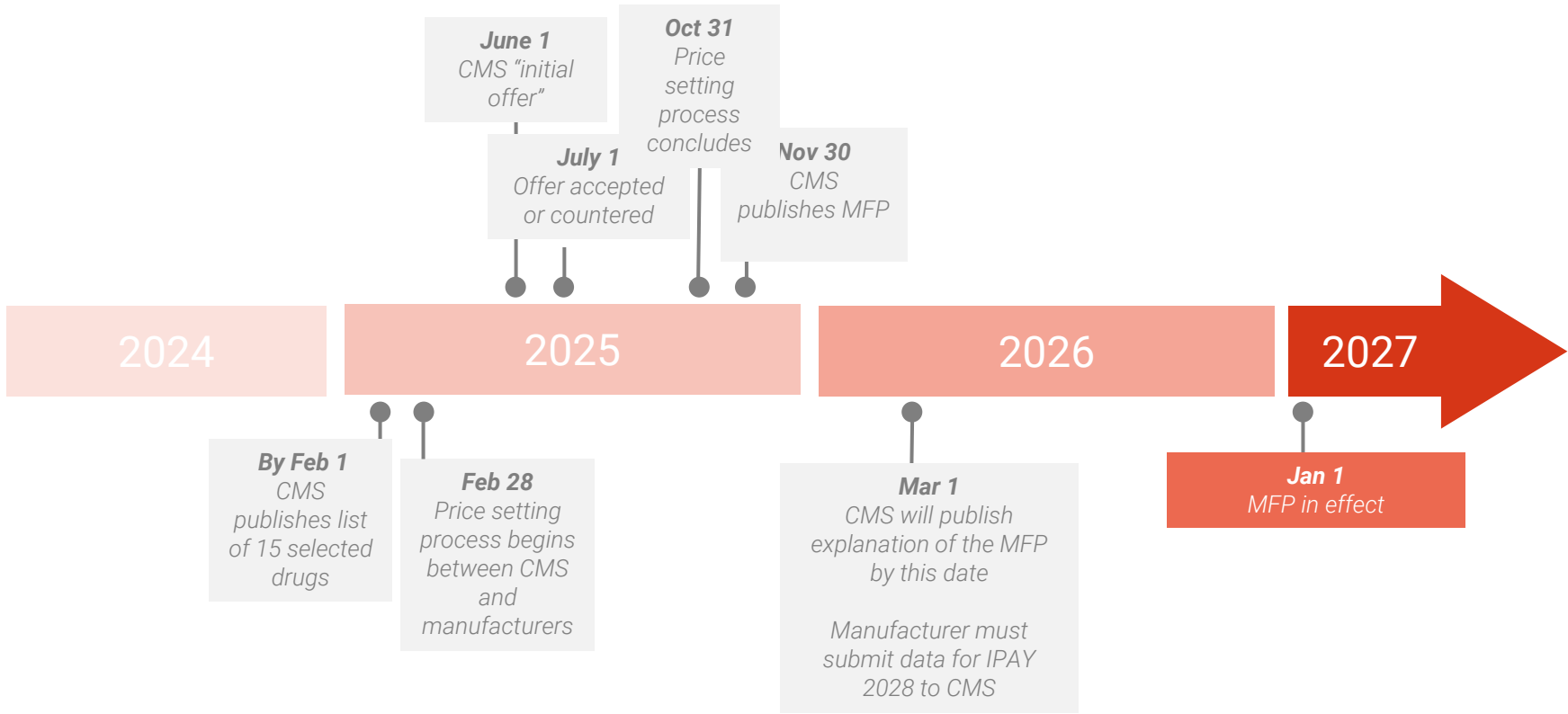
- Selection of drugs each year is cumulative, adding to the number of previously selected drugs.



# Price setting for the first group of Part D drugs will take effect in 2026



# Timeline for 2027 and beyond: a two-year process





## *2 Inflation rebate provision*

# Manufacturers must already rebate Medicaid if their prices rise faster than inflation.



*Price changes are measured cumulatively against a fixed benchmark*





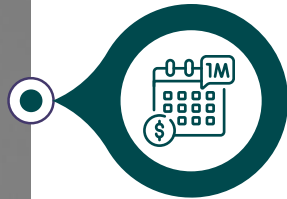
# IRA brings inflationary rebates to Medicare but with a different reference date.



