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SPRING 2023

Inflation Reduction Act of 2022: Payer Insights Survey

SUMMARY REPORT

Signed into law on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) represents a landmark shift in federal policy governing the Centers for Medicare and Medicaid Services' (CMS) approach to prescription drug pricing and reimbursement. Legislative provisions have changed the market-based system that has been in place for decades. IRA provisions aim to improve accessibility and affordability of healthcare by lowering prescription drug costs for patients, addressing rising drug prices, and reducing federal drug spending through policy reforms and changes to the Medicare program.

Key Healthcare Provisions in the IRA

Medicare Drug Price Negotiation Program (DPNP)

CMS will directly negotiate prices for select single-source, high-spend branded drugs or biologics without generic or biosimilar competition covered under Medicare Part B and Part D

Medicare Part B and Part D Inflation Penalties

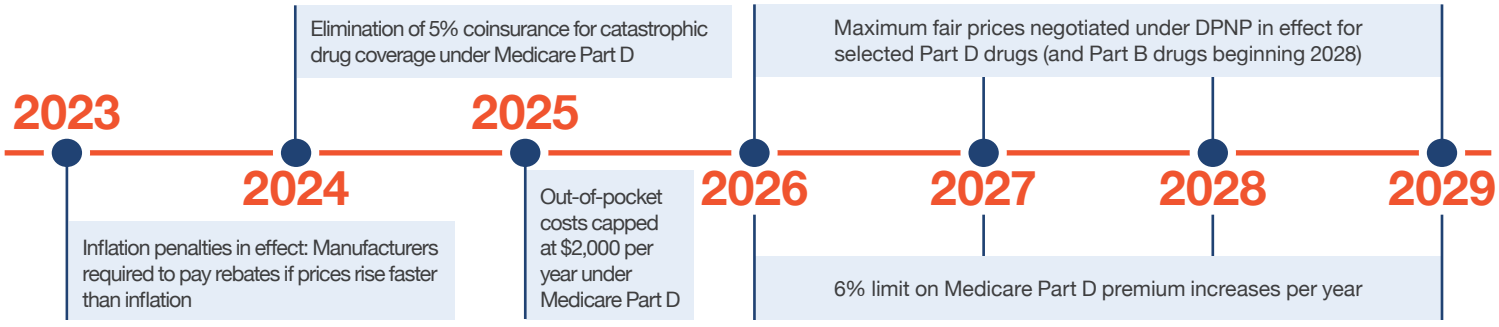
Manufacturers must pay a rebate to the federal government if prices for single-source drugs and biologics covered under Medicare Part B or Part D increase faster than the rate of inflation

Medicare Part D Redesign

Changes the Part D benefit by lowering patient costs (eliminating the coverage gap phase and 5% beneficiary coinsurance requirement above catastrophic coverage, capping out-of-pocket spending at $2,000 per year, and limiting annual premium increases to 6%) and mandating manufacturer discounts on branded drugs in the initial and catastrophic coverage phases

IRA Timeline

Since the enactment of the IRA that outlined general provisions of the law, CMS has implemented and released additional guidance on certain provisions. More information and guidance are needed and will be coming out as the federal government, payers, and manufacturers further implement and respond to the IRA provisions.



Gathering Early Perceptions of Payer Response to the IRA

Magnolia Market Access (MMA) surveyed medical and pharmacy directors at national and regional payers and PBMs that account for over 290 million covered lives and conducted interviews with actuaries about the IRA. Our goal was to understand how payers and manufacturers will react to this sweeping legislation, and how participants expect the IRA [and] Part [D programs] will affect the future of the pharmaceutical industry and access to care. This survey is the second in a series that MMA is fielding.

MMA's survey provides comprehensive insights into how payers will change their plan offerings, adjust their formularies, and implement cost control measures. The survey illuminates how payers believe the future of drug price economics will play out in an ever-changing regulatory environment.

