

Stakeholder perspectives on the transformative IRA Part D benefit redesign

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Summary

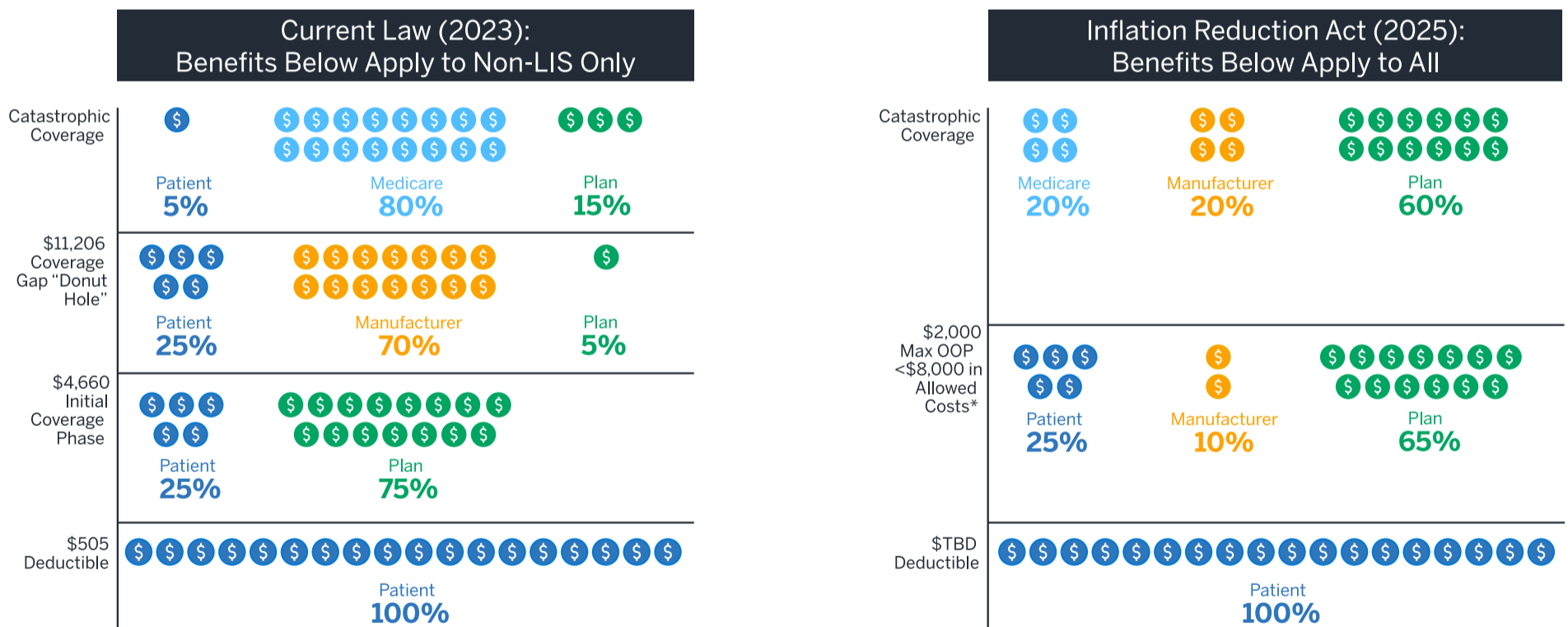
The Inflation Reduction Act (IRA) was passed into law on August 16, 2022. It contained several major changes to Medicare Part D, including a redesign of the benefit allowing Medicare to negotiate drug payments with manufacturers, limits on premium increases, limits on drug price inflation, and caps on insulin copays. This white paper explores the transformative nature of the IRA and discusses how the IRA could affect Part D plan sponsors, members, the federal government, and pharmaceutical manufacturers.

Part D vs. B Drug

Medicare Part D covers prescriptions filled at a pharmacy. Part B covers prescriptions administered by a healthcare professional.

The IRA contains the most significant changes to Part D benefit designs since the program's inception. As shown in Figure 1, the IRA will shift claim liability away from the government and members to Part D plan sponsors and pharmaceutical manufacturers. Part D plan sponsors and manufacturers will naturally adapt their business strategies in response to the additional liability and changes in consumer behavior.