*Rebate = Quantity sold x Price Growth in Excess of Inflation*

- The benchmark price is **Q3 2021 for Part B** medicines, and **January through September 2021 for Part D** medicines.
- The benchmark CPI-U for both rebates is **January 2021**.
- Price is measured based on the payment amount (e.g., average sales price (ASP) + 6%) in Part B and average manufacturer price (AMP) in Part D
- Most branded drugs are included in the provision but there are some *exclusions*:
  - For **Medicare Part B**, medicines with an annual cost of <\$100 in 2023 and preventative vaccines.
  - For **Medicare Part D**, drugs with annual cost of <\$100 in 2023.

Rebates are calculated by the Secretary of HHS and key determinations *are not subject to judicial or administrative review.*



Invoices will be sent to manufacturers no later than 6 months after the end of the quarter for Part B drugs, and 9 months after the end of the 12-month rebate period for Part D drugs.\*



Rebate payments are required within 30 days of receipt of invoice, and are to be deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund.

\*For Part B, the Secretary may delay invoices for all quarters in 2023 and 2024 until Sept 30, 2025; for Part D, the Secretary may delay invoices for the rebate periods beginning Oct 1, 2022 and Oct 1, 2023 until Dec 31, 2025.

For medicines that owe an inflation rebate under Part B, IRA will reduce patient cost sharing to 20% of the inflation-adjusted price.



- Currently, under Medicare Part B, patient cost sharing for most medicines is 20% of the Medicare payment amount
- As of April 1 2023, patient cost sharing will be reduced to 20% of the inflation-adjusted payment amount for medicines that owe an inflation rebate
- There will be no effect on patient cost sharing for Medicare Part D



### *3 Medicare Part D benefit redesign and other provisions*

# The IRA reallocates prescription drug costs between patients, manufacturers, plans, & gov't



The Medicare Part D redesign is intended to:

Lower cost sharing for patients, including a limit on annual out-of-pocket spending (\$2,000 beginning in 2025)



Decrease direct federal government liability and increase Part D plan liability above the catastrophic threshold



