

# Weathering the reform storm

Key components and stakeholder implications of drug pricing and other healthcare-related changes in the Inflation Reduction Act

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On August 16, 2022, President Biden signed the Inflation Reduction Act (IRA) into law. The IRA contains healthcare reforms, tax changes, and environmental policy provisions and impacts several layers of the U.S. healthcare ecosystem with major implications for the Medicare Advantage and Medicare Part D programs.

This article explores the key healthcare provisions of the IRA with an emphasis on the key changes to Medicare and potential implications to stakeholders within the healthcare and pharmaceutical sectors. The IRA also includes significant changes that will impact the individual commercial health insurance market as well as smaller changes affecting the rest of the commercial market and Medicaid, which are detailed in [the full IRA text](#).

With several of these changes coming as soon as 2023 and others phasing in through 2028 and beyond, understanding the key changes and implications will be critical for all stakeholders as IRA provisions are implemented over the next several years.

## Key healthcare components of the IRA

The IRA includes numerous drug pricing reform components affecting Medicare Advantage and Medicare Part D. Key provisions include a restructuring of the Part D benefit design, drug price inflation rebates, insulin copay maximums, and authorizing the Secretary of the U.S. Department of Health and Human Services (HHS) to negotiate drug prices, among other changes discussed in this section. The IRA most significantly affects Medicare, but also includes provisions affecting the commercial and Medicaid lines of business.

### GETTING AROUND

The Inflation Reduction Act is a massive bill, with many moving parts impacting many healthcare stakeholders. Click below to go directly to key components or perspectives.

KEY COMPONENTS
Part D Benefit Redesign
Drug Price Negotiation
Inflation Rebates
Insulin Copay Caps
Other Medicare Provisions
Commercial Market
Medicaid

PERSPECTIVES
Manufacturers
MAOs and PBMs
Government
Medicare Beneficiaries
Commercial
Providers
Medicaid

**PART D BENEFIT REDESIGN**

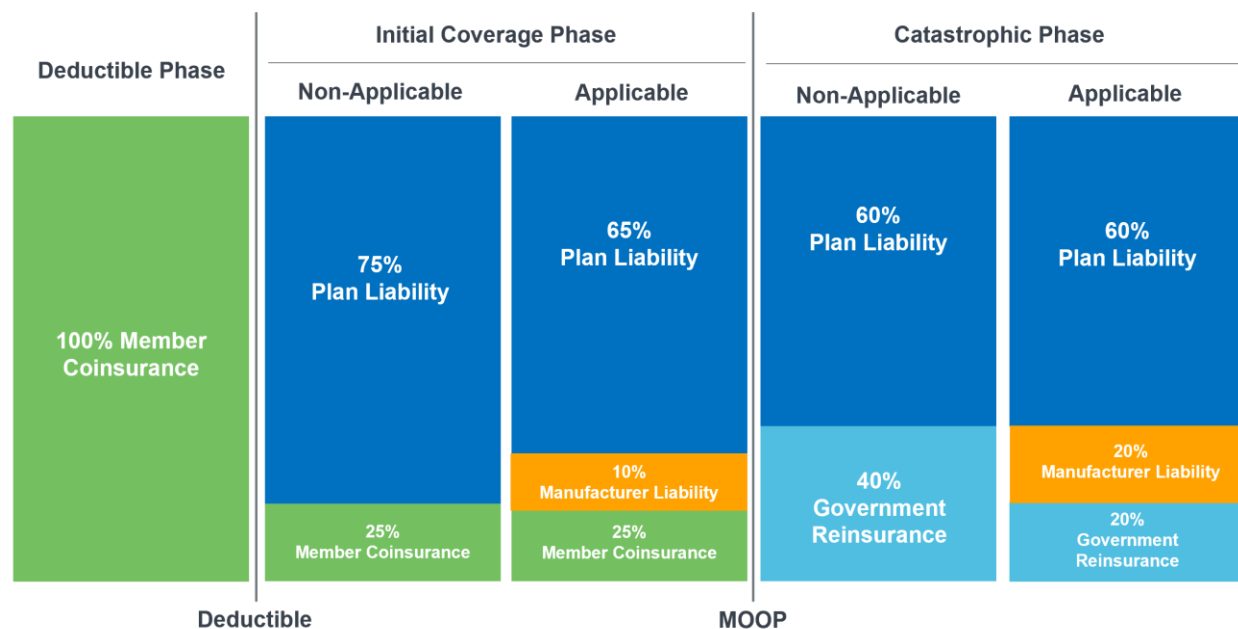
The IRA will significantly alter the Part D benefit, with key changes shown in Figure 1.

**FIGURE 1: PART D REDESIGN COMPONENTS BY YEAR**

INITIAL YEAR	PART D REDESIGN PROVISIONS
2023	<ul style="list-style-type: none"> <li>Beneficiary cost sharing for all covered insulins and all beneficiaries is limited to \$35 per month supply.</li> <li>\$0 beneficiary cost sharing for Part D vaccines.</li> </ul>
2024	<ul style="list-style-type: none"> <li>Beneficiary cost sharing is eliminated in the catastrophic phase, i.e., above the 2024 true out-of-pocket maximum (TrOOP).</li> <li>National average member premium (NAMP) growth capped at an annual rate of 6% through 2029 with some additional limits for 2030 (minimum of 20% of Medicare program costs).</li> </ul>
2025	<ul style="list-style-type: none"> <li>The benefit is reduced from four to three phases: deductible, initial coverage, and catastrophic. The maximum out-of-pocket (MOOP) is set at \$2,000.</li> <li>The Coverage Gap Discount Program (CGDP) is removed and replaced with the Manufacturer Discount Program (MDP).</li> <li>MDP will have a different liability before (10%) and after (20%) the MOOP for both non-low-income (NLI) and low-income (LI) beneficiaries on applicable (typically brand) claims, after the deductible.</li> <li>For LI beneficiary claims from “specified” manufacturers and all claims from “specified small” manufacturers, the 10% and 20% MDP liability are phased in over time, reaching final levels by 2031.<sup>1</sup></li> <li>Catastrophic phase plan liability increases to 60% of allowed costs, and federal reinsurance decreases to 20% for applicable drugs and 40% for non-applicable (typically generic) drugs.</li> <li>Availability of cost-sharing smoothing.</li> <li>Accumulation of cost sharing toward catastrophic phase based on basic benefit cost sharing.</li> </ul>

Figure 2 shows a high-level overview of each stakeholder’s liability under the new benefit design. We include the current Defined Standard Part D benefit design in Appendix B for comparison. Notably, under the IRA, plan liability increases significantly in the catastrophic phase and manufacturers have liabilities in the initial coverage phase and in the catastrophic phase.

**FIGURE 2: IRA PART D BENEFIT REDESIGN – ASSUMING FULLY PHASED MANUFACTURER LIABILITIES**



<sup>1</sup> A “specified” manufacturer is defined as a manufacturer where Medicare’s associated expenditures for all of the manufacturer’s drugs account for less than 1% of all expenditures in Part D and Part B. A “specified small” manufacturer is both specified and has more than 80% of total Part D expenditures attributable to a single drug.