Figure 1: Benefits between the 2023 plan design and 2025 IRA - Changes to Medicare Part D for brand-name drug costs



Note: OOP = Out-of-pocket; The Inflation Reduction Scenario represents 2025 benefits whereas Current Law represents 2023 benefits; In 2024, the patient cost sharing is reduced to 0% in Catastrophic and the plan liability increases to 20%; The TrOOP amount is \$7,400 in 2023, which translates to about \$11,206 in member cost sharing assuming a weighting of 92.13% Brands and 7.87% Generics; At this time, the 2025 deductible level is unknown; *Actual allowed costs will vary based on the 2025 deductible;

Changes to benefit phases due to the IRA

- Eliminates the coverage gap phase and simplifies the benefit design
- Introduces a maximum out-of-pocket (MOOP) for the member
- Increases plan liability in the catastrophic phase
- Adds a manufacturer subsidy in the post-catastrophic phase
- Introduces a smoothing mechanism for members to spread their cost sharing into monthly installments (known as the Medicare Prescription Payment Plan, or M3P)¹

Examples of major transformations that could occur due to the IRA include the following:

- The emergence of new Part D plan competitors, drug manufacturers, or drug distributors and purchasing organizations to serve Medicare Part D plans
- Shifts in Part D enrollment among plans (new or existing) or increases in Medicare Advantage or Part D enrollment
- Changes in drug prices or drug spending
- Changes in which Part D drugs are used by members
- Significant decreases in abandonment or increases in adherence to drug regimens

As with any transformative legislation the full scope of changes to the Part D program may not be known for years.

Background: Strengths and weaknesses in the current Part D program

The introduction of the Part D program in 2006 was seen as a beneficial addition to Part C Medicare Advantage plans and members by:²

- Adding comprehensive pharmacy benefits to Medicare
- Creating many coverage choices for the vast majority of members
- Bringing about cost efficiencies such as the increased use of generic drugs, which comprise over 90% of pharmacy prescriptions used by Medicare members today
- Providing stable premium rates for members

However, certain benefit design features of the Part D program were seen as problematic by a number of organizations, including the Medicare Payment Advisory Commission (MedPAC), the U.S. Government Accountability Office (GAO), the Congressional Budget Office (CBO), and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS).^{3, 4, 5, 6}

- Member coinsurance in the catastrophic phase was unlimited, which could be burdensome for members with high spending.
- Federal spending in the catastrophic phase (mostly for high-cost drugs) grew very rapidly and plans had low liability (15%) for members with high spending.
- High rebates for brand drugs, along with the 70% manufacturer subsidy in the coverage gap, meant plans could benefit from encouraging the use of higher-price brand drugs compared to lower-priced alternatives.
- Members with the highest spending were not protected with limits on cost sharing, but members with the lowest spending had the advantage of low premiums.
- Of the total drug cost, the manufacturer subsidy can be disproportionately low for manufacturers with the highest-cost drugs.
- The Part D benefit was relatively complex, with variable stakeholder liabilities depending on the phase, the drugs members are taking, and when drugs are filled in the calendar year. In addition, the accumulation to the catastrophic phase is based on the combination of member out-of-pocket cost plus the coverage gap discount program, for non-low-income (NLI) members only.
- There are often material changes to formularies or pharmacy networks from year to year, which can cause member confusion and churn.

Is there potential for transformation?

For each Part D stakeholder (plan, member, government, and drug manufacturer), we focus on the following Part D changes introduced by the IRA:

Price negotiation exclusions

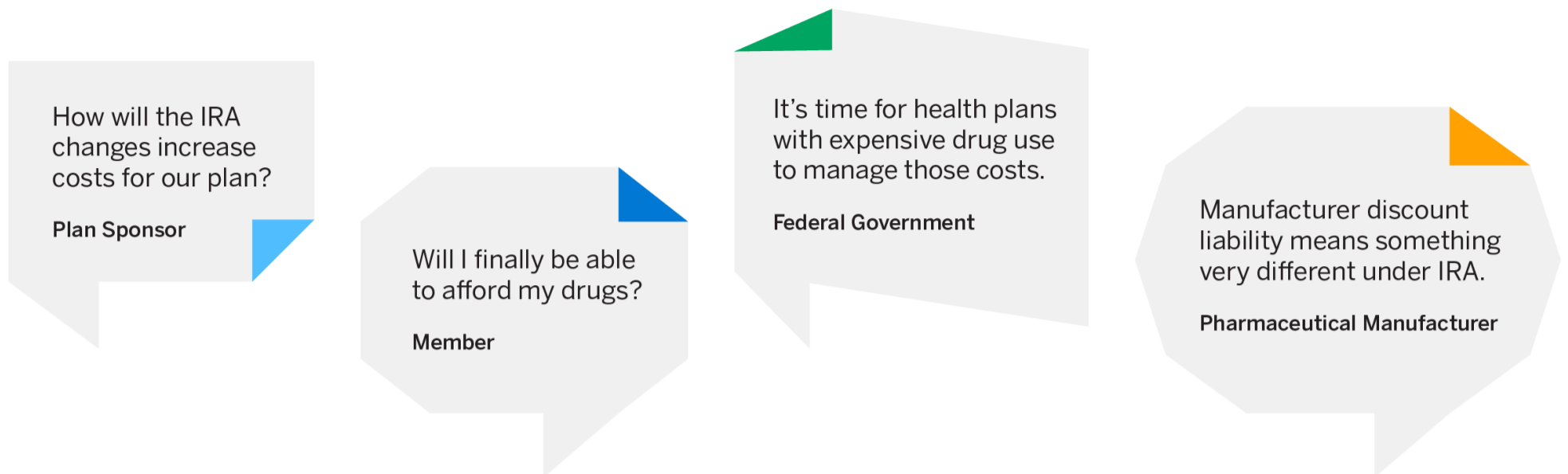
Price negotiation is excluded for the following classes/types of drugs/situations:

- Part B drugs – until 2028
- Small biotech drugs – until 2029
- Single Source Drug products (no generic competitor) with less than 7 years since the date of FDA approval
- Biologics (with no biosimilar competitors) with less than 11 years since the date of FDA approval
- Certain orphan drugs
- Low spend Medicare drugs
- Plasma derived products

- **Benefit redesign:** Reduced government subsidies in the catastrophic phase spread manufacturer liability throughout the benefit, including in the catastrophic phase, the optional smoothing of cost sharing over the calendar year through M3P, and the reduced member liability through the maximum out-of-pocket (MOOP).
- **Price negotiation:** Beginning in 2026 with Part D drugs, the government will choose 10 to 20 drugs each year (creating a cumulative list), with 10 selected for 2026⁷ that will be negotiated down to the maximum fair price.⁸ This new lower price will be set at the point of sale (POS). The 10 drugs selected for 2026 were commonly used brand drugs for chronic conditions.⁹
- **Other:** Base beneficiary premium stabilization at 6% year over year, inclusion of members up to 150% of the federal poverty level (FPL) for the full low-income subsidy (LIS), up from 135%, a limit on cost sharing of insulins at \$35 and vaccines at \$0, and rebate inflation penalties.

Figure 2 shows some simplified questions or thoughts various Part D stakeholders might have about the IRA. Of course, stakeholder considerations are much more complicated than these illustrations.

Figure 2: High-level questions or thoughts by Part D stakeholders



Plan perspective

Direct subsidy

A risk adjusted payment based on the difference between national average bid amount (average plan paid, admin, and profit) and national average member premium.

Benefit redesign

Although the benefit design changes are significant, government payments have the potential to partially offset the increase in plan liability occurring with the implementation of a cost-sharing cap and shifting of catastrophic liability to the plan.

- Direct subsidy payments are expected to increase with the additional plan liability.
- The Part D national average member premium will be limited in how much it can increase due to the premium rate cap—set at 6% of the prior year's premium. Any excess in premium above the 6% cap will be shifted into the direct subsidy payment to the plan. This 6% premium rate cap is only applicable to the basic member premium (for defined standard benefits) and does not apply to the supplemental member premium (for enhanced benefits).
- Despite the uncertainty inherent in large program changes, the Part D program offers plans protection against large fluctuations in gain or loss through the risk corridors that absorb some losses or gains above prespecified thresholds.

The IRA has the potential to change plan dynamics because:

- Plans with lower risk scores relative to other plans may not see the full benefit of the direct subsidy if their risk scores do not reflect the expected morbidity of their populations. Plans with more substantial diagnosis coding efforts may receive relatively higher government payments. The IRA may alter the relative importance of capturing particular diagnoses due to an increase in the magnitude of the payment (direct subsidy) subject to risk adjustment. However, the Centers for Medicare and Medicaid Services (CMS) may change the risk adjustment model and methodology.
- Plans may see changes in drug liability not only due to new drug utilizers, but also from the potential for increased adherence and utilization for current members due to capped cost sharing and the ability to smooth cost sharing over the calendar year.

Although the government payments will likely increase under the IRA, we expect to see plan, member, and pharmaceutical manufacturer reactions to these changes, which are likely to transform the Medicare Part D program in intended and unintended ways.

Under the IRA, highly rebated, high-cost drugs may lose some of the advantages they have in the current benefit structure:

Reducing drug cost

Some methods plans have to reduce drug costs include formulary management (quantity limits, prior authorization, or step therapy – requiring specific product to be used before other products are tried), promoting generics over brands, promoting mail over retail utilization, re-negotiate discounts on brand and generic products as well as rebates on brand products, changing the drugs covered on the formulary or updating cost sharing by formulary tiers.

