Inflation Reduction Act

Drug pricing and access provisions

Implications for biopharma companies and people who depend on medicine

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Goals for panel discussion

Inflation Reduction Act (IRA)

Focus on drug pricing and access provisions

- Consider some second order effects of the law including: on patient costs, development of evidence, investment in clinical development, access to branded and generic medicines, differential impact to small and large companies
- Know the timelines for implementation and consider how the law may evolve
- No talk about an individual drug's price or its pricing strategy

Politics constraining drug price and access

Macro-economics	Economic stagnation, inflation and rising energy costs, add pressure to reduce budgets including healthcare globally
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

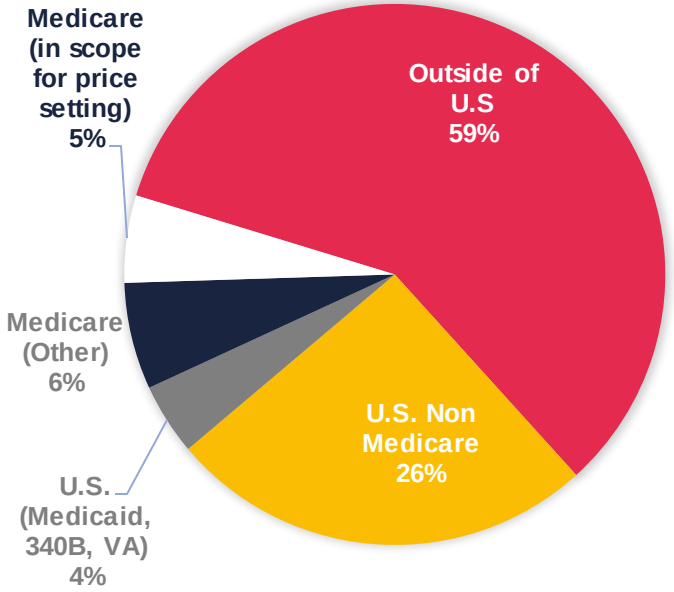
Global drug policy pressures around the world affect investment in biopharma and drug development

US becoming more restrictive

Inflation Reduction Act (IRA) being implemented in Medicare

Existing price controls expanding

- 340B growth
- state review boards



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 fromx

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)

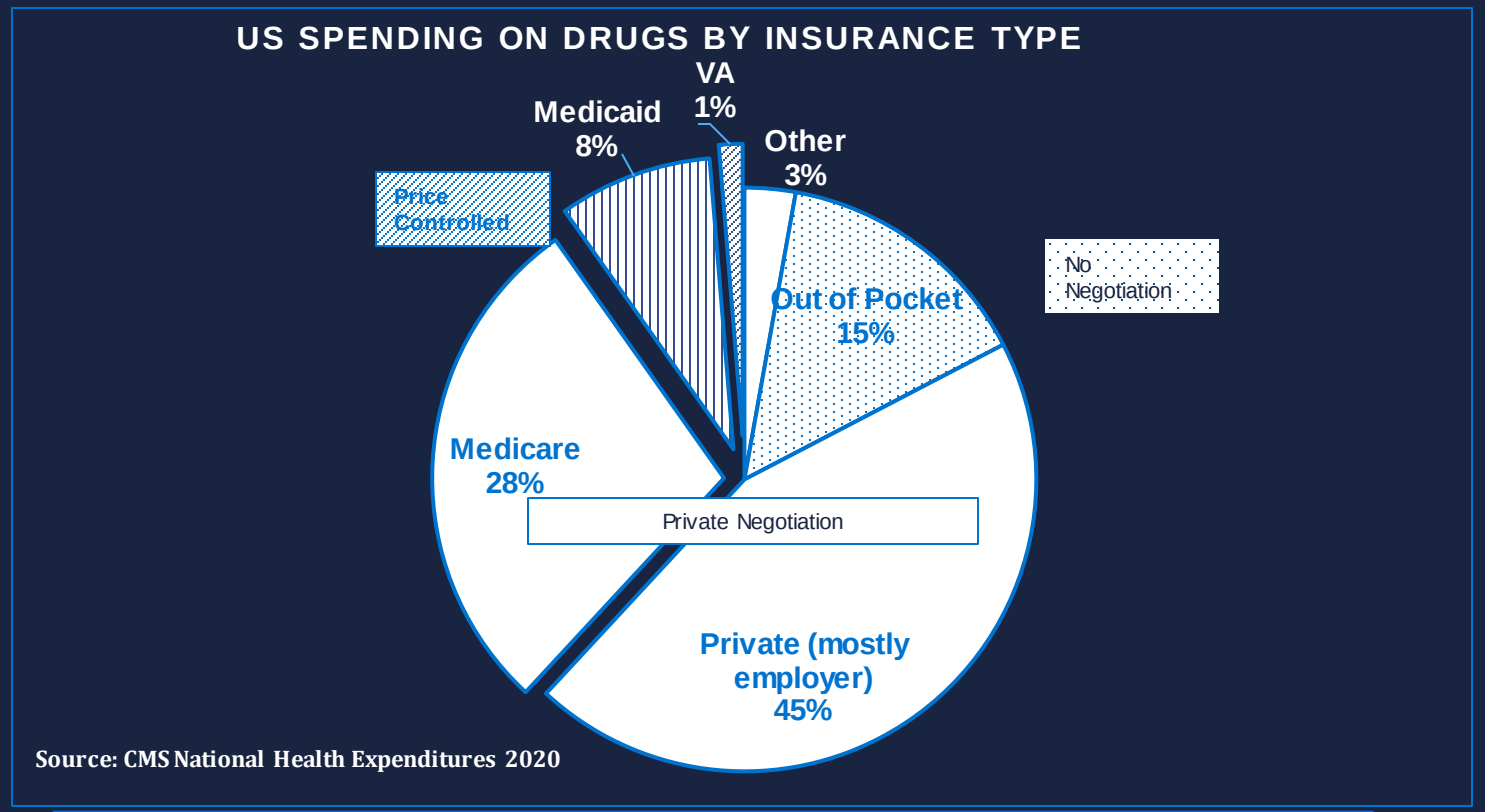
- *Increased Medicaid rebates*
- *Expanded 340B discounts*
- *Brought uninsured into insurance system*
- *Increased discounts from biopharma to Medicare Part D (coverage gap)*