Increase the share of the benefit financed by manufacturers

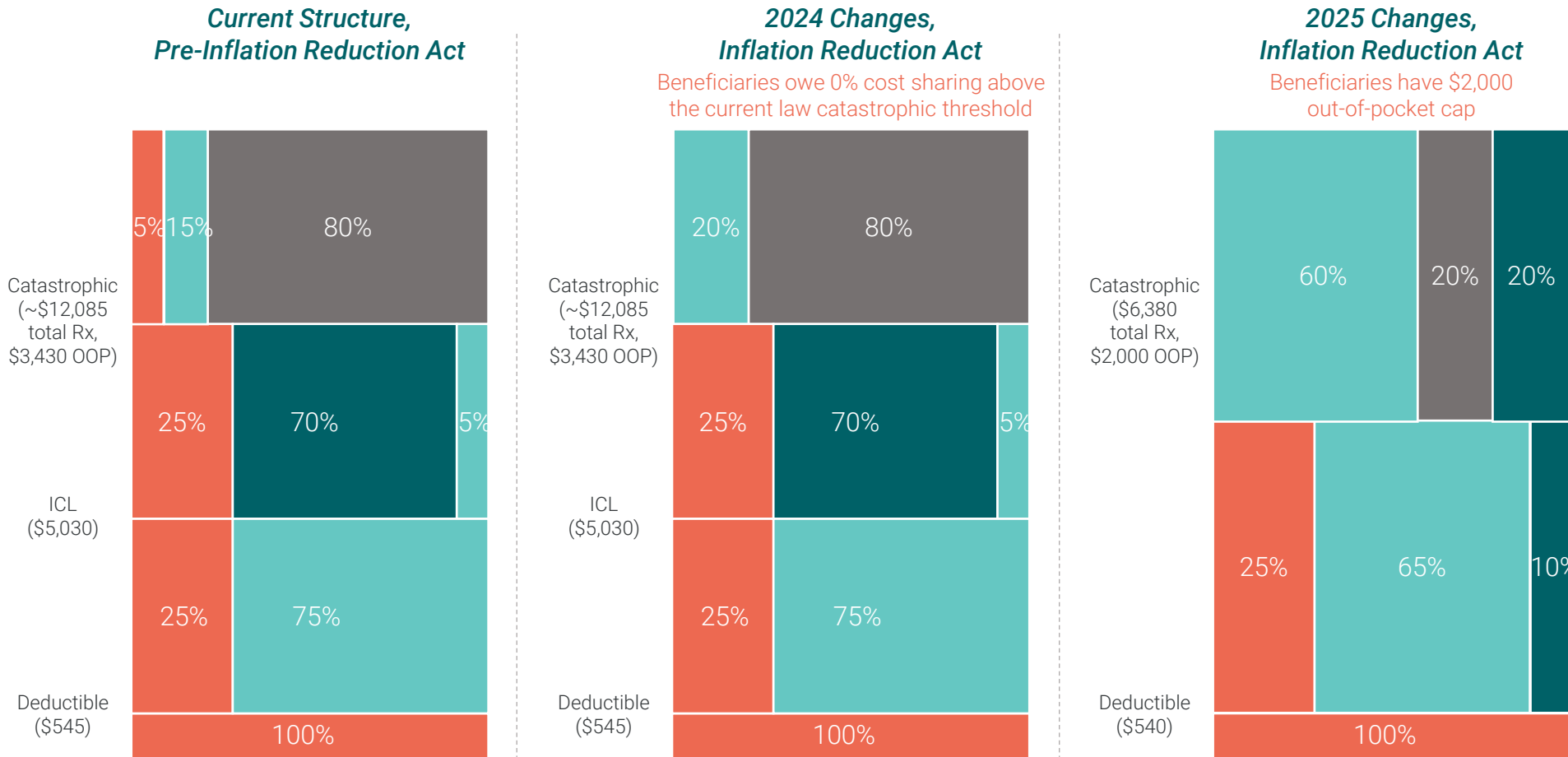


Limit premium growth to 6% annually through 2029





# Cost sharing changes

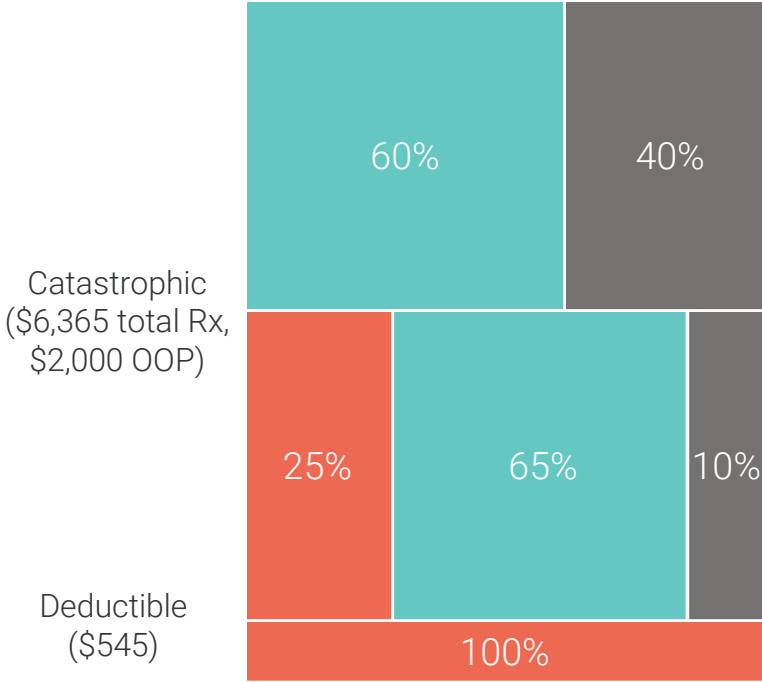


- Replaces coverage gap discount program with new manufacturer discount (10% below catastrophic threshold and 20% above catastrophic threshold) for both LIS and non LIS beneficiaries
- Financial liability changes for all stakeholders; liability increases for manufacturers overall while-simultaneously decreasing for the federal government and increasing for Part D plans above the catastrophic threshold and eliminating cost-sharing above catastrophic for beneficiaries