Survey Respondents

30 PAYERS

5

National Health Plans

- 4 medical directors
- 1 pharmacy director

18

Regional Health Plans

- 4 medical directors
- 14 pharmacy directors

7

Pharmacy Benefit Managers (PBMs)

- All pharmacy directors

Highlights from the IRA Payer Insights Survey Report

Most respondents believe the IRA will result in Medicare Part B **prices lower** than their current negotiated rates, while current Medicare Part D negotiated prices are believed to already be lower than what will be negotiated

70%

For drugs not subject to negotiation, **70%** of respondents indicated that net price is still their main determinant when making drug coverage decisions

83%

While most respondents agree that the IRA inflation penalties could keep the growth of drug prices steady, **83%** believe the penalties will result in increased launch prices

Payers expect to employ several cost controls as a result of the Medicare Part D redesign, including **increased** utilization management, tighter formularies, and expecting larger manufacturer rebates

Payers think manufacturers will react by increasing launch prices, decreasing flexibility to negotiate rebates for commercial plans, and increasing the use of outcomes-based contracting agreements

While some respondents are planning to lobby for the repeal or reform of the IRA, most respondents are uncertain what legislative action their organization may consider in the future, if any at all

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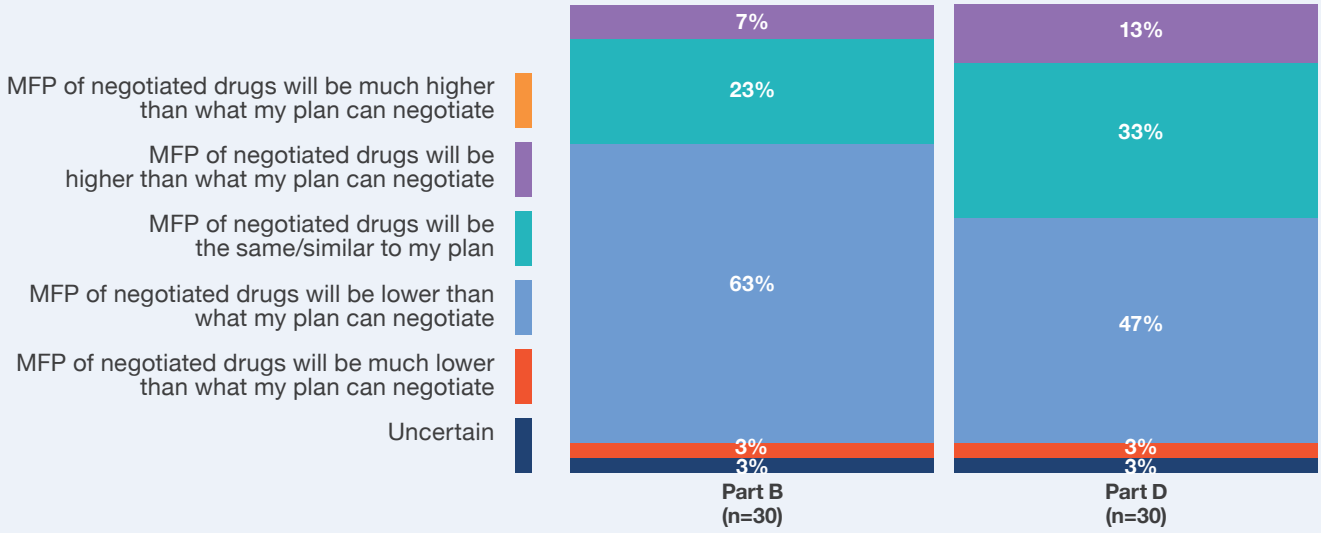
Medicare Drug Price Negotiation Program (DPNP)

The IRA allows the federal government to negotiate prices for select drugs covered under the Medicare Part B and D programs directly with their manufacturers. Medicare will select certain single-source branded drugs and biologics without generic or biosimilar competition with the 50 highest total Medicare Part D spending and an additional 50 with the highest total Medicare Part B spending. CMS released final guidance on the Medicare DPNP provision and its implementation on June 30, 2023, which provides information on the factors for selecting drugs, exclusions from being selected, and the negotiation process. CMS will announce the 10 drugs that are selected for negotiation under Part D on September 1 of this year. The negotiated prices of these drugs, referred to as the Maximum Fair Price (MFP), will go into effect starting in 2026. CMS will continue to expand the number of drugs selected and negotiated, and will include Part B drugs as the provision is implemented over time.

Medicare Negotiated Prices vs Currently Contracted Rates

Among All Respondents



Payers have mixed perceptions on how the government-negotiated prices of the selected high-spend drugs will compare to the prices that they currently negotiate with manufacturers.

Nearly two-thirds of respondents believe the IRA will result in Part B drug prices lower than what their plan currently negotiates for the selected drugs, while nearly half of respondents believe their plan's Part D contracted rates are already lower than what government negotiation will yield.