## PART B AND PART D PRICE NEGOTIATION

The price negotiation provisions of the IRA authorize the HHS Secretary to negotiate maximum fair prices (MFP)<sup>2</sup> for single-source drugs and biologics in Medicare Part B and Part D.

The HHS Secretary is advised to follow key guidelines when selecting drugs for negotiation:

- Drugs are selected from the 50 highest-cost Part B and 50 highest-cost Part D drugs, with a carve-out for biotech drugs with small market share.<sup>3</sup>
- Part D drugs are eligible for MFP negotiation beginning in 2026 while Part B drugs will be eligible in 2028. Further, drugs are eligible for negotiation at different points relative to their launch dates, where small-molecule drugs are eligible for MFP negotiation seven years post-launch and biologics are eligible for price negotiation 11 years post-launch.
- Biologic drug negotiation could be delayed by up to two years if requested by the biosimilar manufacturer in the case of a forthcoming biosimilar launch.
- Drugs selected for negotiation in previous years will no longer continue to be selected if a generic or biosimilar has been on the market for at least nine months.

The number of drugs subject to MFP negotiation increases each year and will accumulate to a maximum of 80 total drugs between Part B and Part D by 2030. Figure 3 displays the maximum number of drugs subject to price negotiation by year from 2026 to 2030. The addition of 20 negotiated drugs each year applies to 2029 and beyond.

FIGURE 3: MAXIMUM NUMBER OF NEGOTIATED DRUGS BY YEAR, 2026-2030

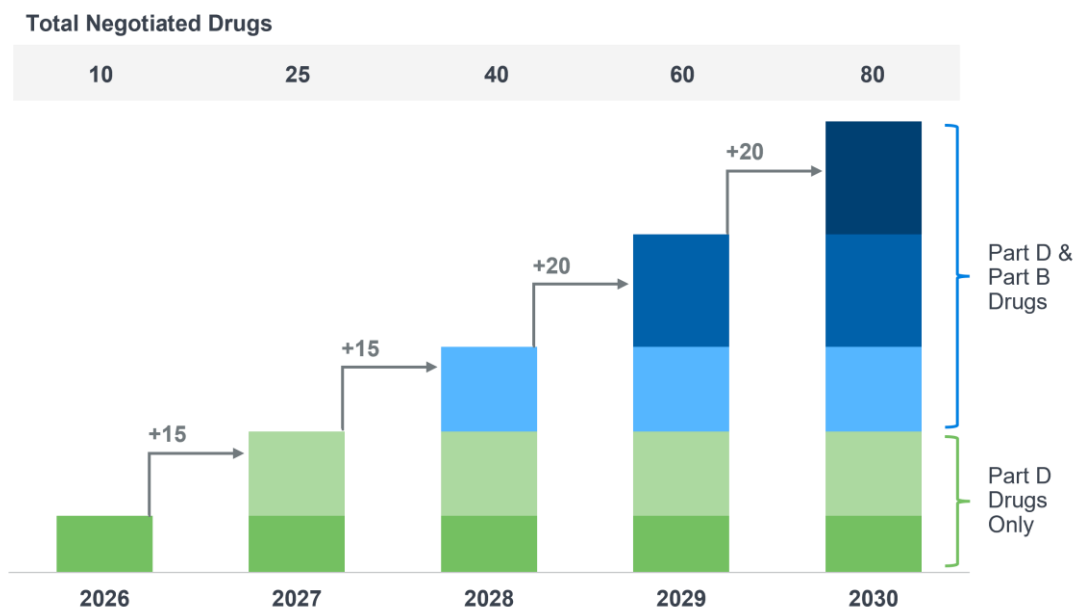


Figure 4 illustrates the calculation of the maximum negotiated price for selected drugs. This maximum negotiated price determination relies on the following key metrics:

- *Nonfederal average manufacturer price (non-FAMP)*: The average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers but not taking into account

<sup>2</sup> Defined as the negotiated price of the drug in Section 1191 of the IRA.

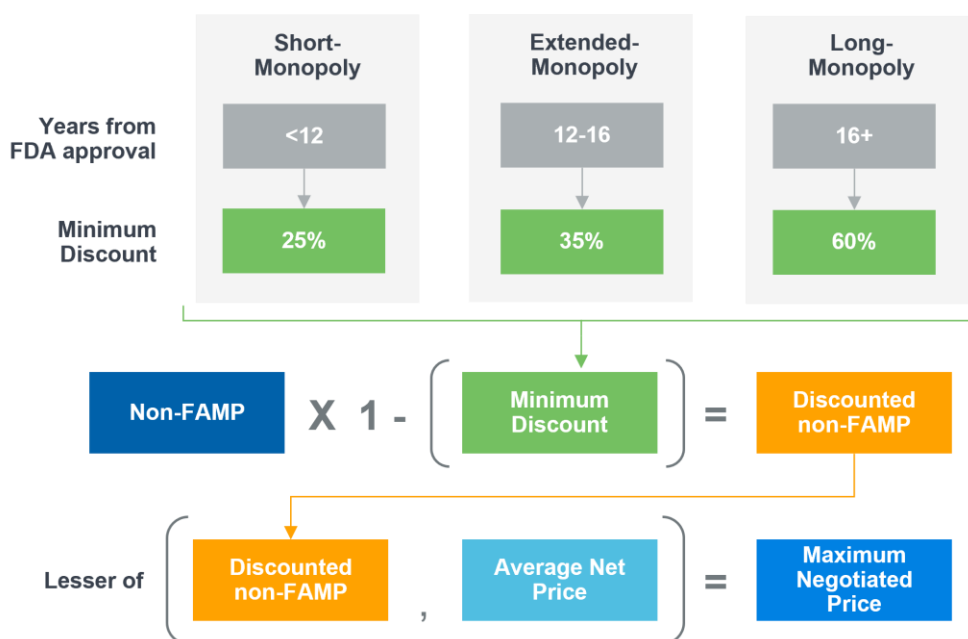
<sup>3</sup> Defined as a drug that accounts for less than 1% of Part D or Part B expenditures and accounts for 80% or more of expenditures attributable to the manufacturer's Part D or Part B total expenditures.

any prices paid by the federal government. Non-FAMP does not reflect rebates paid by the manufacturer to third-party payers for most drugs.<sup>4</sup>

- **Minimum discount:** The minimum discount for a given selected drug aligns with the number of years since approval by the U.S. Food and Drug Administration (FDA). The IRA divides minimum discounts into three categories:
  - Short-monopoly: Less than 12 years since FDA approval (25% discount).
  - Extended-monopoly: 12 to 16 years since FDA approval (35% discount).
  - Long-monopoly: More than 16 years since FDA approval (60% discount).
- **Average net price:** The average net price is the enrollment-weighted drug price net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan for the most recent year for which data is available within the Medicare Part D market. The enrollment is adjusted for the ratio of enrollment of plans with claims for the given drug to the total Medicare Advantage Prescription Drug (MA-PD) plan or Prescription Drug Plan (PDP) enrollment.

The interaction of each of these mechanics to arrive at a maximum negotiated price is shown in Figure 4.

