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How Drug Developers can Navigate the Inflation Reduction Act of 2022

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Executive Summary

1. The Inflation Reduction Act (IRA), which became law on August 16, 2022, has several provisions that will impact the healthcare/pharma industry. These include lower cost sharing for beneficiaries, new Medicare cost sharing responsibilities for manufacturers, and with introduction of CMS price negotiation with with drug manufacturers, directly regulating prescription drug prices for the first time.

- Among the IRA's Medicare provisions are free vaccines to beneficiaries, capped out-of-pocket costs and Part D premium increases, a reimbursement boost for eligible biosimilars, and negotiated "maximum fair prices" for select drugs.
- The IRA also increases and expands tax subsidies for health insurance purchased via Affordable Care Act (ACA) marketplaces, reducing premium costs.
- Drug companies will be penalized for increasing prices faster than inflation, required to pay rebates for the difference.

2. CMS is empowered to negotiate directly with pharmaceutical companies to set the prices for a limited set of high-cost drugs covered by Medicare

- Negotiation-eligible drugs will be selected from the 50 highest total expenditure Part B drugs and 50 Part D drugs per price applicability year; by 2031, 100 drugs will be impacted.
- Single-source name-brand drugs are the target; drugs with generic competition, "small" manufacturers and orphan drugs are excluded.

3. The IRA has the potential both to save beneficiaries money and slow down medical innovation

- While the legislation has been generally received positively by the public, especially beneficiaries, the pharmaceutical industry has been sharply critical, saying that it will result in significantly slower vital investments in medical research and development, and the medical lifesaving innovation that follows.

Legislation will decrease cost sharing for many beneficiaries while shifting costs to manufacturers and health plans, and allow CMS to negotiate and directly regulate Medicare drug prices for the first time

What is the Inflation Reduction Act of 2022?	• The Inflation Reduction Act of 2022 was signed into law on Aug. 16, 2022 and attempts to implement the Biden administration's social, environmental and tax policies. The legislation includes large investments in fighting climate change, funding clean energy and taxing corporations. The law also includes several provisions which will significantly impact drug manufacturers.
How will the IRA impact healthcare?	• Affordable Care Act (ACA) subsidy on insurance premiums extended • Medicare Part B add-on reimbursement for qualifying biosimilars increased for five years • Medicare Part D $35/month/Rx copay cap on insulin • Guaranteed Medicare Part D, Medicaid and CHIP coverage of Advisory Committee on Immunization Practices (ACIP) recommended adult vaccines with no cost-sharing • Required rebates from manufacturers to Medicare for single-source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D with price increases above inflation rate (CPI-U) • Elimination of cost-sharing for Medicare beneficiaries during catastrophic coverage period • Eligibility expansion of Medicare Part D Low-Income Subsidy Program • Cap on Part B payment for biosimilars when average sales price unavailable • Determination of "maximum fair prices" for up to 20 Medicare Part D drugs selected for negotiation • $2000 annual out-of-pocket limit on Medicare Part D drugs • New Medicare Part D Manufacturer Discount Program will require manufacturer discounts for applicable drugs both in the initial coverage phase (10%) and in the catastrophic phase (20%)

Inflation Reduction Act of 2022 CMS timeline for implementation

2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Part B biosimilar reimbursement boost for five years	Medicare cost-share cap on insulin $0 copay vaccines for Medicare and most Medicaid/CHIP beneficiaries Manufacturers pay rebates for Part D drug price increases above CPI-U	Beneficiary cost-share eliminated for Part D catastrophic coverage 6% cap on Part D plan premiums Part D low-income subsidy expanded Cap on Part B payment for new biosimilars when ASP unavailable Manufacturers pay rebates for Part B drug price increases above CPI-U	$2,000 cap on out-of-pocket Part D costs Part D catastrophic coverage restructured/Part D Manufacturer Discount Program begins	Negotiated prices for select drugs in effect					
				10 Part D drugs	Additional 15 Part D	Additional 15 Part B and/or D drugs	Additional 20 Part B and/or D drugs	Additional 20 Part B and/or D drugs	Additional 20 Part B and/or D drugs

Who's most impacted?