MMA Insight:

Plans expect higher savings from negotiation on physician-administered products than on the pharmacy benefit side as a result of the Medicare Drug Price Negotiation Program.

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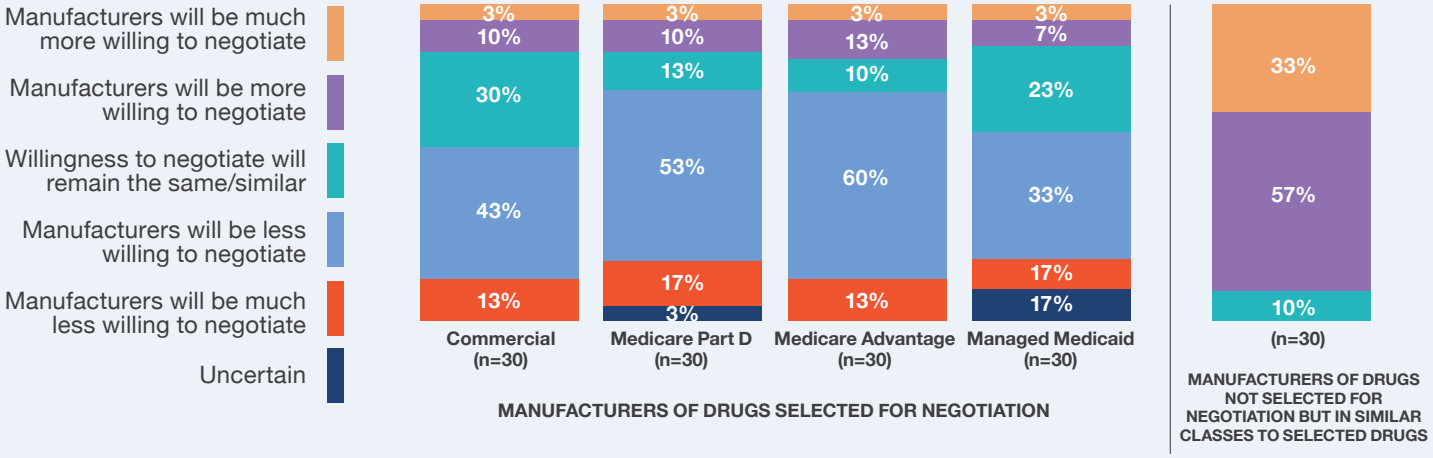
Payers also have varying expectations of how the Medicare DPNP will affect both the manufacturers of selected drugs and manufacturers of drugs not selected for negotiated yet have similar indications or are in similar classes as the selected drugs. Drug manufacturers are expected to have differing degrees of willingness to negotiate rebates beyond the MFPs.

Most respondents believe manufacturers affected by negotiation may be less willing to negotiate additional rebates overall, while all respondents believe manufacturers of drugs not selected for negotiation will remain open to negotiate rebates to stay competitive.

Manufacturer Willingness to Negotiate Rebates Beyond Medicare DPNP Prices

Among All Respondents



How will manufacturers of drugs not selected for negotiation respond?

Does it matter if they're willing to negotiate? If they aren't, then they will just go off formulary. It comes down to leverage and the various parties in the class.

- Actuary

MMA Insight:

This highlights the economic intent of the IRA. By requiring the highest spend product to negotiate with CMS, payers believe additional products will have opportunities to compete by offering larger rebates to "buy" better formulary placement.

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Formulary Placement of Negotiated vs Non-Negotiated Drugs

How will the DPNP affect stand-alone MedicarePrescription Drug Plans (PDP) or Medicare Advantage Prescription Drug (MAPD) formularies?

43% of respondents indicated they will consider significant privately negotiated rebates and other price concessions when designing formularies and may give preference to drugs not subject to the maximum fair price determined by government negotiations.

70% of respondents anticipate that the **net price** of a drug will be the main determinant in coverage decisions and utilization management measures employed for all drugs within the same class as a Medicare-negotiated drug, regardless of the MFP and negotiation status.

How do you anticipate payers will approach coverage decisions for and manage drugs that are not subject to negotiation?

We will still evaluate what products within the class (if they have equivalent clinicals) are the net cheapest for the plan regardless of where the rebate was negotiated.
- Pharmacy director from a national health plan

It all comes down to net cost; MFP drugs will likely have the leg up, and thus stepping through MFP drugs makes complete sense if there is a cost disparity.
- Pharmacy director from a regional health plan

[I] anticipate that same-class options will be adversely impacted and will need to defend market share through price concessions.
- Medical director from a national health plan

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Medicare DPNP and Biosimilars

The Medicare DPNP provision includes a "Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry", meaning that CMS may delay selecting drugs that are listed as reference products for biosimilars that are likely to enter the market for price negotiation. The manufacturer of a biosimilar may submit a request to CMS to delay the inclusion of its reference product if there is a "high likelihood" that the biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year.