FIGURE 4: MAXIMUM NEGOTIATED PRICE CALCULATION



While the negotiated price can be lower than illustrated in Figure 4, HHS can impose this maximum negotiated price if the manufacturer and HHS are unable to agree upon another price. If the manufacturer has agreed to the negotiated price but fails to provide a drug at the negotiated cost, it would be subject to a penalty of 10 times the difference between the actual and negotiated price. If the manufacturer does not have an agreement to participate in the drug price negotiation program in place at the time of selection of a drug for negotiation or fails to agree to the negotiated price following the conclusion of the negotiation period, it would be subject to an excise tax of up to 20 times total sales of the selected drug as long as it has in place a manufacturer agreement under the Manufacturer Discount Program or the drug price negotiation program.

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<sup>4</sup> Congressional Budget Office (February 2021). A Comparison of Brand-Name Drug Prices Among Selected Federal Programs. Retrieved August 16, 2022, from [https://www.cbo.gov/publication/57007#\\_idTextAnchor025](https://www.cbo.gov/publication/57007#_idTextAnchor025).

## PART B AND PART D PRICE INFLATION REBATES

The IRA introduces new inflation rebate payments from manufacturers to the federal government for drugs not selected for negotiation if drug prices, as measured by the average manufacturer price (AMP), increase faster than inflation. Drug prices from the benchmark year (2021) are trended by the Consumer Price Index for All Urban Consumers (CPI-U) and compared to actual prices to calculate the inflation rebate. The CPI-U benchmark period, existing drug price benchmark period, and future launch drug price benchmark periods are as follows:

- CPI-U benchmark period: January 2021.
- Existing drug price benchmark period: Part B – Q3 2021, Part D – Average of Q1 through Q3 2021 AMP.
- Future launch drug price benchmark period: Part B – first three quarters following launch, Part D – first calendar year after launch.

The rebate calculation varies between drugs covered by Medicare Part B and Part D but follows a similar formula:

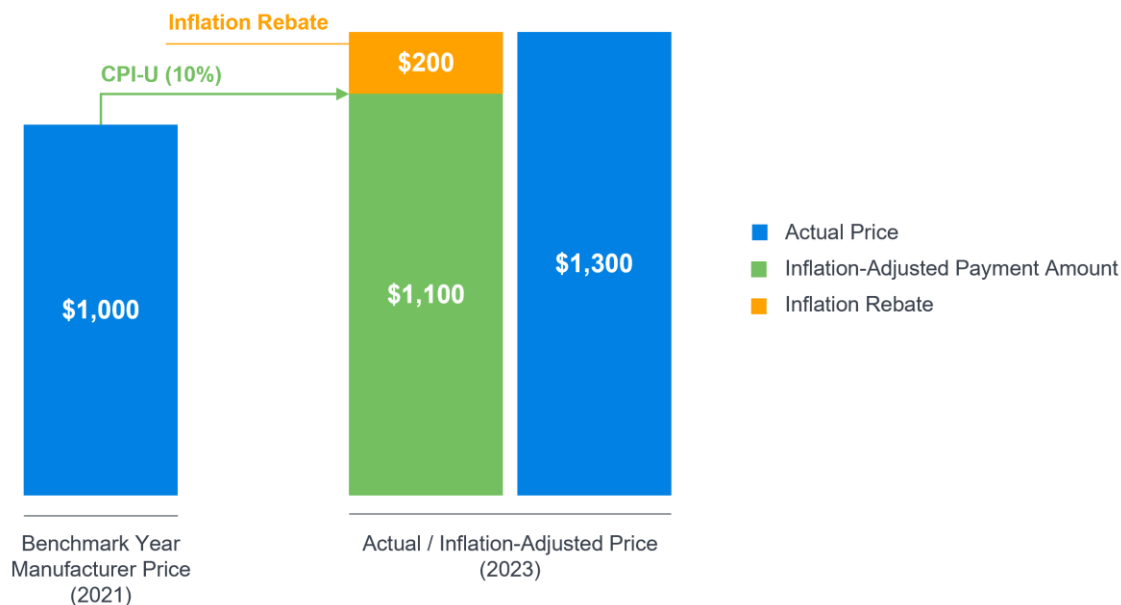
$$\text{Inflation Rebate} = \text{Total Units} \times \text{Maximum (Actual Price - Inflation Adjusted Benchmark, 0)}$$

Further, we highlight the following additional inflation rebate provisions:

- Inflation rebates will apply to single-source and biologic drugs covered by Medicare Part B and Part D
- Beneficiary coinsurance will be calculated net of the inflation rebate
- Manufacturers will be required to pay the inflation rebate within 30 days or be subject to a civil monetary penalty equal to at least 125% of the calculated inflation rebate
- Rebate payments will be deposited directly into the Medicare Supplemental Medical Insurance Trust Fund

Figure 5 displays the inflation rebate dynamics, assuming a drug is priced at \$1,000 in the benchmark year, 2021, and \$1,300 in 2023 where the drug price increase is limited to \$100 using CPI-U growth as maximum change, which would incur no inflation rebate. In this example, because the drug price grew faster than the CPI-U growth rate, the manufacturer owes a \$200 inflation rebate per unit.

FIGURE 5: INFLATION REBATE EXAMPLE



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## INSULIN COPAY MAXIMUMS

Beginning January 1, 2023, Medicare beneficiaries will pay no more than \$35 per one-month supply for insulins. This cost-sharing maximum applies to both non-low-income (NLI) and low-income (LI) beneficiaries for Part B and Part D covered insulins. The IRA includes the insulin cost-sharing maximum as part of the basic Part D benefit design, such

that the defined standard benefit in the coverage gap phase in 2023 would be the copay maximum (i.e., \$35 per month instead of 25% coinsurance). Given that this guidance was not specified when Part D plan bids were submitted, plans did not account for the cost of this benefit. The IRA outlines a provision to provide plans with a retrospective subsidy for 2023 to compensate them for these increased, unexpected costs. The IRA does not specify exactly how the subsidy would be calculated or distributed, and these payments may be subject to Medicare sequestration. Note that insulin cost-sharing maximums do not apply to the commercial market as in previous iterations of similar proposals.