Medicare Part D (Enacted '03)

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

Medicare accounts for a large portion of US 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

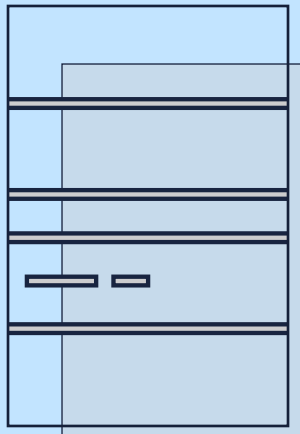
Key provisions in the IRA, potential implications for Biopharma

Requires manufacturer rebates for prescription **drug price increases** that grow faster than consumer inflation.	• 2022: will pay a penalty (-) if price growth before discounts exceeds inflation
Limits **out-of-pocket** prescription drug costs in Medicare part D.	• 2024: positive (+) for adherence and prescription abandonment, for unsubsidized population
Redesigns Medicare part D benefit and **shifts costs for high-cost beneficiaries to plans and biopharma companies**.	• 2025: Discounting obligations may be bigger or smaller depending on drug portfolio, increasing obligation for specialty drugs and low income subsidy population
Mandates **direct price setting** for a select number of therapies that have the highest revenue in the Medicare program.	• 2026: Reduces anticipated revenue for medicines for elderly and disabled, both those price controlled and those competing

Key provisions in the IRA, potential implications for Payers

Requires manufacturer rebates for prescription **drug price increases** that grow faster than consumer inflation.	• 2022: higher launch prices for future medicines likely with big rebates, existing drugs won't take as large a price increase or see as much rebate growth, likely loss of rebates in the short term
Limits **out-of-pocket** prescription drug costs in Medicare part D.	• 2024: cost based formulary tools (tiers) less effective, particularly for people who use specialty drugs or are high cost
Redesigns Medicare part D benefit and **shifts costs for high-cost beneficiaries to plans and biopharma companies**.	• 2025: Far greater financial liability for Part D plans in the catastrophic coverage phase, new cost liability for LIS. Consider distinct implications for PDP (all drugs) and MA-PD businesses
Mandates **direct price setting** for a select number of therapies that have the highest revenue in the Medicare program.	• 2026: Likely to reduce rebates for drugs that are selected for MFP, may also reduce rebates for drugs likely to be selected as the average price after rebates is the MFP ceiling even sooner

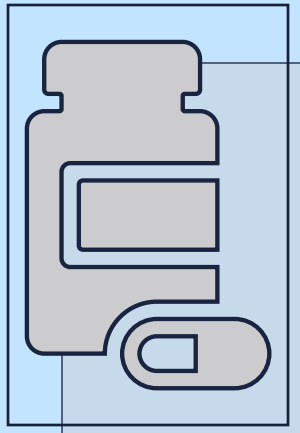
Cost sharing reductions particularly beneficial for certain high need patients



Small but high need group of patients relieved of open-ended OOP drug costs

- 1.4 million spend more than $2000 out of pocket*
- 1.3 million reach catastrophic spending threshold*