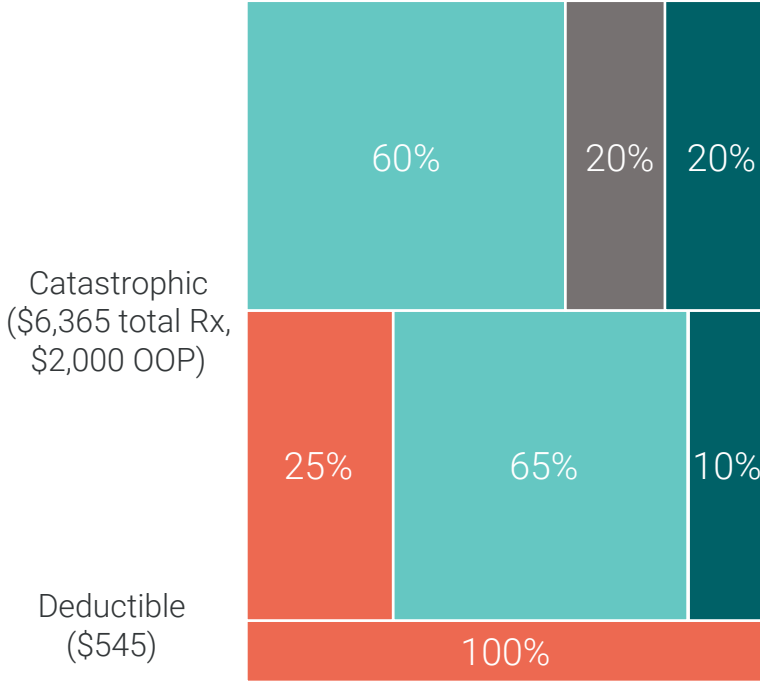
# Additional benefit changes once price setting provisions take effect




*For Brand Medicines Subject to Price Setting*




*For Brand Medicines NOT Subject to Price Setting*




# Additional key provisions include:



Eliminates  
Part D cost  
sharing for  
vaccines



Cap on  
insulin cost  
sharing  
(\$35/month  
limit)



Cost sharing  
smoothing

# Changes in the low-income subsidy (LIS)



Low-income individuals and households get extra help with Part D premiums and cost-sharing

A teal-colored circular graphic with a diagonal line. To the left of the line is an icon of two hands, one holding a stack of money. The text is positioned to the right of the line.

The IRA expands this help to more individuals

A dark grey circular graphic with a diagonal line. To the left of the line is an icon of three stylized human figures standing on an upward-pointing arrow. The text is positioned to the right of the line.

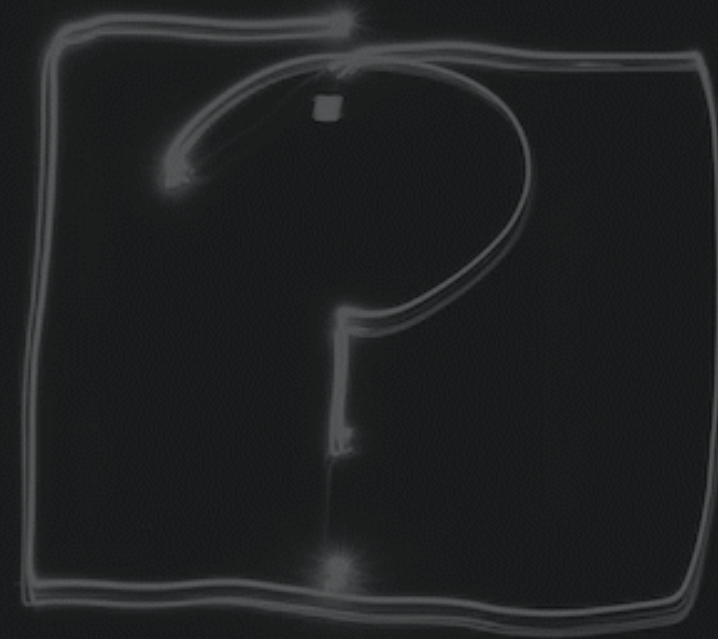


# How did we get here?

Kirsten Axelsen, Senior Policy Advisor, DLA Piper



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Polling  
question



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# Inflation Reduction Act

Drug Pricing and Access Provisions

How Did We Get Here, Anticipating The Implications for Global Health

May 2023

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# Inflation Reduction Act

Drug Pricing and Access Provisions

How Did We Get Here, Anticipating The Implications for Global Health

May 2023

# Goals for Presentation

Inflation Reduction Act (IRA)

## Focus on Biopharma Provisions

- Provide historical context for the elements of the new U.S. law will that affect drug pricing and cost
- Consider some second order effects of the law on Global Health including:
  - Access to medicine
  - Investment in new treatments
  - Development of evidence







## People are Living Longer and Better Because of Medicine

- Longer life spans, increasing wealth and associated diseases results in more demand and spending for drugs
- Prevention, stopping disease, and productivity often doesn't "count" as saving money in fiscal calculations