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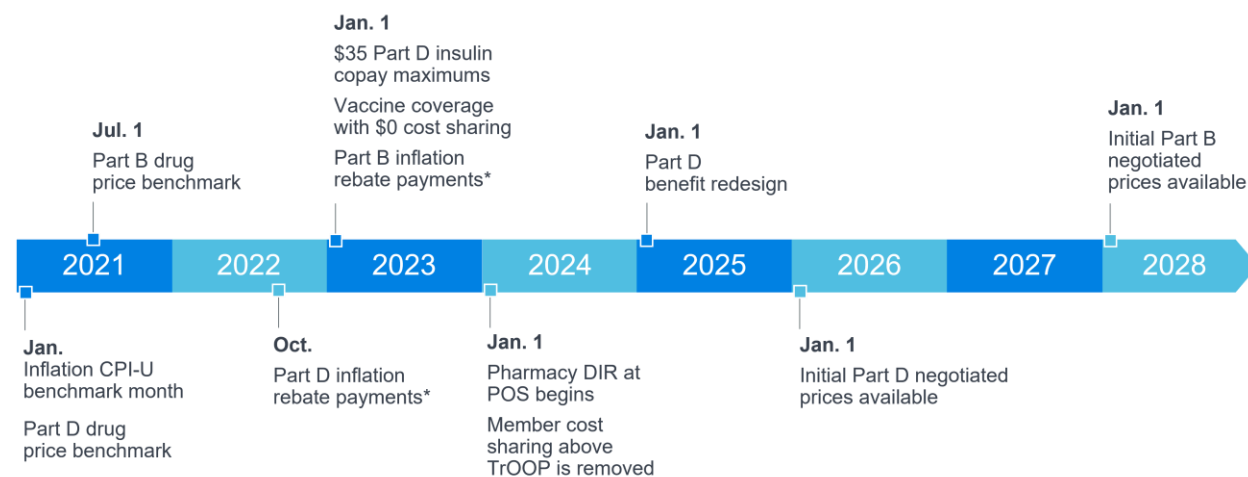
#### OTHER MEDICARE PROVISIONS

The key remaining components related to Medicare include:

- The threshold for full low-income subsidies increases from 135% to 150% of the federal poverty level (FPL) starting in 2024. Note that individuals with household income between 135% and 150% FPL currently receive partial subsidies.
- Initial biosimilar reimbursements are capped at the reference drug's payment rate starting July 1, 2024.
- No cost sharing in Part D for prescription drug vaccines approved by the Advisory Committee on Immunization Practices for the Centers for Disease Control and Prevention (CDC).
- Payments for biosimilars increase up to 108% of the average sales price (ASP) for the first five years on the market (or the first five years starting October 1, 2022, for drugs already available at that time).
- A requirement to reflect manufacturer rebates at the point of sale was scheduled to be implemented in 2026, but has been delayed to at least 2032.

In summary, Figure 6 provides a timeline of the key dates for various IRA provisions beginning with pricing benchmarks in 2021 and extending through 2028, as well as the notable change in pharmacy direct and indirect remuneration (DIR) already scheduled to take effect for 2024 Part D bids.<sup>5</sup>

**FIGURE 6: IMPLEMENTATION TIMELINE FOR MEDICARE PART B AND PART D CHANGES**



\*Reporting for first two years of rebates may be delayed until September 30, 2025 for Part B and December 31, 2025 for Part D; rebate payments are required within 30 days of notification by the Secretary.

Appendix A summarizes the IRA's Medicare provisions.

While most of the healthcare-focused elements are limited to Medicare, several provisions implicate Medicaid and the commercial market.

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<sup>5</sup> CMS (April 29, 2022). CY 2023 Medicare Advantage and Part D Final Rule (CMS-4192-F). Fact Sheet. Retrieved August 16, 2022, from <https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-advantage-and-part-d-final-rule-cms-4192-f>.

## MEDICAID

Medicaid is both directly and indirectly affected by the Part D drug price reforms. Negotiated prices have the potential to increase minimum drug rebates owed by manufacturers for drugs provided to Medicaid beneficiaries. In addition, any change in the overall trajectory of per capita Part D expenditures will influence state drug costs for individuals eligible for both Medicare and Medicaid. The IRA additionally implements adult vaccine coverage requirements on both Medicaid and the Children's Health Insurance Program (CHIP) and prohibits all cost sharing for approved vaccines.

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## COMMERCIAL MARKET

The most costly and impactful commercial provision of the IRA is an extension of subsidy enhancements instituted under the American Rescue Plan Act that were scheduled to expire at the end of 2022. Additionally, Congress formalized permission for high-deductible health plan (HDHP) issuers to provide coverage for insulin prior to the deductible, representing a limited expansion of flexibility issued by the IRS in guidance in July 2019.<sup>6</sup>

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## Stakeholder perspectives

The numerous provisions in the IRA will have significant impacts and pose new strategic, financial, and operational obstacles and questions for all stakeholders within both the pharmaceutical supply chain and in the broader, interconnected systems of healthcare. For each key stakeholder, we outline several of the new challenges, which will need to be thought through to respond successfully to the changes the IRA brings.

### PHARMACEUTICAL MANUFACTURERS

#### Current contracting will need to be reevaluated

The transition from the Coverage Gap Discount Program (CGDP) to the Manufacturer Discount Program (MDP), price negotiation, and inflation rebates will undoubtedly affect future contracting between manufacturers, pharmacy benefit managers (PBMs), and plan sponsors. These three aspects will impact revenue for manufacturers, depending on the degree of negotiation for their drugs and which categories of beneficiaries use their drugs due to the uncapped liability of MDP. Drugs selected for negotiation will be exempt from MDP, which may offset potential lost manufacturer revenue due to negotiation.

To the extent manufacturers anticipate lower revenues in Part D for drugs with negotiated prices, they may consider broader changes in Part D or commercial market contracting to offset these impacts. Additionally, manufacturers will need to be cognizant of downstream implications on the Medicaid Drug Rebate Program (MDRP) as they make these decisions, as negotiated prices will be included in the calculation of best price in Medicaid.

#### Utilization may change due to the negotiation and the new Part D benefit design

Part D drug utilization may increase as a result of benefit design changes and price negotiation. Key benefit design changes that may increase utilization, due to improved affordability to beneficiaries, include:

- Beneficiaries using insulin will have a maximum monthly copay of \$35 (beginning in 2023)
- Beneficiaries who reach the MOOP will have no future cost sharing in that calendar year (beginning in 2024)
- Beneficiaries can opt to spread their cost-sharing liability across the calendar year (beginning in 2025)

These factors may increase utilization for beneficiaries currently filling prescriptions or eliminate the friction of beneficiaries who may have previously elected to forgo prescriptions due to cost. In addition, for drugs that are negotiated, the point-of-sale (POS) cost would be lower than current POS prices, resulting in beneficiaries with coinsurance benefits or deductibles having lower cost sharing. These potential increases to utilization may serve to at least partially offset the lower revenue per script for manufacturers.

<sup>6</sup> IRS. Additional Preventive Care Benefits Permitted to Be Provided by a High-Deductible Health Plan Under § 223. Retrieved August 16, 2022, from <https://www.irs.gov/pub/irs-drop/n-19-45.pdf>.

### **Inflation rebates extend price increase guardrails to Medicare**

Currently the MDRP inflation rebates protect Medicaid drug costs against price increases. The inflation rebates under the IRA would provide a similar function in the Medicare market, effectively eliminating the ability of manufacturers to increase Part B and Part D revenue by increasing price relative to the current level of inflation. The introduction of Medicare inflation rebates coupled with the forthcoming removal of the average manufacturer price (AMP) cap on Medicaid rebates in 2023,<sup>7</sup> which currently limits MDRP rebates to 100% of AMP, will contribute to rising pressure to limit price increases to CPI-U going forward. Of note, the preceding 12-month CPI-U as of July 2022 is 8.5%, the highest in over 40 years.<sup>8</sup> The historically high inflation in 2022 may leave the door open for greater increases in the short term without triggering inflation rebates.