- *lower prescription abandonment and non-adherence*



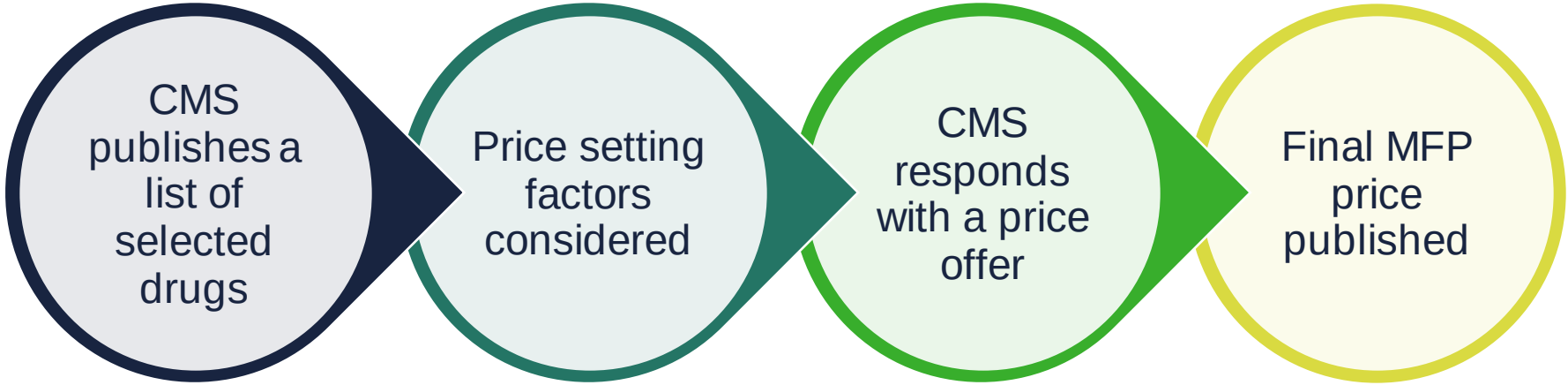
Lower prices and costs for certain conditions

- People who reach high levels of spending more likely to have cancer, rheumatoid arthritis, neurological conditions such as Parkinson's
- *Some conditions and people will experience lower costs but may also result in higher costs or restricted access if rebates are displaced by price setting*

Source: *Kaiser Family Foundation analysis of 2020 prescription drug event claims data

Process for price setting In IRA

CMS Selects the Drugs, Publishes A Maximum "Fair" Price (MFP)



- September 1, 2023 for 2026
- In February two years prior for 2027 and beyond

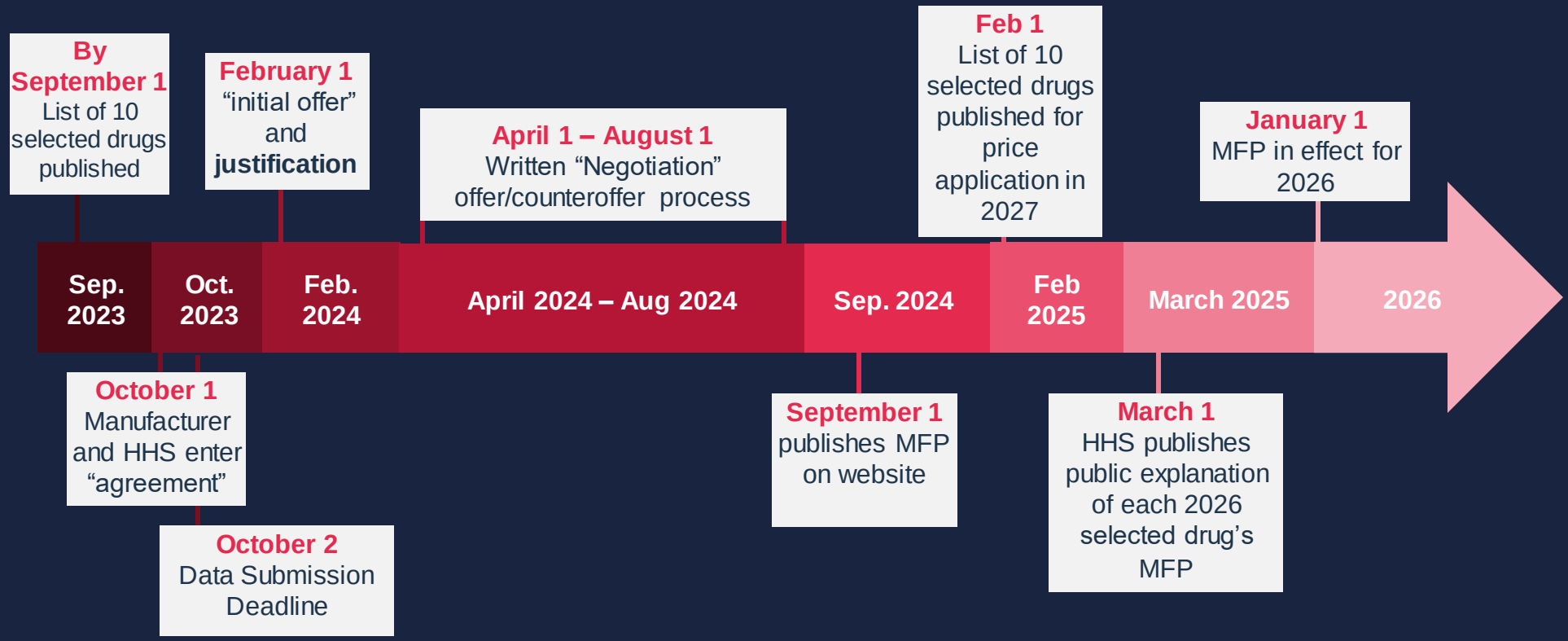
- Clinical value and comparative effectiveness
- Investment in research and development, including federal funds
- Unmet medical needs addressed
- Discounts, rebates
- Revenues, units
- FDA approvals, patent information

