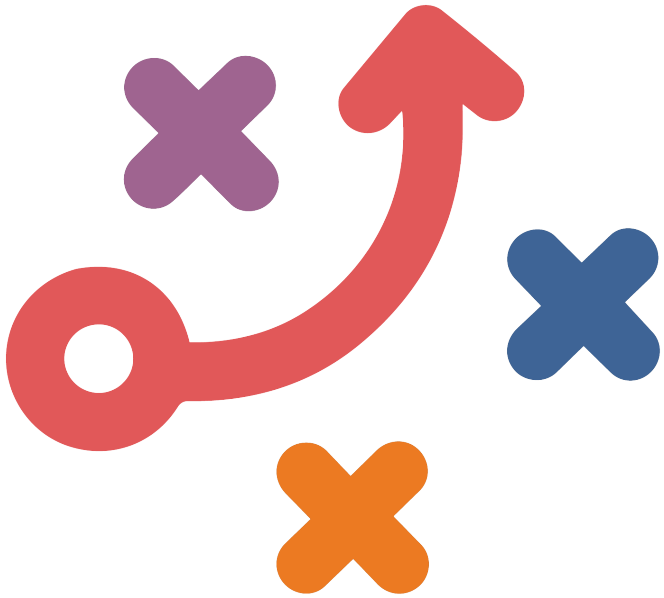

The Inflation Reduction Act

Strategic Considerations for Drug Manufacturers

Camm Epstein and Joshua Cohen

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About This Report

The Inflation Reduction Act: Strategic Considerations for Drug Manufacturers is a 60-page analysis of the IRA's Medicare drug-pricing provisions — inflation rebates, the Part D redesign, and price negotiations — identifying more than 80 strategic considerations for manufacturers' pricing, contracting, and evidence-generation decisions.

The report was published in December 2023, before the Part D redesign took effect and before the first negotiated prices were announced.

> *"A great report that easily distills down key components of the IRA for subject matter experts. Frames up the IRA in a way that gets you thinking about the implications for your organization and can serve as a great primer for leadership and people not steeped in the landscape changes going on."* — Small Biotech Manufacturer

The pages that follow — the table of contents, the report's objectives, and sample pages — illustrate its scope and approach. The full report is available only through purchase and is not distributed online. For more information, contact Camm Epstein at **camm@currantinsights.com** or (518) 429-0875.

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Prologue (continued)

Objectives

This report will:

1. **Describe the IRA's three main drug pricing provisions, including**
   a. Inflation rebates
   b. Part D redesign
   c. Price negotiations
2. **Discuss strategic considerations for**
   a. Drug manufacturers
   b. Small biotechs
   c. Orphan-drug manufacturers
3. **Explore how manufacturers' responses may elicit responses from:**
   a. Competitors
   b. Payers
4. **Describe feedback loops including those between:**
   a. Medicare and commercial plans
   b. Parts B and D drugs
   c. IRA provisions