### **Optimal pricing strategy decisions will be more complex**

As discussed above, the IRA limits many traditional levers for revenue changes for manufacturers. As a result, manufacturers may place increased emphasis and resources on determining optimal, long-term pricing strategies in a more nuanced and complicated drug life-cycle environment. Historically, brand manufacturers have had 12 to 16 years without generic competition, on average.<sup>9</sup> For drugs selected for negotiation, decreases in revenue may begin earlier as brands can be selected as soon as seven years from approval. Unlike delaying generic competition through additional approved indications, the seven-year timeline does not reset for new indications. Compounding potential decreases in long-term revenue from negotiation, the replacement of CGDP with the uncapped MDP liability in Medicare Part D will also change how manufacturers forecast and set launch prices. Additionally, unlike the current environment, price increase options will be limited as inflation rebates will limit manufacturer ability to increase revenue through price increases. As list price increases affect all markets, in order to differentiate commercial net prices, manufacturers would need to adjust rebates or other contracting strategies to offset potential lost revenue in the Medicare market.

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## **MEDICARE ADVANTAGE ORGANIZATIONS AND PHARMACY BENEFIT MANAGERS**

### **Copay maximum provisions of the IRA will impact 2023 plan financials and cash flow timing**

As the new copay maximums for insulins and vaccines were not incorporated at the time of 2023 Part D bid submission, these provisions will increase plan costs in 2023. Recognizing these implications on plan financials, the IRA includes a provision to provide Medicare Advantage organizations (MAOs) with a retrospective subsidy for 2023 to compensate plans for the increased, unexpected costs. The IRA does not specify exactly how the subsidy will be calculated or distributed, though it appears likely that this payment will be subject to Medicare sequestration. While the government will subsidize MAOs for these costs, the timing of this reconciliation process may also create cash flow concerns for some MAOs, particularly because costs presumed to be covered by this temporary subsidy are excluded from Part D risk corridors. Further guidance will be necessary to understand whether and how the implementation of any retrospective subsidy programs may impact specific plans.

### **New operational responsibilities will be required to support beneficiary decision making**

The IRA allows beneficiaries to spread cost sharing across the remaining months of the year, which will necessitate new operational capabilities. In addition to the requirements to include information in educational materials and notify prospective enrollees of this option prior to the beginning of the plan year, plan sponsors and/or PBMs will also need to develop a mechanism to notify pharmacies of when an enrollee would reach MOOP for their current claim, triggering their ability to select the option to spread their cost sharing across the remaining months of the year. Apart from the required operational changes, plan sponsors may also incur losses as the result of nonpayment of due amounts for beneficiaries electing this option and should seek to understand the magnitude of this implementation and cost of nonpayment.

<sup>7</sup> This provision was repealed as part of the American Rescue Plan Act of 2021.

<sup>8</sup> See press release for CPI-U change here: <https://www.bls.gov/news.release/pdf/cpi.pdf> (accessed August 10, 2022).

<sup>9</sup> Kesselheim, A.S. (September 13, 2017). Determinants of Market Exclusivity for Prescription Drugs in the United States. Commonwealth Fund. Retrieved August 16, 2022, from: <https://www.commonwealthfund.org/publications/journal-article/2017/sep/determinants-market-exclusivity-prescription-drugs-united>.



### Opportunities to differentiate Part D plan designs may be more limited

The provisions of the IRA would cause plan sponsors to align to a greater degree on two key, competitive levers in Part D: formulary design and cost-sharing structure.

- *Formulary design:* Drugs selected for price negotiation are required to be on formulary. While this may converge brand coverage decisions for MAOs over time, depending on the methodology for selecting the drugs to be negotiated, there may be circumstances where only a subset of brand drugs within a specific therapeutic class is selected. This dynamic may cause MAOs or PBMs to opt to not cover a previously covered drug if contracting of the nonselected drug cannot compete with the price negotiated drug on net cost.

More broadly, the new benefit design has much more significant plan liability beyond the initial coverage phase relative to the current benefit design. With greater plan net liability for members with high spending, plans will likely have greater focus on moving from brand to generic drugs upon patent loss and aggressively pursuing rebates while tightening formularies in classes with competing brands.

- *Cost-sharing structure:* Some plans today elect to participate in the Senior Savings Model (SSM) and offer enhanced gap benefits as differentiators geared toward increasing adherence for beneficiaries using insulin and maintenance medications, respectively. The IRA will standardize these benefits, thus removing the differentiation for plans offering them today. As the defined standard benefit compresses to three phases in 2025, only the deductible and cost-sharing changes in the single, post-deductible phase below the MOOP will have differentiated cost sharing. For insulins, beneficiaries will have copay maximums in place, regardless of the plan design. Additionally, the presence of a MOOP, coupled with requirements to allow cost-sharing smoothing for beneficiaries, would minimize plan design differentiation for beneficiaries who expect to reach the MOOP.

### Plans will need to react to significant expected premium changes

The changing landscape of plan premiums could accentuate existing differences in contracted rates as plan liability increases and bids become more closely aligned with the overall payment for covered drugs. MAOs will need to consider how these changes may influence competitive position in the market. This is likely to place additional importance on formulary construction, pharmacy networks, and other specific elements of benefit design as higher-cost plans seek to avoid being priced out of the market.

Because Part D benefit redesign is expected to result in a significant reduction in average beneficiary costs, bid costs (inclusive of federal reinsurance) are expected to increase materially. The IRA includes caps that limit average premium growth to 6% each year through 2029 and, if required, modify the 25.5% (of total program costs) multiplier currently used to determine premium to cap growth from 2029 to 2030 at 6%, with the modified multiplier continuing to apply in 2031 and beyond. While it is currently unclear whether this premium growth cap will apply in later years, the cap is much more likely to apply in 2024 and 2025. This should have limited effect on overall plan payments as the premium reduction is expected to be offset by an increase to the direct subsidy. However, plans targeting the LI population should consider how a fixed premium affects the direct subsidy and their projections of low-income benchmark premiums.

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## FEDERAL GOVERNMENT

### New administrative tasks and challenges

Drug price negotiation and inflation rebates create significant new operational and administrative tasks for federal regulators. The price negotiation system will require the Centers for Medicare and Medicaid Services (CMS) to develop regulations and operational procedures with regard to a wide variety of topics, including:

- Determination of negotiation-eligible drugs
- Approach for prioritizing drugs for selection (particularly once Part B and Part D drugs are both eligible for negotiation in the cycle that begins in 2026)
- Approach in the negotiation phase, including when HHS's initial offer is the maximum allowable price
- Reporting implications of negotiated prices in the absence of changes to list prices

Similarly, Part B and Part D inflation rebates will require their own operational ecosystem to maintain the quarterly reporting requirements outlined in the IRA. Lawmakers gave HHS significant flexibility in timing for the first two reporting years of rebates under each program, suggesting they are aware this could take some time to implement.