CMS and Medicare beneficiaries will benefit most from the Inflation Reduction Act requirements; responsibilities of manufacturers and plans increase to make up the difference

Groups who will be most impacted from the Inflation Reduction Act

Medicare

Manufacturers

Plans

Beneficiaries...

- With high-cost drugs
- Who make up to 150% of the federal poverty line
- Ages 65+
- Eligible for select biosimilars
- Insulin users

Under the Inflation Reduction Act, cost sharing for Medicare beneficiaries will be significantly decreased

Part D Low Income Subsidy (LIS) eligibility expanded (2024)

Eligibility for Medicare Part D premium and cost-sharing assistance will be expanded from 135% of Federal Poverty Level to 150% of Federal Poverty Level

$2,000 Cap on Annual Out-of-pocket costs (2025)

Medicare beneficiaries' out-of-pocket costs will be capped at $2,000 for the plan year

Elimination of 5% coinsurance in catastrophic phase (2024)

The coinsurance will no longer be the responsibility of the beneficiary after reaching the catastrophic phase ($7,050 OOP in 2022)

Improved vaccine access (2023)

Vaccine cost sharing will be eliminated for adult Medicare, Medicaid, and CHIP beneficiaries

Payment boost for eligible biosimilars is intended to realign incentives and reduce healthcare costs

CMS has stated that the temporary 5-year increase (2022-2027) will encourage competition, lower costs for prescription drugs, and improve patient access to biosimilars.

Under Part B's standard ASP+ 6% reimbursement, providers may lack incentives to use biosimilars. Reimbursement for the originator is often higher and switching to a biosimilar requires administrative work and patient education

As a result, patient co-insurance burden may be unnecessarily high

Hypothetical Example

	ASP	2021 provider reimbursement methodology	IRA provider reimbursement methodology	Patient cost-share (20%)
Originator biologic	$1500	**$90 (6% of ASP)**	**$90 (6% of ASP)**	$300
Biosimilar	$1000	**$60 (6% of ASP)**	**$120 (8% of ASP of originator biologic)**	$200

Impacted originator products (as of December 2022)

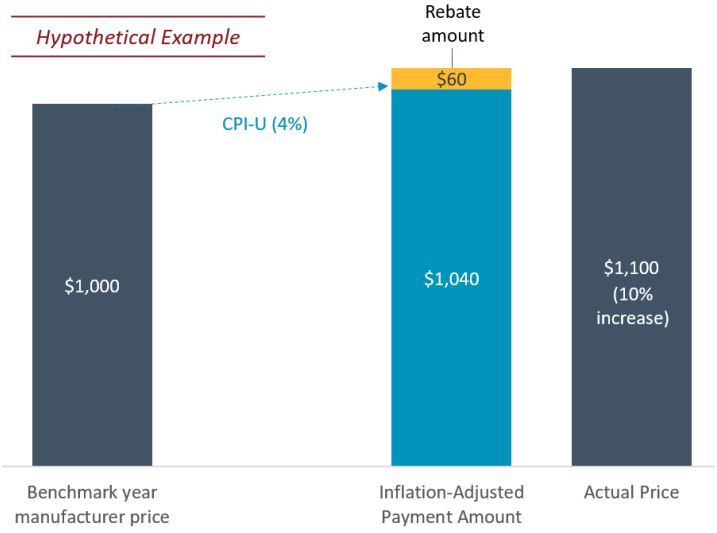
- Neupogen
- Remicade
- Epogen/Procrit
- Avastin
- Herceptin
- Rituxan

The IRA's temporary payment boost reimburses providers 8% of the ASP of the originator biologic for using the biosimilar, providing a financial incentive to switch. To qualify, a biosimilar's ASP must be less than originator

Source: CMS, Biosimilars Forum

The IRA requires manufacturers to pay rebates on Medicare drugs whose overall price (AMP for Part D, ASP for Part B) increases faster than inflation

Because AMP and ASP are calculated based on overall (private and Medicare) market prices, inflation rebates in Medicare will have spillover effects on commercial market pricing.