Biopharma can submit evidence

- Will include an explanation for the price "offer"
- Manufacturer may accept or counter-offer

- By September 1, 2024 for 2026
- By Nov. 30 of two years prior to price setting taking effect for 2027 and beyond
- Price remains set until re-setting is triggered
  - Ages into new category
  - New indication or evidence
  - Material change to price setting factors

Timeline for HHS for price setting in initial years



First 10 drugs selected for maximum fair price

Released on Aug. 29, 2023, drugs selected from data June 2022-May 2023 data

Drug Name	Commonly Treated Conditions	Part D Gross Prescription Drug Costs (B)	Number of Medicare Part D Enrollees Used the Drug	Part D Covered Prescription Drug Costs Per Enrollee
Eliquis	Prevention and treatment of blood clots	$16.5	3,706,000	$4,448
Jardiance	Diabetes; Heart failure	$7	1,573,000	$4,487
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$6	1,337,000	$4,511
Januvia	Diabetes	$4	869,000	$4,703
Farxiga	Diabetes; Heart failure; Chronic kidney disease	$3.3	799,000	$4,091
Entresto	Heart failure	$2.9	587,000	$4,915
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2.8	48,000	$58,148
Imbruvica	Blood cancers	$2.7	20,000	$133,178
Stelara	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$2.6	22,000	$119,951
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Diabetes			

Key Observations

- No analyst predicted accurately
- Several drugs may have generic competition before MFP
- Many products grouped together
- Disproportionate impact on diabetes and cardiovascular]

Notable in the Revised Guidance

Following feedback, CMS addressed certain issues: comparison of the March 15, 2023 guidance on MFP to revisions (March in italics)

- Maintains original broad definition of "selected drug" which creates a penalty for post market investment in clinical development
- Sustains disincentive to launch complex generics or biosimilars, potential for shortages

- Maintains narrow criteria for orphan drug exclusion
- MFP consideration starts at the earliest approval (even if it was for an orphan designation only)

- Maintains flawed R&D cost calculation and only current NDA holder designation

- Does not clarify how the different factors will be weighted when setting MFP
- Declined to weigh patient benefit over manufacturer data (e.g., R&D recoupment)
- Does not clarify how it will arrive at MFP

Inflation Reduction Act

Summary of key provisions

The Inflation Reduction Act affects the price of medicines for patients and costs for biopharma companies in four principal ways

1. Mandates **direct price setting** between the federal government and drug manufacturers for a select number of therapies that have the biggest revenue in the Medicare program.
2. Requires manufacturer rebates for prescription **drug price increases** when prices grow faster than consumer inflation.
3. Limits **out-of-pocket** prescription drug costs in Medicare part D, particularly for those with high drug costs and those taking insulin or vaccines.
4. Redesigns Medicare part D benefit and **shifts costs for high-cost beneficiaries to Part D plans and biopharma companies,** reducing the federal reinsurance subsidy.

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, furthermore there is significant potential for disruption in private as well as the public market

Plan management of drugs, in particular specialty and protected classes

Process for setting price is not transparent, unclear how clinical value will be assessed

Investment in certain types of clinical study particularly second indications likely to be reduced

Potential to discourage entry of generic and biosimilar medicines and access to those medicines

Rebates, discounts and contracting agreements in private plans may be interfered

Pay for value or outcomes is not emphasized