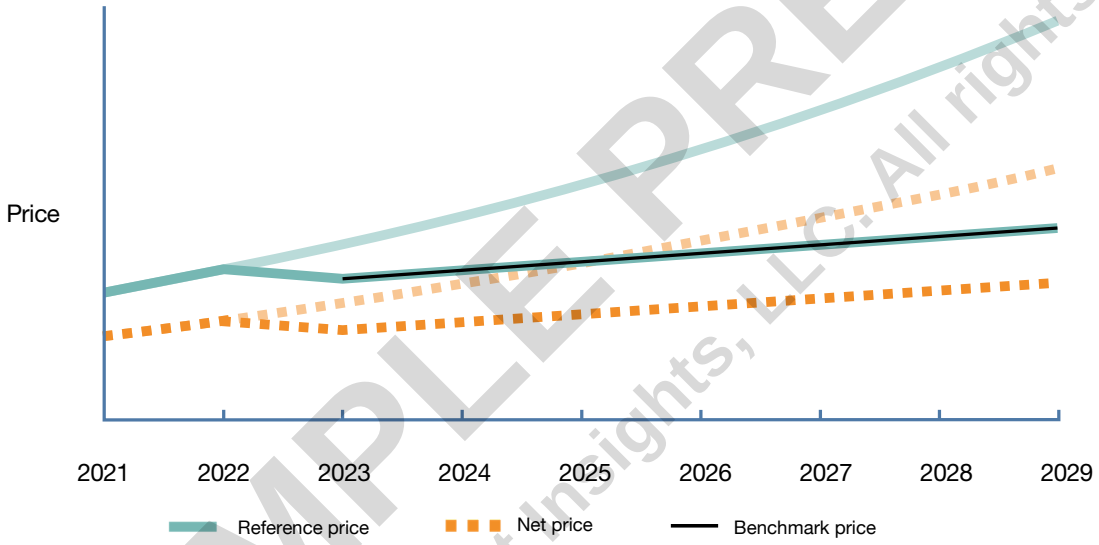
Inflation Rebates

Potential Approaches for Manufacturers (continued)

The CBO does not illustrate a scenario in which the manufacturer is unable to reduce rebates and discounts due to negotiated contracts or is unwilling to do so because of competition and the risk of formulary restriction or exclusion. It is important to remember that PBMs are often contractually obligated to guarantee rebates (typically a percentage of rebates or an amount per type of script) to plan sponsors and will look for opportunities to deliver on their guarantees. Conceivably, some manufacturers may reduce the reference price to avoid the inflation rebate penalty and maintain the same rebates and discounts. Under this scenario, the net price is immediately lowered and increases only at the same rate as the benchmark price (Figure 8).

Some manufacturers may be willing and able to avoid the inflation rebate and, later on, not reduce rebates and/or discounts.

FIG. 8 Maintain Rebates and Discounts



Source: Currant analysis

Strategic Considerations: Manufacturers offering rebates and/or discounts should explore the extent to which they can reduce price concessions to stabilize net prices and consider how lower rebates and discounts may impact market access. Manufacturers must also consider the timing of any contract changes and their impact on contracts for other products.

Part D Redesign (continued)

Evolution of the Part D Benefit, 2024–2025

Changes to the Part D benefit structure are phased in over 2 years. In 2024, the 5% coinsurance requirement for the catastrophic phase is eliminated. In 2025, the coverage gap is eliminated and an out-of-pocket spending cap for beneficiaries takes effect.

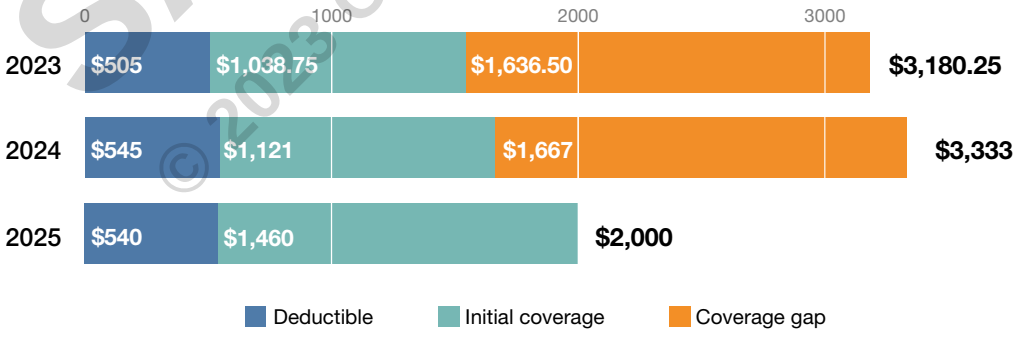
Because the cost of orphan drugs and small-biotech products is typically high, two aspects of Part D redesign are of paramount importance to small biotechs and orphan-drug manufacturers:

1. Patient cost-sharing in the catastrophic phase effectively drops to zero. In 2024, once OOP spending for Part D enrollees who take only brand-name drugs reaches $3,333 — the threshold for reaching this phase — they will hit a *de facto* spending cap. In 2025, the spending cap becomes official, dropping further to $2,000 (Figure 9).
2. The government's responsibility in the catastrophic phase drops from 80% to 20%, with manufacturers facing a new mandated 20% discount in this phase in 2025. Part D plans pick up the remainder of costs for a beneficiary who reaches this phase, meaning that the majority of drug costs are shifted to payers in 2025 (Figure 10, page 23).

In 2025, Part D redesign caps out-of-pocket spending and raises plans' and manufacturers' costs in the catastrophic phase.

Strategic Considerations: Manufacturers of high-cost drugs should consider estimating how the OOP cost cap may boost demand. Manufacturers should also consider how greater plan liability in the catastrophic phase may increase restrictions and exclusions. Manufacturers should also consider modeling how their greater liability in the catastrophic phase impacts profits.

FIG. 9 Out-of-pocket Part D Drug Costs



Source: Currant analysis, KFF

Part D Redesign

Implications for Utilization, Pricing, and Competition (continued)

TABLE 2 Monthly Expenditure, by Stakeholder, for a Hypothetical Drug at $6,400 per Month*

(US$)

Month	Enrollee		Part D Plan		Medicare		Manufacturer	
	2023	2025	2023	2025	2023	2025	2023	2025
January	505.00	540.00	–	–	–	–	–	–
	1,038.75	1,460.00	3,116.25	3,796.00	–	584.00	–	–
	435.00	–	87.00	12.00	–	4.00	1,218.00	4.00
February	1,201.50	–	240.30	3,840.00	–	1,280.00	3,364.20	1,280.00
	79.70		239.10		1,275.20		–	
March	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
April	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
May	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
June	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
July	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
August	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
September	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
October	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
November	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
December	320.00	–	960.00	3,840.00	5,120.00	1,280.00	–	1,280.00
TOTAL	**6,459.95**	**2,000.00**	**13,282.65**	**46,048.00**	**52,475.20**	**14,668.00**	**4,582.20**	**14,084.00**

Deductible | Initial coverage | Coverage gap | Catastrophic

*Assumptions: A covered, single branded drug with a wholesale acquisition cost of $6,400 per month: prescription is filled monthly over 12 months of the year; beneficiary is fully adherent to dosing regimen; CMS standard benefit is applied to deductible and initial coverage phases.

Strategic Considerations: Manufacturers of specialty drugs will need to account for the 20% discount that will be required in 2025 when Medicare beneficiaries are in the catastrophic phase. Manufacturers of drugs costing $6,400 per month or more, which includes specialty drugs and most orphan drugs, will need to consider that the 20% discount will apply for nearly the entire plan year.

TABLE 3 Monthly Expenditure, by Stakeholder, for a Hypothetical Drug at $1,000 per Month†

(US$)

Month	Enrollee		Part D Plan		Medicare		Manufacturer	
	2023	2025	2023	2025	2023	2025	2023	2025
January	505.00	540.00	–	–	–	–	–	–
	123.75	115.00	371.25	299.00	–	46.00	–	–
February	250.00	250.00	750.00	650.00	–	100.00	–	–
March	250.00	250.00	750.00	650.00	–	100.00	–	–
April	250.00	250.00	750.00	650.00	–	100.00	–	–
May	165.00	250.00	495.00	650.00	–	100.00	–	–
	85.00		17.00		–		238.00	
June	250.00	250.00	50.00	650.00	–	100.00	700.00	–
July	250.00	95.00	50.00	247.00	–	38.00	700.00	–
		–		372.00		124.00		124.00
August	250.00	–	50.00	600.00	–	200.00	700.00	200.00
September	250.00	–	50.00	600.00	–	200.00	700.00	200.00
October	250.00	–	50.00	600.00	–	200.00	700.00	200.00
November	250.00	–	50.00	600.00	–	200.00	700.00	200.00
December	51.50	–	10.30	600.00	–	200.00	144.20	200.00
	39.70		119.10		635.20		–	
TOTAL	**3,219.95**	**2,000.00**	**3,562.65**	**7,168.00**	**635.20**	**1,708.00**	**4,582.20**	**1,124.00**