## Growing Cost of Healthcare Has a Limit

- Even treatments, with value estimated to be greater than their price are often restricted or asked to be discounted
- Health systems around the world increasingly price sensitive with constrained budgets
- Drug revenue and investment in new drugs are positively related

# Politics Constraining Price and Access in 2023, Affect Investment In Drugs for Aging Population

## Macro-economics

Economic stagnation, inflation and rising energy costs, add pressure to reduce budgets

## Popular Support

Constraining drug prices and limiting the power of “big businesses” is politically appealing

## Specialty not “special”

Health policy evaluators increasingly conclude that even medicines that address “unmet need” are over-rewarded with their price (e.g. specialty drugs, rare disease)

## Global influence

Health reforms in one country draw inspiration for others, NGOs, academics and other organizations engage and promote comparisons

## Local preference

Preferential access conditions for local manufacturer vs imported medicines particularly as countries aim to build their own biopharma sectors, protectionist policy is popular

# These pressures are manifesting in influential approaches to set price and access for biopharmaceuticals around the world



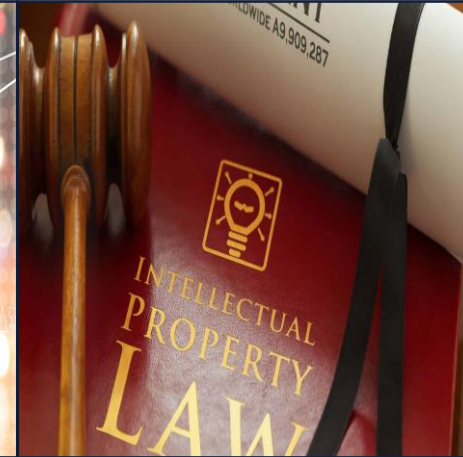
Inflation Reduction Act (IRA) U.S. allows the federal government to set drug price and new discounts for certain drugs in Medicare. State drug review boards also aim to adopt price setting.



Limit access to “breakthrough” drugs and rare disease (e.g. CMS Coverage with Evidence Development, EU consideration of orphan drug reforms)



Growing price pressure in other major markets (e.g. Germany Finance Stabilization Act) and low willingness to pay in growing wealth countries



Pressure for IP erosion to provide access in both higher and lower income countries, particularly for anti-virals and anti-microbials following COVID-19 precedent

# Global BioPharma Revenue Distribution and Access Pressures Around the World

## U.S. becoming more restrictive

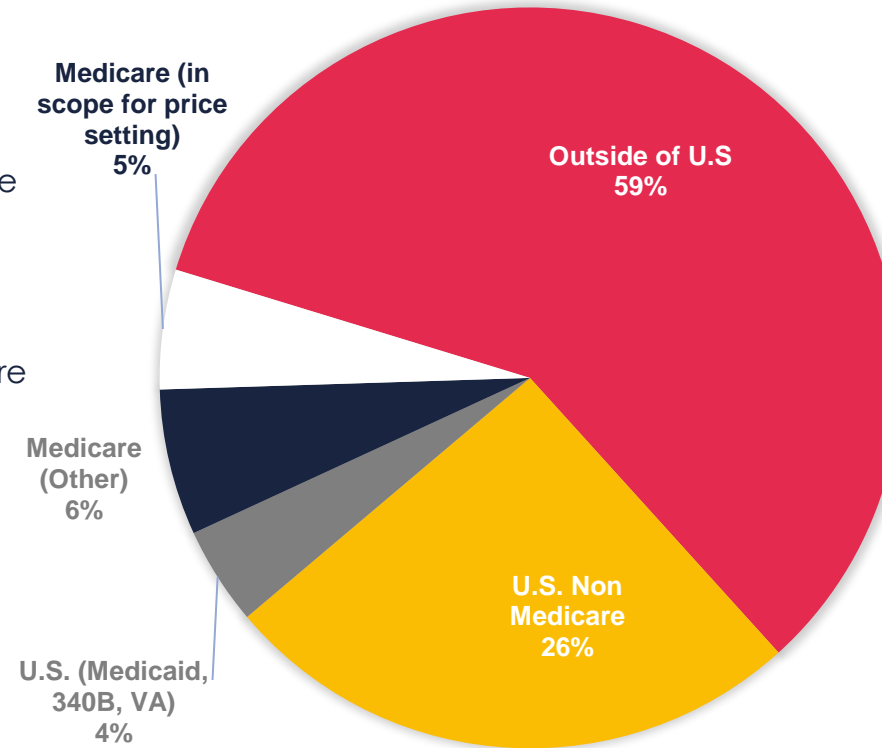
### Inflation Reduction Act (IRA) being implemented in Medicare