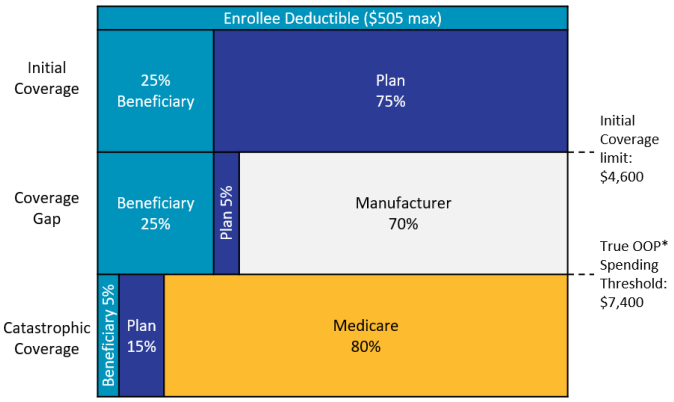


	Part D	Part B
Impacted drugs	All Part D drugs, including line extensions	Single-source drugs and biologics, excluding vaccines and drugs costing less than $100/year
Measurement period	12-month periods beginning October 1, 2022	Quarterly, beginning January 1, 2023
Price metrics used	Weighted Average Manufacturer Price (AMP), weighted by units for each quarter of year	106% of Average Sales Prices (ASP) for quarter six months prior to current quarter
Benchmark Year Manufacturer Price	Weighted average AMP for or first calendar year post-launch	106% of ASP for , or for 3rd full quarter post-launch
Inflation adjustment	CPI-U from 2021, or January post-launch, to January of current year	CPI-U from 2021 or first quarter post-launch, to quarter six months prior to current quarter

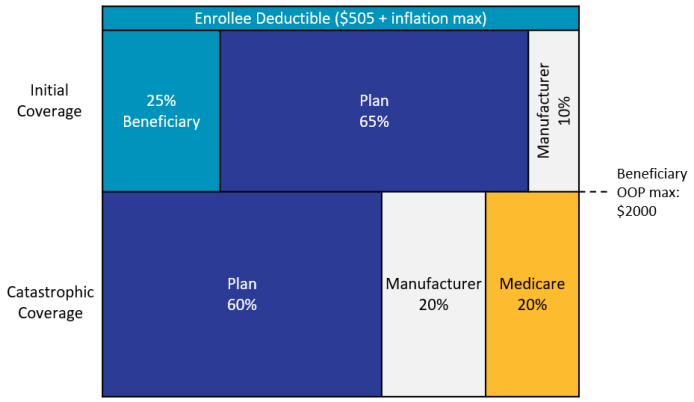
The IRA shifts responsibility for Part D drug costs from beneficiaries to plans and manufacturers via a $2000 patient OOP cap, manufacturer discount program, and other Part D changes

Under the new "pay to play" program, starting in 2025, manufacturers participating in Part D must offer a 10% discount during the initial coverage period and a 20% discount after beneficiaries have reached the $2000 OOP threshold.

Existing Part D Structure (2023)



Inflation Reduction Act (2025)



*** Includes manufacturer discounts during coverage gap**
Source: kff.org, Manatt, Phelps & Phillips, Hogan Lovells

Negotiation-eligible drugs will be selected from the 50 highest total expenditure Part B drugs and 50 Part D drugs per price applicability year; by 2031, 100 drugs will be impacted

Negotiation-eligible drug selection methodology

Manufacturers submit information on the non-Federal average manufacturer price to the Secretary by March 1st of the year of the selected drug publication date (beginning 2026)

By June 1, the Secretary will provide the manufacturer of a selected drug with a written initial offer for the maximum fair price of the drug and a list of factors/explanations