The IRA also implements a temporary increase in payment under Medicare for qualifying biosimilars:

- Increased payment of average sales price (ASP) plus 8% of the reference biological product's ASP for a 5-year period
- Increase in the add-on payment whose ASP is not more than the price of the associated reference biological product

86%

of respondents indicated they are likely to give preferential placement to biosimilars with the best contract, regardless of interchangeability status.

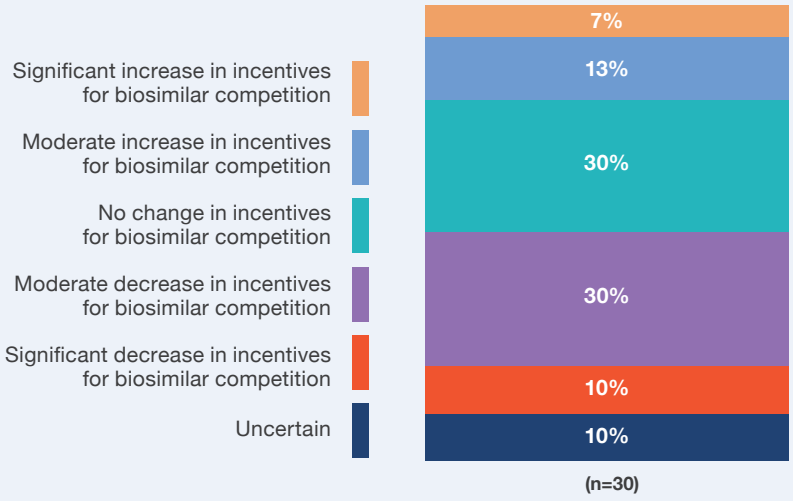
How do actuaries see the DPNP affecting biosimilar competition?

What does the IRA do for [biosimilar competition]? I don't think it hurts it, should only help. [It] might even incentivize manufacturers to try to roll out their own biosimilar on their own drug in order to protect that primary legacy drug from government price negotiation.

- Actuary

Expected Impact of Medicare DPNP on Incentives for Biosimilar Competition

Among All Respondents



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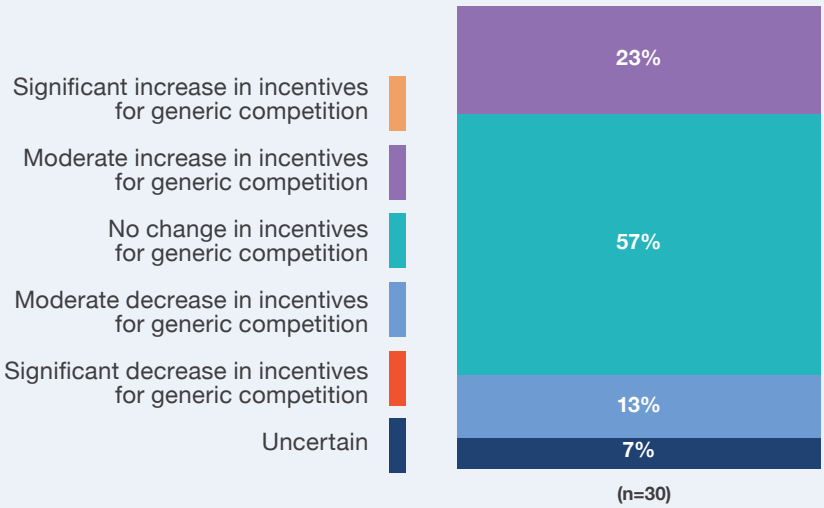
Medicare DPNP and Generic Drugs

Expected Impact of Medicare DPNP on Incentives for Generic Competition

Among All Respondents



A MAJORITY OF RESPONDENTS do not believe incentives for generic competition will be affected by the Medicare Drug Price Negotiation Program.

MMA Insight:

Given the way CMS is defining products to be selected for negotiation, this could lead to an increase in the number of generics on the market. Payers currently have varying preferential payment policies for generics - given the upcoming demonstration projects that the Centers for Medicare & Medicaid Innovation (CMMI) have announced, including capping out-of-pocket costs for a specified list of generic drugs at $2 for Medicare Part D beneficiaries, preferential policies for generics may be likely.