- sets prices in Medicare
- rebate for drug price increases above inflation
- out-of-pocket costs are limited
- transfers some risk to drug companies and insurers

### Existing price controls expanding

- 340B growth
- state review boards

### Increasing interconnected drug market approval and reimbursement (CMS/FDA)



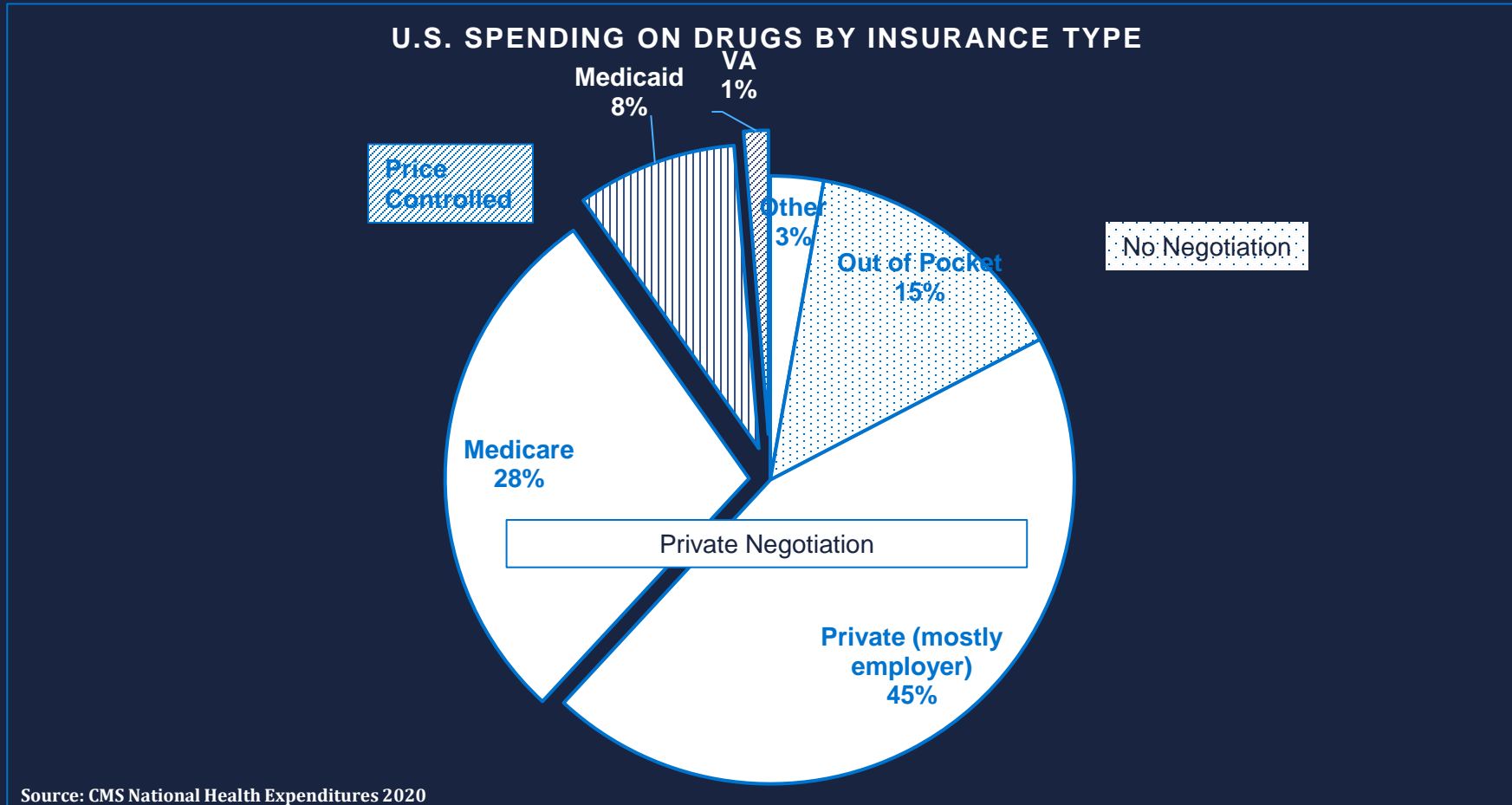
## Global markets are continuing to constrain price and access