- Currently, plan liability is lowest for the later phases where spending is higher—compared to the IRA, where plan liability is higher throughout the benefit phases.

- Currently, manufacturer rebates on highly rebated drugs could often be higher than the plan liability in the later benefit phases, resulting in a net positive for the plan for each script filled. Under the IRA, the higher plan liability means far fewer products will produce net positive results for the plan.

Plan liability under the IRA in the catastrophic benefit phase increases dramatically on brand drugs (from 15% to 60%) due to the reduction in federal reinsurance.

To minimize the impact on plan expenses, plan sponsors may decide to implement additional drug utilization management programs or renegotiate contracts with manufacturers and pharmacies to reduce drug costs and therefore plan liability.

Coverage gap benefits

The coverage gap is the period between the ICL, which can have copays, and the catastrophic phase, where members pay only 5%. This phase between the ICL and catastrophic is typically covered at 25% coinsurance. However, plans can offer lower cost sharing in this phase, typically for the generic tiers, to differentiate themselves from competitors and provide more consistent cost sharing for their members.

With the IRA introducing sweeping changes to Part D, members may be more willing to look at other plans or switch carriers. Plan sponsors may try to preserve membership by making their plans more attractive. For example, some plans may try to keep or attract members by reducing cost sharing, especially on lower-cost drugs where the plan has relatively less risk. This could be used to differentiate plans from competitors. However, the opportunity to reduce member cost sharing may be limited due to the elimination of the coverage gap phase, insulin copay caps, and approved vaccines with mandated \$0 copays.

MA-PD vs PDP

MA-PD plans include medical and pharmacy coverage through a plan sponsor (like Humana, CVS, etc.). These plans can include additional supplemental benefits such as transportation, dental, or spending cards. PDP plans are pharmacy coverage only through a plan sponsor (like ESI, Cigna, etc.). PDP plans can be used in tandem with traditional Medicare fee-for-service coverage.

Insurers offering multiple plans may respond to the IRA in ways to minimize losses and mitigate risk. For example:

- Insurers with both Medicare Advantage Part D (MA-PD) plans and Prescription Drug Plans (PDPs) may want to transition members from PDP to MA-PD plans, because the MA plan's per person spending is much larger than the prescription drug portion and allows for more financial stability and ability to manage risk across benefits.
- Plan sponsors with multiple plans may decide to consolidate their plans, as the MOOP may make the variations in cost sharing driving distinct plan offerings seem relatively unimportant to members.

POS

Point-of-sale or POS, in terms of pharmacy drugs, refers to what happens at the pharmacy. For example, when used in reference to POS rebates or discounts, this means that the rebates or discounts will be applied at the pharmacy and not passed directly to the plan. This means that if a member has coinsurance, their cost sharing for that drug will be lower due to the additional discount or rebate applied at POS.

Price negotiation may alter how plans consider manufacturer rebates and formulary placement, although the details of how this will be implemented are uncertain. Plans could see increases in utilization on lower-cost negotiated products but will not see the benefit of rebates on those products, given the low net price. In addition, plans will need to decide if they want to promote those negotiated products over other brands or utilize additional formulary management.

Government perspective

The IRA's Part D redesign will significantly shift the reinsurance liabilities between the federal government and health plans. Currently plans receive significant rebates from drug manufacturers and, under the current Part D benefit design, claims in the catastrophic phase are covered 80% by federal reinsurance. This has allowed plans to shift the burden of higher-cost members to the federal government and in some cases has provided limited incentive for plans to reduce expensive drug use.

Under the IRA, the federal government's responsibility in the catastrophic phase will be 40% for most generic drugs and 20% for most brand drugs. This greatly reduces the federal government's reinsurance liability (and increases the health plan liability) once members exceed the \$2,000 MOOP. Because plan sponsors are liable for most of the post-MOOP cost under this new design, plans will be incentivized to reduce costs, instead of relying on the federal government reinsurance. In addition, the government previously paid for low-income (LI) members in the coverage gap but the coverage gap is removed under the new plan design, so it is expected that liability will shift to the direct subsidy. To stabilize the market, given the rapid changes, the government will cap the annual increase to the base beneficiary premium at 6%. To account for the additional risk the plan takes between the catastrophic phase responsibility and premium increase capping, we expect an increase to the direct subsidy payments made by the federal government to plan sponsors.