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Medicare Part B and Part D Inflation Penalties

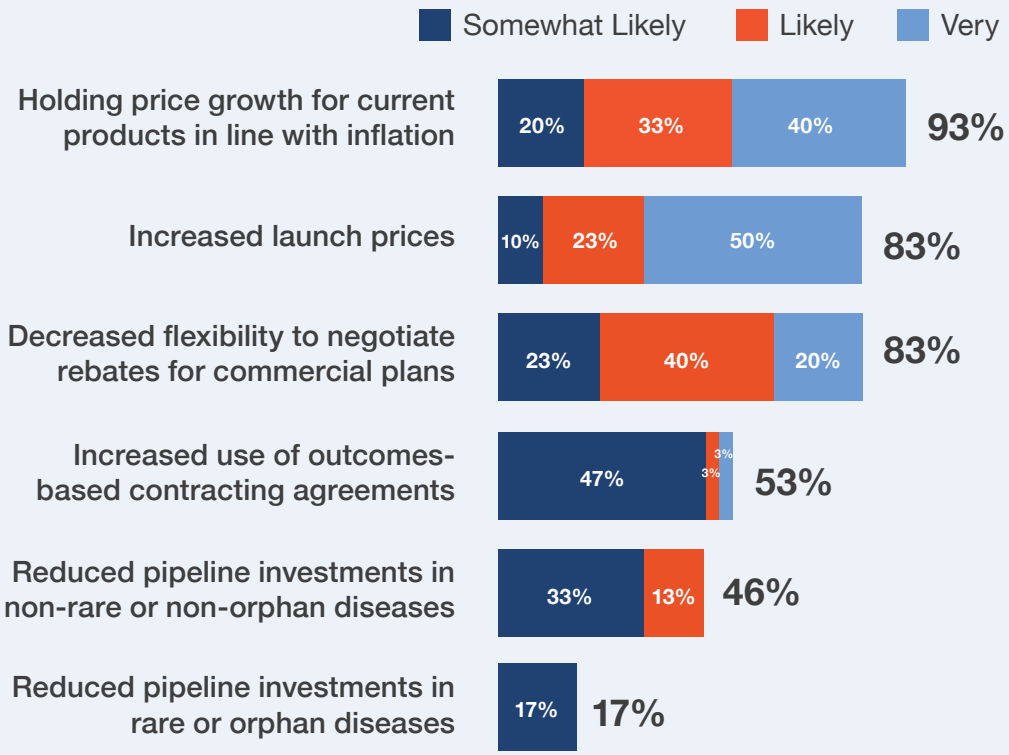
The IRA also addresses drug price increases with the Medicare Part B and Part D inflation penalty provisions. Through these provisions, manufacturers are required to pay a rebate to the federal government if prices for single-source drugs and biologics covered under Medicare Part B or Part D increase faster than the rate of inflation. The rebate amount is equal to the total number of units sold in Medicare times the amount (if applicable) a drug's price exceeds the inflation-adjusted price each year. There are additional penalties if manufacturers do not pay the required rebate amount.

MMA Insight:

CMS released a preliminary list of 27 Part B drugs with inflation penalties, which included unclear calculations and some drugs that are traditionally paid for under Part D. Based on industry feedback, CMS revised the list, but it still includes some Part D drugs. This highlights a lack of transparency from CMS and the need for manufacturers with drugs on the list to review their calculations immediately.

Expected Impact of Inflation Penalties on the Following Manufacturer Actions

Among All Respondents (n=30)



WHILE MOST RESPONDENTS AGREED that inflation penalties could keep price growth steady, **83%** believe they will result in increased launch prices. **83%** of respondents also believe manufacturers will decrease their flexibility in negotiating rebates for commercial plans due to the Part B and Part D inflation penalties.