The varying applicability dates will create challenges for federal regulators, particularly for items scheduled to apply to 2023 as they balance the value of implementing potentially administratively burdensome requirements for programs that are temporary in nature, such as how the temporary subsidy program for insulin and vaccine costs will be implemented or how the new insulin requirements interact with plans currently participating in the SSM. The laborious nature of federal rulemaking means that some of these key decisions may not be finalized prior to the start of the benefit year.

### **Who pays the intermediaries within the supply chain?**

The pharmaceutical supply chain involves a large number of stakeholders, and negotiated prices are both the maximum amount a manufacturer can be paid for a drug and the maximum amount a beneficiary can be charged at the point of sale. Federal regulators may need to consider how pharmacies, PBMs, wholesalers, and other participants in the supply chain may be compensated for providing these drugs if the consumer's point-of-sale price and the amount received by the manufacturer are identical.

### **Future Medicare risk score models will likely be impacted**

The IRA creates a significant shift in liability between the federal government and the health plan, particularly once beneficiaries exceed the MOOP. Plan sponsors will be responsible for 60% of costs above the MOOP, as opposed to 15% today. The benefit design in the IRA will additionally change the plan liability for various types of beneficiaries due to changes in the benefit both above and below the MOOP. This could meaningfully affect expected plan costs for certain conditions. Changes to risk score model coefficients and, therefore, risk-adjusted direct subsidy payments, could meaningfully affect plan decisions with regard to benefit design, formulary construction, and even participation in Medicare Advantage and Medicare Part D.

Additionally, the timeliness of the risk model update will be critical for minimizing large differences in expected plan costs relative to risk model coefficients. To the extent that risk model updates are lagged even one year, disconnects between expected net plan costs and risk scores could provide incentives to attract specific types of beneficiaries where the disconnect most benefits the MAO. While these opportunities will exist under any risk model, the lag may result in an increased number of these situations.

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## **MEDICARE BENEFICIARIES**

### **Certain NLI beneficiaries will see reduced cost sharing**

- The elimination of beneficiary cost sharing in the catastrophic phase for NLI beneficiaries in 2024 and the subsequent introduction of a \$2,000 MOOP in 2025 will insulate beneficiaries from high cost-sharing amounts and will be particularly beneficial to those who rely on high-cost therapies. One study estimated approximately 3.75% of NLI beneficiaries accumulated out-of-pocket expenses above \$2,000 in 2019.<sup>10</sup> While the portion of beneficiaries who accumulate cost sharing above \$2,000 is relatively small, these beneficiaries may represent a disproportionately large share of costs.
- The implementation of a \$35 insulin copay maximum will provide cost-sharing relief for insulin-dependent beneficiaries beginning in 2023. This provision will apply to all covered insulins and all beneficiaries for all 2023 claims and for all claims up to the MOOP in 2024 and beyond. This will improve affordability for NLI beneficiaries who are not enrolled in a Medicare Advantage or Medicare Part D plan offering reduced insulin cost sharing through the SSM in 2023.
- Some affordability barriers may persist for first fills, and beneficiaries may continue to hesitate beginning therapy with drugs with high list prices if they are subject to \$2,000 in cost sharing on a first claim. This dynamic gives way for price negotiation to further improve affordability by reducing list prices and for beneficiaries to leverage the new cost-sharing smoothing option to distribute payments more uniformly throughout the year.

<sup>10</sup> Cubanski, J., Neuman, T., & Damico, A. (September 10, 2021). Potential Savings for Medicare Part D Enrollees Under Proposals to Add a Hard Cap on Out-of-Pocket Spending. Kaiser Family Foundation. Retrieved August 16, 2022, 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/#:~:text=Average%20out%2Dof%2Dpocket%20spending,%243%2C100%20cap%20\(Figure%202.](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/#:~:text=Average%20out%2Dof%2Dpocket%20spending,%243%2C100%20cap%20(Figure%202.)

### **A subset of LI beneficiaries will see reduced cost sharing and greater premium subsidies**

LI beneficiaries who fall between 135% and 150% FPL will explicitly benefit under the IRA Part D benefit redesign. Under the current subsidy structure, these beneficiaries may not receive a full premium subsidy, depending on their income levels, and are subject to a non-zero standard deductible, 15% coinsurance up to the TrOOP, and nominal copays in the catastrophic phase. Beginning in 2024, these beneficiaries will have fully subsidized premium and will be subject to \$0 deductible and nominal copays up to their MOOP.

This group of beneficiaries represents a relatively small portion of the LI population but will see significant cost-sharing relief compared to other LI beneficiaries, who will largely be unaffected due to their already limited liability under the current benefit.

### **Beneficiaries will likely see a reduction in total costs in aggregate**

While a subset of beneficiaries will realize financial relief through reduced cost sharing, premium-paying beneficiaries will be affected by premium changes resulting from IRA drug pricing reform. Absent behavioral changes, Part D benefit design changes alone would increase beneficiary premium largely due to reduced beneficiary cost sharing and increased plan liability in the catastrophic phase (from 15% to 60%). Reduced prices through HHS price negotiation and an increased direct subsidy payment may mitigate some of the increase in plan liability but may be insufficient to overcome increased plan liability driven by benefit redesign. In summary, we expect premiums would increase relative to the current state, but reduced cost sharing may outweigh premium hikes and drive overall savings for beneficiaries in Medicare Part D, in aggregate. However, over the next several years, the premium stabilization provisions of the IRA will limit beneficiary exposure to rising premiums. In the long run, these savings will be most significant for individuals who reach the new MOOP, but individuals with lower total drug expenditures may actually see increased costs as Part D premium increases outweigh any decreases in their cost sharing.

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#### **PROVIDERS**

The temporary increase in Medicare payments to providers for certain Part B biosimilars starting in October 2022 (through September 2027) may influence provider prescribing patterns and overall reimbursement. Currently, providers generally receive ASP plus 6% of the reference drug's price, but this increases to 8% under the IRA for biosimilars. Historically, Part B biosimilar use has been relatively low but increasing in recent years.<sup>11</sup> Increased reimbursement may influence more providers to consider prescribing biosimilars over biologics.

Additionally, providers may be indirectly impacted to the extent price negotiation and formulary changes influence beneficiary requests for specific prescriptions (where medically interchangeable). If provider payments continue based on a percentage of ASP model, payments for negotiated Part B drugs may cause decreases in provider revenue.

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#### **MEDICAID AND CHIP**

While the IRA has significant implications for most stakeholders involved in the Medicare program, there are several implications for states and managed care organizations in the Medicaid program.

### **Direct effects of drug price negotiation**

The Medicaid statute sets minimum drug rebates based on the difference between the “average manufacturer price” and the “best price,” subject to a percentage floor. While many state Medicaid programs negotiate supplemental rebates with manufacturers, these base rebates are intended to ensure that Medicaid gets the best deal currently available outside of other federal healthcare programs on drugs. Costs under Part B and Part D have historically been excluded from these minimum rebate calculations, but the IRA adds the new federal negotiated price to the list of prices considered in the determination of “best price.” If these negotiated prices end up lower than current best price levels, it would increase the base rebate manufacturers must provide to Medicaid programs.