- Restrictive pricing systems and intensification of price controls in higher income countries
- Interest in waivers to reduce intellectual property protections

Source: Calculations Based on, Avalere Analysis of Potentially Affected Drugs Updated 7-2022 <https://avalere.com/insights/updated-reconciliation-package-changes-drugs-eligible-for-negotiation>, CMS National Health Expenditures 2020, and IQVIA Global Use of Medicines 2022, Medicaid from CMS, 340B estimated to equal Medicaid, VA from x

# Medicare accounts for a large portion of U.S. biopharma sales

The IRA expands the market where drugs can be price controlled to nearly 40% (not all Medicare drugs will be affected while all Medicaid and VA drugs are subject to price controls )



Medicare is the insurer for 65 million people, it is subsidized by the federal government and is the focus of drug pricing provisions in IRA



# Federal price controls for drugs considered for years, particularly to pay for other spending

Controlling drug prices has Federal support, after many attempts they were enacted into law in August 2022

## Inflation Reduction Act (Became Law '22)

- *Allows government price setting for top-spending Medicare drugs*
- *Imposed an inflation rebate for price increases above consumer inflation, **only in Medicare B and D***
- *Changes manufacturer discount requirements in Medicare Part D, more liability for higher cost beneficiaries*



**Drug price controls were considered but not passed**

## Affordable Care Act (Enacted '10)

- *Increased Medicaid rebates*
- *Expanded 340B discounts*
- *Brought uninsured into insurance system*
- *Increased discounts from biopharma to Medicare Part D (coverage gap)*

## Medicare Part D (Enacted '03)

- *Initiated prescription drug coverage for seniors and disabled people eligible, so insurance companies could negotiate rebates on their behalf*

# Inflation Reduction Act Builds on Policy In Discussion for Years, Deprioritizes Value Emphasizes Drug Discounts and Price Controls

Common Elements Legislation Affecting Drug Price and Access	IRA
Limits total patient cost obligation “out of pocket cap”	<input checked="" type="checkbox"/>
Reduces federal subsidy for high-cost Medicare D beneficiaries	<input checked="" type="checkbox"/>
Limits to drug price increases (Medicare)	<input checked="" type="checkbox"/>
Allows CMS to set drug prices (focus older drugs, big selling drugs)	<input checked="" type="checkbox"/>
Requires manufacturer discounts for all patients and all drugs	<input checked="" type="checkbox"/>
Passes through rebates from PBMs to patients or require transparency	<input type="checkbox"/>
Value based care initiatives	<input type="checkbox"/>
Incentives for care quality or prevention	<input type="checkbox"/>

# Shift from mostly private negotiation to Federal price controls will disproportionately impact investment in medicines for conditions of the elderly and disabled

Today, Medicare and private insurance drug coverage is administered by a commercial insurer with competitively negotiated drug prices.

- The biopharma manufacturer sets a list price and then may negotiate discounts or rebates with health insurers and their intermediaries for preferable formulary status.
- While protected classes of drugs have coverage requirements in part D, there is still pricing pressure.

The Inflation Reduction Act (IRA) focuses on Medicare drugs and limits the prices

This adds public price setting on top of the mostly private market system.

Greatest effect on conditions affecting the elderly and disabled (e.g., cancer, macular degeneration) that are covered by Medicare

- This results in greater exposure to the law's impact for those patients and conditions, both in patient cost saving and potential loss of access to innovative medicine.

# Implications of the Inflation Reduction Act

## Key Points In This Discussion

The IRA is to be implemented quickly with little opportunity for input, and oversight into its implementation is limited and there is significant potential for disruption in private as well as the public market

Costs for certain Medicare patients, particularly those who use a lot of medicines, will go down

Certain drug costs for the federal government will go down, but not necessarily healthcare costs

Return on investment in certain types of medicines likely to be reduced, particularly small molecules and post approval research

Reduced potential for entry of generic and biosimilar medicines and access to those medicines

Changes in plan competitive dynamics likely to disrupt patient access

Value of evidence will be affected, particularly if not considered in price setting

# Audience Q&A

Explaining the Inflation Reduction Act



THANK YOU

Explaining the Inflation Reduction Act