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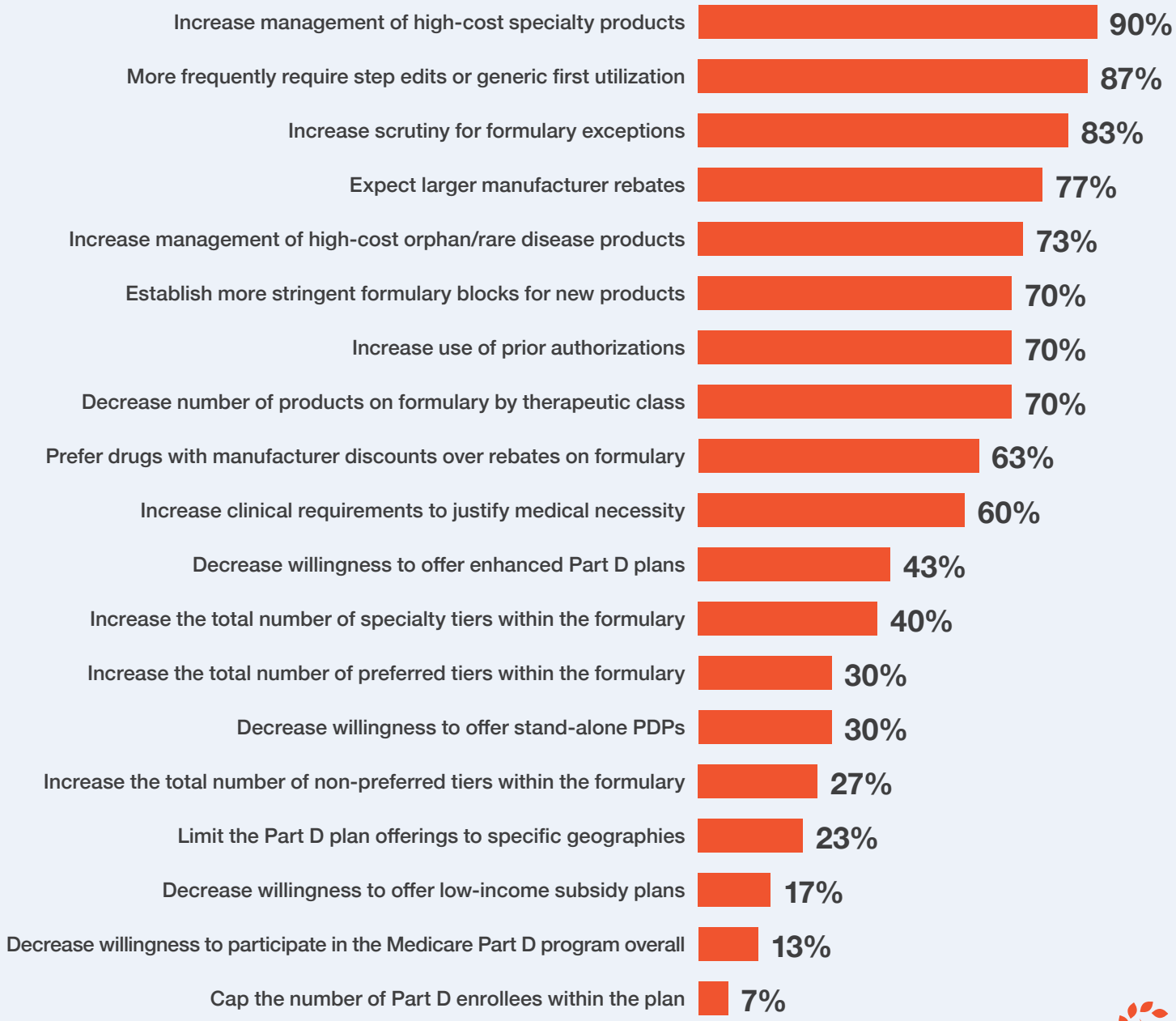
Medicare Part D Redesign

The Medicare Part D redesign provision of the IRA shifts a greater portion of drug costs to Part D plans and manufacturers, and reduces beneficiary cost-sharing over time through 5 key components: benefit redesign, out-of-pocket caps, premium increase limits, mandatory manufacturer discounts, and changes to the Low-Income Subsidy (LIS) program.

Nearly all respondents indicated they expect to employ significant cost control measures in response to patients' out-of-pocket spending being capped at $2,000 per year. While we can expect increased utilization management on high-cost drugs and tighter, more-controlled formularies, payers indicated they are less likely to cap enrollment, limit plan offerings to specific geographies, or choose not to participate in the Medicare Part D program overall.

Actions Payers May Take in the Next 12 Months Based on the Part D Redesign

Among All Respondents (n=30)



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Under the Medicare Part D redesign provision of the IRA, base premium annual increases for patients will be limited to 6% from 2024 to 2029. Beginning in 2023, an additional provision will lower the beneficiary cost-share of standard drug coverage. A majority of respondents believe capping premium increases at 6% will negatively affect plan designs between 2024 and 2029.