<sup>11</sup> Holcomb, K., Klein, M., & Wang, M. (July 2021). Biosimilars in the Medicare Part B Market. Milliman White Paper. Retrieved August 16, 2022, from <https://www.milliman.com/-/media/milliman/pdfs/2021-articles/7-6-21-biosimilars-in-medicare-part-b.ashx>.

### Knock-on effects of Part D benefit redesign

State drug expenditures for individuals enrolled in both Medicare and Medicaid as determined by the phased-down state contribution process, commonly referred to as the Part D clawback, were roughly \$11 billion in 2020. Per capita contribution amounts are determined using a statutory formula based on historical state costs as opposed to actual costs incurred under the Part D benefit.<sup>12</sup> An element of this calculation is the annual percentage increase in per capita Part D drug costs, which is typically published in the annual Medicare Advantage and Part D rate announcement. As such, state Medicaid program pharmacy spending for dual-eligible beneficiaries will also be affected by any change in the trajectory of per capita Part D expenditures that arise from drug price negotiations and benefit redesign.

### Required coverage of approved adult vaccines

The IRA formally adds a requirement that all state Medicaid programs provide coverage for adult vaccines approved by the CDC Advisory Council on Immunization Practices with no beneficiary cost sharing beginning in 2023. This requirement has also extended the CHIP programs in states that provide coverage for individuals over 18 through CHIP (such as through pregnancy-related assistance). The IRA also provides a one-percentage-point increase in the Medicaid Federal Medical Assistance Percentage (FMAP) for vaccines and their administration, though a similar increase is not provided for the CHIP program.

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### COMMERCIAL

The IRA's provisions have the most direct impact on the commercial individual market, but their effects will also extend more broadly across the entire commercial market segment.

### Extension of enhanced premium subsidies in the individual market

The IRA notably includes provisions to extend enhanced subsidies in the Patient Protection and Affordable Care Act (ACA) individual market. These temporary subsidies were introduced in 2021 in the American Rescue Plan Act and both increased subsidies by lowering the percentage of income a household is required to contribute toward healthcare premiums and expanded subsidies by removing the household income cap on subsidy eligibility.<sup>13</sup> The subsidies were scheduled to expire at the end of 2022 and would have resulted in significant subsidy reductions and corresponding out-of-pocket premium increases for beneficiaries currently receiving these subsidies, estimated to be between 12 million and 13 million individuals in early 2022.<sup>14</sup> The IRA extends these temporary federal subsidies through 2025 and is expected to encourage beneficiaries who entered the ACA market in 2021 due to the enhanced subsidies to continue to stay in the ACA market, though ACA issuers could face the same challenges during 2025 rate filings, and individuals receiving subsidies may face increased net premiums when enrolling for coverage at that point in time.

### Formalization and modest expansion of pre-deductible coverage of insulin in high-deductible health plans

The IRA also adds a formal exception to the first dollar coverage prohibition for HDHPs, explicitly permitting plans to cover all dosage forms and types of insulin before members reach the minimum required deductible. July 2019 IRS guidance already permitted this coverage by permitting insulin to be viewed as a preventive drug for individuals diagnosed with diabetes,<sup>15</sup> but this provision could increase adoption of this flexibility as the law ensures plans do not have to validate presence of a diagnosis prior to provision of first dollar coverage. Otherwise, the law does not impose any requirement to provide this coverage, and so the overall effect is likely to be limited.

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<sup>12</sup> Federal Funds Information for States (June 8, 2020). Medicare Clawback Update: CY 2020 Savings, CY 2021 Estimates. Retrieved August 16, 2022, from <https://ffis.org/PUBS/issue-brief/20/15>.

<sup>13</sup> Karcher, J., Norris, D., & Benz, K. (March 3, 2021). American Rescue Plan: Impacts on Private Health Coverage. Milliman Insight. Retrieved August 16, 2022, from <https://www.milliman.com/en/insight/americas-rescue-plan-impacts-on-private-health-coverage>.

<sup>14</sup> The CMS 2022 open enrollment report indicates that almost 13 million individuals selected a plan and were eligible for financial assistance. There currently is no effectuated enrollment data for 2022, but historically about 96% of individuals eligible for subsidies effectuate coverage and receive subsidies. See <https://www.cms.gov/files/zip/2022-oep-state-level-public-use-file.zip> (Zip file download).

## Next steps

In the coming months—and years—we expect substantial guidance from CMS and HHS prior to implementation of many IRA provisions affecting Medicare Advantage and Part D. The IRA will arguably deliver the most significant drug pricing reform in the history of the Medicare program since the inception of Part D. This legislation will have countless implications for all industry stakeholders and will alter the Medicare landscape in 2023 and beyond.



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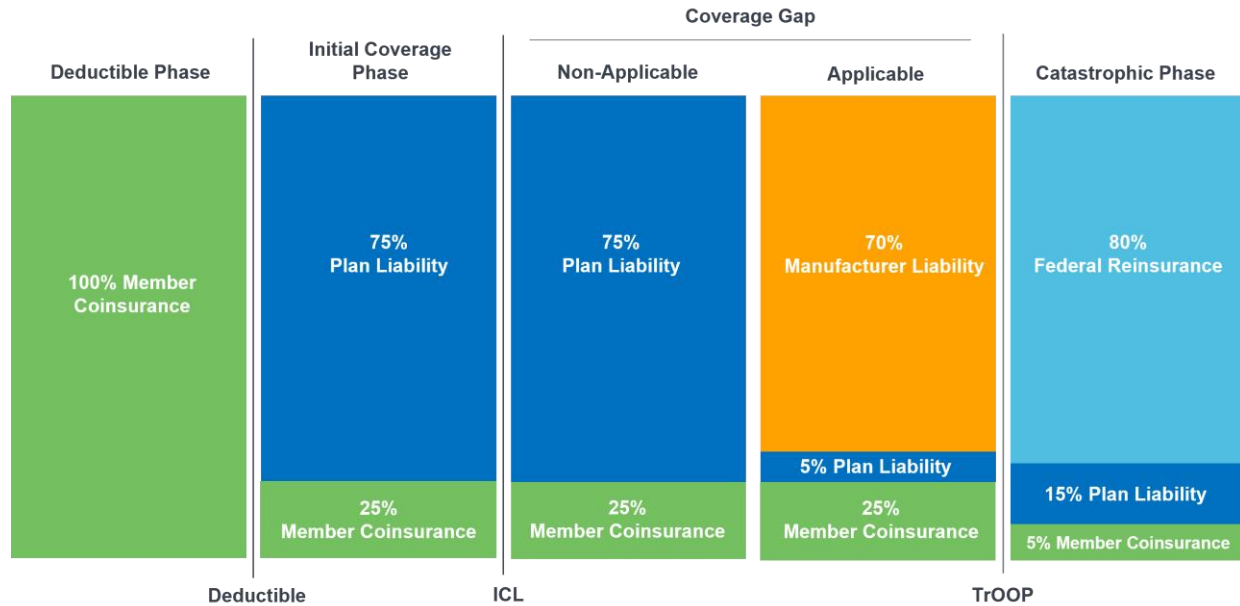
## Appendix A: Key Medicare Provisions of the Inflation Reduction Act as of August 9, 2022

All page numbers are based on the enrolled version of H.R. 5376 as published by the U.S. Government Publishing Office at <https://www.congress.gov/117/bills/hr5376/BILLS-117hr5376enr.pdf>.