The IRA contains provisions for negotiated drug prices and inflationary rebates, which will directly affect drug manufacturers. Drug price negotiation provisions will reduce point-of-sale prices (and, therefore, member cost sharing for members with coinsurance—where cost sharing is a percentage of the drug price) for selected high-cost or highly utilized Part D and Part B drugs by allowing the government to negotiate maximum fair prices for nonexempt drugs and biologics. Price negotiations between the government and manufacturers will begin in 2024 for selected Part D drugs and in 2026 for selected Part B drugs, but the negotiated price for selected drugs will not take effect until 2026 for Part D and 2028 for Part B. The government will also be liable for the Manufacturer Discount Program payments on behalf of the manufacturer for Part D drugs selected for negotiation.

Inflation rebates for drug manufacturers began in Q4 2022 for Part D and Q1 2023 for Part B. This provision requires manufacturers to make payments to the federal government for any drugs not selected for price negotiation if the drug price increases faster than inflation. This results in an increase in revenue for the federal government if prices are increased above inflation. If price increases are below inflation, the government (and members) benefit from lower relative drug prices. This component of the IRA should help to reduce costs for consumers.

Insulin and vaccine

Some plans have already accounted for \$35 (or lower) copays on insulin products as well as \$0 Part D vaccines for the 2023 plan year prior to the IRA taking effect. Plans could take part in the voluntary Senior Savings Model (SSM), which offered lower cost sharing for insulins for plan years 2021-2023. Plans could also have created a separate drug formulary tier, specific to vaccines, which would allow them to offer vaccines at a \$0 cost share separate from other drugs.

Starting in 2023, the IRA requires \$35 insulin copay limits and \$0 copays for approved vaccines. Because the IRA was not released until after the 2023 bid submission, the incremental plan costs associated with these limits were not priced into the 2023 bids. The government will provide plans that did not participate in the Senior Savings Model (SSM) or have a vaccine tier at \$0 cost sharing with retrospective subsidy payments for 2023 to compensate them for the additional costs.