Within 30 days of receiving the initial offer, the manufacturer must either accept the offer or propose a counteroffer in writing and justified with evidence

The Secretary will respond in writing to the counteroffer, and all negotiations will end prior to November 1st that year

Each manufacturer will need to provide the following information, which the Secretary of Health and Human Services uses to negotiate lower prices for the most expensive drugs that lack market competition:

- Research and development costs for the drug and the extent to which the manufacturer has recouped research and development costs
- Market data for the drug
- Unit costs of production and distribution for the drug
- Clinical trials data
- 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
- National sales data for the drug

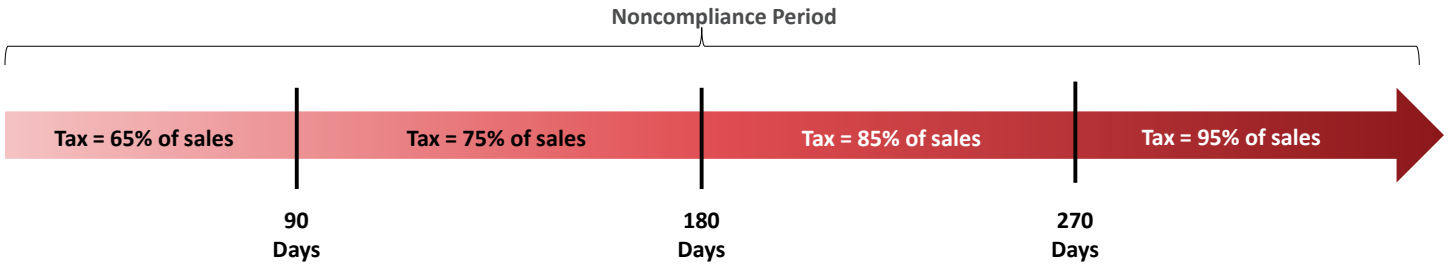
Single-sourced name-brand drugs with the highest total expenditure of Medicare Part D (outpatient) and Part B (physician-administered) are likely to be targeted for negotiation

Exceptions to price negotiation

- Single-source name-brand drugs that have biosimilar or generic competition
- Small- molecule drugs whose FDA approval is less than 7 years
- Large-molecule biologics whose FDA approval is less than 11 years
- "Small" biotech companies
- Orphan drugs
- Plasma derived drugs

Manufacturers that fail to negotiate drug pricing are subject to a large sales tax that increases along the noncompliance period

In order to enforce the lowering of prescription drug costs for Medicare beneficiaries, any manufacturers, producers, or importers that fail to negotiate drug pricing when eligible will pay a nondeductible excise tax on each drug sale until compliance is reached.



The IRA has seen pushback from manufacturers/biotech companies and those investing in future drug development

The pharmaceutical industry believes that these restrictions will create uncertainty around the pharmaceutical marketplace which attracts many companies and investors

Pharmaceutical Research and Manufacturers of America (PhRMA) suggests that an implication of pricing control could be the dampening of future drug development

Many companies express that this will have significant disproportioned effects on small molecule drugs produced by smaller biotech companies – specifically imposing price negotiations for small molecule drugs 7 years after FDA approval, as opposed to 11 years post-approval for biologic drugs, noting that 7 years is not enough time to generate a return on investment and will consequently defund many promising drugs.

How can we help?

The Inflation Reduction Act will significantly impact how new drugs are marketed and prices are established and negotiated. Negotiating drug pricing while preparing for lower reimbursements can be challenging to even the most experienced companies. Since these Medicare changes will have far reaching implications across the ecosystem, assessing potential impacts is more important than ever.

Certara works with you as a partner, providing evidence-based strategic guidance, and keeping you informed of changes so that you can respond to them quickly. Our dedicated consultants are speaking with managed care professionals, physicians, and patients every day to ascertain the commercial impact of legislative and regulatory changes, new product launches, and market events such as competitor and loss of exclusivity.

SCAN ME

Contact us today to learn more about how Certara can help you navigate this new law and its challenges.

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