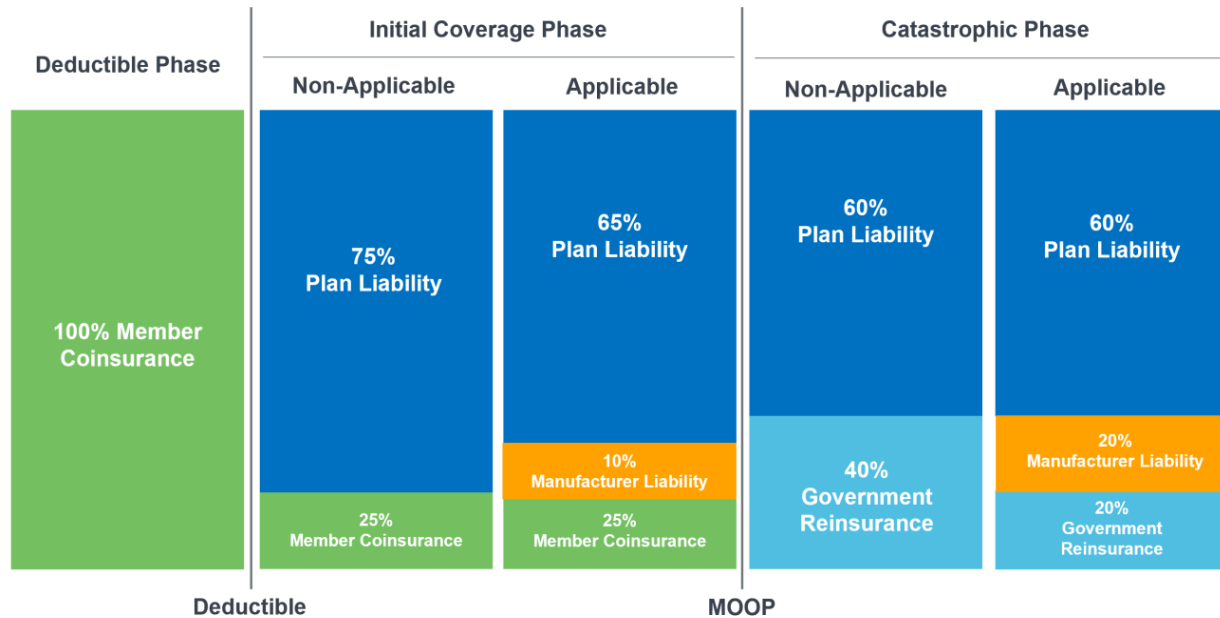
TOPIC (PAGE)	KEY DATES	BRIEF DESCRIPTION
Lowering prices on high-cost single source drugs (p. 16)	<b>Negotiations begin in 2024 for prices applicable in 2026</b>	<ul style="list-style-type: none"> <li>Allows HHS Secretary to negotiate maximum fair prices for single-source drugs and biologics.</li> <li>Drugs are selected from the 50 highest-cost Part B and 50 highest-cost Part D single-source drugs, with a carve-out for small biotech drugs.</li> <li>Part D drugs are negotiation-eligible beginning in 2026 while Part B drugs will be eligible in 2028.</li> <li>Biologic drug negotiation could be delayed by up to two years if requested by a biosimilar manufacturer.</li> </ul>
Medicare Drug Price Inflation Rebates in Part B (p. 48)	<b>First rebated quarter is Q1 2023</b>	<ul style="list-style-type: none"> <li>Requires manufacturers to pay rebates when the average cost of a rebatable drug is higher than the average price in Q3 2021 trended using CPI-U.</li> </ul>
Medicare Drug Price Inflation Rebates in Part D (p. 54)	<b>First rebated quarter is Q4 2022</b>	<ul style="list-style-type: none"> <li>Requires manufacturers to pay rebates when the average cost of a rebatable drug is higher than the average price in Q1 to Q3 of 2021 trended using CPI-U.</li> </ul>
	<b>2024</b>	<ul style="list-style-type: none"> <li>No beneficiary cost-sharing liability in the catastrophic phase.</li> <li>Part D premium growth capped at an annual rate of 6% through 2029 with some additional protection for 2030 (subject to premiums representing a minimum of 20% of plan and federal costs).</li> </ul>
Medicare Part D Benefit Redesign (p. 60)	<b>2025</b>	<ul style="list-style-type: none"> <li>The CGDP is removed and replaced with a new discount program (see below).</li> <li>The MOOP is reduced to \$2,000.</li> <li>Catastrophic phase plan costs are 60% of allowed costs.</li> <li>New post-deductible Manufacturer Discount Program with different rebate rates before (10%) and after (20%) the MOOP for both NLI and LI beneficiaries on applicable claims.</li> <li>For LI beneficiary claims from "specified" manufacturers and all claims from "specified small" manufacturers, the 10% and 20% MDP liability are phased in over time, reaching ultimate levels by 2031.</li> <li>Availability of cost-sharing smoothing.</li> <li>Federal reinsurance decreases to 20% for applicable drugs and 40% for non-applicable drugs.</li> <li>Accumulation of cost sharing toward catastrophic based on basic Part D benefit cost sharing.</li> </ul>
Delay of manufacturer point-of-sale rebate rule (p. 79)	<b>2032+</b>	<ul style="list-style-type: none"> <li>A requirement to reflect manufacturer rebates at the point of sale was scheduled to be implemented in 2026, but now has been delayed to at least 2032.</li> </ul>
Insulin provisions (p. 85)	<b>2023</b>	<ul style="list-style-type: none"> <li>Insulin cost sharing in Part D capped at \$35 (or 25% of the maximum fair price or the negotiated price, if less), with costs for 2023 to be reimbursed as part of the plan's LI subsidy payments.</li> <li>Insulin cost sharing under Part B will be reduced to the lesser of \$35 and 20% coinsurance starting July 1.</li> <li>Temporary retrospective subsidies to plans for 2023.</li> </ul>
Other provisions (p. 79)	<b>Varies</b>	<ul style="list-style-type: none"> <li>Starting in 2023, Part D will be required to cover approved vaccines without any beneficiary cost sharing, with costs for 2023 to be reimbursed through the plan's LI subsidy payments.</li> <li>Starting July 1, 2024, initial biosimilar reimbursements will be capped at the reference drug's payment rate.</li> <li>Increased payments for biosimilars up to 108% of ASP for first five years on the market (or first five years starting October 1, 2022, for drugs already available at that time).</li> </ul>
Expanded eligibility for low-income subsidies (p. 83)	<b>2024</b>	<ul style="list-style-type: none"> <li>The threshold for full low-income subsidies increases from 135% to 150% FPL (which currently reflect partial subsidy beneficiaries).</li> </ul>

## Appendix B: Defined Standard Benefit Design Comparison – Non-Low-Income Beneficiaries

### CURRENT DEFINED STANDARD BENEFIT DESIGN



### IRA DEFINED STANDARD BENEFIT DESIGN



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