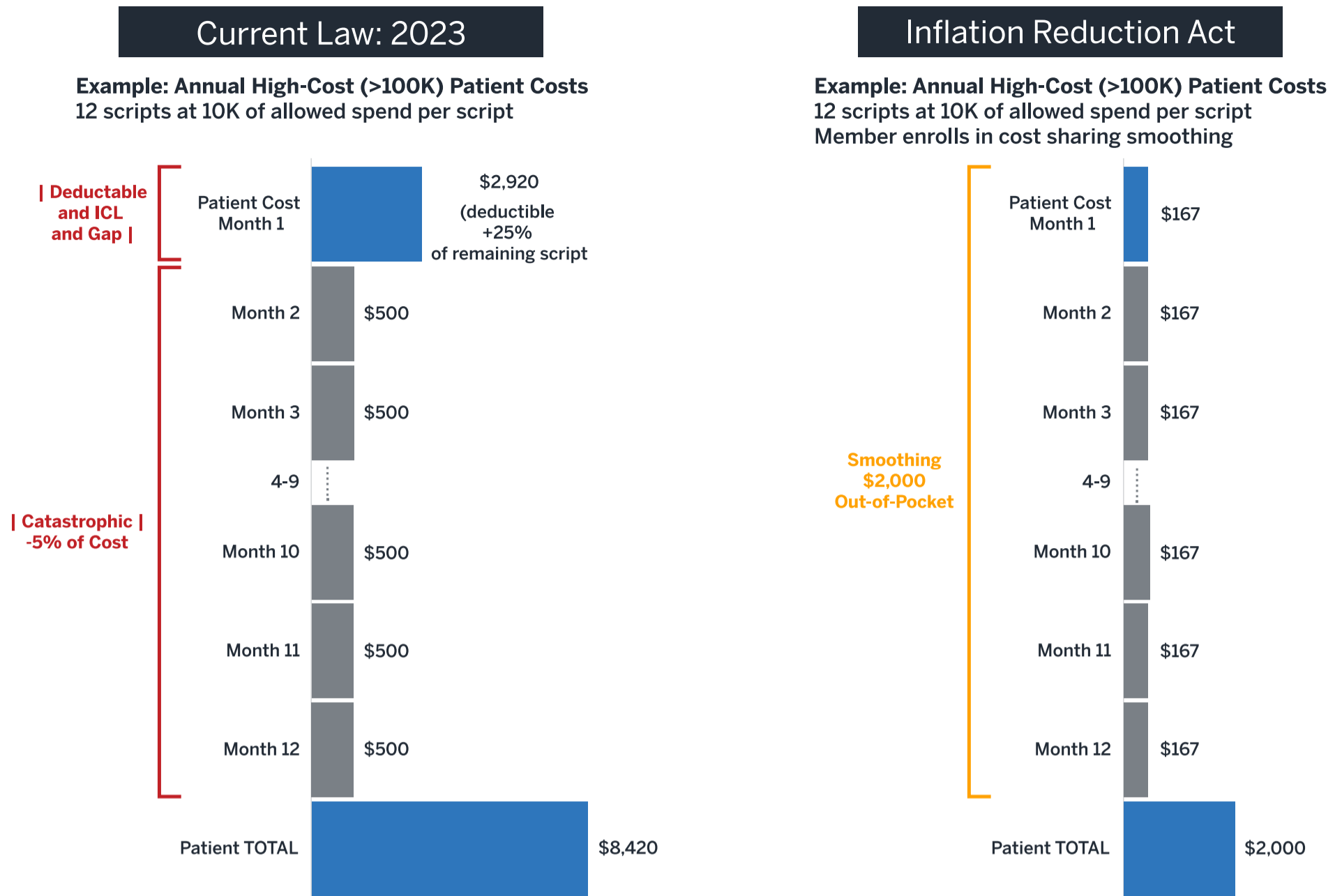
Member perspective

Capping annual drug costs at \$2,000: A boon to members

In 2025, the IRA will implement a \$2,000 MOOP for members, who can elect to pay for their costs through monthly installments throughout the year under M3P. This is expected to improve drug affordability for members. An example of the monthly installment payment is shown in Figure 3. The ability to smooth cost sharing will be valuable to members who take costly specialty drugs because they would be able to pay smaller monthly installments rather than a significant amount of money up-front.

Before the MOOP is implemented in 2025, there will be a transitional elimination of catastrophic cost sharing for members in 2024. Currently, members must pay 5% of drug costs after already paying an estimated \$3,100 out-of-pocket prior to reaching the catastrophic phase, with no aggregate limit on how much someone with Medicare might have to pay for their prescription drugs.

Figure 3: Medicare Prescription Payment Plan (M3P) cost sharing, monthly example¹⁰



Member cost sharing

Although there is no absolute limit on cost sharing in Part D under the current design, member liability is greatly reduced to 5% once the member reaches the catastrophic phase. The catastrophic phase is triggered once the combination of member cost sharing and manufacturer discount reaches \$7,400 (based on 2023 benefits). Although the amount of member cost sharing will vary based on plan design and brand utilization, on a basic benefit assuming about 90% brand utilization, we would expect about \$3,100 of the \$7,400 to be attributable to member cost sharing.

For members who use insulin, all plans will be mandated to cap member cost sharing at \$35 per month for covered insulin products. In addition, vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) will have a \$0 copay. A select number of brand drugs with high total annual spending nationally will be subject to lower costs for members through price negotiation starting in 2026, as prices for drugs decrease under price negotiation.

Most LI members (those with incomes below 150% FPL) will see almost no effect from the IRA, as members with incomes below 135% FPL already receive significant cost-sharing reductions and premium subsidies. The number of NLI members who would have paid less in 2019 from a lower MOOP of \$2,000 is estimated to be roughly 1.2 million¹¹ (or 4% of the total 32.8 million) NLI Part D members.

Finally, members may also increase adherence to high-cost prescribed medication or start taking a prescription if any combination of the above measures reduces the member's anticipated cost burden.

Other member implications of IRA

As plans will take on more risk in the catastrophic phase under the IRA benefit redesign, they may respond in ways to manage expected increases in plan liability. As mentioned in the Plan Perspective section above, plans currently benefit from low liability of prescription drug costs filled in the catastrophic phase, where rebates may exceed plan liability and produce a net positive cash flow for plans covering members with high-cost drugs. With plans liable for a much greater proportion of claim costs under IRA, members taking high-cost drugs are less likely to be profitable to the plan. Because these members are less profitable, plans may react in a way that could make costs higher for members taking non-specialty brand drugs, many of whom previously may not have reached the \$2,000 annual spending MOOP.

Members who expect to spend more than \$2,000 may be less concerned in their plan selection process, as superior tier placements and lower copays are irrelevant when a member expects their annual drug costs to exceed \$2,000 anyway. However, because members can be price-sensitive, significant changes to the parameters and plan response to those changes due to the IRA can result in substantial swings in some plans' premiums. Therefore, there may be movement between plans as premiums change due to the IRA.