MMA Insight:

Actuaries recognize that while they can only increase premiums to beneficiaries by 6% through 2029, they can pass the additional increased costs to CMS. Actuaries have less concern about premium stabilization than other respondents of the survey (who manage formularies) who are more concerned about increased premiums. We note this as an educational opportunity as payers may not fully understand this provision of the IRA.

A majority of survey respondents expect premiums will also increase beginning in 2023 and onward – ranging anywhere from 4% to more than 11% per year. However, actuaries offered a number of other factors that may have a significant influence on whether premiums will increase or decrease over time as a result of the premium stabilization provision.

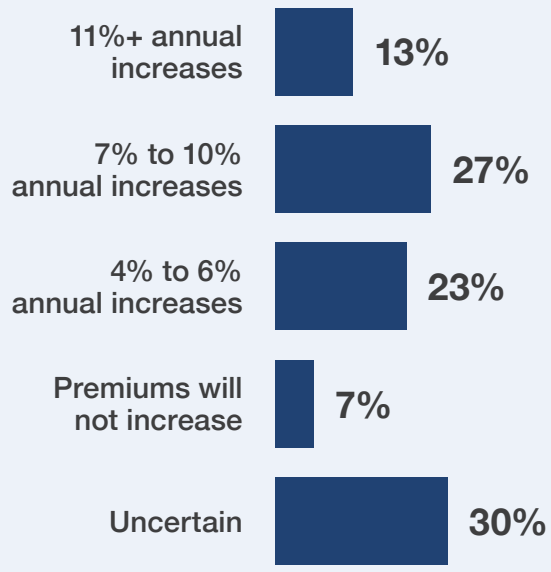
How will Medicare Part D premiums adjust in 2023 and beyond?

[It] depends on their competitive positioning. You have counterbalancing effects in this legislation, so I think that [the Part D] redesign will bring upward pressure on plan liability and therefore upward pressure on premium rates, but [plans] will still have competitive pressures that are different in each region among each of the players. Plans can still raise premiums and still have the same profit margins, [but] those that don't compete well may drop out. They have to continually find ways to manage that; it comes back to being competitive and membership growth to raise market cap and aggregate profits. It's a volume game.

- Actuary

Expected Part D Premium Adjustments in 2030 and Beyond

Among All Respondents (n=30)



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When asked about the Part D "smoothing" provision:

43%
of respondents believe it will have no financial impact on their organization, while 30% believe it will have a negative impact

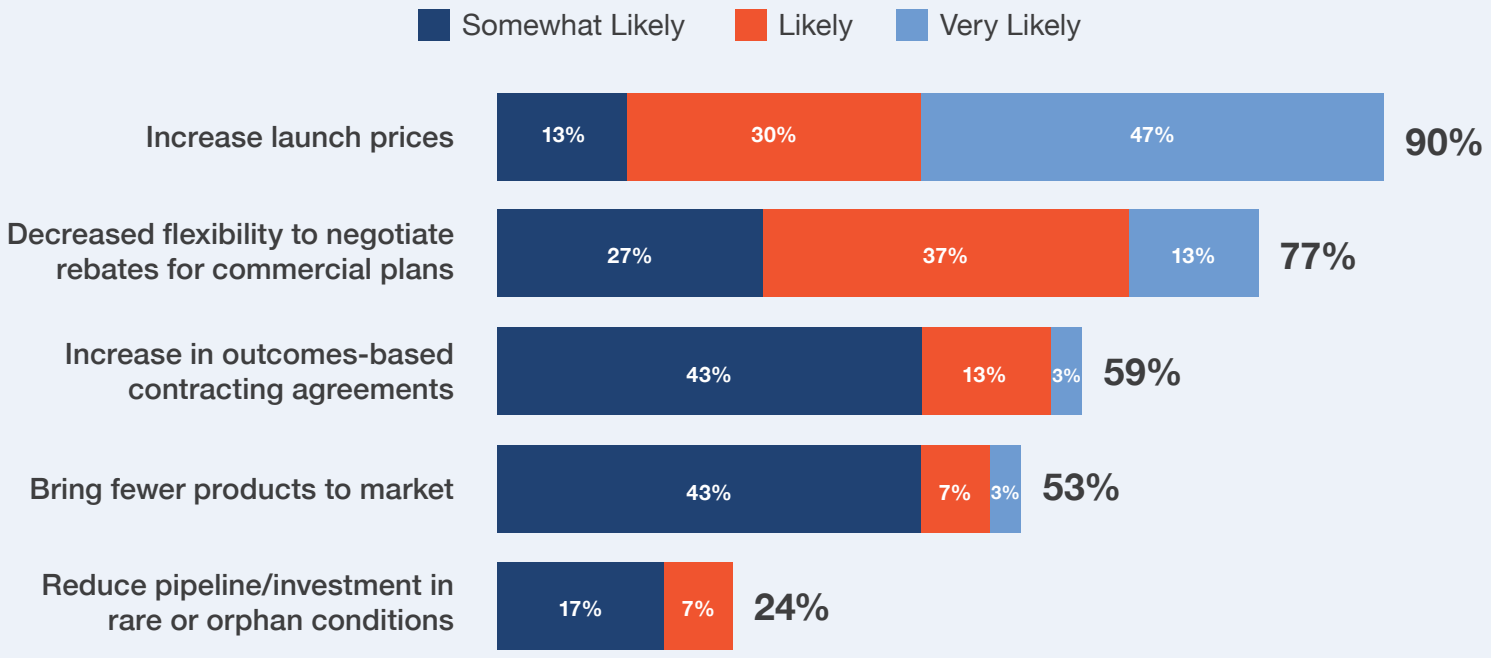
67%
of respondents plan to provide only the minimum outreach required by CMS