Deductible | Initial coverage | Coverage gap | Catastrophic

†Assumptions: A covered, single branded drug with a wholesale acquisition cost of $1,000 per month: prescription is filled monthly over 12 months of the year; beneficiary is fully adherent to dosing regimen; CMS standard benefit is applied to deductible and initial coverage phases.

Price Negotiations (continued)

Potential Drug Targets for Medicare Price Negotiation

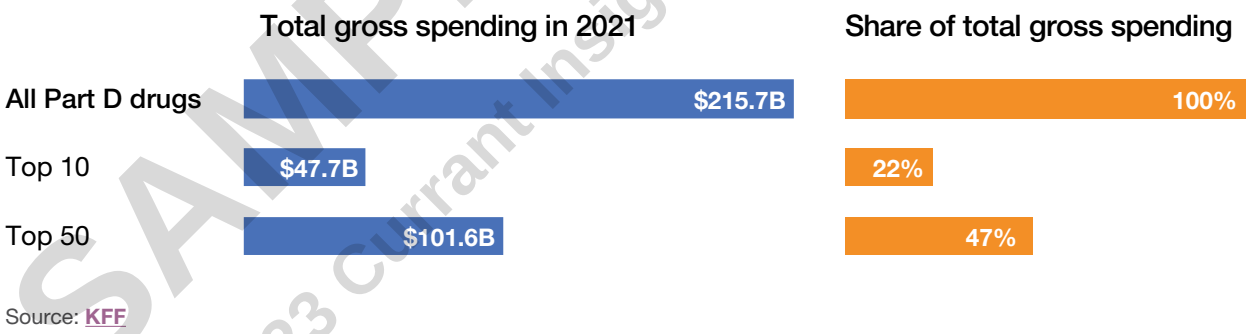
The IRA requires that by 2027, CMS choose up to 20 drugs for price negotiation each year. Considering the IRA's criteria for drug selection, however, it may be difficult for CMS to select as many as 20 drugs in 2027, let alone implement MFPs for 60 drugs by 2029.

The selection criteria themselves may limit the number of drugs for which CMS can negotiate prices.

First, not all of the top 50 drugs in Medicare Part D spend will qualify for price negotiation. Further, there aren't many Part B drugs to select. Part B drugs are not subject to MFP implementation until 2028, and even then, it is possible that **as few as two qualifying Part B drugs** will be selected. Far fewer than half of the 20 drugs scheduled for MFP price implementation in 2029 will likely be Part B drugs. And by the 2030s, no more than a handful of Part B drugs will be available for selection each year. This is because Part B drugs will increasingly face biosimilar competition — and if CMS deems that competition to be meaningful, then they can't be selected.

Even if 20 drugs are not selected in 2027 and MFPs are implemented for fewer than 60 drugs by 2029, those selected will account for a significant amount of Medicare drug spending. The first 10 drugs selected for price negotiation account for about **20% of gross Part D spend**, and the top 50 Part D drugs will likely account for nearly 50% of gross Part D spending (Figure 15).

FIG. 15 Small Number of Drugs Drive a Disproportional Share of Part D Spending



Source: KFF

At one time, CMS had its sights set higher than 50

Early draft language of the IRA reported in the House on September 27, 2021, specified the 125 drugs with the greatest "net spending." The reference point for price negotiations likely shifted to "gross spending" later because of the proprietary nature of contracts between manufacturers and Part D plans and/or the absence of contracts between CMS and manufacturers.