Pharmaceutical manufacturer perspective

For pharmaceutical manufacturers, the IRA's impact will depend on their product portfolios. In general, under the IRA benefit redesign, manufacturers of primarily non-specialty brand products will be impacted less than manufacturers whose product portfolios primarily include specialty brand products (as defined by CMS for 2024,¹² drugs costing more than \$950 per 30-day script). Of the changes within the IRA, this section focuses on two components likely to have the biggest impact on pharmaceutical manufacturers: Medicare Part D benefit redesign and price negotiation.

Benefit redesign

The impact on manufacturers from the IRA benefit redesign will depend on the type of drug and the responses of plan sponsors and members to these changes. The addition of manufacturer liability in the catastrophic phase will translate to some manufacturers having their liability decrease while others will see their liability increase substantially. However, all manufacturers now have added manufacturer discount liability for low-income subsidy (LIS) patients. Also, the shifting of catastrophic liability from the federal government to plan sponsors could result in plan sponsors looking for new revenue streams and other options to lessen their increased liabilities—which may include additional rebates from manufacturers.

The manufacturer discount is no longer limited and applies to all drugs, all phases (except deductible), and all member types (including LIS). Manufacturers of high-cost drugs whose members spend most of their time in the catastrophic benefit phase will take on 20% liability for all scripts filled in this benefit phase, which could be the majority of a member's scripts for specialty product drugs. In addition, the increase in plan sponsor liability to 60% in the catastrophic phase will likely translate to plans asking for more rebates from manufacturers of high-cost products, placing lower-priced drugs on preferred tiers, and/or introducing additional utilization management—especially for high-cost drugs whose members will spend the majority of their time in the catastrophic phase.

Conversely, manufacturers of lower-cost (non-specialty) brand drugs are likely to see their liabilities stay flat or decrease, depending on the exact cost of the drug, medication adherence, the mix of LI and NLI members, and the mix of drugs a member takes. The reason for this dynamic is that the manufacturer liability pre-MOOP is 10% as opposed to 70% in the coverage gap—and the majority of members taking these drugs either do not reach the catastrophic phase or do so near the end of the year. Still, plan sponsors will likely ask manufacturers for additional rebates and/or price concessions.

At a high-level, the Medicare Part D redesign's increase in plan sponsor liability will result in plan sponsors looking for new ways to cover (or potentially decrease) their liabilities, as well as mitigate risk—including in the forms of rebates and price concessions from manufacturers, placement of high-cost products on higher tiers to incentivize utilization of lower-cost alternatives, and the implementation of utilization management to restrict or reduce utilization. Plan sponsors will also receive payments for taking on increased risk from the government through the direct subsidy.

For members, the MOOP will cap their cost sharing, which for those taking high-cost drugs would mean the reduction of a financial cost barrier. As a result, medication adherence may increase and abandonment rates may decrease, which would increase manufacturer revenue. However, manufacturer revenue could decrease as members may face formularies with more restrictions or adhere to new utilization management policies (i.e., step therapy edits) to obtain certain prescribed drugs.

Price negotiation

While price negotiation will immediately directly impact the manufacturers of only a handful of drugs, the lower point-of-sale prices, exclusion from the manufacturer discount program, and automatic formulary inclusion will have secondary impacts on the manufacturers of a selected drug's competitors.

For brand products selected for price negotiation, net revenue may stay relatively flat, as many of the manufacturers of these products are already paying high rebates to plan sponsors, which will likely go away for drugs subject to price negotiation. In addition, depending on what CMS implements, some of this loss in net revenue may be offset by exclusion from the manufacturer discount program (based on initial CMS guidance).¹³ Lower-cost brands have higher portions of spend in the coverage gap, which currently has a 70% manufacturer discount. However, for specialty products—particularly those with low or no rebates (e.g., protected class drugs like oncology)—selection for price negotiation could have a much larger impact on net revenue. With that said, the selected drugs will also have more of an offset from exclusion of the manufacturer discount as much of these drugs' spending is in the catastrophic phase.

For negotiated drugs, automatic formulary inclusions (required for negotiated drugs) do not necessarily mean the product will get preferential formulary placement but guarantees formulary coverage. There is still the opportunity for competitors of negotiated drugs to compete for preferred formulary placement through offering rebates or discounts. It is also possible negotiated drugs may need to offer rebates or discounts to secure preferred formulary placement or to minimize utilization management requirements. CMS will require justification of non-preferential formulary placement for selected drugs and will be scrutinizing utilization management for selected drugs.¹⁴

Conclusion

The IRA has the potential to be transformative—for Part D plans, members, the government, and manufacturers. In particular, the absence of a phase-in of the new benefit designs (with the MOOP preceding the changed corridors by one year), may encourage sudden shifts by nimble organizations or members. But there are aspects of Medicare Part D limiting the transformative nature of the legislation for these stakeholders.