67%
of respondents will be flexible with patients and late payments

In addition to capping out-of-pocket costs for patients at $2,000 per year beginning in 2025, the IRA also includes a "smoothing" provision to further help beneficiaries afford the cost of their prescription drugs under Medicare Part D. In 2025, Part D plans will be required to offer beneficiaries the option to spread their out-of-pocket costs across the full calendar year, as opposed to paying the entire amount the first month of treatment. While these "smoothing" requirements are intended to assist the patient with the financial responsibility of starting and adhering to treatment, payers have mixed perceptions on how they will structure these programs and how their organizations will be financially affected as a result.

Expected Impact of Part D Redesign on Manufacturer Actions

Among All Respondents (n=30)



Payers overwhelmingly believe that manufacturers will increase prices at launch and increase use of outcomes-based contracting agreements in response to the Part D redesign provision.

These responses suggest that payers expect manufacturers to decrease their flexibility in negotiating rebates for commercial plans, but most respondents expect larger manufacturer rebates on Part D drugs due to the IRA. Respondents also indicated payers will give formulary preference to drugs with manufacturer discounts over rebates due to the out-of-pocket cap.

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What's Next for the Inflation Reduction Act and the Biopharmaceutical Industry?

Respondents foresee the IRA's Medicare DPNP having the largest impact on their organizations, followed by the Medicare Part D redesign. Examining the overall impact of the IRA's healthcare provisions, payers believe manufacturers will increase launch prices yet remain open to negotiating rebates to remain competitive with the government-negotiated prices of drugs. Payers are also anticipating increasing management of higher-cost drugs, as well as employing greater control measures and narrowing formularies in response to the IRA. However, payers are anticipating that the net price of the drugs will remain the primary driver in making coverage determinations and establishing formulary preferences, regardless of the IRA.

Most respondents are uncertain what action their organizations may consider in terms of repealing or reforming the IRA, if any at all. To date, we have not seen as a significant push from the industry to repeal the IRA as we did for the Affordable Care Act. As CMS releases additional guidance on the mechanics of implementing the IRA provisions, significant comment periods and lawsuits challenging CMS' approaches may follow. While the impact of the IRA on patient access, drug prices, innovation in pharma, and the healthcare ecosystem is yet to be determined, the IRA Payer Insights Survey findings have continued to highlight the areas where the industry needs additional guidance and transparency from CMS and a need for educational opportunities across all stakeholders to drive toward the same goal of increasing patient access to affordable prescription drugs.

AT MAGNOLIA MARKET ACCESS, our goal is to help you navigate federal policies like the Inflation Reduction Act through customized IRA Playbooks that provide biopharmaceutical manufacturer-specific gameplans to analyze key considerations and strategic recommendations for future clinical trials, distribution and labeling strategies, policy, advocacy, patient support services, and pricing and contracting.

If you are interested in discussing the detailed findings of the IRA Payer Insights Survey, or would like to purchase a copy of the full report, please contact us at **IRA@magnoliainnovation.com.**

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