Part D plans are taking on more liability and with this comes additional financial risk. These provisions will change the formulas determining net spending—and seem likely to increase the incentives plans have to reduce net spending. Net spending will change because of the MOOP, changes in the manufacturer discount program, and the increased plan liability in the catastrophic phase.

The additional plan liability and accumulation to MOOP solely based on patient spending, including LI cost-sharing subsidies (rather than including the manufacturer discount) may encourage promotion of generics or biosimilars over brands or moving PDP members into MA-PD plans. The financial incentives favoring high-priced drugs with high rebates over low-priced drugs will be reduced. The IRA will likely disrupt the

high-cost high-rebate incentives that sometimes resulted in plan gains on scripts filled under the pre-IRA benefit structure. However, the direct subsidy payment provided to Part D plans, along with existing features of the Part D benefit such as risk corridors, may help to offset some of this additional plan liability and risk, lessening the transformative impact this legislation could have on plans.

The IRA will have a large impact on certain members, especially members who have or are concerned about high out-of-pocket costs as costs will be limited by the MOOP. For members who typically spend upwards of \$2,000 out-of-pocket, or even members who do not but believe they will one day, the protections the IRA provides from high out-of-pocket costs will be a welcome change. Other members (e.g., current LI members with full subsidies, members who generally have low drug spend) will not see much change in their Part D benefits from this legislation but may see higher premiums (although this may be mitigated with expected increase in the direct subsidy). These members may see changes to their existing plans' formularies. The implementation of the IRA (both the benefits redesign in 2025 and price negotiation in 2026) may encourage members to shop around and choose a plan that best fits their needs knowing the additional reinsurance protections the IRA now provides them.

The IRA's increase in plan liability in the catastrophic phase may stabilize the government's spending on Part D, which has escalated due to the explosive growth in the catastrophic phase drug spending. The government will likely experience savings due to certain aspects of the IRA such as inflation rebate payments and price negotiation. The government's liabilities will move from higher LI subsidies and federal reinsurance to higher direct subsidy and manufacturer discount payments (depending on the type of drug).

The IRA will change the manufacturer space. Under the IRA, some manufacturers will have drugs selected for price negotiation. These negotiations will mostly affect their highest-spending brands and selected drugs will have prices potentially lower than their current net prices, reducing revenue for the brand. However, negotiated drugs will receive full access and the brand will not be subject to the manufacturer discount—which are pluses to the manufacturer of selected drugs. Because the IRA limits the manufacturer's ability to increase prices past an inflation rate without paying a rebate, newly launched brands may start with higher-than-typical prices. Additionally, the inclusion of the manufacturer discount in the catastrophic phase is a headwind for specialty brand manufacturers, for whom the majority (upwards of 90%) of the spending can occur in the catastrophic phase.

All of these changes have the potential to change the Medicare Part D landscape and many of these changes are improvements to weaknesses identified by MedPAC in Medicare Part D. Transformative changes to some of the stakeholders seems like a real possibility.

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⁷ CMS. Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026. Fact Sheet. Retrieved December 14, 2023, from <https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf>.

⁸ CMS (March 15, 2023). Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments. Retrieved December 14, 2023, from <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>.

⁹ Cates, J., Holcomb, K.M., Klaisner, J.K., & Swenson, R.L. (September 12, 2023). Medicare Price Negotiation: A Paradigm Shift in Part D Access and Cost. Milliman White Paper. Retrieved December 14, 2023, from <https://www.milliman.com/en/insight/medicare-price-negotiation-paradigm-shift-part-d-access-cost>.

¹⁰ Additional guidance and examples of the M3P program are available here: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>.

¹¹ Cubanski, J. et al. (September 10, 2021). Potential Savings for Medicare Part D Enrollees Under Proposals to Add a Hard Cap on Out-of-Pocket Spending. KFF. Retrieved December 14, 2023, from <https://www.kff.org/medicare/issue-brief/potential-savings-for-medicare-part-d-enrollees-under-proposals-to-add-a-hard-cap-on-out-of-pocket-spending/>.

¹² CMS (April 4, 2023). Final Contract Year (CY) 2024 Part D Bidding Instructions. Retrieved December 14, 2023, from <https://www.cms.gov/files/document/final-cy-2024-part-d-bidding-instructions.pdf>.

¹³ CMS (June 30, 2023). Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, p. 175. Retrieved December 14, 2023, from <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf#page=175>.

¹⁴ Ibid.

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